

# We are IntechOpen, the world's leading publisher of Open Access books Built by scientists, for scientists

3,800

Open access books available

116,000

International authors and editors

120M

Downloads

Our authors are among the

154

Countries delivered to

TOP 1%

most cited scientists

12.2%

Contributors from top 500 universities



WEB OF SCIENCE™

Selection of our books indexed in the Book Citation Index  
in Web of Science™ Core Collection (BKCI)

Interested in publishing with us?  
Contact [book.department@intechopen.com](mailto:book.department@intechopen.com)

Numbers displayed above are based on latest data collected.  
For more information visit [www.intechopen.com](http://www.intechopen.com)



---

# Medico-legal Aspects of Pain Medicine

---

Gabor Racz, Carl Noe and Rajesh Munglani

Additional information is available at the end of the chapter

<http://dx.doi.org/10.5772/58754>

---

## 1. Introduction

Deviation from an acceptable standard of care is one of the central issues in a lawyer's mind in any malpractice lawsuit. However, the trigger for a lawsuit is the occurrence of a complication. That is, intense scrutiny of a doctor's practice usually only occurs once harm has occurred to a patient.

Thus avoiding complications is the maxim to follow. Understanding the situations in which complications leading to law suits may arise is most important.

Not all complications will lead to law suits depending on how they are handled and, for example non negligent complications and side-effects may be successfully defended if appropriately consented.

The trend towards more accreditation may reduce rare but serious complications. Many Boards (in the USA) and Faculty of Pain Medicine (in the UK) amongst others and international organizations such as World Institute of Pain (WIP) have introduced standards of training in an attempt to reduce complications rates.

If you are sued, remember no one is going to care more about the result than you do. Pick the best lawyer and experts to defend you.

## 2. Principles that may help avoid lawsuits

### 2.1. Physician attitude towards patients

There is evidence that avoiding distressed or angry patients are associated with better outcomes and fewer complaints and lower rates of litigation [1]. Always be respectful and

pleasant with patients and communicate with them, this leads to lower rates of complaints and litigation. Patients are treated in private but you practice in public, in front of a jury of your peers [2-5].

## **2.2. Minimizing errors during conduct of interventional procedures**

Steps to promote safety for interventional pain procedures include the “time out” where activity stops and the team of the patient, nurses and physicians verify the patient’s identity, the diagnosis, the procedure, the side of the procedure (right or left), a valid consent form, allergies and other critical information before proceeding with the procedure. Labeling syringes and marking the site of the procedure is also helpful. Numerous deaths have occurred from erroneous labeling and administering the wrong drug.

Performing the correct procedure for a specific pain problem is more important than performing an alternative procedure first because it may be less expensive.

The practice of performing series of procedures and the use of algorithms of multiple procedures is non-specific and needs to be refined to be not only more cost effective but to reduce risk.

The use of physician extenders is a risk factor for medical-legal disputes in pain management. Physician standards of care are the standard that patients expect and the evolving practice of pain management does not lend itself well for delegation of decision making for opioid prescribing and procedure selection [6].

Monitoring the patient, having venous access and having equipment for anaphylactic reactions and other emergencies is advisable for procedures other than simple peripheral injections.

## **2.3. The increasing use of anticoagulation**

Anticoagulation has become very common in the United States, as has daily aspirin therapy. The management of these medications before and after pain management procedures is problematic since existing data does not answer all questions. Discontinuing aspirin has been associated with stroke and myocardial infarction; however, new platelet function tests are markedly abnormal with one 325 mg tablet per day. Patients with mechanical valves or recent coronary stints or pulmonary emboli are not good candidates for discontinuing anticoagulation. Coordination with the anticoagulant managing physicians is important when these patients need procedures.

Discontinuing platelet inhibitors has more advocates than opponents but the risk of bleeding versus infarction is a subject that is well suited for a discussion with the patient’s other physicians and with the patient.

### 3. Medical malpractice

Medical legal issues may arise in the form of a lawsuit, brought by a patient or their representative or from a hostile action from a licensing agency, a hospital privilege committee, a medical society, an insurance company or government health plan, a certifying board or other government agency or non-government party.

#### 3.1. Four conditions constitute a malpractice claim

1. A duty must exist between a physician and the patient. In other words, a doctor –patient relationship must exist.
2. the duty must have been compromised by negligence.
3. the patient must have suffered damages.
4. the alleged negligence must be proven to have caused the damages.

##### 3.1.1. Related to the above concepts is the burden of proof test

In order to bring a successful claim against you, the patient, or other person bringing the claim, has to prove on the balance of probabilities:

Breach of duty – that the treatment was such that no reasonable practitioner would have delivered that care

##### 3.1.2. Causation and negligence

Causation – that the breach of duty or negligence caused or contributed to the injury, loss or damage suffered, and that the patient would not have suffered that injury without the breach  
Causation, or proof that damages resulted from negligence and were not coincidental, has a threshold of being more likely than not, otherwise known as the 50.1% test

Both these tests have to be established to prove negligence [7].

Negligence, or a breach of duty, is a deviation from the standard of care. Standard care is the care provided by a reasonable and prudent physician of the same specialty and under the same circumstances, otherwise known as the Bolam test [8].

#### 3.2. Effects of medical malpractice of healthcare delivery

Physicians claim that medical malpractice liability increases healthcare costs and limit access to care for which there is now increasing evidence [9]. There is some evidence that practicing “defensive medicine” probably worsen outcomes for patients [10].

Advocates of the medical malpractice system argue that malpractice insurance premiums are a result of poor insurance company management. The Harvard Medical Practice Study in 1990 reported that only a small fraction of patients with negligent injuries sued and that more suits were in order rather than less.

### 3.3. Tort and it's reform

A tort is a civil wrong that causes injury, exclusive of a breach of contract. Medical malpractice is a tort resulting from negligence, which is defined as conduct that falls below the standard established by law for the protection of others against unreasonable risk of harm. An intentional tort may arise when informed consent is not obtained.

Tort reform initiatives have proposed several ways to reduce the costs of malpractice awards. [11, 12]

Caps on noneconomic damages limit the amount of money that can be awarded for pain and suffering. Some jurisdictions have limits of \$250,000. Economic damages cover medical expenses, lost wages and costs of re-education and/or rehabilitation.

Caps on punitive damages limit the amount of money awarded for conduct that is beyond negligence and includes fraud or evil. Advocates for caps have argued that evidence must be "clear and convincing" rather than "a preponderance" before punitive damages are awarded [13]. It has been argued that a portion of punitive damages go to a fund for a public purpose rather than to the plaintiff.

Abolishing joint and several liability would prevent each defendant from being liable for 100% of the damages. The principle of joint a several liability serves to assign liability equally to all defendants rather than allow defendants to divide responsibility based on their portion of conduct.

The collateral source rule allows plaintiffs to be compensated twice for the same injury. Abolishing this rule would result in an offset of damages based on other resources such as insurance payments and disability payments [14].

Contingency fee limits would require attorneys to be paid based on the amount of work they perform rather than a percentage of the awarded damages but in other jurisdictions such as the UK there are imperatives which state the costs in a case must be proportionate [15]

Statues of limitations require malpractice lawsuits to be filed within a time period from the injury. In the UK this is generally accepted to be 3 years in most circumstances [16]. If an injury is not discovered immediately or of the injured person is a child, the limitation is frequently expanded to allow a suit to be brought. A newborn baby is obviously unable to file a lawsuit but can when adulthood is reached. In the UK the statute of limitation only starts when the child reaches 18 [17] Medical records tend to degrade after years and memory is of limited help. These factors disadvantage the defense of a physician though the advent of electronic records may prove helpful in this respect.

## 4. The American society of anesthesiologists closed claims study

The ASA closed claim study has resulted in a number of reports regarding pain management and related liability. The number of claims against anesthesiologists for pain management

doubled between 1985 and 1989. It doubled again between 1990 and 1994 [18]. Claims for postoperative pain management increased from 6% during the 1980's to 8% in 2000 [19]. Claims from chronic pain management increased from 7% between 1985-1994 to 12% between 1995-2004. [20]

In a large report, the number of claims increased since the 1980's before pain management began to grow as a specialty. Deaths from epidural injections were associated with epidural injection of local anesthetic and opioid. Nerve damage and pneumothorax were reported to be most common causes of claims. Intra-thecal pump mishaps were also associated with deaths. [21]

44% of medication errors have been related to incorrect dosing, 30% are related to wrong drug administration, 10% are related to contraindicated drugs and 8% are related to incorrect timing of administration. [22]

Most medication claims are associated with medication misuse and both patient and physician conduct contribute to a high proportion of deaths.

Medication management claims were associated with men with back pain who were prescribed long acting opioids and also taking other psychoactive medications and had signs of medication misuse. [23]

Blocks accounted for 84% of claims during the 1990s. [24]

50% of nerve injury claims involved spinal cord injury. Pneumothorax from trigger point injections has been a common claim. [25]

Spinal cord injuries have been reported to be associated with cervical procedures in women under general anesthesia. [26]

22% of chronic pain claims are related to cervical procedures and the injuries are commonly permanent and disabling.

Brain damage and death were associated with epidural steroid injection only when used with local anesthetic or opioid [21].

Ultrasound guided nerve blocks have been associated with fewer claims [27].

Other factors have been reported as a part of the closed claim study.

Agreement among experts in malpractice cases has been shown to correlate poorly. (k 0.37) [28]

However, publishing and publicizing examples of questionable expert testimony has been discouraged for legal reasons. [29]

Malpractice insurance rates vary widely from \$15,000 to \$64,000 per year depending on the states' legal system and award amounts over time [30].

The recommended amount of malpractice insurance coverage varies but 1-3 million dollars per claim and 3-6 million dollars in aggregate have been proposed [31].

The closed claims study data is limited statistically because it reports the numerator but not a denominator, so trending is difficult to evaluate. However, it clearly serves a good purpose in identifying potential problems.

The closed claims study does not include information from non-anesthesiologists and pain management has become a multi-specialty field with a variety of specialists performing procedures oftentimes with little training.

In the State of Georgia, one malpractice insurance carrier no longer offers coverage for physiatrists who perform trigger point injections because of the high rate of pneumothorax. The use of a 25 or 30 gauge needle and fanning injections is associated with pneumothorax. Fanning injections with a small gauge needle tends to produce multiple punctures along the same track rather than injecting in multiple directions as intended with the fanning motion. The reason is that the small gauge needle lacks the stiffness necessary to overcome the “grip” of the muscle and has a “woodpecker effect” producing multiple punctures of the pleura. Using 22 gauge needles for trigger point injections or avoiding fanning, we have not seen this problem.

## 5. Some complications and their mechanisms

25 plus years of serving as an expert in 350-400 cases (GBR) as well taking into account the UK perspective (RM) has revealed some patterns of complications and likely mechanisms. Many cases settle and no record of the complication is made and valuable information is lost. The following section represents some of that information.

With increasing emphasis on treatment of pain, there has been recognition of recurring patterns of complications. Therefore once understanding reaches a broad base of practicing clinicians, a reduction of these serious but rare complications should be possible.

### 5.1. Pneumothorax

Pneumothorax is a complication for trigger point injections. Frequently the needle used was 25 G or smaller. These needles bend easily and when “fanning” injections are made, the needle tract is uncontrollable. A “woodpecker” effect can result with multiple holes in the pleura and a pneumothorax requiring a chest tube is a common trigger for a lawsuit. Medicare will no longer pay for treatment of a pneumothorax from a central line placement and similar reimbursement patterns may be forthcoming for pain related complications.

### 5.2. Injections near the cranium

This same mechanism can occur with other injections. For example, injecting a painful scalp scar after craniectomy for acoustic neuroma has resulted in local anesthetic being injected intracranially.

### **5.3. Cervical sympathethetic injections**

Cervical nerve root injection occurs after cervical sympathetic (stellate ganglion) block using the classic technique. Needles directed to Chassignac's tubercle are directed to the vertebral artery and cervical nerve root. Local anesthetic injection may result in immediate seizures or paralysis but delayed complications may result from subdural blocks after patients have been discharged. Patients should be monitored for longer periods of time in an environment with full resuscitative personnel and equipment. A lesson learned from this is that the needle tip migrates into a nerve or artery where injection occurs. The new Bella D needle (Epimed, International) has a sealed tip and a side port for directional injection, and may reduce this occurrence.

### **5.4. Spinal transforminal injections and the erroneous concept of a "safe" area for injection**

Deaths after transforaminal injections have occurred and the notion of a "safe" avascular area in the posterior foramen has been shown to be false. Local anesthetic injection or arterial injury can result in catastrophic spinal cord injury and/or death. Huntoon has demonstrated arterial supply in each posterior cervical neuroforamina which effectively discredits the concept of a safe area [32]. The increasing number of cases of catastrophic neurological injury in the lumbar region following otherwise supposedly correct injection appropriate have also undermined the concept of this "safe" area and an alternative site; Kambins triangle has been alternatively proposed [33] [34].

Unfortunately catastrophic has occurred following injection of saline, contrast and steroid and is not prevented by digital subtraction angiography [35] The onset of neurological signs may be delayed and may be associated with the lack any obvious untoward effects at the time of a test dose of local anesthetic which was used to confirm epidural placement. The authors suggested Utilizing blunt needles or larger bevel needles in place of sharp, cutting needles may minimize the chances of this event occurring. Subdural injections may also be associated causes vasospasm and infarction.

### **5.5. The debate over sharp versus blunt needles**

Sharp needles by their very design minimize the feedback produced as bodily structures are penetrated. This means there will be minimal awareness of vascular, neural and spinal cord structure with needle advancement. Such injections seem to be associated with more lawsuits. The dural can be more easily punctured and local anesthetic and corticosteroid preparations can be injected.

Despite the fact no randomized controlled data exist for sharp needle injection safety, serious concerns have been raised. Sharp needle movement after initial placement seems to be a factor as well. In response The Bella D needle has been designed in an attempt to reduce punctures and migration associated with small movements. The tip is blunt and a side port is located proximal to the tip. Blunt needles have been shown to be less likely to puncture nerves and arteries in animal studies [36]. Interscalene block complications have also been associated with sharp needles. Intra-cord injections, quadriplegia, Brown-Sequard and brachial plexopathy

have been reported. The true incidence of major complications is unknown. Sweet reported one death and several hematomas in a series of 7000 foramen ovale procedures. This may be a similar complication rate for pain procedures

The RX-2 coude (Epimed International) epidural needle has a second stylet, which is blunt to convert the needle tip from sharp to blunt to reduce the incidence of a dural or venous laceration when rotating the needle in the epidural space. The second stylet is placed once the epidural space is reached but before any rotation. The blunt tip stylet projects 1mm beyond the tip of the needle and acts as a guard to the sharp edge of the needle.

The RX-2 coude needle is gaining wider acceptance for epidural needle and catheter placements as well as spinal cord stimulation electrode placements.

A lesson learned is that every case of spinal cord injury and death until has been associated with the use of sharp needles by direct trauma or the mechanism of arterial penetration and comprise of the arterial supply. Experimental studies suggest that blunt needles have not been associated with arterial wall penetration [36].

The available clinical information and animal data supporting the use of blunt needles only applies to blunt needles and cannot be extrapolated to pencil point tip needles. Pencil point tip needles are designed to penetrate the dura and have not been studied with regard to puncturing arteries and nerves.

The pencil tip needles have not been studied regarding perforation into nerves or arteries. The blunt needles have been shown not to perforate from 18 gauge to 25 gauge.

The disastrous vascular and neurological complication seen with stellate ganglion procedure should theoretically be avoidable using the Bella D needle. Most of these complications seem to be related to the classic C 6 approach to Chassaignac's tubercle. The teaching to make bony contact and then pull back 1mm is an inexact process and the needle tip and injection can be placed in an artery or nerve. Cases of immediate or delayed total spinal block, brain or spinal cord infarction have occurred. Using the Bella D needle placed at the lateral body of C7 may reduce the incidence of these complications.

Whilst some of the evidence does suggest blunt needles may be safer, the first cases of spinal cord injury the use of blunt needles are now being reported to be associated with vascular spread [37]

The curved, blunt RF (Racz-Finch) needle is being used increasingly in an attempt to avoid intraneural, intracord and intra-arterial placement especially with the use of particulate corticosteroids. Thus far, no cases involving these needles have surfaced.

The curved blunt needle must be used with an introducer but once it is placed, it can be used as a percutaneous navigation devise (PND) and directed around other structures to the target area.

This same concept is behind the Rx 2 coude and the 14-gauge spinal cord stimulation electrode epidural needle, which can be used to steer the electrode safer and in less time.

## 5.6. Particulate steroids

Patients with acute and chronic pain have received steroids in neuraxial blockade for many years. There has been recent controversy about their efficacy but also about the possibility of neurological complications associated with the use of particulate steroids such as methylprednisolone, triamcinolone and betamethasone. In contrast dexamethasone is a non-particulate steroid with less platelet aggregating properties [38].

Scanlon et al reported that in the USA between 1998 and 2003, the number of cervical and thoracic TF ESI almost doubled. They noted at the time of writing 27 cases of brain and spinal cord infarction following TF ESI and their survey revealed a further additional 78 cases following a survey of 1400 or so physicians despite a response rate of approximately only 21%. In no case was the use of non-particulate steroid dexamethasone associated with adverse neurological outcomes. Depomedrone, a particulate steroid was 7 times more likely to have been used in cases where there was evidence of brain and spinal cord infarction than either triamcinolone or betamethasone. No cases were reported with dexamethasone. However it could be argued this simply reflected a frequency of use rather than a propensity to cause problems.

In particular it was hypothesized inadvertent intra-arterial injections of particulate steroids is thought to lead to spinal cord ischaemia by blocking of small arterioles and secondary catastrophic neurological and other complications and indeed studies showed that methylprednisolone and triamcinolone were more likely to aggregate than dexamethasone or betamethasone, sometimes up to 100um in diameter on microscopic slides which have the theoretical ability to block small arteries [39]. [40] [41] [42].

Use of contrast and aspiration is no guarantee that vascular uptake has not or will not take place. The overall incidence of intravascular uptake during lumbar spinal injection procedures as determined by contrast enhanced fluoroscopic observation is 8.5%. Preinjection aspiration failed to produce a flashback of blood in 74% of cases that proved to be intravascular upon injection of contrast dye [43] Despite this evidence, a survey in 2012 suggested a significant proportion of UK pain consultants continued to use particulate steroids for cervical injections and even greater proportion for lumbar root injections [44]. A clinical negligence barrister in the UK has commented the current position of UK pain consultants who continue to use particulate steroids is uncertain in terms of breach of duty if they haven't offered patients the probably safer option of non particulate steroids even if they continue not to accept the evidence as regards of particulate steroids. [45].

## 5.7. Unreliability of the ligamentum flavuum as a loss of resistance sign

Anatomical studies have shown the inconsistent presence of the ligamentum flavuum. Ligamentum flavum resistance is an unreliable sign in the cervical spine and the first resistance appreciated may be the dura or cord. [46] This means that intracord injection may easily occur with interlaminar epidural steroid injections with Tuohy spinal needles using "loss of resistance" techniques as the latter is an unreliable sign in these circumstances.

### 5.8. Spinal haematomas and peri venous counter spread

Subdural, subarachnoid or intra-cord needle placements followed by injections of contrast, local anesthetic or corticosteroid can produce spinal cord injury, paralysis and death.

The cervical venous plexus is predominantly lateral and ventral as opposed to the thoracic, which is predominantly posterior. Epidural hematomas are usually upper thoracic and lateral recess stenosis compounds the problem.

Lawsuits are rare when an epidural hematoma is diagnosed early and surgical decompression is carried out expeditiously [47]. A second opinion consult should be obtained if the first surgeon wishes to delay surgical treatment of an acute epidural hematoma though conservative management has been described [48]

Peri-venous counter spread (PVCS) has been reported and occurs when epidural injection leads to pressure building on one side which forces flow to the opposite side [49]. If fluid is unable to escape the spinal canal, pressure can compress the cord and produce quadriplegia. When recognized, the patient should flex and rotate the neck. This causes the pars of the facet joints to slide over one another and enlarge the neural foramina. This provides an escape route for injected material and pressure release.

This procedure has become a standard of practice and is described in multiple publications. It should be used to spread cervical injectate and allow lateral run-off.

When pressure builds up, the patient will complain of ipsilateral pain possibly spreading bilaterally. Neck and arm pain precede chest pain and spinal cord ischemia. Numbness, weakness and paralysis can be prevented by repetitive exercises.

PVCS has been described as a mechanism for acute compression, which may be relieved by repetitive chin to shoulder flexion exercises. These movements increase the size of the cervical canal, allowing spread of injectate and pressure reduction. Thoracic catheter placement and advancement to the cervical level in the lateral epidural space may reduce the risk of compartmental injection by opening lateral run off. The practice of avoiding the lateral epidural space may predispose patients to loculation and syrinx formation.

We recommend caution or avoidance of epidural injections in patients with a syrinx, arnold chiari malformations and arachnoiditis. Paralysis and other severe neurological complications have been seen. [50, 51]. The only effective treatment for injecting the wrong contrast is irrigation of cerebrospinal fluid with saline. Injections in patients with arachnoiditis is hazardous because dissection can occur into the subdural space and loculation can occur leading to circulatory compromise to the spinal cord.

### 5.9. Sub-occipital injections

Sub-occipital injections have been associated with the "locked in phenomenon", brain stem infarction and death. Injectate can tract retrograde along the occipital nerve and dissect into the CNS.

Sub-occipital decompression has not been associated with the “lock in” phenomenon. 10 cases of complications with intraneural injection have occurred but not with the use of the Stealth (Epimed, International) 20-gauge 2” needle aimed just below and slightly posterior to C1. The “locked in” phenomenon, while rare, is an example of the importance of recognizing an emergency and being able to respond with resuscitative measures.

#### **5.10. Arachnoiditis**

It is still not clear what causes arachnoiditis, though epidural injection of modern drugs are unlikely to be associated with such a complication. In contrast intrathecal injection of steroids has been associated with histological changes in animal studies and also probably humans [52] [53]. Studies of epidural steroids and contrast suggest greater changes with the injection of contrast media. [54]. Therefore contrast injection should be limited to agents, which are safe for intrathecal use.

The cause of a recent report of urological problems and severe dense foot drop following a few days post blind caudal injections for contralateral radicular pain is uncertain but infection has been postulated for the arachnoiditis seen on imaging [55]. Recently, a 30 million dollar lawsuit was brought after a patient developed arachnoiditis after multiple wet taps during attempted spinal cord stimulator electrode placement. The allegation was that an epidural blood patch caused the arachnoiditis. The medical records weighed 97 pounds and the trial lasted 2 weeks but the defense prevailed. Nevertheless, it is not uncommon for the Tuohy type needle to enter the subdural space without the physician recognizing it. Cerebrospinal fluid may not appear during the procedure.

#### **5.11. Radiofrequency of the medial branches**

In principal radiofrequency of the medial branch seems to be an inherently safe procedure [56]. It is however important to warn patients about post operative soreness and inconsequential long term numbness due to lesioning of the lateral branch [57]. Such procedures may have poorer prognoses in those patients who appear to catastrophize and alternative treatment offered, certainly initially [58], though subsequently such procedures can be beneficial to the overall pain and psychological state [51, 59].

Radiofrequency procedure complications and medicolegal cases include instances where sharp needles enter nerves or arteries and where injection created pressure, which is transmitted to a distant structure. Additionally, thermocoagulation of unintended structures, such as the vagus nerve during a C2-3 facet denervation, can occur. Permanent losses of voice and hoarseness have been complications. The vagus nerve courses slightly anterior and lateral to the target [60]. For this reason, performing bilateral upper cervical facet denervations at the same sitting is not advisable. Patients should be brought back for the second side. In addition, weakness of cervical muscles can occur resulting in a permanent inability to raise the head. [61]

## 5.12. Complications of opioid therapy

The prescription of a strong opioids is a significant therapeutic which can be associated with poor outcomes including overdose and death. It is important that the rationale for such a prescription is fully documented with informed consent [62].

Opioid rotation in the presence of benzodiazepines is associated with respiratory arrest. Outpatient spinal opioid trials are as well. Many patients receive psychiatric care in secrecy to avoid insurance premium increases. These patients may not disclose their complete medication list and may be taking centrally acting drugs without the knowledge of the pain physician. Urine drug testing may help to some degree but many drugs are not routinely tested. Opioid rotation, at least at high doses, should not be done in one stroke [63] [64]. One opioid can be reduced while another one titrated.

Some centers now recommend benzodiazepine tapering before optimization/ rotation of opioid therapy especially in the elderly.

Methadone, while inexpensive, is falling out of favor due to deaths associated with its use for chronic pain [65]. Spinal opioid trials are best done as an inpatient [66] [67].

Many patients take herbal products and the pharmacologic effects of these products are unknown but should be documented as there is growing evidence that they may interact with more standard pharmaceutical agents.

## 6. Informed consent

Written informed consent should be obtained before any procedure to document education of the patient regarding risks of the procedure and to fulfill the legal requirement and avoid a charge of battery.

In Texas, new laws require specific language for informed consent for three types of pain procedures.

### 6.1. Neuroaxial procedures (injections into or around spine)

Failure to reduce pain or worsening of pain

Nerve damage including paralysis (inability to move)

Epidural hematoma (bleeding in or around spinal canal)

Infection

Seizure

Persistent leak of spinal fluid, which may require surgery

Breathing and/or heart problems including cardiac arrest (heart stops beating)

## **6.2. Peripheral and visceral nerve blocks and/or ablation**

Failure to reduce pain or worsen pain

Bleeding

Nerve damage including paralysis (inability to move)

Infection

Damage to nearby organ or structure seizure

## **6.3. Implantation of pain control devices**

Failure to reduce pain or worsening of pain

Nerve damage including paralysis (inability to move)

Epidural hematoma (bleeding in or around spinal cord)

Infection

Persistent leak of spinal fluid which may require surgery

## **6.4. Brief comments as regards serving as an expert witness**

Before serving as an expert witness, one must feel comfortable holding themselves out as experts. Many fine physicians are not experts and the expert must have a curriculum vitae and enough experience to qualify as an expert in a court of law. Experts must limit their expert opinion to their area of expertise. Being an expert in one area does not qualify one to be an expert in a related by different area. Medical societies may expel members for testifying against other members if the testimony is unprofessional.

Second, before committing to serve as an expert, the records should be reviewed. No conflict of interest should exist between the expert and either party to a lawsuit. For example, one should avoid defending or testifying against a business partner or a business competitor. Testifying against another physician is a difficult task, as is, defending a doctor who has had a serious complication. Each side will have compelling arguments and the expert must be completely comfortable with the testimony they will give. While physicians are given considerable leeway to testify, the expert's reputation is at stake as much as the defendant's. The expert should make certain that the attorney, who calls them to testify, is aware of what the expert is willing to say and what the expert is not willing to say before any trial is scheduled. Experts must be willing to make themselves available once they have committed to a case. Court schedules change and delays are inevitable. Fees for serving as an expert should be in a similar range with what the physician would generate during the same time in practice, plus any expenses for travel, etc.

The medical legal aspects of pain management are unlikely to become less complex with time. Physicians need to increase their activity in specialty societies and political action committees in order to avoid the consequences of remaining silent.

## 7. Summary

This chapter has been but a brief introduction to how to reduce complications and by taking on board some of the messages in the chapter we hope you will not find a two or three period of your life being dominated by litigation with your professional and personal integrity being scrutinized in a harsh way.

*Primum non nocere*, or first do no harm is the maxim to follow. An awareness of the likely scenarios for complications, recognizing both patient, disease and technique related factors associated with such adverse outcomes and avoiding them can achieve a great deal in continuing to both enjoy ones clinical practice and get a good night's sleep.

We as the authors, intend to expand this chapter significantly in future years based on our experience of having to deal with many such cases in the medicolegal setting. We wish you well and invite you to share any cases with us that you might wish us to consider including in future years, to inform and educate us all.

### A summary of some potential complications of injection and other therapies and how to avoid them

PROCEDURE	COMPLICATION	MECHANISM	POTENTIAL SOLUTION
Thoracic and cervical trigger point injection	Pneumothorax	25-30 g needle Fanning technique	22 g Avoid fanning
Transforaminal	Spinal cord or vertebral artery injection	Sharp needle intravascular or intraneural penetration	Use a blunt needle use
Single shot epidural steroid injection	Subdural injection	Dural laceration from sharp touhy or spinal needle	Use of blunt needle e.g RX 2 coude
Epidural needle placement	Intracord injection	Initial loss of resistance is deep to epidural space due to inconsistent ligamentum flavum at cervical levels	Entry level at t 2 Catheter placement to cervical level :use contrast
Occipital block-	total spinal from injection in foramen magnum, intra-arterial injection and local anesthetic toxicity, occipital nerve injury, hematoma		Use of 20 gauge stealth needle and suboccipital decompression technique. Use of contrast and avoid large volumes

<b>PROCEDURE</b>	<b>COMPLICATION</b>	<b>MECHANISM</b>	<b>POTENTIAL SOLUTION</b>
Cervical transforaminal steroid injections	total spinal, vertebral artery injury, cerebellar hemorrhage, spinal cord infarct	Use of sharp needle	Use of blunt coude needle Avoid particulate steroid
Cervical interlaminar steroid injections	spinal cord injury, epidural hematoma, epidural abscess, loculation of injectate	Use of sharp needle	Use of blunt needle Rx 2 coude epidural needle
Cervical sympathetic block	total spinal, pneumothorax, horner's syndrome, recurrent laryngeal nerve block, brachial plexus block, intravascular injection and seizure, pneumochylothorax	Classic technique	Use of C7 lateral body technique blunt needle with Bella D needle
Atlanto occipital block	ataxia	Central local anesthetic effect	Minimize local anesthetic volume
Cervical 3 facet denervation	Hoarseness	Vagus nerve injury	Avoid bilateral procedure
Bilateral cervical injections	Respiratory arrest	Bilateral phrenic nerve blockade	Avoid bilateral procedure
Cervical facet injection	total spinal, spinal cord injury	Medial needle placement	Frequent use of Anterior posterior flourosopic localization
Intercostal block	pneumothorax	Plural puncture with sharp needle	Use of flouroscopy and fixation of needle at skin puncture site
Lumbar sympathetic block	retroperitoneal hematoma, lymphatic injury	Vascular structure puncture	Use of blunt coude needle
Lumbar transforaminal injection	paraplegia	Segmental Arterial injection	Use of blunt coude and avoid deep foraminal placement Avoid particulate steroid
Lumbar sympathetic block Hypogastric plexus block	impotence, bladder dysfunction	Autonomic block	Avoid bilateral procedure

## Author details

Gabor Racz<sup>1</sup>, Carl Noe<sup>2</sup> and Rajesh Munglani<sup>3</sup>

1 Texas Tech University Health Science Center, Lubbock Texas, USA

2 University of Texas Southwestern Medical Center, Dallas Texas, USA

3 West Suffolk Hospital Cambridge University Hospitals Trust, Bury St Edmunds, UK

## References

- [1] NICE. CG88 Low back pain: Early management of persistent non-specific low back pain. NICE Clinical Guidelines: NICE; 2009.
- [2] Rudol G, Rambani R, Saleem MS, Okafor B. Psychological Distress Screen as Predictor of Outcome of Epidural Injection in Chronic Lower Back Pain. *Bone & Joint Journal Orthopaedic Proceedings Supplement*. 2013;95(Supp 20):17-.
- [3] Domino J, McGovern C, Chang KW, Carlozzi NE, Yang LJ. Lack of physician-patient communication as a key factor associated with malpractice litigation in neonatal brachial plexus palsy. *J Neurosurg Pediatr*. 2014;13(2):238-42.
- [4] Hamasaki T, Takehara T, Hagihara A. Physicians' communication skills with patients and legal liability in decided medical malpractice litigation cases in Japan. *BMC Fam Pract*. 2008;9:43.
- [5] Improving Communication, Cutting Risk: MPS New Zealand; 2012 [cited 20 1]. 10-1]. Available from: <http://www.medicalprotection.org/newzealand/casebook-january-2012/improving-communication-cutting-risk>.
- [6] Jackson JZ. HW, ATC, Hahn, CK. Physician Assistants ; Liability and Regulatory Issues 2012. Available from: [http://www.mdmc-law.com/tasks/sites/mdmc/assets/Image/MDAdvisor\\_FALL\\_12\\_ONLINE\\_FINALrev.pdf](http://www.mdmc-law.com/tasks/sites/mdmc/assets/Image/MDAdvisor_FALL_12_ONLINE_FINALrev.pdf).
- [7] MPS. Clinical negligence claims-what to expect. 2013.
- [8] Bolam v Friern Hospital Management Committee. Wikipedia2014.
- [9] Manner P, A. Practicing defensive medicine-Not good for patients or physicians. *AAOS Now*. 2007;Jan/Feb.
- [10] DeKay ML, Asch DA. Is the defensive use of diagnostic tests good for patients, or bad? *Med Decis Making*. 1998;18(1):19-28.

- [11] Cohen H. Medical Malpractice Liability Reform: Legal Issues and Fifty-State Survey of Caps on Punitive Damages and Noneconomic Damages. Received through the CRS Web: The Library of Congress, 2005 Contract No.: Order Code RL31692.
- [12] Office CB. Medical Malpractice Tort Limits and Health Care Spending. Background Paper: The Congress of the United States; 2006.
- [13] Shearer P. Punitive Damage Awards, Caps and Standards. 2007 Contract No.: 2003-R-0743.
- [14] Association ATR. Collateral Source Rule Reform.
- [15] Lord Neuberger of Abbotsbury MotR. Proportionate Costs. Fifteenth Lecture in the Implementation Programme; The Law Society 2012.
- [16] Limitation Act 1980. Wikipedia.
- [17] Limitation Periods in the UK. Wikipedia.
- [18] Kalauokalani D. Malpractice Claims for Nonoperative Pain Management: A Growing Pain for Anesthesiologists? ASA Newsletter. 1999;63(6):16-8.
- [19] Bird M. Acute Pain Management: A New Area of Liability for Anesthesiologist. ASA Newsletter. 2007;71(8).
- [20] Liao D. Trends in Chronic Pain Management Malpractice Claims.. ASA Newsletter. 2007;71(8).
- [21] Fitzgibbon DR, Posner KL, Domino KB, Caplan RA, Lee LA, Cheney FW, et al. Chronic pain management: American Society of Anesthesiologists Closed Claims Project. *Anesthesiology*. 2004;100(1):98-105.
- [22] Sandnes D, Stephens L, Posner K, Domino KB. Liability Associated with Medication Errors in Anesthesia: Closed Claims Analysis. *Anesthesiology*. 2008;109(A770).
- [23] Fitzgibbon DR, Rathmell JP, Michna E, Stephens LS, Posner KL, Domino KB. Malpractice claims associated with medication management for chronic pain. *Anesthesiology*. 2010;112(4):948-56.
- [24] Fitzgibbon D. Liability Arising From Anesthesiology-Based Pain Management in the Nonoperative Setting. ASA Newsletter. 2001;65(6):12-5.
- [25] Domino K, Fitzgibbon D. Clinical lessons in chronic pain management from the Closed Claims Project. ASA Newsletter. 2004;68(2):25-7.
- [26] Rathmell JP, Michna E, Fitzgibbon DR, Stephens LS, Posner KL, Domino KB. Injury and liability associated with cervical procedures for chronic pain. *Anesthesiology*. 2011;114(4):918-26.

- [27] Lee L, Posner K, Kent C, Domino K. Complications Associated With Peripheral Nerve Blocks: Lessons From the ASA Closed Claims Project. *Int Anesthesiol Clin*. 2011;49(3):56-67.
- [28] Posner KL, Caplan RA, Cheney FW. Variation in expert opinion in medical malpractice review. *Anesthesiology*. 1996;85(5):1049-54.
- [29] Caplan R, Posner R. The expert witness: Insights from the Closed Claims Project.. *ASA Newsletter*. 1997;61(6):9-10.
- [30] Domino K. Availability and Cost of Professional Liability Insurance.. *ASA Newsletter*. 2004;68(6):5-6.
- [31] Cheney F. How Much Professional Liability Coverage Is Enough? Lessons From the ASA Closed Claims Project.. *ASA Newsletter*. 1999;63(6):19,21.
- [32] Huntoon MA, Martin DP. Paralysis after transforaminal epidural injection and previous spinal surgery. *Reg Anesth Pain Med*. 2004;29(5):494-5.
- [33] Alturi S, Glaser SE, Shah RV, Sudarshan G. Needle position analysis in cases of paralysis from transforaminal epidurals: consider alternative approaches to traditional technique. *Pain Physician*. 2013;16(4):321-34.
- [34] Glaser SE, Shah RV. Root cause analysis of paraplegia following transforaminal epidural steroid injections: the 'unsafe' triangle. *Pain Physician*. 2010;13(3):237-44.
- [35] Chang Chien GC, Candido KD, Knezevic NN. Digital subtraction angiography does not reliably prevent paraplegia associated with lumbar transforaminal epidural steroid injection. *Pain Physician*. 2012;15(6):515-23.
- [36] Heavner JE, Racz GB, Jenigiri B, Lehman T, Day MR. Sharp versus blunt needle: a comparative study of penetration of internal structures and bleeding in dogs. *Pain Pract*. 2003;3(3):226-31.
- [37] Ilkhchoui Y, Koshkin E. A blunt needle (Epimed®) does not eliminate the risk of vascular penetration during transforaminal epidural injection. *Surg Neurol Int*. 2013;4(Suppl 5):S404-6.
- [38] Scanlon GC, Moeller-Bertram T, Romanowsky SM, Wallace MS. Cervical transforaminal epidural steroid injections: more dangerous than we think? *Spine (Phila Pa 1976)*. 2007;32(11):1249-56.
- [39] Tiso RL, Cutler T, Catania JA, Whalen K. Adverse central nervous system sequelae after selective transforaminal block: the role of corticosteroids. *Spine J*. 2004;4(4):468-74.
- [40] Baker R, Dreyfuss P, Mercer S, Bogduk N. Cervical transforaminal injection of corticosteroids into a radicular artery: a possible mechanism for spinal cord injury. *Pain*. 2003;103(1-2):211-5.

- [41] Derby R, Lee SH, Date ES, Lee JH, Lee CH. Size and aggregation of corticosteroids used for epidural injections. *Pain Med.* 2008;9(2):227-34.
- [42] Lyders EM, Morris PP. A case of spinal cord infarction following lumbar transforaminal epidural steroid injection: MR imaging and angiographic findings. *AJNR Am J Neuroradiol.* 2009;30(9):1691-3.
- [43] Sullivan WJ, Willick SE, Chira-Adisai W, Zuhosky J, Tyburski M, Dreyfuss P, et al. Incidence of intravascular uptake in lumbar spinal injection procedures. *Spine (Phila Pa 1976).* 2000;25(4):481-6.
- [44] Tharakan L, Gupta S, Munglani R. Survey of current UK practice in use of fluoroscopy, contrast material and steroids in neuraxial injections *Pain News.* 2012:3.
- [45] Nash A. Use of particulate steroids in neuraxial injections: a common but negligent practice? *Pain News.* 2012:2.
- [46] Lirk P, Kolbitsch C, Putz G, Colvin J, Colvin HP, Lorenz I, et al. Cervical and high thoracic ligamentum flavum frequently fails to fuse in the midline. *Anesthesiology.* 2003;99(6):1387-90.
- [47] Chien GC, McCormick Z, Araujo M, Candido KD. The Potential Contributing Effect of Ketorolac and Fluoxetine to a Spinal Epidural Hematoma following a Cervical Interlaminar Epidural Steroid Injection: A Case Report and Narrative Review. *Pain Physician.* 2014;17(3):E385-95.
- [48] Makris A, Gkliatis E, Diakomi M, Karmanioulou I, Mela A. Delayed spinal epidural hematoma following spinal anesthesia, far from needle puncture site. *Spinal Cord.* 2014.
- [49] Smith HS, Racz GB, Heavner JE. Peri-venous counter spread-be prepared. *Pain Physician.* 2010;13(1):1-6.
- [50] Chiapparini L, Sghirlanzoni A, Pareyson D, Savoiaro M. Imaging and outcome in severe complications of lumbar epidural anaesthesia: report of 16 cases. *Neuroradiology.* 2000;42(8):564-71.
- [51] Smith AD, Jull G, Schneider G, Frizzell B, Hooper RA, Sterling M. Cervical radiofrequency neurotomy reduces central hyperexcitability and improves neck movement in individuals with chronic whiplash. *Pain Med.* 2014;15(1):128-41.
- [52] Lima RM, Navarro LH, Carness JM, Barros GA, Marques ME, Solanki D, et al. Clinical and histological effects of the intrathecal administration of methylprednisolone in dogs. *Pain Physician.* 2010;13(5):493-501.
- [53] Latham JM, Fraser RD, Moore RJ, Blumbergs PC, Bogduk N. The pathologic effects of intrathecal betamethasone. *Spine (Phila Pa 1976).* 1997;22(14):1558-62.
- [54] Kitsou MC, Kostopanagiotou G, Kalimeris K, Vlachodimitropoulos D, Soultanis K, Batistaki C, et al. Histopathological alterations after single epidural injection of ropi-

- vacaine, methylprednisolone acetate, or contrast material in swine. *Cardiovasc Intervent Radiol.* 2011;34(6):1288-95.
- [55] Nanjayan SK, Swamy GN, Yallappa S, Bommireddy R. Arachnoiditis following caudal epidural injections for the lumbo-sacral radicular pain. *Asian Spine J.* 2013;7(4):355-8.
- [56] Cheng J, Abdi S. COMPLICATIONS OF JOINT, TENDON, AND MUSCLE INJECTIONS. *Tech Reg Anesth Pain Manag.* 2007;11(3):141-7.
- [57] Kornick C, Kramarich SS, Lamer TJ, Todd Sitzman B. Complications of lumbar facet radiofrequency denervation. *Spine (Phila Pa 1976).* 2004;29(12):1352-4.
- [58] Smith AD, Jull G, Schneider G, Frizzell B, Hooper RA, Sterling M. A comparison of physical and psychological features of responders and non-responders to cervical facet blocks in chronic whiplash. *BMC Musculoskelet Disord.* 2013;14:313.
- [59] Smith AD, Jull G, Schneider G, Frizzell B, Hooper RA, Dunne-Proctor R, et al. Cervical radiofrequency neurotomy reduces psychological features in individuals with chronic whiplash symptoms. *Pain Physician.* 2014;17(3):265-74.
- [60] Chinosornvatana N, Woo P, Sivak M, Sung C-K. Iatrogenic Unilateral Vocal Fold Paralysis after Radiofrequency Lesioning for Cervical Facet Joint Denervation. *The Laryngoscope.* 2009;119(Supplement S1):S29.
- [61] Stoker GE, Buchowski JM, Kelly MP. Dropped head syndrome after multilevel cervical radiofrequency ablation: a case report. *J Spinal Disord Tech.* 2013;26(8):444-8.
- [62] Munglani R. Numbers needed to heal, numbers needed to harm, numbers needed to kill: reflections on opioid therapy and the primary duty of medicine. *Pain News.* 2013;11(1):5.
- [63] Fine PG, Portenoy RK, Rotation AHEPoERaGfO. Establishing "best practices" for opioid rotation: conclusions of an expert panel. *J Pain Symptom Manage.* 2009;38(3):418-25.
- [64] Centre MGDNP. Practice Toolkit. Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain. Michael G. DeGroot National Pain Centre: Michael G. DeGroot National Pain Centre.
- [65] Prevention CfDCa. Prescription Painkiller Overdoses: Methadone 2014. Available from: <http://www.cdc.gov/features/vitalsigns/methadoneoverdoses/>.
- [66] Rathmell JP, Miller MJ. Death after initiation of intrathecal drug therapy for chronic pain: assessing risk and designing prevention. *Anesthesiology.* 2009;111(4):706-8.
- [67] Coffey RJ, Owens ML, Broste SK, Dubois MY, Ferrante FM, Schultz DM, et al. Mortality associated with implantation and management of intrathecal opioid drug infusion systems to treat noncancer pain. *Anesthesiology.* 2009;111(4):881-91.