

# Topics in PAIN MANAGEMENT

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## CME ARTICLE

### Complications Associated With Intrathecal Pumps

Clifford Gevirtz, MD, MPH

*Learning Objectives: After participating in this activity, the physician should be better able to:*

1. Diagnose complications associated with the implantation of intrathecal delivery devices.
2. Diagnose complications that arise from intrathecal drug delivery.
3. Prepare a workup for unexpected pump-related problems.

Intrathecal drug therapy is one of the major pain management advances of the last few decades, useful in the treatment of numerous conditions that cause chronic pain. However, the advance has come at a price for some patients: Complications are distressingly frequent in intrathecal drug therapy. When these complications are successfully managed, an intrathecal delivery device (IDD) can continue to provide excellent pain relief. In contrast, poorly managed complications can lead to disaster.

Complications of intrathecal drug therapy can be divided into 3 major categories: implantation procedure-related, drug-related, and delivery device-related.

#### Procedure-Related Complications

Procedure-related complications include subcutaneous tissue necrosis and seroma formation, seen especially in emaciated patients with low subcutaneous fat, small abdominal area, or atrophic skin, which results from chronic corticosteroid use.

A physician requires a significant level of surgical skill to place an IDD successfully. Meticulous technique should minimize the risk of infection and the formation of hematoma and seroma.

Turner et al<sup>1</sup> summarized complications derived from 10 separate reports of complications related to IDD implantation. A surprisingly high wound-infection rate of 12% was documented

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*Dr. Gevirtz is Associate Professor of Anesthesiology, Louisiana State University Health Center, New Orleans, and Medical Director, Somnia Pain Management, 627 W St, Harrison, NY 10528; E-mail: cliffgevirtzmd@yahoo.com.*

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*The author has disclosed that fentanyl, sufentanil, and vancomycin are discussed in the context of off-label use in this article.*

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across 3 studies. A bacterial meningitis rate of 2% was described in 3 studies. And problems of pump malposition were described in 2 studies with a combined complication rate of 17%.

## There is a complete lack of prospective, randomized, placebo-controlled studies on implantation techniques.

The development of a chronic cerebrospinal fluid (CSF) leak around the catheter resulting in postdural puncture headache, is another potential complication. Transverse myelitis due to catheter-tip infection has also been reported.

Although the overall rate of device-related infection is higher than one would expect, a useful guideline<sup>2</sup> for prevention and management of infection related to intrathecal therapy has been published. For other complications, seromas and local hematomas, conservative management with an abdominal binder and external pressure is recommended as a first step in management. On the rare occasion when meningitis develops, removal of catheter and pump may be required. In patients who decline having the IDD removed, management with intrathecal vancomycin 10 mg/d for 10 days has been successful, according to some reports.<sup>3</sup>

It is worth noting that there is a complete lack of prospective, randomized, placebo-controlled studies on implantation techniques. There is only a recommendation for the devices that the tissue layer between the device and the skin surface should not exceed 25 mm to maintain effective remote control of the device.

The continuing education activity in *Topics in Pain Management* is intended for clinical and academic physicians from the specialties of anesthesiology, neurology, psychiatry, physical and rehabilitative medicine, and neurosurgery as well as residents in those fields and other practitioners interested in pain management.

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**Table 1. Drug-Related Complications of Intrathecal Therapy<sup>1</sup>**

<b>Drug-related adverse events/adverse effects for intrathecal infusion of opioids for persistent pain</b>	<b>No. studies reviewed that report this complication</b>	<b>Total no. patients in combined studies</b>	<b>Rate or range reported within studies, %</b>
Nausea/vomiting	11	478	12–60
Constipation	7	334	0–62
Fecal incontinence*	1	90	1
Loss of appetite	2	136	12–62
Urinary retention	8	274	8–47
Urinary incontinence*	2	119	3–49
Disturbance of micturition	3	166	3–62
Pruritis	9	422	1–55
Respiratory depression	3	119	0–1
Provocation of asthma	2	136	1–15
Edema	5	272	3–58
Sedation/somnolence/lethargy	6	221	0–78
Difficulty with concentrating, thinking, memory	2	126	34–48
Hallucination	2	106	3–32
Headache	1	38	30
Insomnia	1	16	25
Nightmares	2	136	23–40
Depression	1	16	58
Moodiness	1	38	21
Menstrual disturbance (women < 50 years)	1	88	47
Amenorrhea	1	120	2
Sexual dysfunction (including disturbance of potency and libido)	6	317	4–71
Sweating (diaphoresis)	5	280	4–70
Dry mouth	2	136	4–32
Convulsion	1	120	1
Myoclonic jerk/spasm	1	16	58
Clonus	1	90	3
Transient numbness of lower extremities*	1	24	4
Transient paresthesia*	1	90	33
Transient paresis*	1	90	22
Dizziness	3	174	2–62
Arterial hypotension*	1	90	10
Opioid withdrawal	1	90	19
Morphine tolerance (morphine > 25 mg/d)	1	30	30
Escalating pain	1	30	3
Breakthrough pain	1	50	90
Weight gain	1	88	52
Arthralgia	1	88	25
Hypothyroidism	1	120	2

\*May be due to the presence of the local anesthetic, bupivacaine, in the mixture administered.

## Drug-Related Complications

Drug-related complications can be very serious and are more likely to lead to mortality than are the other categories

of IDD complication. These reported complications run the gamut from intractable nausea to menstrual problems to hypothyroidism.

A compendium of these problems was published by Reid et al,<sup>4</sup> and a modified summary is presented in Table 1. Most of the problems listed respond to decreasing the dosage of medication administered and treatment of symptoms rather than discontinuing the therapy: most complications can be simply managed and do not require explantation of the IDD.

### Intrathecal Granuloma

Intrathecal granuloma at the tip of the spinal catheter has the potential to cause spinal cord compression with all its sequelae. More than 100 cases have been reported of catheter-associated granuloma since the first case report in 1991.<sup>5</sup> It is commonly seen with morphine and seems to be a function of concentration (>25 mg/mL), dosage (>10 mg/d), and long duration of therapy.<sup>6-8</sup> Among the opioids, fentanyl and sufentanil have an apparent granuloma-sparing effect.<sup>9</sup>

### Most complications can be simply managed and do not require explantation of the device.

Signs suggestive of granuloma formation include progressive loss of analgesic effect and progressive neurologic symptoms such as weakness or urinary and fecal incontinence. Small granulomas that are diagnosed early require cessation of the drug and observation of the patient, along with pulling back the spinal catheter

2 spinal segments or completely changing the catheter. Large granulomas require neurosurgical consultation and removal.

When assessing any patient who has an IDD, it is important that the clinician makes sure that there has been, in fact, an evaluation of the catheter if there are 2 or more risk factors present. When patients are seen by different physicians over time, key symptoms may be missed when the problem is still minor, allowing it to grow into a major problem.

### Device-Related Complications

Device-related complications can cover a wide range of issues that include: catheter problems, such as kinking, breaking, obstruction, disconnection, or displacement; failure of the pump or battery; pain at pump site; nerve root irritation; lower extremity edema; postdural puncture headache; diplopia; and cranial nerve palsies. All have been reported in the literature. A detailed list<sup>4</sup> is presented in Table 2.

### Dose of Intrathecal Opioid

Turner et al<sup>1</sup> reported that the dose of intrathecal opioid required for pain relief increased over time. Study findings cited in the Turner paper ranged from a 2.6-fold increase (from 1 month after implantation to a follow-up ranging 10–56 months) to a 7.4-fold increase (from the initial dose to a 24-month follow-up). They documented that the time course of intrathecal-dose increases varied between studies. One of the studies (n = 30) reported that the average dose increased relatively rapidly during the first 3 to 6 months of intrathecal therapy, then remained

**Table 2. Device-Related Complications of Intrathecal Therapy<sup>1</sup>**

Device-related adverse events/adverse effects for intrathecal infusion of opioids for persistent pain	No. studies that reported the complication	Total no. patients in studies reviewed	Rate or range of complication, %
Meningitis	6	318	0–4
CSF leaks	3	165	0–17
CSF seroma development	1	30	10
Wound infection	5	274	0–22
Pump pocket infections	1	39	5
Catheter kinking	4	222	2–39
Catheter breakage	2	162	1–4
Catheter obstruction or occlusion	3	129	0–10
Catheter closure/occlusion or disconnection	3	164	12–27
Catheter displacement or blockage	2	132	21–25
Catheter migration or dislodgment	6	338	2–17
≥1 catheter-related complication	2	39	6–26
Mechanical failure of the pump or battery	5	104	0–17
Pump malposition	3	129	6–22
Pump replaced	2	136	6–12
≥1 equipment revisions (reoperation)	5	191	3–40
Requiring additional surgery	4	212	13–76
Device permanently removed	8	269	0–21

CSF, cerebrospinal fluid.

fairly constant over the next 12 months, and then increased again from 18 to 24 months. In another study (n = 26) the average dose increased gradually over the first 15 months, followed by smaller increases from 15 to 21 months. In a third study (n = 26), there were stable average doses from 1 to 3 months, and then gradually increasing from 3 to 24 months.

Turner et al<sup>1</sup> also reported several other serious adverse events such as traumatic syrinx due to penetration of the spinal cord by the intrathecal catheter; local erythema and edema in the area of the abdominal wall pocket; lower extremity edema; transverse myelitis due to catheter-tip infection; postdural puncture headache, diplopia, cranial nerve palsy, and intracranial subdural hematoma; and an episode of a “dissociative mental state.”

### Withdrawal Rates Due to Adverse Effects

Noble et al<sup>10</sup> undertook a meta-analysis of withdrawal rates due to adverse effects. The authors reviewed 6 studies, with a total sum of 154 patient participants. This study demonstrated that only 6.3% of patients with complications chose to have their IDD removed (95% confidence interval, 2.9%–13.1%) at the longest follow-up (at least 6 months).

### Instrument-Related Complications

Instrument-related complications arise from faulty programming of the instrument or from instrument failure (battery failure, motor failure, etc). Serious complication can arise from the spinal catheter also. The spinal catheter has a thinner-wall spinal segment and a thicker-wall proximal segment, which are subjected to different physical stresses. Catheter disconnection, breakage, occlusion, microfracture, and microleak are quite possible and can result in gross underdosing.

## A misfill may result in either overdosage or underdosage of drugs, both of which are dangerous and mandate immediate attention.

The catheter has a dead space or inner space that must be calculated and filled. Faulty estimation of catheter volume will cause sudden over- or underdosing, either of which is dangerous. Misses of refill ports while refilling the instrument with medicine, resulting in extravagation, is another possibility.

On January 14, 2011, the FDA posted a class I recall for specific lots of implantable infusion pumps manufactured by Medtronic. The recall was issued for Medtronic SynchroMed II (model no. 8637) and SynchroMed EL implantable infusion pump (model nos. 8626 and 8627) and refill kits (model nos. 8551, 8555, 8561, 8562, 8564, 8565, and 8566). The problem with the devices is the potential for “pocket fills” to occur, in which the drug is injected into the pump pocket (the area under the skin where the pump is placed) instead of in the pump itself. Between 1996 and 2010, 8 deaths and 270 events requiring medical intervention were reported related to the occurrence of pocket fills, according to the FDA. The rate of occurrence per refill opportunity is at least 1 in 10,000.

A misfill may result in either overdosage or underdosage of drugs, both of which are dangerous and mandate immediate attention. In underdosage, the patient presents with withdrawal symptoms and increased pain. Baclofen withdrawal (vide infra) may be fatal as the patient presents with fever, altered mental status, and profound muscular rigidity. Conversely, overdosage of drug can cause respiratory depression, hypotension, and coma. A complication needs immediate hospitalization, careful diagnosis, and sensitive management as they are quite serious and often fatal.

### Approach to the Diagnosis of Unexpected Problems

Prompt diagnosis of unexpected pain or other symptoms is important to prevent complications. A suggested diagnostic approach is listed below:

- Initial evaluation, including patient history, will often identify the source of the problem.
- Verification of pump contents, volume, and pump settings is the critical initial step.
- Plain radiography (posteroanterior and lateral to visualize the entire catheter).
- Serial radiography or fluoroscopy to confirm that the pump roller is moving at the expected rate.
- Myelography to see if there is CSF flow around catheter.
- Nuclear medicine scan.
- MRI study (if the pump is MRI compatible).
- CT scanning is often not helpful because the metal of the pump causes additional scattering of the x-ray and distorts the image.

### Complications From Intrathecal Baclofen Therapy

Dario et al<sup>11</sup> reviewed the pharmacologic complications and adverse effects of chronic intrathecal baclofen infusion in patients with intractable spinal spasticity. In their series, 3 (12%) patients with developed hypotonia, 2 had erectile dysfunction (8%), and 1 (4%) had constipation; 5 (20%) patients showed also tolerance but only 1 (4%) needed a “drug holiday.” In the literature, the adverse effects range from 4% to 16%. Moreover, the tolerance is reported from 3% to 15%. Overdose has been reported to range from 0% to 14%, whereas the syndrome of withdrawal was reported in 16 patients with 6 fatalities.

Green and Nelson<sup>12</sup> reported a 21-year-old man with C1 sensory-incomplete ventilator-dependent quadriplegia. He was treated with good results with an intrathecal baclofen pump for intractable spasticity since age 17 years but developed increasing spasticity and seizures when his pump began to malfunction. He became unresponsive and developed hypotension, severe hyperthermia, and ventricular tachycardia that required chemical and electrical cardioversion. Although he was receiving oral baclofen when his pump failed, and he was given an intrathecal

bolus of baclofen, he subsequently developed rhabdomyolysis, hepatic enzyme elevations, and a consumptive coagulopathy. Cerebral ischemia then occurred, causing brain death.

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## **Overdose has been reported to range from 0% to 14%, whereas the syndrome of withdrawal was reported in 16 patients with 6 fatalities.**

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What is so disturbing about this case is the fact that, even with equivalent oral replacement of the baclofen, mortality still occurred.

Delhaas and Brouwers<sup>13</sup> published a report alerting clinicians to the insidious symptoms of baclofen overdose and its prevention and treatment. In a group of 43 patients suffering from previously intractable spasticity and a total treatment time of 2422 weeks, 7 events of intrathecal baclofen overdose happened in 5 patients. On 2 occasions, a bolus injection caused an overdose (dose 50 and 280 mcg).

The 5 events during continuous infusion intoxication only happened in high-dosed patients. The overdose symptoms occurred in 1 patient when she was lying in supine position (800 mcg/24 h), in another patient after repair of CSF leakage by an autologous epidural blood patch (1920 mcg/24 h), and in tolerant patients, once during maximal dose adjustments (2400 mcg/24 h) and twice about 6 hours after reinitiation of the intrathecal baclofen infusion after a “drug holiday” treatment (27 and 55 mcg/h).

The lack of a pure baclofen antagonist and the varying symptoms associated with intrathecal baclofen intoxication make a single, simple treatment plan difficult. Delhaas and Brouwers<sup>13</sup> observed that the recommended physostigmine therapy is not always effective and safe. The occasionally doubtful antidotal benefits of physostigmine must be weighted against major adverse effects. The classical approach of decreasing the absorption of a drug by lowering baclofen levels in the CSF by lumbar puncture drainage can be used. They concluded that this approach, together with conservative symptomatic treatment in an intensive care environment, is probably a better and safer alternative than physostigmine alone as an antidote.

### **Complications of Intrathecal Ziconotide Therapy**

Ziconotide is a peptide with a powerful analgesic that has a unique mechanism of action involving potent and selective blocking of the N-type calcium channels, which control neurotransmission at many synapses. Ziconotide was the subject of a *Topics in Pain Management* continuing medical education review article (2005;21(1):1-6). The analgesic efficacy of ziconotide likely results from its ability to interrupt pain signaling between various Rexed laminae of the spinal cord. Importantly, prolonged administration of ziconotide does not lead to the development of addiction or tolerance.

Rauck et al<sup>14</sup> summarized data from double-blind, placebo-controlled (DBPC) trials that indicated that patients with neuropathic pain reported a mean percent improvement in pain

score with ziconotide monotherapy that ranged from 15.7% to 31.6%. A low starting dose and slow titration of ziconotide resulted in an improved safety profile in the aforementioned trials.

Common adverse effects associated with ziconotide include nausea and/or vomiting, dizziness, confusion, urinary retention, and somnolence. Episodes of suicidal thoughts have also been reported. It is important not to dismiss this ideation and to assess whether there is a real risk of suicide. If there is evidence of planning, then appropriate precautions need to be taken including psychiatric consultation and observation. Transfer to a psychiatric emergency department may also be required.

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## **The lack of a pure baclofen antagonist and the varying symptoms associated with intrathecal baclofen intoxication make a single, simple treatment plan difficult.**

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Evidence from DBPC trials, open-label studies, case series, and case studies suggests that ziconotide, as either monotherapy or in combination with other intrathecal drugs, is a potential therapeutic option for patients with refractory neuropathic pain.

A major problem with ziconotide, however, is its steep dose-response curve. Burton et al<sup>15</sup> reviewed 3 methods of ziconotide trialing: continuous infusion, limited-duration infusion, and bolus injection. They determined that patients often achieve analgesia during trialing with ziconotide, regardless of the trialing method. Adverse events reported during ziconotide trialing studies were similar to those reported during ziconotide clinical trials. Preliminary evidence suggests that both effectiveness and safety may be dose-related.

However, given the small sample size and lack of controlled ziconotide trialing studies, it is not possible currently to determine the relative safety and effectiveness of various methods of ziconotide trialing or to determine whether trialing is predictive of patient response to long-term ziconotide therapy. Burton et al<sup>15</sup> concluded that all 3 methods of ziconotide trialing seem to be viable options, and no method can be considered superior on the basis of the evidence presented in this review. Comparative controlled studies of ziconotide trialing methods are needed to delineate the best approach.

### **Conclusion**

Although intrathecal therapy has been a major advance in the management of pain, the IDD is not without risk. Prompt management of complications can often salvage the treatment plan by addressing cases of infection, extravasation, granuloma, and other risks. It may not be necessary to remove the device, and patients' pain can be addressed with a readjustment, if necessary. ■

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## “Accountable Care Organization” Model—Part of the Federal Affordable Care Act—Could Change the Role of Interventional Pain Management Physicians

The evolving national policies on reimbursement and approval for health care could have a big impact on pain practices—especially those of anesthesiologists who specialize in interventional pain management, says Mark J. Lema, MD, PhD, professor and chair of anesthesiology at University at Buffalo-The State University of New York and Roswell Park Cancer Institute.

The potential changes and their impact were among the hot topics at the New York State Society of Anesthesiologists Post-Graduate Assembly in December.

Lema urged interventional anesthesiologists to join with their peers in other interventional specialties and speak with a unified voice to make sure that the procedures they perform remain a viable option for patients who need them. (See “Council of Pain Physician Societies Seeks to Establish a Unified Voice,” page 10.)

### Reimbursement Model Is Changing

The reimbursement model in place for decades tends to favor payment for a procedure rather than for educating a patient or starting with the most conservative treatments—which can also be time consuming to both patient and doctor.

**An ACO is a group of health care providers who provide coordinated care and chronic disease management, with the goal of improving the quality of care patients receive while also controlling costs.**

But that model could give way as the Affordable Care Act begins to establish a model for Medicare payments that is based on accountable care organizations (ACOs). An ACO is a group of health care providers who provide coordinated care and chronic disease management, with the goal of improving the quality of care patients receive while also controlling costs. The organization’s payment is tied to achieving health care quality goals and outcomes that result in cost savings. Participation in an ACO is voluntary for now, for both health care providers and patients.<sup>1</sup>

A new approach could, if successful, lead to more patients getting appropriate pain care earlier, and from their primary care providers. In an ideal world, it could reduce or even prevent some chronic pain by better addressing acute pain.

The concept is admirable, but some interventional anesthesiologists fear it could dramatically affect their ability to sustain a private practice that is not affiliated with an ACO, and that it may become harder for patients who really could benefit from these procedures to have access to them under Medicare or, eventually, private insurers.

### Who Can Form an ACO

The Affordable Care Act specifies that an ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- ACO professionals (ie, physicians and hospitals meeting the statutory definition) in group practice arrangements;
- Networks of individual practices of ACO professionals;

- Partnerships or joint-venture arrangements between hospitals and ACO professionals, or hospitals employing ACO professionals; and
- Other Medicare providers and suppliers as determined by the US secretary of Health and Human Services.

The ACO must take responsibility for at least 5000 beneficiaries for a period of 3 years, and must have a governing board that includes health care providers, suppliers, and Medicare beneficiaries.

## Conversation: Mark J. Lema, MD, PhD, on the Impact of Health Care Reform and Accountable Care Organizations on Interventional Pain Medicine

The scientific panel sessions at the New York State Society of Anesthesiologists Post-Graduate Assembly (PGA) in December included one that generated many questions—to which there are still no firm answers.

Interventional anesthesiologists who provide pain management procedures and who attended the PGA were concerned about a change in health care reimbursement and approval practices that could drastically change their practice.

Mark J. Lema, MD, PhD, professor and chair of anesthesiology at University at Buffalo-The State University of New York and Roswell Park Cancer Institute, gave the attendees a summary and analysis that did little to calm them down. He urged them to remain vocal on a national level.

Before his talk, Lema gave an interview to *Topics in Pain Management (TPM)* about the potential impact, especially for anesthesiologists who work primarily in interventional pain management.

**TPM: What's the rationale behind the accountable care organization (ACO)?**

**Lema:** First of all, I think it's important to say that the accountable care organization is a concept, and the government is looking for best practices on how to save money. It's a cost-saving measure that tries to preserve quality while reducing the cost of health care.

Second, there are a number of people who don't believe it's going to be successful because the way the incentives are built in, the cost for ramping up to qualify for accountable care organizations does not provide the return on investment that [interventional physicians] expect. They said you'd almost have to increase your productivity by 20% in order to effectuate the necessary profits for accountable care.

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Third, the ACOs seem to be driven more by primary care than hospital-based specialties. So the question of whether hospital-based specialties will be able to participate in ACOs depends very heavily on how integrated they are with the administration that's making the decisions.

The fourth point with accountable care organizations is that there aren't going to be that many across the state: In every state, there

might be only 1 ACO designated. You have to apply to become an accountable care organization now because it's in a study phase. I think there's only 1 or 2 places in all of New York state that are designated accountable care, while everyone else is gearing up to try to participate.

**TPM: What kind of a partnership is an ACO, and what role do physicians play?**

**Lema:** It's like the old physician-provider organization. It's a system that involves putting money at risk, payment at risk, to demonstrate efficiency. Then, the government will share the savings with you over a 3-year period.

Then, after that period, the savings will go away. You'll have to benchmark your practice according to what you've been able to produce over 3 years. There could be penalties for not meeting those benchmarks. So it really is a cost-reduction plan that's designed to partner with physicians and hospitals. It's actually physician-driven, not hospital-driven, so hospitals are very enthusiastic about getting as many physicians as they can into their networks. The payments are to the physicians, not the hospital.

**TPM: Who is the accountable organization?**

**Lema:** The ACO could be a hospital or a physician practice—it's physician-based.

**TPM: What is unique about interventional pain management when it comes to ACOs?**

**Lema:** The issue with pain medicine is it's not really integrated into anything. There are a lot of private clinics that are set up. The government is actually looking at those from a separate perspective, with the Rand Corporation. They're looking at the CPT codes that the government has to pay the most money to, and they're trying to find out if the cost is justified by the outcomes.

The Rand Corporation is also looking at outcome data to determine, for pain procedures, whether there are data to show that the high cost justifies the payment.

As an example, intradiscal electrothermic therapy—or IDET—procedures were evaluated by the Rand Corporation a couple of years ago. The Rand Corporation found out there was no benefit to those patients 65 and older having IDET procedures because the disc had already become, for lack of a better word, dried out. There wasn't a sponginess to the disc anymore, so it didn't make a difference to do the procedure. CMS then issued an announcement that they were no longer going to pay for IDET procedures in patients 65 and older who qualified for Medicare.

If that's the case, HMOs will follow suit, and they may go even further and say "We're not going to pay for any IDET procedures

unless you get prior approval.” They’re continuing to do that with discographies and all sorts of other procedures.

**TPM:** *What other procedures might get dropped by CMS, and how do they decide?*

**Lema:** They’ll just systematically take the most expensive procedures—such as spinal cord stimulators and peripheral nerve stimulators—and look at the cost of implantation and maintenance, and then look at the long-term benefits.

The long-term benefits currently don’t support the use of such technology for neuropathic pain. CMS won’t pay it. And if they don’t pay it, you better believe every HMO and insurer is going to say, “If it’s good enough for the Rand Corporation, it’s good enough for us, and we’re not going to pay for it unless you can really justify to us why this person needs it.”

**TPM:** *Why did interventional pain medicine become so procedure-oriented?*

**Lema:** I think the way pain medicine evolved, from the early 1980s in anesthesiology, was sort of an aberration of how a new specialty would evolve. It really evolved as an interventional specialty, whereas pain medicine should not be intervention first.

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## They come up with a procedure, and basically it’s a hammer-and-nail concept: I have a hammer, so everything becomes a nail.

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It should be that we go from the least invasive to the most invasive. But because of the medications that we give for pain medicine and because the E and M [evaluation and management] codes for seeing patients in a clinic do not favor people engaging in that kind of activity on a large scale, they went where the money is, and this is really what CMS is all about.

In 1965, CMS wanted a procedure-based payment system. And in 2012, CMS has a procedure-based payment system out of control, where every doctor looks at her or his specialty, and thinks “Where can I make the most amount of money for the time I spend seeing a patient.” They come up with a procedure, and basically it’s a hammer-and-nail concept: I have a hammer, so everything becomes a nail.

So I don’t know how pain medicine is going to fit in ACOs, unless they actually form mega-groups, so that they can be cost-effective. To be cost-effective for interventional pain medicine is almost an oxymoron, because interventional pain medicine is the expensive alternative to noninterventional pain medicine. And if you have [a patient who tries] interventional pain medicine first, you’re automatically going through more expensive therapy.

**TPM:** *Are we looking at a radical change coming up? And for whom?*

**Lema:** It could radically change, but it depends on whether you see the glass as half full or half empty. What I think, seeing the glass half full, is that the number of procedures are going to drop dramatically, and only those who are most qualified and certified to do them, will be doing procedures all day.

So if you have the procedures and you have the number of people doing the procedures, nothing changes.

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## There are a lot of part-time interventionalists doing relatively low-risk procedures of questionable value in some patients.

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**TPM:** *But which physicians will see the most change?*

**Lema:** There are a lot of part-time interventionalists, doing relatively low-risk procedures—epidural steroid injections, trigger-point injections, some peripheral nerve blocks, et cetera—of questionable value in some patients.

As those become eliminated, they may find that they’re either going to have to find another specialty, or they’re going to have to focus on doing noninterventional pain medicine with a smattering of interventional medicine, or you’re going to have to go back and recertify for more interventional kinds of procedures.

As they try to recertify, it’s going to be more difficult to get that certification, because most of the grandfathering for pain medicine board certifications is over. Now you have to demonstrate that you’re doing fellowships.

So for someone to come out of practice to do a fellowship, you’d really have to do some soul-searching. You’re going, really, from multiple 6-figure salaries to 5-figure salaries. You have to really look at your finances.

**TPM:** *Aren’t pain practices already tied to hospitals?*

**Lema:** There are not a lot of pain practices that align themselves with hospitals because most pain practices use ambulatory settings where they can also bill for part A, the facility fee. And that’s where many of the pain practices make much of their money, because it might be \$300 for the procedure, but \$1500 for the facility fee, and if they own the facility, or some share of it, they will make a non-professional fee income, or it will allow them to pay for the services of the employees that they need to do the billing, et cetera.

**TPM:** *So what do you predict will happen?*

**Lema:** I think procedure payments will be based on outcomes.

It will be more difficult for people who don’t do a lot of procedures to get the certification they need to do them.

I believe that there will be a better payment system for non-interventional pain visits.

And I think fewer anesthesiologists will seek pain medicine as being the lucrative field it is, if they realize that they can’t do as many procedures and collect the facility fees as well as the professional fees.

**TPM:** *What will be the basis of the new system?*

**Lema:** The new payment system will be based on outcomes. Right now, in pain medicine, payment guides practice. And once that changes, where practice guides payment, people will have to see how much they’re going to get paid for the practice and determine whether or not it’s something they want to do.

And anesthesiologists, who are being paid at the higher end of the pay scale, may not find it as lucrative to be doing clinic work, whereas internists and neurologists might find it more lucrative,

because those procedures they're doing in the clinics—epidural steroid injections, nerve blocks—will still produce a higher salary for them.

So while interns and neurologists might raise their incomes by adding pain medicine, interventional pain anesthesiologists might begin to leave pain practice to join the OR anesthesia team, because they have that skill set and training.

**TPM: Are hospitals courting pain physicians at all?**

**Lema:** I don't think that hospitals are quite as excited about grabbing pain practices because I think that these practices are overutilized for interventional procedures and that that will likely end. And the other half of that is that to have a noninterventional pain clinic in an age where drug-seeking behavior is epidemic in this country produces a whole new class of patients that the hospitals probably don't see as profitable for them.

So I don't think the outlook is good for pain medicine.

**TPM: What will the outlook be for practices and patient access to these procedures?**

**Lema:** From the standpoint of an interventional pain practitioner, you're going to see payment cuts for procedures, you're going to see greater denial by CMS for procedures.

As a result of the greater denials by CMS, you're going to see fewer people going into interventional pain medicine.

**TPM: Will more primary care practitioners be able to fill in the gaps and provide better management of pain, or refer patients to specialty care?**

**Lema:** For practitioners in general, I don't believe the paradigm for pain practice has been universally applied. And you're taking care of some of the most difficult patients—problem patients, for not much more money than you would get by just doing your regular clinics. So because of that, there's no real desire to do noninterventional pain medicine on a national scale. And if

they're not practicing interventional pain management, I don't think they're going to revert to noninterventional—they're going to find something else to do.

So I'm not sure that primary care practitioners are going to be embracing pain care, unless the government or hospital systems really saw some sort of public relations benefit from doing so, or if the outcomes on a large scale put people back in the workplace.

Unless you can see good outcome data, they're not likely to apply the specialty of pain medicine universally. It will just be "siloed" activity based on who's doing what, and it will continue to be what I call the "Wild West" of pain practice. The laws will be made up from town to town by the marshal in the town, exerting his will on law and order.

## As a result of the greater denials by CMS, you're going to see fewer people going into interventional pain medicine.

**TPM: What about patients? Pain is already undertreated. Will this make it worse for them to find a practitioner?**

**Lema:** I don't see a good result for the patient and the practitioner in the short term. There's no real national task force. The Institute of Medicine talked about pain [and issued a report in June 2011], and you have the Pain Care Coalition. You have the IASP [International Association for the Study of Pain] and the American Pain Society. All pretty much like blind men touching different parts of the elephant and describing what they think is in front of them.

But what you don't have are people who are willing to say, "We're the noninterventionalists and we're the base of the pyramid. We

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## For Greater Influence Council of Pain Physician Societies Seeks to Establish a Unified Voice

Changes at the federal level in health care are among the forces that have prompted pain physicians from various societies and disciplines to form a council with representatives from each society.

The council has a website, [www.cppsocieties.org](http://www.cppsocieties.org). To read material on the website, one must register as a member, which is free.

The Council of Pain Physician Societies includes representatives from the following medical societies:

- American Society of Anesthesiologists
- American Society of Interventional Pain Physicians
- American Academy of Pain Medicine
- American Academy of Pain Management
- International Spine Intervention Society
- North American Neuromodulation Society

One of the members, Marc Huntoon, MD, professor and chief of the division of pain medicine at Vanderbilt University, said the members meet via teleconference and are looking forward to finding issues on which they can speak with one voice to carry more influence with regulators and legislators.

## Topics in Pain Management CME Quiz

To earn CME credit, you must read the CME article and complete the quiz and evaluation assessment survey on the enclosed form, answering at least 70% of the quiz questions correctly. **Select the best answer and use a blue or black pen to completely fill in the corresponding box on the enclosed answer form.** Please indicate any name and address changes directly on the answer form. If your name and address do not appear on the answer form, please print that information in the blank space at the top left of the page. Make a photocopy of the completed answer form for your own files and mail the original answer form in the enclosed postage-paid business reply envelope. Your answer form must be received by Lippincott CME Institute by **January 31, 2013**. Only two entries will be considered for credit.

**Online quiz instructions:** To take the quiz online, log on to your account at <http://www.topicsinpainmanagement.com>, and click on the “CME” tab at the top of the page. Then click on “Access the CME activity for this newsletter,” which will take you to the log-in page for [CME.lwwnewsletters.com](http://CME.lwwnewsletters.com). Enter your *username and password for this screen as follows*: Your *CME username* will be the letters LWW (case sensitive) followed by the 12-digit account number above your name on the paper answer form mailed with your issue. Your *CME password* will be 1234; this password *may not* be changed. Follow the instructions on the site. You may print your official certificate *immediately*. Please note: Lippincott CME Institute, Inc., *will not* mail certificates to online participants. **Online quizzes expire at 11:59 pm Pacific Standard Time on the due date.**

1. **The spinal catheter has a thinner-wall spinal segment and a thicker-wall proximal segment, which are subjected to various physical stresses. Catheter disconnection, breakage, occlusion, microfracture, and microleak are possible, and if one or more occurs, can result in gross underdosing.**
  - A. True
  - B. False
2. **Fentanyl and sufentanil are not associated with granuloma formation.**
  - A. True
  - B. False
3. **Abrupt cessation of baclofen therapy is without risk.**
  - A. True
  - B. False
4. **Risk factors for the development of catheter-tip granuloma formation include all of the following *except***
  - A. high concentration of morphine
  - B. long duration of therapy
  - C. clonidine as an additive
  - D. high daily dosage of morphine
5. **Ziconotide is effective for treatment of neuropathic pain and has no withdrawal syndrome associated with its use.**
  - A. True
  - B. False
6. **Traumatic syring is a rare complication caused by penetration of the spinal cord by the catheter.**
  - A. True
  - B. False
7. **The catheter has a dead space or inner space that must be calculated and filled. Faulty estimation of catheter volume will cause sudden over- or underdosing, either of which is dangerous.**
  - A. True
  - B. False
8. **A patient with an intrathecal pump delivering morphine and ropivacaine presents for refill along with a report of new onset of weakness in both lower extremities and increased visual analog scale scores over the past month. Appropriate actions include all of the following *except***
  - A. increasing the infusion rate of the pump
  - B. obtaining a CT scan that includes the catheter tip
  - C. performing a detailed neurologic examination including sensory testing of all dermatomes
  - D. performing a rectal examination
9. **A patient receiving intrathecal ziconotide for neuropathic pain reports increasing thoughts of suicide. Appropriate actions include all of the following *except***
  - A. obtaining psychiatric consultation
  - B. reassuring the patient that these thoughts will pass
  - C. transfer to psychiatric emergency department with an escort
  - D. decreasing the infusion rate by 20%
10. **A patient who underwent a pump refill with morphine notes increasing pain, sweating, piloerection, some abdominal cramps, diarrhea, and vomiting. All of the following techniques may assist in determining whether there was a “pocket fill” *except***
  - A. ultrasonography of the pocket
  - B. CT scan of the area around the pump
  - C. MRI scan of the pump (if the pump is MRI compatible)
  - D. plain radiography of the abdomen

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need to be feeding the interventionalists.” But there’s no cohesiveness. We need to be addressing the two realms.

**TPM: Might not an integrated model come of this?**

**Lema:** An integrated model ought to be like the model for any other disease process, if it were done correctly.

If we had a perfect system, you would come in with the start of pain from a disc problem in your back. So you go in and find a primary care physician who knows how to interact with patients with low back pain—does a history and physical exam, tries a couple of interventions in some sort of protocol that includes medications, physical therapy.

Let’s say symptoms persist to a type of neuropathic pain. The patient then goes to either a neurologist or a pain specialist who makes the diagnosis of discogenic disease. A protocol then is followed based on what kind of discogenic disease it is, what sorts of symptoms there are. Perhaps it’s conservatively managed with noninterventional types of things—stretching exercises. If it gets worse, it now goes to a specialist, and the specialist could be someone who does steroid injections or IDET. In other words, procedures that are interventional, but needle procedures.

And if that didn’t work, they’d say, well you have to see the neurosurgeon. The neurosurgeon then might do a procedure or send the patient back to the pain specialist, and they do some rehab. Eventually the patient goes back to the primary care physician.

That would be similar to how diabetes is treated. Diabetes gets controlled, but then it can get a little worse, and you go to the emergency room or even the intensive care unit. They have an

[endocrinologist] work you up. A dietitian looks at your eating habits. So that’s when you go back to your primary care physician, with the new regimen.

The model for pain could be like diabetes. But there is no integrated model like this. It should be this way in pain medicine. Pain patients shouldn’t be the hot potato, where primary care pushed the potato over to the pain specialist and said, “It’s yours forever now.”

**TPM: Could an ACO lead to a cohesive model for pain medicine?**

**Lema:** I think the two are not diametrically opposed. They are about 5 steps removed from each other. Could you come up with a model for integrated pain medicine? Absolutely.

Is there an infrastructure present nationally that could support it? No.

Are there hospitals or health care systems that will get into accountable care that will maybe be able to implement this? Yes.

Is it a priority? Probably not.

**TPM: Doesn’t anyone out there have an integrated pain care model?**

**Lema:** The closest thing to an integrated pain care model would be the Mayo Clinic, with all sorts of different pain specialists. ■

**Reference**

1. HealthCare.gov, a federal government website managed by the U.S. Department of Health & Human Services. <http://www.healthcare.gov/news/factsheets/2011/03/accountablecare03312011a.html>. Accessed December 13, 2011.

**Coming Soon:**

- Intravenous Acetaminophen, Another Tool for Management of Postoperative Pain

## NEWS IN BRIEF

### What Are the Causes of Opioid-Related Deaths?

A recent study in *Pain Medicine* tried to address the root causes of opioid-related overdose deaths in the United States. But it may have ignored one central cause of opioid-related fatalities—the role of modern medicine in facilitating this epidemic.

A panel “of experts in pain medicine and public policy” headed by Lynn R. Webster, MD, looked at evidence from scientific studies, government sources, and malpractice lawsuits, and came to a consensus judgment about the causes of opioid-related deaths.

This group concluded that the causes are multifactorial and will have to be addressed with multifactorial solutions. Here is a list of the main factors the group identified: physician error due to knowledge deficits; patient nonadherence to prescribed medication regimen; unanticipated medical and mental health comorbidities; payer policies that mandate methadone as a first-line therapy; sleep-disordered breathing; and concomitant

use of central nervous system depressants (such as alcohol, benzodiazepines, and antidepressants).

The panel suggested that solutions should address, among other factors, provider behavior, patient-specific risk factors, non-medical-use patterns, and “systemic failures.”

The group suggested that action should be immediate: “Although analysis of risk factors is ongoing, pain care providers and public health officials have a duty to act now to prevent as many deaths as possible,” according to Webster et al.

However, this group neglected one other important root cause: the collective misreading of the evidence by pain specialists and other physicians regarding the long-term risks and benefits of opioid therapy. Many physicians have prescribed opioids intemperately—in the absence of clear evidence that they benefit patients with chronic noncancer pain over the long term. And perhaps the productive strategy to prevent opioid deaths would be to reduce opioid treatment as a monotherapy for chronic noncancer pain. (*Pain Medicine*, 2011;12:S26–S35.) *Editor’s Note: This article was initially published in Lippincott Williams & Wilkins’ The BackLetter, Vol. 26, No. 8 (August 2011).* ■