

CSA Bulletin

California Society of Anesthesiologists



Vol. 61 No. 1



Winter 2012

Less pain. Less opioids. From the start.

OFIRMEV® provides significant pain relief*1

- OFIRMEV 1 g (Q6h) + patient controlled analgesia (PCA) morphine demonstrated significant pain relief vs placebo + PCA morphine ($P < 0.05$ over 6 h)
- OFIRMEV 1 g (Q6h) + PCA morphine showed greater reduction in pain intensity over 24 h (SPID24)² compared to placebo + PCA morphine ($P < 0.001$)

OFIRMEV reduces opioid consumption*1

- OFIRMEV 1 g (Q6h) + PCA morphine significantly reduced morphine consumption vs placebo + PCA morphine (-46% over 6 h, $P < 0.01$; -33% over 24 h, $P < 0.01$)
- The clinical benefit of reduced opioid consumption was not demonstrated

OFIRMEV from the start

- Consider administering the first dose of OFIRMEV PreOp or post-induction
- Schedule OFIRMEV Q6h for first 24 h and continue as clinically warranted

Indication

OFIRMEV is indicated for the management of mild to moderate pain; the management of moderate to severe pain with adjunctive opioid analgesics; and the reduction of fever.

Important Safety Information

OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation. Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment.

Do not exceed the maximum recommended daily dose of acetaminophen. Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death.

OFIRMEV should be administered only as a 15-minute intravenous infusion.

*Randomized, double-blind, placebo-controlled, single- and repeated-dose 24-h study (n=101). Patients received OFIRMEV 1 g + PCA morphine or placebo + PCA morphine the morning following total hip or knee replacement surgery. Primary endpoint: pain relief measured on a 5-point verbal scale over 6 h. Morphine rescue was administered as needed. SPID24—sum of pain intensity differences, based on VAS score, from baseline, at 0 to 24 h.

References: 1. Sinatra RS, Jahn JS, Reynolds LW, Viscusi ER, Grudine SB, Payer-Champenois C. Efficacy and safety of single and repeated administration of 1 gram intravenous acetaminophen injection (paracetamol) for pain management after major orthopedic surgery. *Anesthesiology*. 2005;102:822-831. 2. Data on file. Cadence Pharmaceuticals, Inc.

Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy.

The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients.

OFIRMEV is approved for use in patients ≥ 2 years of age.

The antipyretic effects of OFIRMEV may mask fever in patients treated for postsurgical pain.

To report SUSPECTED ADVERSE REACTIONS, contact Cadence Pharmaceuticals, Inc. at 1-877-647-2239 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on adjacent page or full Prescribing Information at OFIRMEV.com.



OFIRMEV[™]
(acetaminophen) injection
100 mg/100 mL (10 mg/mL)



Brief Summary (For full Prescribing Information refer to package insert.)

INDICATIONS AND USAGE

OFIRMEV® (acetaminophen) injection is indicated for

- the management of mild to moderate pain
- the management of moderate to severe pain with adjunctive opioid analgesics
- the reduction of fever.

CONTRAINDICATIONS

Acetaminophen is contraindicated:

- in patients with known hypersensitivity to acetaminophen or to any of the excipients in the intravenous formulation.
- in patients with severe hepatic impairment or severe active liver disease.

WARNINGS AND PRECAUTIONS

Hepatic Injury

Administration of acetaminophen in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death. Do not exceed the maximum recommended daily dose of acetaminophen.

Use caution when administering acetaminophen in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia (e.g., due to dehydration or blood loss), or severe renal impairment (creatinine clearance \leq 30 mL/min).

Allergy and Hypersensitivity

There have been post-marketing reports of hypersensitivity and anaphylaxis associated with the use of acetaminophen. Clinical signs included swelling of the face, mouth, and throat, respiratory distress, urticaria, rash, and pruritus. There were infrequent reports of life-threatening anaphylaxis requiring emergent medical attention. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. Do not use OFIRMEV in patients with acetaminophen allergy.

ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Hepatic Injury
- Allergy and Hypersensitivity

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed cannot be directly compared to rates in other clinical trials and may not reflect the rates observed in practice.

Adult Population

A total of 1020 adult patients have received OFIRMEV in clinical trials, including 37.3% (n=380) who received 5 or more doses, and 17.0% (n=173) who received more than 10 doses. Most patients were treated with OFIRMEV 1000 mg every 6 hours. A total of 13.1% (n=134) received OFIRMEV 650 mg every 4 hours.

All adverse reactions that occurred in adult patients treated with either OFIRMEV or placebo in repeated dose, placebo-controlled clinical trials at an incidence \geq 3% and at a greater frequency than placebo are listed in Table 1. The most common adverse events in adult patients treated with OFIRMEV (incidence \geq 5% and greater than placebo) were nausea, vomiting, headache, and insomnia.

Table 1. Treatment-Emergent Adverse Reactions Occurring \geq 3% in OFIRMEV and at a greater frequency than Placebo in Placebo-Controlled, Repeated Dose Studies

System Organ Class - Preferred Term	OFIRMEV (N=402) n (%)	Placebo (N=379) n (%)
Gastrointestinal Disorders		
Nausea	138 (34)	119 (31)
Vomiting	62 (15)	42 (11)
General Disorders and Administration Site Conditions		
Pyrrexia*	22 (5)	52 (14)
Nervous System Disorders		
Headache	39 (10)	33 (9)
Psychiatric Disorders		
Insomnia	30 (7)	21 (5)

* Pyrexia adverse reaction frequency data is included in order to alert healthcare practitioners that the antipyretic effects of OFIRMEV may mask fever.

Other Adverse Reactions Observed During Clinical Studies of OFIRMEV in Adults

The following additional treatment-emergent adverse reactions were reported by adult subjects treated with OFIRMEV in all clinical trials (n=1020) that occurred with an incidence of at least 1% and at a frequency greater than placebo (n=525).

Blood and lymphatic system disorders: anemia

General disorders and administration site conditions: fatigue, infusion site pain, edema peripheral
Investigations: aspartate aminotransferase increased, breath sounds abnormal

Metabolism and nutrition disorders: hypokalemia
Musculoskeletal and connective tissue disorders: muscle spasms, trismus
Psychiatric disorders: anxiety
Respiratory, thoracic and mediastinal disorders: dyspnea
Vascular disorders: hypertension, hypotension

Pediatric population

A total of 355 pediatric patients (47 neonates, 64 infants, 171 children, and 73 adolescents) have received OFIRMEV in active-controlled (n=250) and open-label clinical trials (n=225), including 59.7% (n=212) who received 5 or more doses and 43.1% (n=153) who received more than 10 doses. Pediatric patients received OFIRMEV doses up to 15 mg/kg on an every 4 hours, every 6 hours, or every 8 hours schedule. The maximum exposure was 7.7, 6.4, 6.8, and 7.1 days in neonates, infants, children, and adolescents, respectively.

The most common adverse events (incidence \geq 5%) in pediatric patients treated with OFIRMEV were nausea, vomiting, constipation, pruritus, agitation, and atelectasis.

Other Adverse Reactions Observed During Clinical Studies of OFIRMEV in Pediatrics

The following additional treatment-emergent adverse reactions were reported by pediatric subjects treated with OFIRMEV (n=355) that occurred with an incidence of at least 1%.

Blood and lymphatic system disorders: anemia

Cardiac disorders: tachycardia

Gastrointestinal disorders: abdominal pain, diarrhea

General disorders and administration site conditions: injection site pain, edema peripheral, pyrexia

Investigations: hepatic enzyme increase

Metabolism and nutrition disorders: hyponatremia, hypokalemia, hypomagnesemia, hypophosphatemia, hypovolemia

Musculoskeletal and connective tissue disorders: muscle spasm, pain in extremity

Nervous system disorders: headache

Psychiatric disorders: insomnia

Renal and urinary disorders: oliguria

Respiratory, thoracic and mediastinal disorders: pulmonary edema, hypoxia, pleural effusion, stridor, wheezing

Skin and subcutaneous tissue disorders: periorbital edema, rash

Vascular disorders: hypertension, hypotension

DRUG INTERACTIONS

Effects of other Substances on Acetaminophen

Substances that induce or regulate hepatic cytochrome enzyme CYP2E1 may alter the metabolism of acetaminophen and increase its hepatotoxic potential. The clinical consequences of these effects have not been established. Effects of ethanol are complex, because excessive alcohol usage can induce hepatic cytochromes, but ethanol also acts as a competitive inhibitor of the metabolism of acetaminophen.

Anticoagulants

Chronic oral acetaminophen use at a dose of 4000 mg/day has been shown to cause an increase in international normalized ratio (INR) in some patients who have been stabilized on sodium warfarin as an anticoagulant. As no studies have been performed evaluating the short-term use of OFIRMEV in patients on oral anticoagulants, more frequent assessment of INR may be appropriate in such circumstances.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C. There are no studies of intravenous acetaminophen in pregnant women; however, epidemiological data on oral acetaminophen use in pregnant women show no increased risk of major congenital malformations. Animal reproduction studies have not been conducted with IV acetaminophen, and it is not known whether OFIRMEV can cause fetal harm when administered to a pregnant woman. OFIRMEV should be given to a pregnant woman only if clearly needed.

The results from a large population-based prospective cohort, including data from 26,424 women with live born singletons who were exposed to oral acetaminophen during the first trimester, indicate no increased risk for congenital malformations, compared to a control group of unexposed children. The rate of congenital malformations (4.3%) was similar to the rate in the general population. A population-based, case-control study from the National Birth Defects Prevention Study showed that 11,610 children with prenatal exposure to acetaminophen during the first trimester had no increased risk of major birth defects compared to 4,500 children in the control

group. Other epidemiological data showed similar results.

While animal reproduction studies have not been conducted with intravenous acetaminophen, studies in pregnant rats that received oral acetaminophen during organogenesis at doses up to 0.85 times the maximum human daily dose (MHDD = 4 grams/day, based on a body surface area comparison) showed evidence of fetotoxicity (reduced fetal weight and length) and a dose-related increase in bone variations (reduced ossification and rudimentary rib changes). Offspring had no evidence of external, visceral, or skeletal malformations. When pregnant rats received oral acetaminophen throughout gestation at doses of 1.2-times the MHDD (based on a body surface area comparison), areas of necrosis occurred in both the liver and kidney of pregnant rats and fetuses.

In a continuous breeding study, pregnant mice received 0.25, 0.5, or 1.0% acetaminophen via the diet (357, 715, or 1430 mg/kg/day). These doses are approximately 0.43, 0.87, and 1.7 times the MHDD, respectively, based on a body surface area comparison. A dose-related reduction in body weights of fourth and fifth litter offspring of the treated mating pair occurred during lactation and post-weaning at all doses. Animals in the high dose group had a reduced number of litters per mating pair, male offspring with an increased percentage of abnormal sperm, and reduced birth weights in the next generation pups.

Labor and Delivery

There are no adequate and well-controlled studies with OFIRMEV during labor and delivery; therefore, it should be used in such settings only after a careful benefit-risk assessment.

Nursing Mothers

While studies with OFIRMEV have not been conducted, acetaminophen is secreted in human milk in small quantities after oral administration. Based on data from more than 15 nursing mothers, the calculated infant daily dose of acetaminophen is approximately 1 – 2% of the maternal dose. There is one well-documented report of a rash in a breast-fed infant that resolved when the mother stopped acetaminophen use and recurred when she resumed acetaminophen use. Caution should be exercised when OFIRMEV is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of OFIRMEV for the treatment of acute pain and fever in pediatric patients ages 2 years and older is supported by evidence from adequate and well-controlled studies of OFIRMEV in adults. Additional safety and pharmacokinetic data were collected in 355 patients across the full pediatric age strata, from premature neonates (≥ 32 weeks post menstrual age) to adolescents. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients < 2 years of age.

Geriatric Use

Of the total number of subjects in clinical studies of OFIRMEV, 15% were age 65 and over, while 5% were age 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Patients with Hepatic Impairment

Acetaminophen is contraindicated in patients with severe hepatic impairment or severe active liver disease and should be used with caution in patients with hepatic impairment or active liver disease. A reduced total daily dose of acetaminophen may be warranted.

Patients with Renal Impairment

In cases of severe renal impairment (creatinine clearance ≤ 30 mL/min), longer dosing intervals and a reduced total daily dose of acetaminophen may be warranted.

OVERDOSAGE

Signs and Symptoms

In acute acetaminophen overdose, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and thrombocytopenia may also occur. Plasma acetaminophen levels > 300 mcg/mL at 4 hours after oral ingestion were associated with hepatic damage in 90% of patients; minimal hepatic damage is anticipated if plasma levels at 4 hours are < 150 mcg/mL or < 37.5 mcg/mL at 12 hours after ingestion. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis, and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

PHARMACOKINETICS

The pharmacokinetics of OFIRMEV have been studied in patients and healthy subjects from premature neonates up to adults 60 years old. The pharmacokinetic profile of OFIRMEV has been demonstrated to be dose proportional in adults following administration of single doses of 500, 650, and 1000 mg.

The maximum concentration (C_{max}) occurs at the end of the 15 minute intravenous infusion of OFIRMEV. Compared to the same dose of oral acetaminophen, the C_{max} following administration of OFIRMEV is up to 70% higher, while overall exposure (area under the concentration time curve [AUC]) is very similar.

The pharmacokinetic exposure of OFIRMEV observed in children and adolescents is similar to adults, but higher in neonates and infants. Dosing simulations from pharmacokinetic data in infants and neonates suggest that dose reductions of 33% in infants 1 month to < 2 years of age, and 50% in neonates up to 28 days, with a minimum dosing interval of 6 hours, will produce a pharmacokinetic exposure similar to that observed in children age 2 years and older.

NONCLINICAL TOXICOLOGY

Carcinogenesis

Long-term studies in mice and rats have been completed by the National Toxicology Program to evaluate the carcinogenic potential of acetaminophen. In 2-year feeding studies, F344/N rats and B6C3F1 mice were fed a diet containing acetaminophen up to 6000 ppm. Female rats demonstrated equivocal evidence of carcinogenic activity based on increased incidences of mononuclear cell leukemia at 0.8 times the maximum human daily dose (MHDD) of 4 grams/day, based on a body surface area comparison. In contrast, there was no evidence of carcinogenic activity in male rats (0.7 times) or mice (1.2-1.4 times the MHDD, based on a body surface area comparison).

Mutagenesis

Acetaminophen was not mutagenic in the bacterial reverse mutation assay (Ames test). In contrast, acetaminophen tested positive in the *in vitro* mouse lymphoma assay and the *in vitro* chromosomal aberration assay using human lymphocytes. In the published literature, acetaminophen has been reported to be clastogenic when administered a dose of 1500 mg/kg/day to the rat model (3.6-times the MHDD, based on a body surface area comparison). In contrast, no clastogenicity was noted at a dose of 750 mg/kg/day (1.8-times the MHDD, based on a body surface area comparison), suggesting a threshold effect.

Impairment of fertility

In studies conducted by the National Toxicology Program, fertility assessments have been completed in Swiss mice via a continuous breeding study. There were no effects on fertility parameters in mice consuming up to 1.7 times the MHDD of acetaminophen, based on a body surface area comparison. Although there was no effect on sperm motility or sperm density in the epididymis, there was a significant increase in the percentage of abnormal sperm in mice consuming 1.7 times the MHDD (based on a body surface area comparison) and there was a reduction in the number of mating pairs producing a fifth litter at this dose, suggesting the potential for cumulative toxicity with chronic administration of acetaminophen near the upper limit of daily dosing.

Published studies in rodents report that oral acetaminophen treatment of male animals at doses that are 1.2 times the MHDD and greater (based on a body surface area comparison) result in decreased testicular weights, reduced spermatogenesis, reduced fertility, and reduced implantation sites in females given the same doses. These effects appear to increase with the duration of treatment. The clinical significance of these findings is not known.

OFIRMEV (acetaminophen) injection

Manufactured for:
Cadence Pharmaceuticals, Inc.
San Diego, CA 92130

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OFIRMEV™

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Editor's Notes

A Societal Pot Hole in Need of Repair

By Stephen Jackson, M.D., Editor



Marijuana (derived from late nineteenth-century Mexican Spanish) refers to the dried leaves and flowers of the hemp plant, especially *Cannabis sativa*, and contains trace to 20 percent delta-9-tetrahydrocannabinol (THC) as its predominant psychoactive chemical. Although its “medicinal” and widespread recreational use in California has been aided and abetted by California law, it nonetheless is considered to be an illegal substance by the federal government (“feds”). The public discourse and general support for the “legalization” of cannabis in California have, in large part, been uninformed and politicized. **Nonetheless, what has transpired is that Californians unwittingly have put the physician into the role of “gatekeeper” for access to this allegedly harmless “medicinal.”**

In 2010, the California Medical Association (CMA) weighed in on this public health controversy by creating a technical advisory committee on the Legalization and Taxation of Marijuana, tasked to recommend policy on the legalization, appropriate regulation and taxation for cannabis. The major conclusion, outlined in a CMA white paper released in October 2011, was that effective regulation of *medicinal* (not recreational) cannabis would be possible only if the feds reclassify it from Schedule 1 to a “lesser” and more appropriate drug-grouping Schedule. This change at the federal level, then, legally would permit research that, in turn, would guide responsible regulation of cannabis, just as with tobacco and alcohol. Research would determine the benefits and risks of using cannabis, thereby providing patient safety and public health policy with scientific underpinnings. In later pages of this issue there appear two informative articles on “pot clubs” (dispensaries) and societal “pot holes” (both the legal and regulatory voids) in need of repair (pages 83–90).

What are the current state and federal laws regarding cannabis? Let’s start in 1996, when Californians approved Proposition 215, which decriminalized the cultivation and use of cannabis by seriously ill people upon securing a physician’s recommendation. In 2004, the Medical Marijuana Program Act (MMP) provided for an identification card program to achieve greater consistency in the application and enforcement of Prop 215. MMP also permitted a physician to be paid for services that enabled qualified patients to use marijuana for “serious medical conditions.” The statutory list of medical

Editor's Notes (cont'd)

conditions that qualified as “serious” was and remains overly broad, and almost none are supported by credible scientific evidence. Moreover, patients were permitted to cultivate up to six mature plants or possess up to half a pound of processed cannabis for medical purposes. In 2010, another California law advanced decriminalization by making the possession of less than 1 ounce of marijuana a civil rather than criminal infraction. The next *attempt* to decriminalize recreational use was Prop 19 in 2010, which would have permitted adults over 21 years to possess as much as an ounce for private use and allowed local governments to license and tax the sale of cannabis. It retained prohibitions against driving under the influence of marijuana, but also prevented employers from drug testing for cannabis. While failing passage, Prop 19 did gather 46.5 percent of the vote!

Federal law is much less complicated, and attempts to decriminalize cannabis nationally have not been successful. Cannabis is regulated through the Controlled Substances Act, which does not recognize a difference between recreational and medicinal use. Solidifying federal authority, the Supreme Court ruled in 2005 that the existing federal prohibitions against possession, cultivation and distribution of marijuana were legal and appropriate. The penalties for violation are significant, including imprisonment (up to 10 years) and fines (up to \$500,000). Physicians convicted under federal law can lose their Drug Enforcement Administration registration and be excluded from Medicare/Medi-Cal programs.

The major barrier to scientific research-based discourse is the federal classification of cannabis as a Schedule 1 drug. This relegates cannabis to a class of drugs that have *no* accepted medical use, yet possess a *substantial potential* for abuse. Thus, physicians cannot legally prescribe it for any reason outside of research settings. Indeed, Schedule 1 drugs are unlikely to be researched for their potential therapeutic value—as well as their risks—and this has been the case with cannabis and its numerous chemical components such as the cannabinoids, flavonoids and terpenoids. After all, how could one support and justify research that would establish an evidence-based regulatory scheme for a substance that is highly restricted by the feds? Could a cogent scheme even be made for such? Well, one California attempt at creating research opportunities was made in 1999 with the passage of a law that commissioned the University of California Center for Medicinal Cannabis Research (CMCR) to fund research to expand understanding of the medicinal value of cannabis.

Flying in the face of the federal position, California and 15 other states (and the District of Columbia) have *decriminalized* the use of *both* recreational and medicinal cannabis. **Under California law, physicians are permitted to recommend the use of cannabis for medicinal purposes, therein placing**

those physicians in the uncomfortable—if not untenable—position of “gatekeeper” for those who want to gain access to a federally *illegal* drug.

Also to be considered is that there currently is only sparse credible evidence for the *medicinal* efficacy of cannabis. With respect to *benefits* of cannabis, the botanical marijuana plant itself, when ingested or smoked, *may be* effective in the treatment of neuropathic pain (CMCR studies), spasticity (in multiple sclerosis—CMCR study), nausea, anorexia, and glaucoma. There are, however, both short- and long-term *risks*. Cannabis intoxication can induce transient mood, anxiety and psychotic symptoms. Distorted perceptions as well as impaired coordination, problem-solving and cognitive function (learning and memory) may persist for days to weeks, and chronic usage may lead to similar disorders of a sustained nature. Addiction to cannabis does occur in 10 percent of users and is more likely in those who begin its use before the age of 18.

With respect to the operation of motor vehicles, however, it is unclear as to whether cannabis use increases the likelihood of accidents, in sharp contrast to the robust evidence of the danger of alcohol. Interestingly, in driving-simulation testing, neurocognitive impairment varies in a dose-related manner, and impaired function is more pronounced with highly automatic driving functions than with more complex tasks requiring conscious control.

All this notwithstanding, knowledgeable, reasonable and thoughtful people believe that the national prohibition of cannabis for *recreational* use has been ineffective (if not counterproductive) and unpopular and has labeled as “criminals” otherwise “ordinary/law-abiding” citizens. Moreover, even if the use of recreational cannabis were to become legally permissible, then there still would be a need for oversight and quality control, for matters such as concentration and purity, in order to protect the public.

The demand for cannabis is a significant driver for violent drug cartels in Mexico and other foreign countries, and serves as a nidus for criminal activity and violence in our own communities. In California, the annual harvest of cannabis is estimated to be worth \$17 billion, which is larger than the top five legal agricultural exports combined! Furthermore, at least for the present time, unless physicians adhere to their *ethical* obligations to their patients (and society) with respect to “recommending” cannabis *only* for “*serious medical conditions*,” then limiting the number of dispensaries and the amount of cannabis that can be cultivated will not prevent the diversion of cannabis for recreational use.

In summary, the first step to repair the “pot holes” alluded to in this column is for the feds to move cannabis to another Schedule so as to enable its long overdue

scientific investigation. Then and only then can we as a society arrive at a credible and responsible public policy with respect to marijuana. Enlightenment regarding the actual pharmacology of cannabis coupled with development of a uniform, evidence-based regulatory approach across the disparate sectors of government will make addressing this societal challenge “pot-whole,” that is, a reasoned decision based on scientific data.



Letter to the CSA

To The Editor:

I would like to commend you for your excellent editorial on sleep deprivation (“Sleepwalking, But Not Well,” *CSA Bulletin*, Fall 2011), a pervasive but largely ignored issue in our specialty (and others as well). It is curious that while anesthesia has been obsessively compared to aviation, the reverse is, to my knowledge, rarely encountered. Purveyors of quality of care speak to checklists, information displays, simulators and such, but when it comes to the topics of sleep deprivation and fatigue, mandatory rest periods just don’t quite make the cut. Why is that? My guess is that it is more challenging for those who address sleep deprivation-induced impairment to couple this issue with the socio-economic dilemmas of manpower and reimbursement. Highlighting this contrast, the Federal Aviation Administration recently proposed strengthening its fatigue rules (rest requirements) for professional pilots to nine hours of rest under certain circumstances, not including transportation time to and from the rest facility, while our specialty remains mute on this subject. Each of us should be reminded of this state of affairs when we fly and be grateful that aviation, unlike our profession, takes fatigue very seriously.

Clarence F. Ward, M.D.

President's Page

The Logic of Embracing Performance Measurement While Rejecting P4P

By Kenneth Y. Pauker, M.D., President



We are confronted with a quandary—how rationally to embrace the nascent science of performance measurement as a tool to improve quality in anesthesiology, while at the same time continuing to reject the flawed logic and self-serving rationale of Pay for Performance (P4P). This notion engenders in me—and I would venture in many of you as well—*cognitive dissonance*, “a state of psychological conflict or anxiety resulting from a contradiction between a person’s simultaneously held beliefs or attitudes.”

Dr. Steve Goldfien, Past President of the CSA, argues that this “performance assessment stuff” is unnecessary, unproven, and degrading to our profession. Dr. Bob Lagasse, former chair of ASA’s Committee on Performance Outcome Measurement (CPOM) and iconoclast at the ASA House of Delegates (HOD), bemoans the lack of scientific evidence and rigorous methodology behind the development of many performance measures to date. He further argues that the creation of what we now call performance measures inevitably leads to confusion about the nature of P4P, a similar-sounding but considerably more malignant scheme devised by allegedly well meaning—but mistaken and uninformed—cost- and quality-conscious health care policy wonks.

Dr. Alex Hannenberg, former ASA President, pushed hard to have the ASA accept P4P as more of an *opportunity* than a threat. But Dr. Mark Singleton, California’s ASA Director, the CSA Delegation, and I mounted a campaign against P4P at the 2007 ASA House of Delegates. Together, we were able to slow down the P4P train, at least temporarily, by suggesting two alternative approaches for anesthesiologists: *data collection* and *benchmarking*. Indeed, we brought forth a successful resolution to the ASA HOD, out of which evolved both the Anesthesia Quality Institute (AQI) and the National Anesthesia Clinical Outcomes Registry (NACOR).

The Perioperative Surgical Home concept (see pages 27–30) will benefit greatly from the massive clinical database that is being built. Measuring clinical outcomes adjusted for risk should, through the vehicles of benchmarking and creating practice parameters based on real science, advance the quality of anesthetic practice. This concept offers perhaps the last best hope for the

survival of anesthesiology amid the torrent of P4P measures that seem to be proliferating in an unrestrained manner.

Demands for More Care at Less Cost

Business, government, insurers and patients all demand more care for less cost. The concept of P4P has led the Centers for Medicare and Medicaid Services (CMS) to develop “value based purchasing,” and we soon will be besieged with other methodologies of bundled payments such as accountable care organizations (ACOs) and “episodes of care.” Both hospitals and physicians are being coerced into participating in this evolving system of proving their own worth. Anesthesiologists are relative latecomers to the game, but payment restructuring looms ahead for us as well.

The real drivers of increased costs include:

- Demographics—both ends of the age spectrum
- The development of new and costly drugs
- The development of new technologies
- New, unproven diagnostic and therapeutic procedures
- Futile interventions near the end of life
- Defensive medicine

These are difficult to address because the nature of our social fabric abhors the idea of rationing care despite our finite resources, and because our political system is highly polarized and dysfunctional.

Certainly we are witness to many of the multitude of examples of unnecessary or unwarranted care. For instance, although not every back surgery is unwarranted, the evidence-based justification for many spinal fusions is being called into question. Moreover, the burgeoning of new but unproven procedures is hardly confined to spine surgery. Examples abound with joint replacements, cardiac and carotid stents, retinal therapies, robotic surgeries, CT scans and MRIs. Financial incentives for physicians and facilities encourage their use. As anesthesiologists, we often can be unwittingly complicit when we administer anesthetics that make unnecessary care possible. We live by the maxim that anesthesia is always necessary, even if the procedure may not be.

To be fair, we appreciate that there is a lack of evidence behind much of what we do as physicians, but also that this dearth of scientifically proven efficacy does not mean that we should not try new methods or procedures. What has become critical is that, in these times of careful cost scrutiny in medicine, the marginal benefit of deploying something new should certainly far outweigh its increase

in costs, such that true innovation is not stifled because it appears unnecessary or unwarranted to someone or some entity in authority.

On many levels, considerable energy is going into the eradication of unnecessary care as a way to control rising health care costs. Unfortunately, non-physicians may pick the wrong procedures or the wrong physicians to be the objects of their scrutiny. Physicians in general, and anesthesiologists in particular, are turning out to be easy targets.

Process, Structural, and Outcome Measures in Anesthesiology

The practice of anesthesiology is different from other medical specialties. Despite careful planning and execution, we are often confronted with perturbations that require immediate judgment and decision-making with no time for rumination. How can performance measures take account of the competing priorities we must address in our most critical work? How can a perioperative beta-blocker be appropriate for a hemorrhaging and unstable patient? How can an outside reviewer balance the appropriateness of one course of action against another in a complex and rapidly changing situation? If performance measures are limited to processes only, they can't be done properly. However, *process* measures are just one of three broad categories of performance measures. There are also *structural* and *outcome* measures.

Process is what we do. It is concerned with appropriate and effective methods, done well. Guidelines and best practices, most familiar to anesthesiologists as substrates for measurement, are in this category. One recent example is the recent approval by the 2011 ASA HOD of Practice Guidelines for Central Venous Access, within which is a recommendation for the use of ultrasound. The 2010 HOD voted down a performance measure on using ultrasound, but with new guidelines, this will likely be revisited in 2012.

High-quality evidence is required for guidelines, and unfortunately, at present, an acceptable level of scientific evidence is often sorely lacking. "The use of recommendations [for performance measures] based solely on expert opinion or standards of care... lacks face validity, especially when such measures are to be used as the basis for public reporting or pay-for-performance."¹ Moreover, complex co-morbidities may call for competing or even mutually exclusive courses of action, and therein confound attempts to follow guidelines. In general, compliance with best practices in hospitals leads to better outcomes in only a modest way. CMS is now moving away from process measures and toward outcome measures in its Physician Quality Reporting System (see www.cms.gov/PQRS).

Structural measures assume that “given the proper settings, good medical care will follow.”² Organizational characteristics, human resources, and technology are in this category. Examples include using state-of-the-art anesthesia machines or monitoring equipment, enhancing nurse or anesthesiologist staffing at designated times or for specific procedures, and implementing an electronic medical record or computerized order entry. Unfortunately, the evidence linking structure to outcomes is not robust. Nevertheless, insurers and regulators use this concept to incentivize information technology, despite the objections of both hospitals and physicians.

Patient outcomes are the final product of all clinical activity. In an individual patient, a specific outcome derives from a complex interplay of individual risk factors, chance, and effective medical care.³ The quality of an outcome measure is a function of risk adjustment, data quality, sample size, and accurately choosing and then identifying appropriate outcomes. Examples are risk-adjusted mortality, perioperative myocardial infarctions and strokes, and long-term postoperative cognitive dysfunction.

With true risk-adjusted outcomes, eventually we will be able to benchmark one method against another. Then we will discover specifically what makes a significant difference to our patients. The fact that we have not yet arrived at that place with clinical data does not absolve us of our responsibility as physicians to try—with whatever tools we have—to improve how we care for patients. The problem for anesthesiologists is that others believe they already know now, and with unwarranted certainty, what quality is and how to measure it.

Anesthesiologists have been resting on our laurels for more than a decade. The Institute of Medicine commended us in 1999 as the one medical specialty that dramatically improved safety by a variety of approaches to reduce errors. However, Dr. Lagasse's analysis of data from multiple studies suggests that “anesthesia-related” mortality is much higher than the commonly quoted 1:250,000.⁴ Clearly, we still have more work to do.

Distinguishing Performance Measurement from P4P

In July 2007, the *ASA Newsletter* published a “Pro/Con” pair of articles on P4P.⁵ Dr. Gerry Maccioli argued that an era of change, including incorporation of P4P models in compensation systems, was upon us, and that if we did not participate, then those who have no idea what we do would impose metrics upon us. The consequence of nonparticipation for our profession, he predicted, would be one of degradation and suffering. He proclaimed that P4P was more of an opportunity than a threat.

I argued, on the “Con” side, against the burden of P4P: its predictable new posse of tinkers; inevitable new ways to game a system with inadequate methods

for risk adjustment; rigid rule making; and a host of unintended consequences (such as paying large groups already in compliance, the avoidance of caring for high-risk patients, and the loss of access to care for disadvantaged patients). Four and one half years later, we witness what initially were small positive bonuses now giving way to increasingly significant negatives.

In my piece, I offered alternatives to P4P, some of which have come to pass:

Payers (including the government) must invest in health information technology [payments for “meaningful use” are in process by the feds]. Specialty societies should mine the data (as with the ASA Closed Claims Project) and then set evidence-based standards and performance measures that enhance quality. Specialties could then construct benchmarks and provide detailed individual data to change individual behavior non-punitively [AQI and NACOR were constructed to do this]. Each specialty should demonstrate quality improvement, and there should be collaboration between specialties in areas of common interest and expertise [CPOM is beginning to take this approach]. Setting up a system of cutthroat competition between individual physicians within or across specialties will only exacerbate divisions within the House of Medicine...

Physicians and patients must be aligned and drawn together; intermediaries that pervert that relationship should be minimized and marginalized. Each specialty must address its unique inefficiencies and instances of profiteering and demonstrate this effort to payers. Further manipulations to squeeze additional “profits” and/or savings from already “pruned out” physicians must cease; instead, cost savings should be sought from “big ticket” items. These “big gorilla” items of waste and cost, such as outlandish health insurance industry profits, unnecessary and inappropriate care, and non-beneficial care at the end-of-life, must be debated and addressed by Medicine, society and government. We must tackle the thorny issue of what level of medical care our society can afford for all.

Although we realize that performance measures ought to be constructed to improve quality, it is inevitable in this political and economic climate that others will use them to try to reduce what we are paid. I used to argue that for that exact reason we had to reject involvement in developing such measures at all. I've now become convinced that if we don't get involved, others—administrators, regulators and legislators—will construct them and impose them on us. They will use administrative instead of clinical data, and fail to employ scientific methods of risk adjustment. I see this in my own hospital where individuals charged with “continuous performance improvement” see only the surface of what anesthesiologists do. Nonetheless, they have specific directives from higher-level administrators to comply with hospital/corporate-centric interpretations of what CMS or The Joint Commission dictates.

Measuring Performance Drives Quality Improvement

We must carefully translate what we know now into performance measures that will improve quality. We must do this now for our patients and ourselves, not merely to satisfy others. We must demonstrate that we know the way and will show the way. We are building NACOR and will benchmark ourselves. This will do more to improve quality and potentially reduce costs than anything else, but even this approach is unproven. Misadventures, misapplied technology, complications, unnecessary and nonbeneficial care, and defensive medicine will drive costs. Constructing better guidelines, understanding more efficient care, analyzing our individual modes of practice in relation to benchmarks—these will enhance safety, and as a byproduct, they will enhance value.

In some ways, Dr. Maccioli's 2007 analysis of what was coming was remarkably on target, but deploying performance measures to reduce payment for services remains a threat. On the other hand, measuring actual clinical performance, comparing it with established credible scientific criteria, and then monitoring for quality improvements in that performance, rather than focusing on cost and payment for meeting poorly or non-established performance parameters, is a worthy enterprise, and one befitting physicians whose priorities are science, safety, and enhancing quality in patient care.

What I have come to appreciate from my work on CPOM is this:

What you don't know about how performance measures are constructed will hurt you.

Understanding in depth how performance measurement is done, including its pitfalls and unintended consequences, is critical to being able to defend yourself from those who are more powerful and do not have your patients' or your best interests in mind. Arm yourself with knowledge to enable you to participate in the discussion, and prepare yourselves to champion science, logic, clarity and fairness in this new field of battle. Don't be a cog in the dissonance. Instead, embrace your cognitive dissonance, and stand ready with your colleagues in the CSA and ASA in advocating for performance measurement while continuing to reject P4P.

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ASA Director's Report

The ASA Looks to the Future

*By Mark Singleton, M.D.,
ASA District Director*



Many highlights of the October 2011 ASA Annual Meeting in Chicago already have been made available to CSA members through various communications from the ASA and the CSA (as in the “CSA Online First” blog posting shortly after the meeting by Dr. Karen Sibert). Perhaps of greatest interest, the House of Delegates (HOD) elected Dr. Jane Fitch, Chair of the Anesthesia Department at the University of Oklahoma and a former nurse anesthetist, President-Elect of the ASA. She is well known and a friend to many of us, and also has served as Chair of the ASA Committee on Governmental Affairs. Another highlight was the Rovenstine Lecture by UCLA Chair of Anesthesiology Dr. Patricia Kapur, in which she boldly challenged anesthesiologists to re-envision our profession, reaching for ever-higher responsibilities in the care of the most complex and difficult-to-manage patients.

Two Reversals

The HOD reversed the thrust of two projects that already had been underway within the Committee on Quality Management and Departmental Administration (QMDA). The “Seal of Quality” initiative, which sought to bestow a distinction of excellence on hospital departments of anesthesiology meeting a matrix of measures, was soundly disapproved, despite a generally positive demonstration project conducted at several volunteer sites around the country. It was clear from the debate that a majority of delegates believed either that the concept was unrealistic and without meaningful value, or that the merit of such an award would not receive sufficient value or recognition from key administrative and regulatory bodies, which had been one of the intended purposes of the project.

Another QMDA project, led by its new chair, Dr. Beverly Philip, and initiated by immediate Past President Mark Warner, M.D., was to develop an educational product on deep sedation by non-anesthesiologist physicians. It was referred back to committee rather than being advanced on the basis of the work that the committee’s task force has presented thus far. There remains vigorous philosophical division regarding the basic notion that non-anesthesiologists should administer deep sedation under any circumstances, or that the ASA should endorse such practices. It is unclear at present where this project is headed, yet

by referral back to committee, the HOD voiced at least some recognition that these practices are taking place, and that ASA must address them.

Four New Measures

The Committee on Performance and Outcomes Measurement (CPOM) submitted four new measures to the HOD, three of which were approved:

- Post-Anesthetic Transfer of Care Measure: Procedure Room to Intensive Care Unit
- Preoperative Use of Aspirin for Patients with Drug-Eluting Coronary Artery Stents
- Registry Participation Measure

The fourth proposed measure, Prevention of Postoperative Vomiting (Pediatrics)—Multimodal Therapy, was referred to the Committee on Pediatric Anesthesia so that it, appropriately, would have an opportunity to review and comment on this document.

Practice Guidelines, Advisories and Recommendations

Four submissions from the Committee on Standards and Practice Parameters were approved. Two were Practice Guidelines: “Central Venous Access” (which had been disapproved last year) and “Acute Pain Management in the Perioperative Setting.” Two were Practice Advisories: “Perioperative Visual Loss Associated with Spine Surgery” and “Preanesthesia Evaluation.”

The Committee on Pediatric Anesthesia submitted for formal adoption as an ASA Statement a revised and updated version of a decade-old committee work product, “Practice Recommendations for Pediatric Anesthesia.” This was approved and will hopefully provide guidance to departments in privileging for different categories of pediatric and neonatal care.

Future Development of the ASA

Administrative issues of importance that generated discussion at the HOD this year had to do with the future development of the society in both its physical needs and areas of administrative staff structure. It has become clear that the present headquarters in Park Ridge are insufficient to meet the growing needs of the ASA. The city of Park Ridge intends to remain a mainly residential community and will not invest in the infrastructural improvements necessary to meet the electronic and communications needs of the ASA in the coming years. In this context, what several years ago may have seemed prudent—the purchase of a commercial property adjacent to the HQ building—may indeed not have been a wise decision. A task force on land use and development

ASA Director's Report (cont'd)

has identified a property 15 miles northwest of O'Hare Airport in an active industrial/high-tech complex that would meet the anticipated needs of the ASA in the coming years. Further proposals regarding this property are expected.

An ongoing debate exists as to how to best dismantle the dual Executive Vice President (EVP) structure (Park Ridge and Washington, D.C.) that has been ASA's working model for most of the past decade. The intent is to replace it with a more effective structure featuring a single executive in the Park Ridge office. There has been continuing debate about whether the current EVP in Park Ridge (Mr. John Thorner, who this past year addressed the CSA HOD) should assume the position of interim Chief Executive Officer (CEO) or if the position should even be termed "CEO." The following language was adopted at the HOD after impassioned and lengthy debate: "The CEO shall be evaluated by the Board of Directors and shall be under the direction and supervision of the President and the Administrative Council. The BOD shall approve the selection of the CEO."

In December, ASA President Jerry Cohen called a special meeting of the ASA BOD by telephone conference call, to inform the board that Mr. Ron Szabat (the current EVP in Washington, D.C.) had indicated that he desired to be considered as a second internal candidate, in addition to Mr. Thorner, for the CEO position. The Administrative Council felt that this situation required the initiation of a national search in order to best serve the interests of the ASA. The BOD voted to approve such a search, although there were some dissenting votes. It is interesting that both the CSA and the ASA are concurrently moving through the difficult process of restructuring senior staff positions and searching for the right person(s) to lead the organizations into the future.

CSA Bulletin Cover for Volume 61, Number 1 "Late Winter Storm Wonderland"

The cover photograph of this *Bulletin* issue was taken in mid-March 2011. A late winter snowstorm blanketed the Lake Tahoe area, turning a usual scene into a quiet wonderland. The image was captured with a Canon 7D DSLR and processed in Photoshop and Silver Efex Pro.

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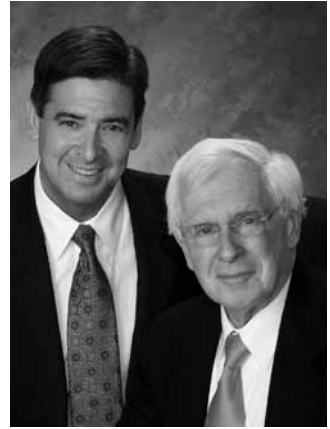
On Your Behalf ...

Legislative and Practice Affairs Division

Election Reforms, Antidote to Political Polarization?

By William E. Barnaby, Sr., and William E. Barnaby III, CSA Legislative Counsel

Excessive political partisanship has been widely blamed for the virtual paralysis in California governmental policy making, especially on fiscal and budgetary matters. Reformers have emphasized two changes that could curtail control of the two major parties by zealously partisan activists. The changes most frequently sought by many reformers for years have been (1) taking away from state legislators the drawing of political boundaries and ability to gerrymander; and (2) open primary elections where voters could choose candidates regardless of party, thereby diluting the influence of party activists and ideologues.



Neither of these reforms had much support from state lawmakers. But over the last four years, both have been enacted into law through voter-approved ballot measures. They will be in effect for the first time for both the June primary and the November general elections.

Redistricting—Ending Legislative Gerrymandering

The California Citizens Redistricting Commission was created by Proposition 11, passed in 2008, to draw boundaries for state Senate and Assembly districts following the 2010 decennial census. In 2010, Proposition 20 extended the authority of the commission to California's 53 congressional districts. These laws specified a number of procedural and policy criteria designed to prevent partisan influence and encourage objective results.

The commission performed its duties and released new state Senate, Assembly and congressional maps last August. The changes were dramatic. Many incumbents are being forced to move, run against fellow incumbents, run for a different position, or simply retire from elected office. At the same time, a good many local government officials and ordinary citizens see the new districts as a unique chance to join the political fray. One positive aspect of the new boundaries is far more competitive districts that could swing from one party to the other more often than before. By the same token, fewer districts will be dominated by the same party year after year.

Many Republicans, even some who had supported independent redistricting, were very critical. The commission had been “hijacked,” they said. Yet the raw numbers show 2.3 million more registered Democratic voters than Republicans on statewide rolls. This strong plurality is bound to be reflected in any new political boundaries.

Referendum and the State Senate Maps

Built into the voter-approved redistricting law was a referendum procedure. Upon verification of sufficient eligible voter signatures (504,000), redrawn maps will go on the November 2012 ballot for voter confirmation or rejection. Also part of the built-in procedure was an expedited review by the California Supreme Court.

The new state Senate plan proved to be the most controversial. It seemed to produce another two seats for Democrats and get them to the magic 27 of 40 or a two-thirds majority. With a two-thirds edge, Democrats could pass tax increases or veto bills without regard to Republicans, who believe that they are being marginalized.

The California Republican Party (CRP) funded a signature-gathering effort that has submitted approximately 700,000 signatures. Whether sufficient numbers are verified remains to be seen. In its effort, the CRP asserted that qualifying a referendum would force the state Supreme Court to appoint a special master (as has been done in the past) to draw new lines. But the state Supreme Court has other options as well. It could use the old lines one more time. This has precedent as does a more likely alternative of allowing the new lines to be used in 2012 pending the outcome of the November vote.

Court Challenges

In late October, the California Supreme Court rejected challenges to the redrawn state Senate and congressional maps. The high court denied the petitions, brought by Republicans, unanimously and without comment.

Apparently undeterred, former GOP Rep. George Radanovich (R–Mariposa) and four others filed a lawsuit in federal court seeking to overturn the newly drawn congressional maps. The suit contends the maps violate the federal Voting Rights Act by failing to protect Latino voters.

In short, the redistricting situation remains unsettled for the moment. Formal declarations of candidacy are due to be filed between Feb. 13 and March 9, 2012. An accurate listing of candidates, and the districts they're running in, may not be available until after the filing deadline.

Open Primary: Same Primary Ballot for All Voters

Proposition 14 of 2010 changed the primary election process for congressional, statewide, and legislative races. It allows all voters to choose any candidate regardless of a candidate's or voter's political party preference. It ensures that the two candidates receiving the greatest number of votes will appear on the general election ballot regardless of party preference. Every voter in a given district will get the same ballot listing all candidates for the office in question. This is commonly known as a "Top Two Primary."

The new system was opposed by both the CRP and the California Democratic Party.

For those districts still dominated by one party, even after redistricting, the general election runoff could well have two Democrats or two Republicans running against each other. The goal is to diminish the influence of party activists to the advantage of moderates and independents. Party activists exercise influence far beyond their numbers because they frequently are the backbone of campaigns.

Activists sometimes produce candidates from their own ranks or they seek out like-minded civic leaders and prominent citizens to run. They know the nuts and bolts of campaign organizing and they supply the manpower for phone banking and door-to-door campaigning. They have strongly held points of view, usually pushing to the extreme left or right of their party. They often raise campaign start-up funds and know how to reach out to statewide funding sources having similar policy interests. They usually equate compromise with weakness and insist candidates remain true to their ideological base and carry through if elected. Over the past decade or two, many of the real contests for legislative office have been in party primary elections where the extremes in both parties have won more than they have lost. The present polarization and policy paralysis is the result.

Conclusion

It may be hard for some to remember, but in times past the legislature and governors fashioned bipartisan solutions to at least some problems. When GOP Govs. George Deukmejian and Pete Wilson were in office (1983–1999), the Democratic-controlled legislature worked with them on numerous issues. There was a certain comity, courtesy and mutual respect instead of the strident and unrelenting "It's my way or the highway" attitude that has infected the political system of late. Political polarization has run amok.

The voter-engineered election reforms taking effect next year offer hope of moving in a better direction. Will they work? Only time and the election results will tell.

Report from the Legislative and Practice Affairs Division (LPAD)

By Paul Yost, M.D., Chair, Legislative and Practice Affairs Division



Federal Issues

Congress approved a two-month Medicare Sustainable Growth Rate payment patch. A 27 percent cut in Medicare physician payments that was scheduled to take effect Jan. 1 has been delayed for two months following a Dec. 23 agreement between the chambers of Congress. A conference committee of representatives and senators will convene in January to work on a longer-term agreement for Medicare payment rates and various other expiring programs.

On a related matter, the ASA recently signed on to a multi-specialty-society letter representing more than 350,000 physicians to repeal a section of the Patient Protection and Affordable Care Act (PPACA) that enacts something called the Independent Payment Advisory Board (IPAB). This board is a group of non-elected, unaccountable individuals who will decide upon future Medicare cuts, with minimal, if any, congressional oversight. Many people view the IPAB as extremely threatening to America's seniors and anyone dependent on Medicare for their health care.

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Another part of PPACA that has taken effect is the national Medical Loss Ratio (MLR). The MLR is the percentage of patient premium dollars that must be spent on actual health care. For many insurance companies the MLR is in the 70 percent range. However, under PPACA, the MLR for large companies must be 80 or 85 percent. What ultimate effect this will have on the health insurance industry is uncertain. There are some people, like Rick Ungar, a columnist for *Forbes*, who think that raising the MLR will not allow private insurance companies to be profitable, and this unprofitability will be the end of private insurance companies as we know them and the beginning of a single-payer methodology.

State Issues

Bloomberg News (12/29, Petterson) reports that U.S. District Judge Christina Snyder has ruled that "California can't cut reimbursements hospitals receive for the skilled-nursing services they provide to low-income people." According to a Nov. 1 complaint by the California Hospital Association, "the cuts of more

than 20 percent would resurrect previous reductions that the courts have found to be in violation of the federal Medicaid Act.” However, “Norman Williams, a spokesman for the state’s Health Care Services Department, said yesterday in an email that the state ‘strongly disagrees with the ruling’ and will appeal it.” Bloomberg adds, “The case is *California Hospital Association v. Douglas*, 11-09078, US District Court, Central District of California (Los Angeles).”

The U.S. Supreme Court case regarding the ability of individuals to sue the state of California in federal court over Medi-Cal cuts is wending its way through the legal system. A decision is not expected until summer.

Practice Affairs

It was recently reported to the CSA that some hospitals are requiring hospital-based physicians (including anesthesiologists) to increase the limits on their malpractice insurance. The hospitals are asking the groups to have coverage of \$2 million per occurrence and \$6 million per year. This translates into premiums approximately 30 to 40 percent higher. California is a MICRA state, and there is little evidence that malpractice claims and payouts have risen to a level that makes this increase necessary. The CMA has been very involved in this issue and LPAD will take up this topic.

Website Update

In keeping with our efforts to make the lives of California anesthesiologists easier, we are expanding the resources in the “Practice Resources” portion of the CSA website. Drs. Mark Zakowski and Linda Hertzberg, with Merrin McGregor, have been organizing Standards, Guidelines, and Statements from various organizations along with significant points for members. Currently there are several pediatric, cardiac and obstetric anesthesia summaries and documents available (with critical care coming soon!). Dr. Zakowski obtained permission from the American College of Obstetricians and Gynecologists (ACOG) to make available to our members a couple of the most important ACOG documents that are normally behind their membership wall. Having original documents organized on the CSA website, along with analysis and summaries, will be a great member benefit. There are also open groups on the membership site that allow discussion threads of issues important to members, including recent queries pertaining to The Joint Commission. If you haven’t been to the “Practice Resources” section of our website, we think you will be pleased with the amount of useful, high-quality information available to our members.

The Dumb-pipe Anesthesiologists

By *Mona Kotecha, M.D.*



Comcast and AT&T executives stay up late at night worrying about becoming “dumb pipe” purveyors, meaning that all they do is transfer bytes of data back and forth. They don’t add any value to the flow. They’re forgettable, interchangeable, and easily replaced. Now, in my opinion, anesthesiologists are in danger of becoming the “dumb pipe” specialty of the medical profession. It’s no exaggeration: When I entered residency in 2005, I never would have thought that my specialty would be viewed as merely enabling the flow of patients from the preoperative area to the recovery room with as little noise and as few adverse incidents as possible. Unfortunately, staunchly clutching the outdated notion that the most effective anesthesiologist—or anesthetic—is the entirely forgettable one has contributed to the challenges our profession faces. Our life’s work has gone unnoticed for too long. We should strive to become as noticeable and unforgettable as possible: noticed by hospitals, colleagues, patients and the public, not only for our professionalism and leadership in the operating room, but even more so for the ownership we take of the patient’s entire perioperative experience and for our expertise in perioperative clinical medicine.

The profession of anesthesiology is at a crossroads. Most of us have felt anxious at the threat of “invaders” on our scope of practice and wondered why no one seems to “get” what we do. Most troubling are the views that anesthesiologists simply sign others’ records, are replaceable by non-physicians, or do little but read the newspaper in the operating room suite. But these incorrect and misinformed perceptions result directly from our failure to engage in meaningful and effective advocacy on our own behalf. Reactively defending our profession is not enough: we must proactively promote and reinvent it. We should continue to champion patient safety, but this is inadequate to sustain our profession in the current socioeconomic and political milieu. We must participate in the entire patient experience of wellness around surgery and view induction and emergence as but two pieces of this experience. And it is time to demonstrate to the public and our colleagues that physician-led anesthesia care is essential to both patient well-being and safety.

The Dumb-pipe Anesthesiologists (cont'd)

First, we should take ownership of the entire perioperative experience. Preoperative planning for any surgical patient should begin with the immediate engagement of an anesthesiologist. Not every patient needs to visit her primary care doctor, see a cardiologist, or have any preoperative testing done at all. It's high time that we fully coordinate the decision of who needs what before surgery. This means insisting on reimbursement for a preoperative clinic visit as we accept full responsibility for the preoperative medical workup, personally deciding upon sub-specialty referrals, and vigorously interfacing with the patient's other health care providers. Successfully leading this endeavor will require us to fine-tune and implement evidence-based protocols for perioperative care. After surgery, we should claim increased responsibility for the patient's postoperative experience by providing safe and effective pain management, and remaining involved in the patient's care beyond immediate discharge from the recovery room. We could continue to consult on inpatients—as do other consultants—for continuity of care. Most surgical patients are not ICU patients, but I argue that they would benefit as deeply as the critically ill from our expertise.

Second, we should strive to become more visible and accessible to the patient and the family. At every opportunity we should connect with our patients and their families before and beyond the day of surgery. For instance, I imagine a world where a newly pregnant patient selects her anesthesia care group with the same care and knowledge with which she chooses her obstetric group. She deserves the right to learn how anesthesia can influence her birthing experience, and she deserves a choice in who provides this important facet of her care. Prenatal classes, given by anesthesiologists for expectant couples, are a good example of this proactivity and a benefit to all concerned when confronted with the throes of labor or an obstetric emergency.

Both the preanesthetic informed consent discussion and the postoperative visit serve as distinct opportunities for more visibility and continuity: They are venues to educate families and caregivers about our role in their loved ones' care as well as for us to learn from our patients' experiences. Indeed, each patient deserves improved access to an anesthesiologist throughout the entire experience of surgery. With respect to continuity of care, we also must strive to minimize unnecessary patient care hand-offs, for nothing discredits our profession more than a revolving door of anesthesia providers.

Third, we personally should market our brand of services directly to hospitals and patients. Orthopedic surgeons attract patients with their cutting-edge and evidence-based interventions and novel surgical techniques. We can attract patients and surgeons with our sub-specialty expertise in the fields of regional, pediatric, obstetric, pain and cardiothoracic anesthesiology. We

The Dumb-pipe Anesthesiologists (cont'd)

can also expand into other arenas including hospice and palliative care. Patients have become more sophisticated and knowledgeable, scoping out their interventions and providers on the Internet. If we expand access to information about our expertise, then eventually they will demand it. Shouldn't an orthopedic patient have the opportunity to pick an anesthesia care team that has adopted evidence-based pain management protocols or one that uses home nerve catheter infusions? Shouldn't parents have full information about the expertise of their newborn's anesthesiologist? Needless to say, this advancement of subspecialty expertise requires a true commitment to research, education and innovation, as they constitute the building blocks for re-branding our profession.

Fourth, nurse anesthetists' unyielding pursuit of independent practice poses a serious challenge to our specialty's ethical goal to provide safe anesthesia care for every patient. In addition to opposing state opt-outs of nurse anesthetist supervision, which I do not believe represents an actual turf battle, our objective should be to redefine and expand the culture and breadth of our specialty. This is, in fact, what will be most critical to the future of anesthesiology. Then we also must educate the public about the key and valued role that anesthesiologists provide for the health care of the citizens of this country. As a workforce, anesthesiologists will not be able to provide solo care to every patient in this country, yet we should continue to stand firmly behind our goal of having an anesthesiologist involved in each patient's care. Indeed, we confidently can support the validity of the statement that anesthesiologists have been—and will continue to be—the sole source and wellspring of the scientific advances in anesthesia, and as such, anesthesiologists are indisputably integral to the “lifeline of modern medicine.”

Finally—and I believe most crucially—we must fully leverage the value of our human capital by nurturing the genesis of a broad set of voices within our ranks. Fostering diversity in our profession is more than paying lip service to a politically correct cliché; it is essential to our success in modern medicine and a long-term, valuable investment for the future. Without a healthy debate among those who are drawn to anesthesiology from different backgrounds and experiences, including those who present dissenting viewpoints, we will not develop innovative solutions to the challenges facing our profession. Indeed, homogeneity of leadership is a pervasive barrier to innovation. I believe that we should welcome those with alternative career tracks, and not attempt to dissuade them from entering anesthesiology. We need to promote our field as an equal opportunity one and create inclusive and flexible work environments. Then we shall succeed in recruiting and retaining the most gifted and creative medical students and young physicians. The talent is out there; let's recruit it, nurture it, and retain it.

The Dumb-pipe Anesthesiologists (cont'd)

Fighting scope-of-practice laws and lobbying government legislators and regulators for higher reimbursements and recognition are only a few of the useful steps that must be integral to a fundamental reinvention of our field. The advancement of anesthesiology requires each one of us—in each interface with administrators, colleagues and patients—to promote our specialty, expand our services, and build a brand and culture of medical care that is irreplaceable, and above all, benefits our patients. The opportunity for the promotion of physician-led anesthesia services exists at every patient and family interaction, departmental personnel and staffing decision, and hospital administration—medical staff interaction. Unless we engage in these goals every single day, we will continue to walk down an ominous path toward becoming a commodity.

Customers of broadband Internet providers take notice of Google, Facebook and Netflix—but they ignore the pipe that delivers the experience to them. Without rethinking the fundamentals of our profession, we will be perceived as the latest “dumb pipes,” no more than affable automatons who enable the flow of cases through the operating room with little fuss or muss. In reality, we have the capacity and opportunity to be hospital managers, advocates for equal opportunity, perioperative team leaders, and sub-specialists who ultimately enhance the safety and improve the well-being of our patients. Do we have the will and courage to make it happen?

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CSA will report CME credits earned to the American Board of Anesthesiology. These credits will be counted as Lifelong Learning and Self-Assessment activities toward your Maintenance of Certification in Anesthesiology (MOCA) requirement. In order to report these credits, doctors need to provide their ABA number. To obtain an ABA number, visit www.theABA.org and create a personal portal account.

The Perioperative Surgical Home

This article is summarized from a report [310-3.2] submitted to the ASA House of Delegates on Aug. 21, 2011, by then ASA President Mark Warner, M.D., entitled “Surgical Home Draft Proposal,” intended to serve as an emerging draft proposal for pilot innovation demonstration projects. Dr. Warner serves as Dean of the Mayo School of Graduate Medical Education.

Issue

There is an undeniable need for a coordinated and widely adopted construct to improve quality of care and outcomes while ensuring patient safety and achieving cost savings across the widest possible range of surgical interventions. This is important because surgical care—and morbidity and mortality during the perioperative period—is associated with approximately 65 percent of all hospital expenses. Reducing the frequency, severity and expense of complications (such as pulmonary thromboembolism, wound infections, opioid-associated respiratory depression, pneumonias) requires coordinated management across the entire surgical episode of care. Anesthesiologists are better positioned than even surgeons to identify potential clinical problems, coordinate and manage the perioperative milieu, reduce costly complications, and improve efficiency of care.

The Institute of Medicine and others recognize anesthesiologists as the leaders in patient safety. Anesthesiologists have training, skills and perspectives that allow them to coordinate and manage the perioperative care of patients by assisting surgeons and proceduralists, as well as hospital administrators and ancillary personnel, in achieving the shared vision of coordinated care with reduced complications and expenses. The “Partnership for Patients” created by the American Association of Medical Colleges and other initiatives present multiple opportunities to advance innovative ideas to meet multiple shared goals.

A demonstration project would evaluate whether anesthesiologists, when supported by Medicare, Medicaid and private health plans, will be able to achieve the following goals:

1. Reduce unjustified variation in utilization and expenditures
2. Improve the safety, effectiveness, timeliness and efficiency of health care
3. Increase the ability of beneficiaries to participate in decisions concerning their care
4. Provide delivery of care that is consistent with evidence-based guidelines in historically underserved areas

Problem

Medical care coordination is frequently lacking or not fully developed. Thus, many entities are evaluating the efficacy and cost-effectiveness of “medical

The Perioperative Surgical Home (cont'd)

homes” and other coordination efforts. Similarly, there is a dearth of appropriate coordination efforts along the surgical continuum of pre-, intra-, and post-operative care. Emerging or existing patient outcome registries represent significant steps to advance optimal technical surgical outcomes, but larger issues associated with inefficient perioperative care and expensive complications are not being comprehensively addressed currently by our health care system. This deficiency results in increased hospital readmissions, hospital-acquired conditions, and added costs, all of which put unnecessary strain on scarce health resources and can lead to protracted patient morbidity and even mortality.

ASA’s Draft Proposal for Innovative Perioperative or “Surgical Home” Demonstration Projects with Medicare

This new perioperative or “surgical home” concept reflects the great potential that coordination and management of surgical patients has to reduce complications and improve efficiencies and cost-effectiveness in perioperative care. The role of anesthesiologists as perioperative physicians is evolving. Because anesthesiologists care for patients with a variety of co-morbid conditions from admission to discharge, they are uniquely suited to help health care organizations improve the quality of care that patients receive. They play a key role in improving surgical care because the perioperative period is often a time when many care providers are acting independently, which can easily introduce errors, expenses and inefficiencies associated with poor coordination of care—and with suboptimal patient satisfaction.

The surgical home concept would more actively integrate anesthesiologists into the patient continuum by increasing their involvement in all parts of the perioperative period, including preoperative assessment, intra-operative stabilization and safeguarding of all body systems and vital organs, and post-operative optimization and pain relief. By coordinating the services provided by other health care professionals in the perioperative period, the anesthesiologist also would improve communication and address system issues that frequently contribute to suboptimal outcomes.

To achieve success for the surgical home, the following may be required (numbers in parentheses indicate capturing the numbered goal listed above):

- Surgeons, internists and family practitioners, in either an inpatient or an outpatient setting, would involve the anesthesiologist in patient assessment, and do so *earlier* in the presurgical period than occurs under the current common practice of non-anesthesiologist physicians and nurses evaluating patients shortly before surgery and determining which tests and studies are needed. This schema for change in practice would potentially avoid unnecessary (and duplicative) tests and

The Perioperative Surgical Home (cont'd)

studies, and the results of those deemed necessary would be available in a timely manner for the anesthesiologist. Surgical delays and last-minute postponements would be minimized. (#1)

- Earlier contacts with patients, soon after decision to operate, would allow for the various anesthetic and postoperative management options to be discussed and explained, making for better-informed patients who now would be more empowered to partner with their physicians. Patient satisfaction would be enhanced. (#3)
- Primary care physicians, anesthesiologists and other medical and surgical physicians would work to improve communication and coordination of care and be better positioned to address complications or patient concerns as well as to provide for efficient and effective transfers of care between all health care settings. (#1)
- Anesthesiologists would become more involved in the development of hospital protocols and systems that positively impact perioperative management. Examples include anticoagulation, transfusion and diabetic management guidelines; strategies to ensure timely administration and re-administration of antibiotics; and educating physicians and nurses on issues, such as pain management, that frequently contribute to prolonged hospitalization. (#2)
- Other areas that can be systematically retooled would include the availability of essential airway management equipment and skills throughout the hospital; development and oversight of rapid response teams; efficient and cost-effective preoperative testing (such as echocardiograms, pulmonary function tests); fluid resuscitation, shock treatment and cardiopulmonary resuscitation protocols. (#1)
- Coordination and oversight of a variety of functions that improve outcomes and curb postoperative pain, morbidity and mortality. (#2)

By taking steps to oversee a patient's care within the surgical home model, anesthesiologists can help hospitals and other health care organizations meet the aims and priorities of the National Quality Strategy and other recent calls for innovation and positive change. Expansion of the role of anesthesiologists within the surgical home concept would assist health care entities to earn additional funds made available through the new Partnership for Patients initiative.

The case for the surgical home concept is not theoretical. Leading institutions have documented savings and improved outcomes with its introduction. For example, anesthesiologists at the Mayo Clinic in Rochester, Minn., reduced transfused blood products by half, while decreasing infection risks and the incidence of renal dysfunction—and saving millions of dollars. Other savings

The Perioperative Surgical Home (cont'd)

at Mayo involved the identification of patients at high risk for developing complications related to obstructive sleep apnea. Such practices will influence facility administrators and health insurers to identify value in this extension of the practice of anesthesiology. Surgical home innovations would help stabilize costs while improving the cost-effectiveness and efficiency of patient care and outcomes.



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Annual Meeting of the CMA House of Delegates

By Michele Raney, M.D., CMA Board of Trustees

The 140th Annual Session of the California Medical Association (CMA) House of Delegates (HOD) took place Oct. 14–17, 2011, in Anaheim, Calif. Representing the CSA in CMA's Specialty Delegation were Brian Cross, M.D., Thelma Korpman, M.D., and Michael Schneider, M.D. In addition, Michele Raney, M.D., served as a Specialty Delegation Trustee on the CMA Board of Trustees; other CSA members on that board (representing some of the geographic and mode-of-practice delegations) were Virgil Airola, M.D., Lee Snook, M.D., and Robert Wailes, M.D. Additional CSA members were present in other delegations: James Merson, M.D., Rebecca Patchin, M.D., and Hugh Vincent, M.D. Stephen Jackson, M.D., served as a member of the Councils of Scientific and Ethical Affairs, and other CSA members provided input through the Organized Medical Staff Section and Hospital Based Physicians Forum. Unfortunately, the total number of CSA members participating in the CMA Annual Meeting was limited by their participation at the concurrently scheduled American Society of Anesthesiologists Annual Meeting in Chicago, Ill.

Officers and Elections

James Hay, M.D., was installed as CMA President; also elected were Paul Phinney, M.D., CMA President-Elect; Luther F. Cobb, M.D., Speaker of the House; and Theodore Mazer, M.D., Vice-Speaker. Steven Larson, M.D., became Chair of the Board of Trustees and David Aizuss, M.D., was elected Vice-Chair.

Reports

The report of the CMA Legalization and Taxation of Marijuana Technical Advisory Committee was accepted by the Board of Trustees and presented to the HOD. You are referred to the editorial (pages 5–8) and two other articles (pages 83–90) in this issue for further information on this topic.

Proceedings of the House of Delegates

Government Health Programs and Health Reform

Once again, since government health programs and health reform were ranked as the CMA's highest priority, the CMA will continue to actively work to ensure that implementation of federal health reform at both the federal and state levels is done in a manner so as to protect and enhance the practice of medicine and protect patients. Specifically, repeal of the Sustainable Growth Rate formula, elimination of limiting charges, and opposition to MEDPAC payment cuts to physicians were supported, as well as providing physicians with information

Annual Meeting of the CMA House of Delegates (cont'd)

regarding selecting and electing a specific Medicare participation status. The CMA will continue to develop member resources for practice assessment and contract analysis specific to a given health care community, and it will continue to monitor the implementation of health care reform and advocate for physician-centered delivery systems that improve quality and efficiency. The CMA opposes financial penalties for physicians who do not adopt health information technology, such as electronic medical records and electronic prescribing.

In the regulatory arena, the CMA will continue its advocacy for stronger regulatory enforcement of the corporate practice-of-medicine bar. In addition, the CMA will monitor the qualifications of physicians appointed to state committees that set standards of care for diagnosis and treatment decisions, guidelines and quality, and it will support participation by actively practicing physicians who have current knowledge of best practice of health care delivery, diagnosis and treatment, and cost-effective quality care.

The CMA will actively collaborate with interested county and specialty societies to submit an application to the Center for Medicare and Medicaid Services for a patient-centered “medical home” pilot project appropriate for California physicians and patients.

Insurance and Reimbursement

A series of resolutions requested specific responses to evolving difficulties in payer relationships. The CMA will oppose payers' unreasonable documentation requirements; will develop additional resources to assist physicians' contract negotiations with PPOs; will take whatever legal, legislative and/or statutory action is necessary to require that all insurers of health services provide physicians with a list of all formulary-covered alternate drugs or devices within the same class whenever coverage of a specific medication or medical device is denied; will take action to require that insurance companies issue payments directly to out-of-network physicians whose patients have signed an assignment of benefits form; will advocate for the immediate dissolution of workers' compensation medical provider networks.

Quality, Ethics, and Medical Practice Issues

The HOD reiterated that remuneration or kickbacks by pharmaceutical companies for specific drug-prescribing is considered unethical (this does not preclude remuneration as part of a bioethics-approved research project). The CMA, through the Council on Ethical Affairs, will study new policy recommendations on ways to relieve the organ donor shortage. The CMA will request that the American Medical Association (AMA) and the Food and Drug Administration require pharmaceutical package inserts to include the

Annual Meeting of the CMA House of Delegates (cont'd)

statement: “Statistical significance of safety data is unknown” whenever that is the case. The CMA will urge federal and state agencies to interpret and implement rules governing the electronic prescription of Schedule II–V drugs.

The CMA was directed to advocate that the AMA conduct a legislative campaign targeted toward extending federal Tort Claims Act protections to all EMTALA-mandated care.

The CMA will support introduction of California legislation similar to that passed in Florida, which, as a minimum, authorizes the state to discipline or deny licensure to physicians who offer deceptive or fraudulent expert witness testimony related to the practice of medicine, and requires that expert witnesses from outside the state apply for and receive a certificate authorizing them to testify. Registration for such a certificate will require a written application and payment of a fee, and subject the holder to discipline in the event that he/she renders deceptive or fraudulent testimony.

The CMA will assist physicians—local physician practices, medical societies, and their communities—in opposing hospitals requiring hospital-based or affiliated physicians or groups to carry minimum medical professional liability insurance policies with limits greater than those deemed appropriate by the medical staffs and consistent with industry standards; in essence, the CMA will vigorously oppose physicians being required to contractually indemnify hospitals for liability.

Health Professions and Facilities

The CMA will form a Technical Advisory Committee to study strategies for reducing medical education debt and addressing modifications to loan repayment financing; will work with the CMA Foundation to develop and implement a health policy elective rotation for interested medical students and house staff; will ask the AMA to study the economic multiplier effect of each residency slot by geographic region and specialty, and ask the AMA to investigate the association of Graduate Medical Education funding with each state’s health care workforce and health outcomes.

Fair peer review was discussed, and the CMA clarified its support for the concept that every hospital should have an independent self-governing medical staff that conducts fair peer review regularly, and that all California hospitals should actively enforce federal and state laws that require regular and fair peer review. In a fair peer review process, physicians should be informed of their option to request external peer review at the onset of an investigation, and any potential conflicts of interest on the part of the reviewer should be actively identified and addressed. Review by a panel of same-specialty physicians not

Annual Meeting of the CMA House of Delegates (cont'd)

affiliated with the hospital at which charges have been brought can be offered as a part of external peer review to achieve unbiased and well-informed peer review. External peer review should supplement and inform, but should not be used to replace, medical staff review.

Science and Public Health

Issues relevant to medical preparedness for disaster; volunteer physicians' liability coverage in disaster response and in providing uncompensated ("free") care for indigent persons; standardized training; and issues relevant to the coordination of existing medical disaster response teams, hospitals, medical societies, and state and federal agencies were discussed.

The CMA supports prohibition of electronic cigarettes and opposes tax incentives for films depicting the use of tobacco in a socially positive and/or contemporaneous manner; voted to encourage the federal government to re-examine the enforcement-based approach to illicit drug use and to prioritize and implement policies that treat drug abuse as a public health threat and drug addiction as a preventable and treatable disease; addressed the marketing of unhealthy food and beverages to children and will encourage media education programs directed to reduce these harmful health influences.

Concluding Remarks

Although fewer than 5 percent of CMA members have designated anesthesiology as their primary specialty, CSA members participate in all aspects of CMA governance—on the Board of Trustees and through the Specialty Delegation, the Organized Medical Staff Section, the Hospital Based Physicians Forum, the geographic delegations, the Mode of Practice Forums, and the Resident Delegation. Each of these individuals continues to maintain the CSA's presence as a respected and influential force in California organized medicine as well nationally. Their efforts are very much appreciated.

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Informed Consent: Respecting Patient Autonomy

By Gail Van Norman, M.D., Professor of Anesthesiology and Pain Medicine and Adjunct Professor of Biomedical Ethics, University of Washington

The Case

Allen, a 35-year-old man, presents for colectomy after a 20-year history of ulcerative colitis. He does not appear nervous, but is animated and friendly. His sister explains that Allen has developmental delay and is also fearful of needles. He has permitted the nurse to start an intravenous drip. Discussion of an epidural for anesthesia and analgesia with Allen will take extra time, and the anesthesiologist is also concerned that he may not have the necessary self-control to cooperate with an epidural. She decides to discuss only general anesthesia and patient-controlled analgesia with the sister.

Moral imperatives for informed consent in Western medicine and medical research are founded in the ethical principle of respect for patient autonomy. The term “autonomy” comes from the Greek *autos* (self) and *nomos* (rule). Originally used to describe political self-governance, “autonomy” also has come to be associated with individuals. This concept of self-determination has attained a powerful vocabulary in Western culture, evoking debates over liberty, privacy, free will, rights and responsibilities. Freedom to choose one’s destiny is a prominent Western ideology. There is broad moral and legal consensus that this freedom is essential when such choices involve medical treatment.

This article is reprinted from *Clinical Ethics in Anesthesiology: A Case-Based Textbook*, ed. Gail Van Norman, Stephen Jackson, Stanley Rosenbaum and Susan Palmer. Cambridge University Press, 2011. Permission for reprint with minor modification from Cambridge University Press.

Of the four “foundational” principles in medical ethics—beneficence, non-maleficence, respect for autonomy, and justice—the principle with the strongest influence in the United States is respect for personal autonomy. Many ethical questions in U.S. medical practice will be answered by asking foremost what the patient *wants*, and not necessarily what the physician, family, or culture believe is *best*. Respect for autonomy is a key principle in other Western nations as well, but it is usually weighted against the other three principles. Thus, the same ethical question may be answered in other Western countries by asking not only what the patient *wants*, but also what is *best* for them according to their family, society, and reasonable medical resources. Non-Western cultures often depart almost completely from an autonomy-based ethic of informed consent and resort to a more “collectivist” decision-making model, in which

Informed Consent: Respecting Patient Autonomy (cont'd)

families and groups make decisions together, based on obligations to care for one another, concepts of preservation of harmony, and values of group interdependence. Table 1 provides a summary of cultural aspects of medical decision-making in Pacific Islander and Asian cultures.

TABLE 1: Values Emphasized in Medical Decision-Making in Some Non-Western Cultures	
Japanese	
■	Shintoism is prominent.
■	Collective family interests take priority over individual interests.
■	The family is responsible to care for elders.
■	Caring for parents must be done with deep feelings of gratitude and happiness.
■	Mention of death is taboo; discussing terminal illness may cause spiritual contamination.
Chinese	
■	Confucian concepts are prominent.
■	Harmony, unity, and survival of the family
■	Hierarchical family relationships
■	Elders are treated with respect and protected from bad news.
■	Discussing illness or death may cause it to happen.
Vietnamese	
■	Concept of karma and fatalistic attitudes toward illness and death
■	Individuals do not control their lifespan; advance directives are de-emphasized.
■	Saying "no" to a physician may be disrespectful and could create disharmony.
Filipino	
■	Filial piety
■	Illness may be "deserved" and seeking health care may be a "last resort."
■	Deference to the physician out of respect
Hawaiian	
■	Acceptance of medical condition
■	Western medicine is seen as autocratic.
■	Holistic approach to health problems and collective decision-making
(adapted from McLaughlin L, Braun K. "Asian and Pacific Islander cultural values: considerations for health care decision-making." <i>Health and Soc Work</i> 1998; 23:116-126)	

Informed Consent: Respecting Patient Autonomy (cont'd)

Although the Nuremberg Code is often cited as the origin of the modern physician's obligation to obtain informed consent, legal precedents enforcing patients' rights actually predate Nuremberg. In France, legal requirements for consent were established in 1910, and were reinforced by the French Supreme Court in 1942.¹ In the U.S. in 1914, the case of *Schloendorff v. Society of New York Hospital* established that "every human being of sound mind and adult years has a right to determine what shall be done with his own body."²

Autonomy

Informed consent involves the concepts of "personal autonomy"—a patient's ability to make choices—and "autonomous choice": whether an autonomous patient's choice is made freely. Respect for patient autonomy involves not only ethical obligations to respect patient choices, but also obligations to *promote* both patient autonomy and autonomous choice.

Autonomous Persons The terms "capacity" and "competence" are both used to describe a group of capabilities necessary for decision-making. In the U.S., "capacity" is used by medical experts to describe functional capabilities while "competence" is a legal term. In the United Kingdom, the usage is reversed: "competence" usually refers to functional capacity while "capacity" is a legal term.³ In this article the terms are used interchangeably.

Capacity is a "threshold" element in informed consent. Without the ability to make decisions, a person is not autonomous. Capacity is task-specific: Patients may be fully capable of making medical decisions even if they are unable to care for themselves in other ways. Capacity waxes and wanes depending on many factors such as the patient's medical condition, psychological state, level of stress, and ability to orient to unfamiliar surroundings. Although any diagnosis of compromised mentation can interfere with competence, *no* diagnosis in a conscious patient invariably identifies incompetence. The presence of memory impairment, dementia, or mental illness, for example, does not prove a lack of capacity to make medical decisions.

Physician paternalism and bias pervade assessment of patient competence. Patients are often referred for competency evaluations simply because they refuse medical advice, although such refusals are not generally evidence of incapacity.⁴ In one study, noncompliant patients comprised almost two thirds of referrals for competency evaluations, yet they were only slightly more likely than compliant patients to be judged incompetent by consultants. Patients who discharge themselves against medical advice from hospitals have a somewhat higher prevalence of alcohol abuse than the general population. However,

Informed Consent: Respecting Patient Autonomy (cont'd)

studies have found that such actions are more often related to insurance status and lower income, or factors such as race (which might be associated with mistrust of physicians or perceptions of disrespectful treatment), than to decisional incompetence.⁵

Physicians frequently judge patient competence based on their perception of the quality of a patient's decision. A recent study of physicians' attitudes toward patients who refuse cancer therapy found that physicians often regarded such decisions as "irrational" and therefore reflecting mental aberrations.⁶ Such judgments place the physician's own values, prejudices and perceptions about medical treatment and quality of life before those of the patient, and do not reflect appropriate respect for patient autonomy. The same study found that patients refuse medical therapy based on personal values and experience more than on medical facts alone. Most experts believe that quality of life measures are at least equal in relevance to medical outcomes in determining if treatment results meet patient needs.

In general, competence to make medical decisions is adjudged to be present when the patient meets four criteria: he or she can communicate a choice, understand the relevant information, appreciate the medical consequences of the decision, and reason about treatment decisions. These criteria generally can be assessed in preoperative conversations with patients and do not usually require expert consultation. When there is conflicting evidence about patient competence, however, a formal re-evaluation may be helpful.

The anesthesiologist in our introductory case made a hasty judgment about whether Allen was capable of participating in a complete discussion of options for his anesthesia care. An actual conversation with Allen would have revealed to her that he is employed and lives independently—although these circumstances do not guarantee he has capacity for medical decision-making. When asked, he says that he needs to have surgery because of his sick intestines, and that he understands that he could get cancer if he does not have the operation. He also hopes that the surgery will reduce his pain and diarrhea. He does not fear anesthesia; he has been through several operations before without problems. Because of his religious beliefs he does not fear death. Allen appears to be an autonomous person with capacity to decide—or at least participate to a great degree—in decisions about his care, and should be given a complete description of his options in language aimed at his level of understanding.

Autonomous Choices Three conditions must be met in order for an act (or choice) to be autonomous: a person must act with *intention*, with *understanding*, and *without controlling influences*.

Informed Consent: Respecting Patient Autonomy (cont'd)

Intention Ethical theory regarding intention is complex, but generally speaking, intentional acts require planning, although not necessarily reflective thought or strategy. We do many things intentionally but without thought, such as reaching for a glass of water in order to drink, scratching an itch, or turning a page in a book.

Unintentional acts can result from accidents or habitual behavior, or even as a byproduct of an intentional act. Imagine that Mary presents with flank pain suggestive of a kidney stone. Her physician orders an intravenous pyelogram (IVP). After administration of the contrast agent and IV fluid, increased urine output washes the stone into the bladder. The IVP is negative, but Mary's pain is resolved. The physician intended to run the test to diagnose the cause of her pain, and he intended to appropriately treat the condition responsible for it. Both things happened. The test was run according to plan, but pain relief occurred because of an unintended side effect of the test. Mary's pain relief was the result of an accident and not a result of intention, even though the outcome of the accident and the intended outcome of the physician's plan are the same.

Patients are asked explicitly and implicitly to consent to both intentional and unintentional acts by physicians. Intentional acts are broadly categorized as those acts that result in the expected outcomes. Unintentional acts are those acts that result in outcomes that are not expected or not desired, such as side effects, accidents and medical catastrophes. When autonomous patients consent following adequate information about both the *known and intended* and *known possible—but unintended*—outcomes of treatment (and they are not manipulated or coerced), then they can be said to have *intended* to consent to the potential unintended consequences of treatment. It would be difficult to assert that a patient *intended* to consent to outcomes about which they were not informed. A patient who is inadequately informed is therefore *not* making an autonomous choice because intention is a requirement for autonomous choice. Adequate information is key to promoting patient autonomy, but what constitutes "adequate information"?

Understanding: What the Physician Must Disclose It was not until the mid-twentieth century that a legal obligation to *inform* patients prior to obtaining consent was established. In *Salgo v. Trustees of Leland Stanford Hospital*⁷ (1957) it was found that physicians must discuss risks and alternatives to treatment, as well as describe the procedures and their consequences. This finding was reinforced in *Canterbury v. Spence* in 1972, which determined: "... it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification."⁸

Informed Consent: Respecting Patient Autonomy (cont'd)

Physicians argued that the courts had imposed an impossible burden: Explaining *all* of the possible risks and outcomes of procedures would be tantamount to providing the patient with a medical education. Patients were neither knowledgeable enough, nor educable to the level of detail needed, to make “competent” medical decisions. Subsequent court findings disagreed. In *Harnish v. Children’s Hospital Medical Center* (1982), the duty to inform patients was further clarified: “A physician owes to his patient the duty to disclose in a reasonable manner all significant medical information *that the physician possesses or reasonably should possess* that is *material* to an intelligent decision by the patient whether to undergo a proposed procedure.”⁹ [italics added]

Without knowing exactly what information is “material” to a patient, one potential strategy could be to simply recite as many relevant medical facts as possible to obtain consent and avoid liability later on. With regard to patient decision-making, however, it is important to understand that **not all medical facts are material ones and not all material facts are medical ones**. Patients base decisions on a number of matters, only some of which are medical facts. They also consider the potential medical and non-medical outcomes of the treatment in the context of their lives, personal values, and personal experiences, as in the following scenario:

Ann and Sarah, each 39 years old, both have a 1.5 cm breast cancer. Both are weighing the same options: lumpectomy with adjunctive chemotherapy, or mastectomy with chemotherapy. Each treatment is associated with similar cure rates. Ann decides to undergo lumpectomy based on her priorities of minimizing surgical recovery and disfigurement, as well as her confidence that the chance of recurrent cancer is small. Sarah also worries about disfigurement, but is more concerned about cancer recurrence because her mother died of breast cancer after protracted treatment and significant suffering. She requests bilateral mastectomies to ease her fears of experiencing bilateral cancer. Relatively few of the medical facts are actually material to either woman’s decision—and even though the facts are the same in each case, the decision is not. The presence of cancer, recurrence rates, and the potential cure rates of each type of proposed surgery are material to both women. Potential disfigurement from the surgery is also material to both—and this becomes decisive for Ann. But for Sarah, other non-medical issues, such as her experience of her mother’s death and how it affected her perceptions and fears about breast cancer and cancer treatment, are both material and decisive.

An exhaustive presentation of non-medical information not only dilutes medical information that is essential to a patient’s decision, but also potentially neglects non-medical information that is also critical to the patient’s decision. Physicians

Informed Consent: Respecting Patient Autonomy (cont'd)

are expected to discuss the proposed treatment and reasonable alternatives. Common risks should be discussed because they are likely to occur, and the patient should be given a chance to consider those possibilities. Nausea and vomiting, pain, dental damage, sore throat, and adverse drug reactions are examples of some common risks that might be discussed. Serious risks, even if rare, should be disclosed because such serious harm may be material to the patient's decision. Stroke, blindness, major cardiac events, cardiac arrests, and death are examples of serious risks that could be addressed. Physicians should also attempt to discover what other issues are germane to the patient: asking the patient about questions, fears and special concerns may uncover other questions that are important to clarify.

Controlling Influences: The Effects of Coercion, Persuasion and Manipulation

Even when acting with intention and understanding, autonomous persons can make non-autonomous choices. The bank teller who is forced at gunpoint to hand over money is an autonomous person, but she is being forced by the robber to make a choice against her will—to give up the money or risk being killed. *She* is autonomous, but her *choice* is not. She acts with both intention and understanding, but is under the irresistible power of a controlling influence. In the informed consent process, physicians have ethical obligations to avoid controlling influences that invalidate autonomous *choice*.

Coercion

Coercion occurs if one person both *intentionally* and *successfully* influences another by making a believable threat of harm that is sufficiently severe such that the other person is unable to resist acting to avoid it. Because it controls the other person's actions and usurps autonomy, coercion is unethical. Even if it is not successful, attempting to coerce someone demonstrates a lack of respect for patient autonomy and is unethical.

Not all threats are coercive. For a threat to be coercive, the threatened person must understand it, believe that it will be carried out, and be unable to resist it. Threatened harms can include physical, psychological, social, legal, and financial harms, among others. Perceptions about what constitutes a believable threat and sufficient harm are subjective and vary from person to person—some threats are universal enough to coerce almost any person, while others are selective enough to only coerce a few. Furthermore, *circumstances* that restrict personal choice are not “coercive,” because circumstances are not persons and cannot have intentions. A patient who requires surgery to relieve a bowel obstruction is confronted with few viable choices and therefore is not entirely “free,” but a choice to undergo surgery can still be autonomous, because within the framework of the circumstances the person can act with intention, with understanding, and without being controlled by the will of other persons.

Informed Consent: Respecting Patient Autonomy (cont'd)

Coercion is not uncommon in anesthesia and surgical practice. Consider Mr. Smith, an 85-year-old man with metastatic colon cancer, who has a large bowel obstruction, severe pain and discomfort, and requires palliative surgery. He has requested a do-not-resuscitate (DNR) order because of his terminal disease. Mr. Smith sincerely hopes to survive his surgery, but he understands that death is a risk. He knows that both his age and his diagnosis make his prospects of surviving a cardiac arrest grim. Furthermore, he believes that death under anesthesia, while not his *intended* goal, would be an acceptable and possibly humane outcome, and he consents to retaining his DNR status during anesthesia. But the anesthesiologist refuses to proceed unless Mr. Smith rescinds his DNR order, even though cardiopulmonary resuscitation (CPR) is not integral to treating bowel obstruction per se. The anesthesiologist is presenting Mr. Smith with a credible threat of harm, and she certainly is capable of carrying out that threat by preventing surgery that will relieve Mr. Smith's pain. The threat is sufficiently severe that Mr. Smith ultimately is controlled by it and agrees to rescind his DNR status. The anesthesiologist has intentionally and unethically coerced him into accepting a treatment he does not want (CPR) and likely will not need, in order to obtain treatment that he both wants and does need (bowel resection).

Persuasion

Persuasion is a non-controlling (resistible) form of influence in which one person *intentionally* and *successfully* uses reason to induce another person to freely and willingly accept the beliefs, intentions and actions of the persuader. Persuasion is an integral part of informed consent as, for example, when the anesthesiologist recommends epidural anesthesia over general anesthesia for an elective cesarean section, due to the advantages of maternal-infant bonding immediately after birth, the possibility of epidural narcotic analgesia for post-operative pain relief, and a perception of decreased risks to mother from pulmonary aspiration. For such a recommendation to qualify as persuasion and not manipulation, it must present accurate and balanced information and must be resistible by the patient (that is, the patient can choose not to follow the recommendation).

Persuasion is entirely ethical. Patients expect physicians to make rational recommendations about medical treatments and alternatives. In fact, physicians may even be held legally liable and morally culpable if they do not at least attempt to persuade their patients to consent to treatments that are medically indicated.

Manipulation

Between persuasion and coercion lies a group of influential behaviors included under the broad definition of "manipulation," including indoctrination, seduction, deception, omissions and lies. In general, manipulation strategies

Informed Consent: Respecting Patient Autonomy (cont'd)

work by either altering actual choices provided to patients or altering the patients' perceptions of their choices.

The degree of control exerted by manipulation (and therefore the degree to which manipulation interferes with patient autonomy) ranges from inconsequential to completely controlling. Not all attempts at manipulation succeed, but many if not all manipulative strategies involve deception, either through false or misleading information or omission of key facts. Manipulation is therefore unethical whether it is successful or not, because it both violates ethical obligations of veracity (telling patients the truth) and disrespects patient autonomy.

In the case introducing this article, the anesthesiologist has engaged in manipulation by not describing the benefits and risks of epidural anesthesia and analgesia, even though it is a common anesthetic alternative. Had she discussed this option, she would have discovered that Allen in fact had opted for an epidural for previous bowel surgery and had done well. By omitting the discussion in order to meet her own goals, she has altered Allen's actual choice, since Allen would probably have chosen to have an epidural if he knew it were possible.

Now, suppose instead that a patient who is a heavy smoker presents for total knee arthroplasty. The anesthesiologist wants to do a subarachnoid block (SAB). She does discuss both general anesthesia and SAB. However, she states that "spinal anesthesia is much safer for knee replacements" and "spinal anesthesia is much safer for smokers." This is an example of manipulation by creating a false perspective of the patient's choices. There is no strong evidence that SAB is safer for most surgeries or safer for smokers, and the statement inaccurately portrays the comparative risks and benefits of these two anesthetic options. Once again, this anesthesiologist has attempted to manipulate the patient, and has disrespected the patient's autonomy.

Therapeutic Privilege and Waiver of Informed Consent

Two exceptions may exist to the rule that competent patients must have risks disclosed to them: the concept of therapeutic privilege and the idea that competent patients may waive their rights to be informed.

In evoking therapeutic privilege, physicians argue that it is ethical to withhold material information from patients in whom such disclosures would cause unacceptable harm, thus causing the physician to violate the ethical principle of nonmaleficence (avoiding harm). Accepting this general argument without restriction, however, is a prescription for paternalism. If the definition of "unacceptable harm" is framed too broadly, then physicians could conceivably

Informed Consent: Respecting Patient Autonomy (cont'd)

justify withholding almost any information, because such disclosures are laden with at least some stress for most patients. Physicians even could use it as an excuse to control the decisions of patients who they feel might refuse therapy after a full disclosure. If unacceptable harm is defined very narrowly as harm that causes the patient to become emotionally, psychologically or intellectually incapable of making a decision, then therapeutic privilege does not technically violate the principle of respect for autonomy because full disclosure would render the patient non-autonomous anyway. The courts have recognized the risk of physician paternalism, and have reinforced the legal emphasis on respect for autonomy:

The physician's privilege to withhold information for therapeutic reasons must be carefully circumscribed ... for otherwise it might devour the disclosure rule itself. The privilege does not accept the paternalistic notion that the physician may remain silent simply because divulgence might prompt the patient to forgo therapy the physician feels the patient really needs. That attitude presumes instability or perversity for even the normal patient, and runs counter to the foundation principle that the patient should and ordinarily can make the choice for himself.⁸

Waiver of disclosure by the patient is conspicuously different from therapeutic privilege. An autonomous patient may decide intentionally, with understanding, and without controlling influences by others, to waive his or her right to have medical information, or may decide to have the facts disclosed to someone else, such as a family member. Because the choice is an autonomous one, respecting such decisions respects patient autonomy and is consistent with ethical practice. Legal ramifications of patient waiver have not, however, been clearly resolved in case law.

Key Points

- The ethical principle of respect for patient autonomy is firmly grounded in Western ethical principles valuing individual freedoms.
- Capacity, or competence, is a threshold element necessary to being an autonomous person: patients have capacity to make decisions if they can communicate a choice, understand the relevant information, appreciate the consequences of the decision, and reason about their decision.
- Physicians have ethical obligations to respect patient autonomy, and to promote autonomy when competence can be restored in a time frame that still renders the medical treatment meaningful.

Informed Consent: Respecting Patient Autonomy (cont'd)

- Disclosure is not required to be comprehensive: rather, ethical and legal disclosure discusses the treatment, reasonable alternatives, common and serious risks, as well as anything the physician knows or reasonably should know is material to the patient in making his or her decision.
- Coercion and manipulation are unethical because they violate the principle of respect for patient autonomy, and because manipulation often involves deception and violates physician obligations of veracity.
- Persuasion does not manipulate or control patient choice and is consistent with ethical physician behavior.
- Therapeutic privilege and waiver of consent are possible exceptions to informed consent, but only under very restricted circumstances.

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Peering Over the Ether Screen: Nurse Anesthesia Supervision and Online Opinion

By Karen S. Sibert, M.D., Associate Editor

Recently I wrote an online column for the “KevinMD” website, which was published under the headline: “Unsupervised anesthesia care by a nurse anesthetist is a threat to patient safety.” I was inspired to write the column after the Centers for Medicare and Medicaid Services (CMS) published new rules in October 2011. Many anesthesiologists were deeply concerned that the new rules might eliminate the requirement for physician supervision of nurse anesthetists; happily, the new rules did not. My column praised the CMS decision, with the goal of educating other physicians and the public about why it matters.

As of this writing, that article still tops the list on “KevinMD” as the most commented-upon column in recent weeks. Commenters wrote passionately, although not always politely, on both sides of the argument—in favor of and opposing nurse anesthetist supervision. Below follows a reprint of the column, and afterward a selection of what I found the most noteworthy and printable comments.

No matter how quickly you tried to switch the television channel lately, you probably couldn’t escape the trial of Dr. Conrad Murray or avoid hearing about propofol, an anesthesia drug that can be fatally easy to use.

What you may not have heard is that the American people just dodged a serious threat to their anesthesia care, and most don’t know how near a miss it was.

The Centers for Medicare and Medicaid Services (CMS) recently issued new rules concerning the conditions of participation in Medicare and Medicaid for hospitals and health care providers. Despite intense pressure, CMS sensibly left in place the rule that requires nurse anesthetists to be supervised by physicians. We should all be thankful, and stay on guard in case anyone tries to change that rule again.

The new rules are open for comment until mid-December, and lobbyists no doubt will continue to argue that all anesthetics can “just as easily” be given by nurse anesthetists alone. This is a bad idea, and CMS should stand firmly against it.

Here's the background. This year, the Obama administration announced a plan to reform health care regulations that were unnecessary in its view. In particular, the administration said, the "use of advanced practice nurse practitioners and physician's assistants in lieu of higher-paid physicians could provide immediate savings to hospitals." In the new rules, CMS reasonably proposes to remove barriers to the work of physician extenders, for example by not making them seek out a physician to co-sign every order.

But if lobbying efforts had succeeded, nurse anesthetists—alone among other mid-level providers—would be allowed to practice without any supervision at all. Hoping to make anesthesia services more profitable for hospitals and insurers, lobbyists purposely blur the differences between the education of physicians and nurses. They want to get rid of the cost-effective anesthesia care team model, where nurse anesthetists or anesthesiologist assistants work under physician direction.

Mid-level providers on every team are essential to health care. When patients go to a primary care doctor's office, they are likely to see a nurse practitioner or a physician's assistant who can treat routine complaints, manage chronic illnesses like high blood pressure, and write prescriptions under the doctor's authority. If you need surgery, a physician's assistant may assist your surgeon in the operating room, and a nurse anesthetist may look after you under the supervision of your anesthesiologist. They're working as part of the team, not replacing the physicians.

Dr. Jane Fitch, recently elected First Vice President of the American Society of Anesthesiologists, began her career as a nurse anesthetist with a master's degree. Troubled by her limited knowledge compared to the physicians she worked with, she soon went back for eight more years of education—completing medical school, residency, and then a fellowship in cardiac anesthesiology. While she was a nurse anesthetist, "I didn't know how much I didn't know," Dr. Fitch says.

Military families may be surprised to learn that if you become a patient in a U.S. military hospital (which isn't bound by CMS rules), you may receive anesthesia from a nurse anesthetist who isn't required to work with an anesthesiologist. This rule applies whether the patient is a healthy civilian having a minor procedure, or a grievously wounded soldier needing major surgery. The anesthesiologist may be called in to rescue the patient only when complications have already occurred.

"Suddenly it's my case, and my problem," says a Navy anesthesiologist in frustration.

President Clinton (whose mother was a nurse anesthetist) signed into law in 2001 a rule that permits states to "opt out" of the CMS requirement for nurse anesthetists to be supervised by a physician. Sixteen states—unfortunately including my own state of California—have adopted this rule to date. While it was originally intended to help rural areas improve access to care, the "opt out" rule supports any hospital that seeks to cut costs by allowing nurse anesthetists to work alone.

By signing the "opt out" rule, President Clinton apparently meant that anesthesia care by a nurse anesthetist working without supervision is all right for you and for other people. When Clinton himself needed heart surgery, a physician specializing in cardiac anesthesiology headed his anesthesia team. The same was true of Governor Schwarzenegger, who signed the letter in 2009 allowing the state of California to opt out of physician supervision of nurse anesthetists. When he needed surgery, a board-certified anesthesiologist personally provided his anesthesia from start to finish.

Now there's a new threat to patient safety. Section 2706 of President Obama's Patient Protection and Affordable Health Care Act (PPACA) prohibits discrimination by insurance companies against health care providers as long as they are acting within the scope of their licenses.

It sounds innocuous. But this "non-discrimination" clause opens the door for non-physicians—like nurse anesthetists or chiropractors—to open clinics without physician oversight and bill insurers directly for anesthesia nerve blocks, epidurals, and other complex pain management procedures. These techniques benefit many chronic pain patients, but they carry the risk of life-threatening complications. Under the misguided logic of this law, I could deliver babies or take out gallbladders because I'm a licensed doctor, even though I'm not an obstetrician or a surgeon.

The Obama administration expresses concern about the "impending shortage" of physicians as a reason to allow more latitude to advanced practice nurses. Certainly, public health nurses in the community don't need immediate physician supervision to deliver care safely within their scope of practice. But anesthesia and surgery always carry the risk of sudden complications requiring physician intervention, whether in a hospital or an outpatient surgery center.

Peering Over the Ether Screen (cont'd)

If we cut out physician involvement in order to make anesthesia cheaper, we're kidding ourselves to think that quality and safety won't suffer. The American people deserve better.

Karen S. Sibert is an Associate Professor of Anesthesiology, Cedars-Sinai Medical Center.

Selected Comments (abridged but not edited)

From a general surgeon:

I have worked with many fine CRNAs but as a general surgeon the problem I always had was: when things are going well in the operating room, CRNAs act like they're a doctor; when things go to hell, it's suddenly, "Hey doc, what do I do, I'm just a nurse." Since at that point the surgeon is up to his neck in alligators too, it's a heckuva time for them to lose their confidence.

From a nurse anesthetist:

Your op-ed lacks any evidence whatsoever. That is the problem. It is "evidence by proclamation" and using fear mongering. Look, if you [the ASA] would just admit for once this is just about business and protecting your wallets I could at least understand it. However the continuous insinuation that this is a "safety" issue for patients is neither accurate, evidenced or fair.

From a military nurse anesthetist:

I am a military CRNA and have just spent the last year working independently in Afghanistan on a Forward Surgical Team with no anesthesiologist. I provided safe anesthesia for some of the worst traumas imaginable to American soldiers, civilian adults and children. I would have loved to have an extra hand in the OR from an anesthesiologist but not too many are volunteering to go to Afghanistan and supervise CRNAs there.

From a Navy anesthesiologist, responding to the above post:

While deployed, military CRNAs indeed do practice independently ... in some places. However, they're treating the healthiest and most aggressively and completely pre-screened patients on earth: young active duty military. Further, they're only doing trauma. Formulaic and procedural ... and let's be honest, even the local national casualties generally aren't sick. They're generally not vasculopath, they don't have end stage renal disease, or cirrhosis ... and let's be even more brutally honest, even if the

Peering Over the Ether Screen (cont'd)

local national patients are sick and they do die, there's no family waiting to sue in the wings. And then there's the Feres Doctrine protection. It is disingenuous to pretend that adequate care from independent CRNAs in Afghanistan proves or even implies that CRNAs should be working independently in the United States.

It is telling that within Afghanistan, there are fewer and fewer independent CRNA billets, because more and more deployed units are insisting on anesthesiologists. Keep an eye on the USMC locations.

Your parting shot to military anesthesiologists ("not too many are volunteering to go to Afghanistan") is simply wrong and insulting. Taskings come down from higher echelons in the military, and we step up to fill them just as you and the CRNA community do. Right now, I'm on the books to go. It will be my third deployment.

From ASA Immediate Past President Mark Warner, M.D.:

In this day and age, anesthesia has become extremely safe. The available monitoring equipment, medications, and knowledge gained through research and development have advanced this profession to the point where severe complications are a rarity. With that being said, complications still do occur. And when they occur, they are often unexpected and require a quick response. Closed claims reviews have shown without a doubt that having an anesthesiologist and a second provider in the operating room on induction and emergence provides the safest delivery of an anesthetic in the event of a catastrophic complication...

Simple anesthetic management principles seem to have a major effect on perioperative mortality. The routine use of an equipment checklist (odds ratio, 0.61), direct availability of an anesthesiologist to help lend a hand or troubleshoot when needed (odds ratio, 0.46), the use of full-time compared with part-time anesthesia team members (odds ratio, 0.41), the presence of two members of the anesthesia team at emergence (odds ratio, 0.69), and reversal of muscle relaxants at the end of anesthesia (odds ratio, 0.10) had dramatic, positive effects that were associated with reduced perioperative mortality within 48 h after surgery and anesthesia. [Arbous et al., *Anesthesiology*, February 2005]

From the President of the American Association of Nurse Anesthetists:

The anesthesia care team model is far from the most cost-effective anesthesia delivery model. According to a study conducted by Virginia-based The Lewin Group and published in the May/June 2010 issue of the *Journal of Nursing Economic*®, the most cost effective model of

anesthesia delivery is a CRNA acting as the sole anesthesia provider. The study, titled “Cost Effectiveness Analysis of Anesthesia Providers,” considered the different anesthesia delivery models in use in the United States today, including CRNAs acting solo, physician anesthesiologists acting solo, and various models in which a single anesthesiologist directs or supervises one to six CRNAs. The results show that CRNAs acting as the sole anesthesia provider cost 25 percent less than the second lowest cost model. On the other end of the cost scale, the model in which one anesthesiologist supervises one CRNA is the least cost efficient model. The study’s authors also completed a thorough review of the literature that compares the quality of anesthesia service by provider type or delivery model. This review of published studies shows that there are no measurable differences in quality of care between CRNAs and anesthesiologists or by delivery model. And, in the name of transparency, it is important to note that the study was supported by the AANA Foundation, but that was where the Foundation’s involvement in the research or publication of the results ended...

Supervision is not for CRNA practice. Supervision is for reimbursement of Medicare part A (facility charges) only. Quit twisting reality.

From an anesthesiologist:

Wow, as a recently minted board certified anesthesiologist, coming from a training program with zero CRNA exposure I had little idea the threat mid-levels pose. This article has been a real eye opener. I was directed to this site by someone at work. Up until now, I always viewed working with CRNAs as a cordial symbiotic affair. I need to re-evaluate this attitude... Writing my check to the ASAPAC right after I get off the computer!

For more comments, including those less fit to print, go to: <http://www.kevinmd.com/blog/2011/11/unsupervised-anesthesia-care-nurse-anesthetist-threat-patient-safety.html>

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Perspectives on the Patient Protection and Affordable Care Act (PPACA)

The Bulletin presents here a perceptive and perhaps provocative opinion piece by Karen S. Sibert, M.D., which originally appeared in “CSA Online First” on the CSA website, as well as responses from Joseph Andresen, M.D., and Steven Goldfien, M.D., CSA Past President, both of which also appeared on the website.

Shall We Toast the End of Obamacare?

By Karen S. Sibert, M.D.

The Supreme Court announced last year that it will hear a challenge to the constitutionality of the 2010 health care reform act, known as “Obamacare.” Before we pop open the champagne, we should take a moment to consider what this may mean for California physicians and for anesthesiologists in particular. “Whatever Court Rules, Major Changes in Health Care Likely to Last,” claims a recent *New York Times* headline. Should we believe that forecast?

The court is allowing a remarkable five and a half hours for argument, as opposed to the one hour that it traditionally permits, because of the complexity of the questions it will decide. The first and arguably most important question is whether or not Congress has the constitutional power to require people to purchase health insurance or face a penalty: the “individual mandate.” This twist on taxation clearly infuriates many people. Whereas taxes support public services, this provision would pressure all of us to buy a product that not everyone wants.

Another key question is whether or not the rest of the law—the Patient Protection and Affordable Care Act (PPACA)—will stand if the individual mandate is struck down. The law forbids insurers to turn away any applicant or charge more for pre-existing conditions, assuming that new revenue from healthy patients would balance out the costs. Without the individual mandate in place, anyone could wait to buy health insurance until an accident happens or disease strikes, and insurance companies wouldn’t survive.

Uninsured patients are everyone’s problem. We all pay—directly or indirectly—when they turn up in our emergency rooms and we have to provide anesthesia for them. There’s a certain appeal to insisting that everyone pay something into the health care system that will be responsible for scooping them up from the freeway after a car wreck. Certainly here in Los Angeles we have our share of personal trainers and aspiring actors who have smartphones and cars but won’t spend the money to buy health insurance.

Perspectives on the PPACA (cont'd)

So let's consider possible consequences of the Supreme Court's decisions. If young, healthy people don't have to buy health insurance, we're back to the starting gate in terms of figuring out how to pay for trauma care. Here in California, changes in state law have already been made to align with the provisions of PPACA, and would be unaffected by the law's repeal. The withdrawal of some proposed insurance rate hikes has saved consumers millions, though I'm willing to bet that doctors have absorbed more of that hit than the insurance companies, as fee-for-service reimbursements continue to shrink.

If the entire law is repealed, many physicians hope to see a return to happier days for the private practice of medicine. I doubt that's realistic. Too many changes have already taken place: the absorption of small practices into large groups, and consolidation of hospital systems. Medical staffs are no longer composed of physicians only, but may include nurse practitioners and other mid-level providers who can provide cheaper care. The drive to have fewer anesthesiologists supervising more cases is only going to escalate.

For anesthesiologists, it would be wonderful to see the repeal of PPACA's Section 2706. This is the innocent-sounding provision that prohibits discrimination by insurance companies against health care providers as long as they are acting within the scope of their licenses. This "nondiscrimination" clause has opened the door for non-physicians to open clinics without physician oversight and bill insurers directly for anesthesia nerve blocks, epidurals and other complex pain management procedures. Putting a stop to that would truly be a service to public safety.

But the repeal of PPACA doesn't answer the question of what we are going to do with our unaffordable health care system. As the recession drags on, more people are joining the ranks of the long-term unemployed, and their COBRA coverage is running out. America isn't going to let the bodies of uninsured people pile up in the streets, so we will continue admitting them to hospitals. Without some motivation to alter the status quo, we will continue to "do everything possible" even for terminally ill patients, and waste billions in the process.

At some level, I think most of us realize how unsustainable the current system has become. My 89-year-old father who lives in South Carolina is as conservative as anyone. His idea of a nice Saturday afternoon is to take a walk around the statehouse grounds to see the monument to Sen. Strom Thurmond and the Confederate flag. But when we were discussing health care, he said, quite seriously, "You know, when your mother and I lived in Canada for a

Perspectives on the PPACA (cont'd)

couple of years, the government paid all our medical bills. We had good doctors and it worked fine. Why doesn't the U.S. just do the same thing?"

I winced. "Dad," I said. "Would it be OK if we wait to do that until I have the last child through college?" He agreed. But in the long run I fear that if the Supreme Court rules against Obamacare, we may be moving that much closer to a single-payer system as the only way out of our current dilemma. I hope I'm wrong.

Celebrate Repeal? Seriously?

By Joseph Andresen, M.D.

As a physician and anesthesiologist for the past 27 years, I offer my own perspective on PPACA.

First, as a physician: Mary was brought to the operating room immediately after admission from the emergency department. She had a high fever, racing heart rate, and low blood pressure. An infection had spread throughout her body and bloodstream. In the pre-op area, before her emergency surgery, I asked Mary why she had not come to the hospital sooner. She tearfully replied, "I have no medical insurance. I came to the hospital only when I knew my life was in danger."

Secondly, as a father: When my daughter was 3 years of age, she had a catastrophic neurosurgical emergency. We didn't know if she would survive. She underwent several operations and thankfully recovered. I am happy to say that 19 years later she is a college student and enjoys good health. However, to this day, she has not been eligible for health insurance and currently relies on a high-risk-pool state program that costs hundreds of dollars a month.

Finally, as a patient: Fifteen years ago, as a father with a young daughter and son, I was diagnosed with cancer. I'm alive today because of the excellent physicians who took care of me and because of medical insurance that covered my care. But ten years passed before I could again qualify for an individual health insurance policy.

Mary is among the growing numbers of both working and unemployed Americans without health insurance. My daughter and I are among those penalized for pre-existing conditions.

Nor are these the only problems with our current health care system. Consider:

Perspectives on the PPACA (cont'd)

- An estimated 40,000 lives are lost annually due to delayed treatment or lack of medical care.
- Medical bills are now the leading cause of bankruptcy, home foreclosures, and financial ruin.
- And as a nation, we find ourselves paying too much for health care—and in many cases getting too little.
- We currently spend more than twice as much on health care as our industrialized counterparts yet rank much lower in many major measures of health and longevity.

PPACA addresses such issues. It offers significant protections for patients: no pre-existing-condition exclusions, no lifetime caps, policy portability, and a requirement of a basic foundation of coverage in all policies. In addition, its benefits include:

- 32 million more Americans will have access to health insurance.
- Medicare services will include free preventive services and closure of the “donut hole” in the Part D drug program.
- New benefits are provided, such as coverage for adult children until age 26.
- Medical decisions remain in the hands of patients and their physicians.
- State-run health insurance exchanges will offer a competitive market of coverage options beginning in 2014.
- Small-business tax credits for employee health insurance coverage are immediately available.
- Medicare gains firmer financial footing for an additional ten years with a reduction in the federal deficit of \$143 billion.

Not that the PPACA health reform law is perfect. It has significant shortcomings. And the challenges to successful implementation are many. First and foremost are the political obstacles. Then there are legal obstacles: Twenty state attorneys general have filed lawsuits challenging the requirement that individuals must buy health insurance coverage (known as the “individual mandate”).

There are significant monopolies in the insurance market that will be hard to overcome. Will there be enough competition to lower health insurance premiums? The public option that was excluded from the final bill was an attempt to create a necessary competing nonprofit insurance alternative, as in most other industrialized nations.

Perspectives on the PPACA (cont'd)

Expensive duplication of hospital services in many urban areas needs to be addressed. There must be a true competitive marketplace for pharmaceuticals. Only in these ways will we be able to save health care dollars without sacrificing quality in our health care services.

Perhaps the biggest challenge is whether adequate funding will be available to cover the costs of providing care. The new health care law will use Medicaid to expand coverage significantly. But Medicaid (Medi-Cal in California) is a state program that is severely underfunded. Patients have difficulty in finding a physician and subsequently use costly emergency rooms to seek treatment, often as a last resort. Doctors limit or close their practices due to low reimbursement. Hospitals are forced to reduce services due to lost revenue. The federal government will assume responsibility for funding all new Medicaid-eligible enrollees at higher Medicare levels, and hopefully this will prevent state governments from raiding federal dollars earmarked for these health services. However, it is clear that physicians and hospitals will face severe financial challenges ahead, and there is reason to fear that these groups will be the victims of budgetary cost containment in future years.

Despite the challenges, going back to the old ways is not an option. The more the public learns of the protections and benefits of this law, the more difficult it will be to return to the time when insurance companies wrote many of the rules.

Health care by its very nature is an emotional topic. Your relationship with your doctor is personal, private, and one that requires the utmost trust at times when we are most vulnerable. No one wants intrusion into this relationship—not from the government, insurance companies, or bureaucrats. Yet we do rely on our government for such things as the safety of the water we drink, the food we eat, the medications prescribed to us; for police and fire protection; for safe airline travel. And if you're a senior citizen, Medicare and Social Security benefits assuredly are welcome. The provision of adequate and universally available health insurance is a reasonable extension of government protections and benefits.

Over my years as a physician, it has been a privilege to enter into each of my patient's lives and provide them with care and comfort, often at a time of crisis and vulnerability. Medicine is and continues to be a noble profession, unparalleled by any other. We are a nation of unbounded dreams and accomplishments. I do believe that we can preserve the best that American medicine has to offer while strengthening and making it accessible for all Americans. Quality medical care for all will only be available if the highest priority is given to adequately fund patient care services. Without it, health

Perspectives on the PPACA (cont'd)

care reform will become only an empty promise. PPACA is a first step in this direction. Its repeal would be no cause for celebration.

Toast the End of Obamacare? I Will!

By Steven Goldfien, M.D., CSA Past President

It may be premature to toast the end of Obamacare but we certainly should be delighted that the Supreme Court may give us that chance. Such a turn could redeem physicians for the enormous political blunder they committed by supporting the Patient Protection and Affordable Care Act (PPACA) in the first place, and thereby give them a rare second chance to do health care reform the right way. Of much greater importance to both our profession and our country is the opportunity this case gives the justices to limit or even reverse the long-time expansion of federal power based on the commerce clause. The nearly tragic irony here is that by working to mitigate the defects of Obamacare instead of supporting its outright repeal, doctors, including the ASA, are making exactly the same mistake they made two years ago. Instead of relying on others, in this case the Supreme Court rather than the Congress, to derail this huge expansion of federal power, they should be working as hard as possible in the court of public opinion to rid themselves of this terrible law. Few get a second chance and no one gets three.

The list of specific reasons to repeal Obamacare is too long for full discussion in this forum but three general objections deserve comment. First, it won't work as claimed; second, it will allow the federal government to control health care quality, depriving the medical profession of its traditional role and damaging the doctor-patient relationship; and third, it will do irrevocable harm to the country.

Obamacare will not decrease health care costs (<http://spectator.org/archives/2011/07/06/obamacare-tragedy-primed-to-fu>). Medicare's own actuary (<http://economics21.org/commentary/cms-medicare-actuary-disavows-medicare-trustees-report>) has said that the financial savings of Obamacare are illusory, based on unwarranted assumptions such as enforcing Sustainable Growth Rate cuts to physician income. In fact, the vast majority of the projected \$15 trillion in savings from the president's plan comes from reducing payments to doctors and hospitals below those of Medicaid, levels too low for them to remain in business. The death of the CLASS Act—a new entitlement program designed to subsidize long-term care for beneficiaries (<http://news.heartland.org/newspaper-article/2011/11/29/>

Perspectives on the PPACA (cont'd)

class-act-exposes-obamacare-accounting-tricks-democrats-oppose-repeal)—reinforced this view as the Obama administration itself was forced to admit to flagrantly double-counting revenues to deceive the public on the true costs of the new law.

Obamacare provides subsidies to buy individual health insurance on government exchanges for those earning up to \$95,000. Original Congressional Budget Office estimates were that 19 million people would avail themselves of this discount at taxpayer expense. But the small penalty employers will have to pay for switching (dumping) their employees into government programs means that it will be cheaper for business to abandon employer-provided private insurance altogether. “Competitive dumping” will follow as businesses struggle to compete by taking advantage of lower labor costs. Recent estimates are that some 78 million individuals could take advantage of these government subsidies, adding some \$6 trillion more to the cost of Obamacare in the first six years alone. In 1965 Medicare was forecast to cost \$12 billion by 1990. The actual cost was \$110 billion. No federal health care program has ever come in on budget and Obamacare will be no exception.

Obamacare will not stabilize the private insurance market. As written, the insurance changes are designed (and intended) to disadvantage the private insurance market in favor of a single government payer. Federal regulators can now dictate to insurers what they must cover at the same time that they also have veto power over premium increases. This financial squeeze, coupled with the loss of market share from employers dumping employees into government plans, will spell the end of the private market. Big-government advocates will get their single-payer system, the productive members of the public will get the tax bill and doctors will lose the ability to cost-shift. About the only thing advocates will still cite as a benefit of PPACA are the few insurance reforms such as the elimination of pre-existing conditions that, while important, are untenable without the individual mandate. These changes are indeed desirable but already enjoy widespread bipartisan support and will be a top priority for whoever leads the next round of reform if Obamacare is repealed.

This titanic shift of people into government plans means that Obamacare is simply a stop along the road to single-payer: Medicare for all, including doctors, who will all suffer the 33 percent problem now unique to anesthesiologists. The only consolation is that once the private insurance market disappears so will the 33 percent problem.

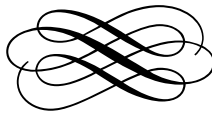
The quality of medical care is the responsibility of physicians and central to our ethical obligations to our patients. This is what distinguishes us from other health care providers. The advent of the Value Based Purchasing Program at

Perspectives on the PPACA (cont'd)

the Centers for Medicare and Medicaid Services (CMS) signaled the intention of the federal government to arrogate that responsibility to itself. Over the last several years, culminating with Obamacare, Congress has passed sweeping health care legislation intended to provide CMS the requisite *authority* to develop and implement a program to define and control quality. Once these sundry programs of performance measures, comparative effectiveness research, and accountable care organizations are in place; the Independent Payment Advisory Board is functioning; and health care data is computerized via electronic health records, the day of physician-led health care is ended.

The most important point of all is one many doctors fail to fully appreciate, to wit, the damage to our country from a federal takeover of the entire health care system is a far greater issue than any benefit or harm it will do to physicians. Working to make Obamacare tolerable for physicians ignores the fact that its final implementation will give the federal government so much control over our wealth and our lives as private citizens that it will become even more difficult, if not impossible, to turn back from our rapid descent into the bankrupt abyss of failed European-style socialism. The medical profession of 1965 understood and exemplified American exceptionalism. Doctors were great because the system they worked in fostered greatness. The fact that the medical profession is now more the tool of its government overseers than an independent voice supporting the right of physicians to practice freely may be in great part the explanation for the decline in its social position and its current status of political nonentity.

As America goes, so goes the medical profession. To save the latter we must first rescue the former. Accepting a government takeover of the health care system and then working out the final details through compromise is not an option; it's socialized medicine that's unacceptable, not the details of its implementation. The demise of Obamacare is an essential step back down the path to freedom, self-reliance and limited central government. If it's the Supreme Court that lowers the guillotine, so be it. I for one will break out the bubbly, while recognizing that far more needs to be done.



Managing the Risk of Uterine Rupture During a Trial of Labor After Cesarean Section

By *NORCAL Mutual Insurance Company*

Introduction

While a successful vaginal birth after cesarean section (VBAC) is associated with less morbidity and mortality than repeat cesarean section (C-section), an unsuccessful VBAC is associated with a small but significant risk of uterine rupture that can result in death or serious injury to both the mother and the infant.¹ When a trial of labor after C-section (TOLAC) ends in uterine rupture, emergency C-section, and the delivery of an infant with brain injuries, there is a good chance that the child's parents will file a lawsuit, or at least consider it. It should be noted that a plaintiff's attorney is supposed to prove duty (responsibility of the physicians involved), negligence (care provided was below the standard of care) and causation (negligence led to the injury) as well as injury. However, the plaintiffs probably won't focus on whether the standard of care was met, and their attorney might not either. In these types of cases, the degree of the infant's brain injuries tends to overshadow other liability issues. This can carry through to trial because juries are generally biased toward severely brain-injured infants and the parents who must provide for them. Because of the complexity involved and the ongoing evolution of guidelines and evidence-based medicine, these cases can be some of the most challenging to defend.

This article originally appeared in the September 2011 issue of *Claims Rx*. It has been edited by Drs. Mark Zakowski, Patricia Dailey and Stephen Jackson to meet the educational needs of anesthesiologists, and is reprinted, as changed, with permission. ©Copyright 2011, NORCAL Mutual Insurance Co. All Rights Reserved. Reproduction permissible with written permission and credit.

In August 2010, the American College of Obstetricians and Gynecologists (ACOG) published an updated guideline on TOLAC/VBAC. Although patient needs vary and their care should be personalized, evidence-based guidelines are frequently used during medical malpractice litigation to establish the standard of care. Departures from ACOG guidelines can expose a physician to liability risk if treatment rationale is not documented in the patient record. The new VBAC guidelines include the following recommendations:¹

Managing the Risk of Uterine Rupture (cont'd)

- Most women with one prior cesarean section with a low-transverse incision are candidates for TOLAC/VBAC.
- Epidural analgesia may be used during TOLAC.
Comment: Chestnut's textbook states that "epidural analgesia is an essential component of a successful VBAC program ... it seems reasonable to provide analgesia—but not total anesthesia—during labor in patients attempting VBAC ... it does not delay the diagnosis of uterine rupture or decrease the likelihood of successful VBAC."² The ASA Practice Guidelines for Obstetric Anesthesia³ state: "Nonrandomized comparative studies suggest that epidural analgesia may be used in a trial of labor for previous cesarean delivery patients without adversely affecting the incidence of vaginal delivery. There are no randomized comparisons of epidural versus other anesthetic techniques. Consultants and ASA members agree that neuraxial techniques improve the likelihood of vaginal delivery for patients attempting VBAC." Thus, the ASA guidelines recommend that neuraxial techniques should be offered to patients attempting VBAC. For those patients, it is also appropriate to consider early placement of a neuraxial catheter that can be used later for labor analgesia or for anesthesia in the event of operative delivery.
- Women at high risk for complications (those with previous classical or T-incision, prior uterine rupture, or extensive transfundal uterine surgery) and women for whom vaginal delivery is otherwise contraindicated (for instance, those with placenta previa) are not generally candidates for planned TOLAC.
- Women who are attempting TOLAC can have labor induced. However, misoprostol should not be used, but augmentation with oxytocin is acceptable.
- Women who have an unknown uterine scar type can attempt TOLAC unless there is a high clinical suspicion of a previous classical uterine incision.
- TOLAC should be attempted only at facilities capable of emergency deliveries.
- If an immediate cesarean delivery is not available, then the patient should be aware of this in weighing the risks and benefits of TOLAC. The hospital should have a plan to provide emergency care for both parturient and neonate.
- The risks and benefits of both TOLAC and elective repeat cesarean section (ERCS) should be thoroughly discussed with the patient.

Managing the Risk of Uterine Rupture (cont'd)

- After counseling, the ultimate decision should be made by the patient in consultation with her health care practitioner.
- Once the trial of labor has begun, the patient should be evaluated by her obstetric professional, and she should have continuous fetal heart rate (FHR) monitoring.
- Personnel familiar with the potential complications of TOLAC should be present to watch for FHR patterns that are associated with uterine rupture.

This article uses a NORCAL Group closed claim to illustrate five broad elements that can improve the safety of TOLAC/VBAC for mothers and infants and can reduce medical liability risk exposure:

1. Identifying which patients are appropriate candidates for TOLAC
2. Identifying appropriate facilities for TOLAC
3. Engaging in a thorough informed consent process and documentation of that discussion
4. Monitoring the patient's progress during a trial of labor
5. Recognizing the signs of uterine rupture and ensuring a prompt emergency response, should it arise

Even in the best medical practices, unforeseen circumstances can and do arise. The case study in this article illustrates how problems associated with communication, documentation and emergency preparedness can affect patient care and weaken the potential legal defense of the involved health care practitioners.

Identifying Which Patients Are at Increased Risk for Uterine Rupture

The most concerning risk of TOLAC is uterine rupture. If the patient has a high-risk of rupture, TOLAC should not be offered.¹ For some patients, their high-risk status will be clear—for example, if the patient has a previous classical or T-incision, prior uterine rupture, or extensive transfundal uterine surgery. For others, the possibility of uterine rupture must be calculated from the totality of the circumstances. Factors that increase the risk of uterine rupture include:^{1,4}

- Having had a single-layer closure in a previous C-section
- Having had more than one or possibly two previous C-sections
- Being induced with misoprostol
- Failing the current trial of labor

Managing the Risk of Uterine Rupture (cont'd)

- Increased maternal age
- Having a high body mass index
- Having a short interpregnancy interval (less than six months)

Women who have had a prior vaginal delivery are less likely to have a uterine rupture.^{1,4} Although these factors appear to statistically increase or decrease an individual's risk for uterine rupture, it cannot be absolutely predicted or ruled out. Therefore, even if the patient seems to have a low probability of uterine rupture, clinicians still need to maintain a high index of suspicion for it during TOLAC.

TOLAC and Maternal Morbidity

A successful TOLAC has a lower rate of maternal injury, as well as decreased rates of complications in future pregnancies, compared to ERCS, but both have risks, including maternal hemorrhage, infection, operative injury, thromboembolism, hysterectomy and death.¹ For a woman undergoing TOLAC, the greatest risk of injury occurs when a repeat C-section becomes necessary. Consequently, the risk of maternal injury is integrally related to the mother's probability of achieving VBAC.¹ Evidence suggests that a woman with at least a 60 to 70 percent chance of VBAC will have maternal morbidity equal to or less than a woman undergoing ERCS. On the other hand, a woman who has a lower than 60 percent chance of VBAC has a greater chance of morbidity than a woman undergoing ERCS.¹ Factors that decrease the probability of a successful trial of labor include:¹

- gestational age greater than 40 weeks
- high neonatal birth weight
- previous labor dystocia
- current need for labor induction or augmentation
- increased maternal age
- non-white ethnicity
- high body mass index
- preeclampsia
- short interpregnancy interval

Factors that increase the probability of successful TOLAC include a prior successful VBAC and current spontaneous labor.¹ An online tool that estimates the probability of successful VBAC for women with one prior cesarean and vertex presentation may be found at www.bsc.gwu.edu/mfmu/vagbirth.html.

Uterine Rupture and Perinatal Morbidity

Just as a failed TOLAC is linked to an increased risk of maternal morbidity and mortality, it is also linked to adverse perinatal outcomes, including stillbirth and neonatal death, hypoxic-ischemic encephalopathy (HIE), respiratory distress syndrome, pneumonia, acidosis, intraventricular hemorrhage, and subgaleal bleeding.⁴ The rate of perinatal death associated with TOLAC is approximately 5.8 per 1,000 and 3.4 per 1,000 with ERCS—a difference of approximately 1 in 417.⁵ Although this may seem like a small number to an outside observer, to a woman making the informed decision between TOLAC and ERCS, it is probably going to be significant. And although it is estimated that the risk of injury to the fetuses of the patients with the highest probability of VBAC is about equal to the risk of injury to fetuses born by repeat C-section,¹ for many patients, ERCS will be the safest option for the fetus.⁵

The Informed Consent Process

Informed consent is an important part of any medical procedure. For TOLAC and VBAC, it is imperative that the woman understand that TOLAC may not result in the vaginal birth of a healthy baby. It is imperative that the obstetrician begin patient education early in the pregnancy, covering TOLAC, the risks associated with TOLAC and VBAC, and the patient's own risk factors. The patient must understand that uterine rupture is an unpredictable event that can happen to any woman who chooses TOLAC, and that uterine rupture can be devastating to both her and her infant. She needs to have the best possible understanding of the risks of TOLAC and VBAC versus the risks of an ERCS, and place them in the context of her future pregnancy planning.

An additional part of the obstetrician's informed consent process should be informing the parturient as to whether the hospital where she plans to deliver provides 24/7 in-house obstetrician, anesthesiologist, neonatologist, and operating room nursing staff services for an emergency cesarean delivery.

Should anesthesiologists inform the parturient that an epidural has the potential to mask the persistent pain (between contractions) associated with the 10 to 30 percent of uterine ruptures that do result in pain?⁶ In the most recent edition of his textbook, Chestnut states that “epidural analgesia does not delay the diagnosis of uterine rupture.”² Furthermore, in an earlier edition of his textbook, Chestnut stated that “epidural anesthesia may improve the specificity of abdominal pain as a symptom of uterine scar separation or rupture.”⁷ Of note, escalation of frequency of epidural dosing may be a marker/clinical sign for impending uterine rupture, suggesting that parturients under epidural analgesia may retain the perception of pain associated with uterine rupture.⁸ If the patient declines regional analgesia in favor of an unmedicated labor, then it

Managing the Risk of Uterine Rupture (cont'd)

may be difficult to distinguish pain caused by uterine rupture from the severe pain experienced by most women during labor. Informed consent should acknowledge and emphasize that FHR abnormalities (present in 71 to 100 percent of ruptures⁹) and changes in fundal tone and fetal station are more reliable signs than pain in signaling rupture. If the parturient can weigh those risks in a meaningful way, then she can make informed decisions. She should not be going into TOLAC thinking, “My doctor is making me do this” or “Internet websites say that VBAC is safe, so I’ll be fine.”

Recognizing the Signs of Uterine Rupture

The rate of uterine rupture during TOLAC is approximately 0.5 to 0.9 percent for women with low-transverse uterine incisions.¹ Uterine rupture is usually sudden and there are no fail-safe antenatal predictors for it. Although the signs and symptoms of acute uterine rupture vary, they may include:¹

- Fetal bradycardia and variable decelerations (FHR abnormality has been associated with 70 percent of uterine ruptures.)
- Increased uterine contractions
- Vaginal bleeding
- Loss of fetal station (decrease of fetal head engagement within the pelvis) or sudden shift in position of the fetus (the rupture leads to intra-abdominal fetal presentation). Note that decreased uterine tone is most accurately monitored via an intrauterine pressure catheter.
- New onset of intense uterine pain that does not diminish between contractions. This pain may be breakthrough in nature (requiring more than the usual epidural dosing), in the area of a prior uterine scar (such as that of a myomectomy), or even shoulder pain (from blood under the diaphragm).

By the time many of these signs and symptoms appear, the fetus can already be in significant distress. The most reliable diagnostic tool for uterine rupture remains the fetal heart monitor. Because of this, TOLAC patients must be carefully monitored and the individuals monitoring them must be competent to recognize fetal distress or an impending uterine rupture.

In most birth injury lawsuits, FHM strips (FMS) play an essential role in standard of care and causation arguments. Unfortunately, a fetal monitor cannot always tell the difference between a fetus that is in immediate danger, one that is demonstrating a normal response to the occasional unusual stresses associated with labor, or even one that has suffered a prior antepartum injury.¹⁰ Likewise, FHM cannot predict a uterine rupture. However, viewed retrospectively, FHS can usually provide evidence of the progression of a uterine rupture.

Managing the Risk of Uterine Rupture (cont'd)

Obstetricians also tend to have differing opinions when interpreting FHS. One study showed that when four obstetricians examined 50 FHS, they agreed in only 22 percent of the cases. When they reviewed the same 50 tracings two months later, the obstetricians interpreted 21 percent of the tracings differently than they had initially. Furthermore, a reviewer is more likely to find evidence of fetal hypoxia if he or she knows that there was a poor outcome.¹¹ This issue can make a seemingly defensible birth injury case unpredictable because it will be up to a jury (based on the opinions of experts) to determine whether the defendant health care professionals reacted to the evidence of fetal distress and uterine rupture in a time frame that is consistent with the standard of care.

Epidural analgesia is *not* contraindicated during TOLAC, and in fact, as outlined above, has been cleared of causing delay in diagnosing uterine rupture or of adversely affecting the likelihood of successful VBAC. Modern labor analgesic techniques typically utilize lower concentrations of local anesthetics, typically in combination with an opioid. Pain that is unusual, sudden in onset, severe, or persistent in nature should signal the obstetrician to evaluate for possible uterine rupture. The anesthesiologist should alert the obstetrician if the patient has atypical analgesic requirements, suggesting the need for an evaluation for uterine rupture. Anesthesiologists should be proactive participants, not just reactionary technicians.

Case Study

Allegation Failure to recognize uterine rupture and timely perform a C-section caused the infant's brain damage.

Labor Summary At 38 weeks' gestation, the patient was admitted to the hospital for a TOLAC. She was 42 years old and had delivered her prior child by C-section for failure to progress. The older child weighed 10 pounds 2 ounces at birth. Her OB decided that an induction was the appropriate course due to his concern that this infant would also be macrosomic if the pregnancy was allowed to proceed to 40 weeks. When the OB examined the patient at 0715 on the morning of her admission, he noted that the fetus was not engaged and that the mother was 25 percent effaced. The OB told the patient that he would allow her two hours of active labor, and if the trial of labor wasn't successful at that point, then a C-section would be necessary.

At 0730 he inserted Cervidil. By 1930, there had been no progress, so he removed and replaced the Cervidil. He told the nurses to call him if they had any concerns and then went home. The facility did not have an in-house OB, pediatrician or anesthesiologist. No one informed the on-call anesthesiologist

Managing the Risk of Uterine Rupture (cont'd)

or pediatrician that a VBAC patient was in the hospital for a trial of labor that night.

At 0130 the next morning, the mother was having strong contractions. Her membranes ruptured shortly thereafter. At 0300 the patient reported that she was in severe, persistent abdominal pain that did not stop following the contractions. She was given Nubain, but her pain was not relieved.

At 0402, the nurse noticed that there were occasional variable decelerations. At this point, she did her first vaginal exam of the patient and determined that the cervix was completely dilated and the fetus was at -2 station. She called the OB, who misunderstood her and thought that she reported that the patient was almost completely dilated. She did not tell him about the mother's pain or the decelerations and did not ask him to come to the hospital. The OB said he would be in later.

At 0435, the nurse did another vaginal exam and found the fetus at -3 station. She was also having trouble getting a good fetal heart tracing. She called the OB again and asked him to come in to assess the patient. The OB arrived at 0450. He confirmed that the cervix was completely dilated with the fetus at -3 station. He placed a fetal scalp electrode because of problems with the tracings from the external monitor. After reviewing the FMS from the internal monitor for a few minutes, he determined that they were showing normal patterns for a woman in the second stage of labor. He then went to the nurse's station to do some charting.

By 0513, there had been no further progress and the FMS showed decreasing variability and deeper variable decelerations. He decided to do a C-section and asked the nursing supervisor to gather together an OR crew as soon as possible (but not stat). He then called the pediatrician and anesthesiologist. The mother was prepared for surgery. By 0520 the FHR had started to drop into the sixties and the OB could no longer feel the fetal head.

The patient arrived in the OR at 0521, but the anesthesiologist (who lived 15 minutes away from the hospital) had not arrived. The FMS showed an FHR of 50 with no variability. At 0535 the anesthesiologist arrived. The first incision was made at 0540. On entry to the abdomen, the OB saw that the fetus had completely extruded into the abdomen through a tear at the site of the previous incision. The infant was delivered at 0545. He was born pale, flaccid, and with no respirations. He was 9 pounds 7 ounces. Apgars were 2 at one minute, 3 at five minutes and 6 at 10 minutes. He was intubated by the pediatrician. Cord gasses showed a pH of 6.8 and base excess of -25. By 0700 he had started

Managing the Risk of Uterine Rupture (cont'd)

having seizures. He was transferred to the children's hospital where he stayed for the next month.

The infant was diagnosed with hypoxic-ischemic encephalopathy (HIE) secondary to the uterine rupture and developed spastic quadriplegia with athetosis and dystonia. The parents sued the OB and the hospital alleging:

- The labor was not adequately monitored by the nurses or the obstetrician.
- The nurses negligently failed to report the patient's severe pain to the obstetrician.
- The nurses negligently failed to report the decelerations to the obstetrician.
- The nurses and the obstetrician negligently failed to recognize the impending uterine rupture.
- An appropriate team of practitioners was not immediately available when the infant's condition required an emergency C-section.
- The C-section was not done quickly enough.

At trial, plaintiff and defense experts gave completely opposite standard of care and causation testimony. The defense experts opined that there was no indication of a uterine rupture until it was too late for the OB to do anything that would have saved the child from brain damage. At trial, however, the jury found the plaintiff experts' opinions more persuasive and awarded the plaintiffs a multimillion-dollar verdict.

Discussion Neonatal outcome following a uterine rupture will depend primarily on the speed with which the C-section is accomplished.¹² Every minute counts. Do not assume fetal injuries will be avoided if the "30-minute decision-to-incision rule" is met.¹³ Fetal hypoxia research suggests that babies born within 10 minutes of complete anoxia or severe hypoxia will survive neurologically intact, while babies born after 17 minutes may have severe damage, or will not survive at all.¹⁴ Because a uterine rupture cannot be reliably predicted or its timing confirmed, it is of utmost importance to have a tested, effective protocol in place to ensure that a cesarean section can be performed as quickly as possible after a possible uterine rupture has been identified. The anesthesiologist should be made aware of all TOLAC patients so that he/she may perform a pre-anesthetic evaluation and be familiar with the patient in case an emergency cesarean delivery is needed.

Managing the Risk of Uterine Rupture (cont'd)

Risk Management Recommendations^{1,15}

- A patient should not be offered a TOLAC in a facility where practitioners capable of performing cesarean sections, anesthesiologists, pediatricians, nurses and technical staff are not in place in a time frame that adequately protects maternal and neonatal safety in the event of an emergency.
- The personnel necessary for an emergency cesarean section should be aware that a VBAC candidate is in labor, and all the personnel should be immediately available during TOLAC.
- There should be agreement on the definition of “immediately available.”
- Members of the labor and delivery team should know how to contact the anesthesiologist in case of an emergency.
- The anesthesiologist should be contacted in the event of any maternal bleeding, FHS indicating fetal intolerance of labor, abnormalities in maternal vital signs, change in fundal tone/fetal station/progress of labor, or atypical need for pain relief.
- A sterile “crash” cesarean operative tray should be immediately available in the event of a uterine rupture.
- There should be regular emergency cesarean drills to ensure that all team members can meet targeted decision-to-incision goals.
- A rapid response protocol for obstetric emergencies should be developed.¹⁵
- In settings where the staff needed for emergency delivery are not “immediately” available, the process for gathering needed staff when emergencies arise should be clear, and all centers should have a plan for managing uterine rupture and other obstetric emergencies.

Conclusion

When a patient is attempting TOLAC, it is best to develop a mind-set and strategies to anticipate problems, prepare accordingly, and react promptly. Make sure that the patient knows enough about the risks and benefits of and alternatives to TOLAC/VBAC to feel confident in her informed decision to go forward—despite the risks. Good communication not only increases patient safety, but it also increases patient trust in her health care practitioners and increases her engagement in her health care encounters. (Practitioners who establish and maintain rapport and communicate effectively are less likely to be sued.¹⁶)

Managing the Risk of Uterine Rupture (cont'd)

Whether an infant's injuries were caused by medical negligence or the inherent risks associated with TOLAC is a central issue during litigation. For the relevant health care practitioners, the optimal resolution of these claims often hinges on whether there is enough documentation to show that there was informed consent and that the health care team's recognition of and reaction to the emergency met the standard of care, and if not, that the infant's brain injuries were not caused during labor and delivery. The task of creating a complete picture of a woman's pregnancy, labor and delivery in the medical record is complicated by a multitude of factors, but in the event that a lawsuit is filed, it will have been well worth the time and effort to document the process thoroughly.

Applying the risk management strategies proposed in this article can potentially minimize the incidence of bad perinatal outcomes and increase the probability of successfully defending them when they do occur.

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Guidelines and/or recommendations contained in this article are not intended to determine the standard of care, but are provided as risk management advice. Guidelines presented should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of the individual circumstances presented by the patient.

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The Ethics of Ending Life: Euthanasia and Assisted Suicide, Part 1

The Language of Ending Life

By Gail Van Norman, M.D., Professor of Anesthesiology and Pain Medicine and Adjunct Professor of Biomedical Ethics, University of Washington, Seattle

Last November, New Zealand forensic scientist Sean Davidson was sentenced to five months' detention for assisting a suicide. His crime? At the request of his 85-year-old terminally ill mother, he crushed up a bottle of morphine tablets, dissolved them in a glass of water, and handed it to her so that she could voluntarily drink it to end her life. The original charge of attempted murder eventually was reduced to counseling and procuring a suicide because of public outcry including the testimonial support of such luminaries as Bishop Desmond Tutu. Such stories are becoming increasingly common.

The moral limits of relieving suffering at the end of life, and where our responsibilities as physicians should lie, are more frequently debated as populations age and the diseases and disabilities of old age present increasing challenges. In the balance are crucial issues: personal autonomy, dignity, compassion, ending suffering, protection of the vulnerable, promotion of good palliative care, and redefinition of the role of the physician in death and dying. In the last 15 years, the Netherlands, Belgium, and three states (Oregon, Washington and Montana) have passed laws permitting physician-assisted suicide and/or euthanasia. In Switzerland, the law even permits assisted suicide by non-physicians. Debate about assisted suicide is currently in full swing in Great Britain, where prosecution of family members who have assisted desperate patients to travel abroad to commit suicide has elicited public outcry.

As moral dilemmas about ending life become increasingly common, physicians of all specialties will be confronted with questions from patients and their families, from our own friends and families, and from our legislators and the media. We need to know precisely what is meant by "assisted suicide" and "euthanasia," understand why some societies have legalized such actions, and anticipate what ethical questions remain to be answered. Part I of this discussion reviews common terminology and definitions relevant to assisted suicide and euthanasia, while Part II (to appear in the Spring 2012 *CSA Bulletin*) reviews ethical issues about ending life and details legislative differences regarding physician-assisted suicide and euthanasia in various countries.

End of Life (cont'd)

The term “euthanasia” comes from Greek roots *eu* (good) and *thanatos* (death). In modern usage, the term always refers to an act of killing that meets certain criteria described in this article. Not every killing is an act of euthanasia, but all euthanasia is killing. Furthermore, even though the Greek roots appear to imply moral “goodness,” the term “euthanasia” itself has no intrinsic moral value: an act of euthanasia may be moral or immoral depending on the context and on society’s values.

Suicide and Assisted Suicide

Suicide is “self-killing,” which may or may not require the aid of another person. “Assisted suicide” is a suicide that does require the aid of another person. In the United States, legally permitted suicide is almost always discussed in the context of physician-assisted suicide (for example, by writing a lethal prescription of barbiturates).

However, not every act *by* a physician is carried out *as* a physician. In Switzerland, for instance, any citizen can legally assist suicide, yet a Swiss physician cannot ethically assist a suicide *as* a physician but may do so as a *private* person. Indeed, it may be reasonable to assume that a suicide in which a physician provides aid that a non-physician would not have been able to provide *does* constitute physician-assisted suicide. Purchasing a gun for another person for purposes of suicide is assisting them, but does not constitute physician-assisted suicide even if the purchaser is a physician. Almost any citizen can provide the service. However, writing a prescription is a privilege afforded to physicians and only a few other allied health professionals, such as some nurse practitioners and some physician assistants. Prescriptive assistance by a physician in a suicide requires that the physician use his or her unique privileges as a physician, and therefore this does constitute physician-assisted suicide.

Euthanasia

Euthanasia *always* requires the act of another party. When more than one person is involved in a sequence of actions that results in death, then that death is termed a suicide when the last person who acts in the sequence is the one who dies. If the last “actor” is someone other than the one who dies, the death is termed a homicide (one human being killing another), even if the person who dies agreed to it.

Euthanasia always involves a special *motive*. Intentions are the specific goals and desired outcomes of an act; “motives” are the reasons for which we have those intentions. In the case of euthanasia, the motive always is required to be *mercy*, and the core value supporting that motive must be *altruism*. This concept is so engrained in our society that euthanasia often is referred to as

End of Life (cont'd)

“mercy killing.” Harold Shipman, a British physician and serial killer, committed murder and not euthanasia when he injected elderly patients with lethal doses of narcotics so that he could inherit money left to him in their wills. Even if his actions actually relieved suffering in some, his motive invalidates a claim of euthanasia.

When is a homicide considered euthanasia? The term “euthanasia” implies a “good” death, and therefore the act should meet commonly agreed criteria for “goodness.” Such criteria may be that it is swift, relatively painless, and causes minimal if any psychological suffering, such as fear, anguish or deep regret. The death should not intentionally inspire horror or revulsion, nor be accompanied by signs of suffering from the dying person. The motive should not be to punish. Beheading, for example, might be swift and even relatively painless, but because it is usually intended to inspire horror in victims and witnesses alike and to punish the recipient, then it would generally not be considered an act of euthanasia.

“Passive” Euthanasia: A Problematic Term

Intention and *foresight* are critical aspects in both the moral and the legal considerations of whether an act constitutes euthanasia, represents another kind of homicide, or is even an act of killing at all. Euthanasia and suicide both require the primary *intention* of causing death. *Foresight* involves conceiving of possible outcomes, some of which we may neither desire nor intend. Certain acts can be reasonably foreseen to result in death, but may nevertheless be committed primarily for reasons other than death.

One example is discontinuing medical treatments at the request of an autonomous patient. Patients have the legal right in the U.S. to say what will be done to them, and in withdrawing such treatments we not only respect their autonomy, but obey the law. Because our intention is to respect autonomy and not to kill, withdrawal of medical treatments under those circumstances is neither suicide nor euthanasia, and it does not even constitute killing because death is *not* the primary intention even though it is a foreseen result. Some authors use the term “passive euthanasia” to describe withdrawal of life-sustaining treatments when death is a virtually certain outcome, but not the primary intention.

Karen Ann Quinlan survived nine and a half years after her parents won the legal right to end her ventilator therapy. Her parents commented that their intention had never been to *kill* Karen, but rather to allow her to live her life, however shortened it might turn out to be, without the indignity of unwanted therapy. The law itself recognizes the crucial difference between intention and foresight: premeditated (intentional) murder is punished differently from

End of Life (cont'd)

negligent homicide (carelessness or negligence that results in a death that might be predictable, but isn't intended). The *primary and necessary intention* of euthanasia is *always* to cause death. Without that primary intention the act is not euthanasia.

The term "passive euthanasia" is therefore problematic. In the first place, euthanasia is an act, and therefore it cannot be passive. The term is further misleading in that it confuses foresight with intention. For these reasons "passive euthanasia" is a term that often confuses rather than enlightens and should not be used.

Competence, Autonomy and Voluntarism in Euthanasia

Patient voluntarism is not necessary for euthanasia. Patients who are incompetent and non-autonomous as a result of medical conditions, or who never were competent or autonomous due to age or other medical issues, may nevertheless be suffering in ways in which a merciful death is desirable, even though they cannot ask for it or agree to it. Yet if a patient is competent to make decisions, killing them against their will violates other necessary criteria for euthanasia (kindness, mercy, preservation of dignity, and avoidance of distress). Furthermore, euthanizing a patient who is capable of making a decision and refuses euthanasia is prohibited by other primary ethical principles, such as respect for autonomy, beneficence and nonmaleficence.

Some authors have coined yet other terms such as "voluntary euthanasia" for patients who are competent and agree to be euthanized; "non-voluntary euthanasia" for those who have never been competent; and "involuntary euthanasia" for which a competent or previously competent patient's wishes are unknown. While commonly used, these terms add nothing to a simpler definition of euthanasia (as a morally neutral term) that requires, in the case of competent patients, that their permission be obtained and, in the case of incompetent patients, that deliberation is undertaken by the appropriate surrogate decision-makers and after review of the patient's advance directive, if available.

"Physician Aid-in-Dying": A Term of Uncertain Meaning and Limited Value

In the theater of political debate, terminology is often used to polarize or to unite. When the debate involves such a fundamentally morally uncomfortable concept as whether certain forms of killing should be legalized, one might expect that vocabulary will develop to enable comfortable discussion, or to ignite debate. However, it is important to understand that such political terms often have little moral, ethical, or medical meaning and not only may not add

End of Life (cont'd)

to, but may even obfuscate, our understanding of underlying issues. “Physician aid-in-dying” is one such term, because it is ambiguous and encompasses a host of morally *dissimilar* actions while simultaneously implying that those actions are morally the same—and therefore should be treated similarly.

“Aid-in-dying,” for example, could include such diverse actions as sitting at the bedside and holding the hand of a dying patient, administering medications to relieve symptoms such as pain, discontinuing life-sustaining medical interventions, providing a lethal prescription for a patient to take voluntarily, or injecting a non-autonomous or incompetent patient with a lethal medication. These acts are morally dissimilar, and yet the term might imply that they can be discussed, understood, and managed as though they were morally the same. Discourse about legalized killing can be uncomfortable, but debating “aid-in-dying” as a morally equivalent group of actions is impossible. Whenever ethical debate is held regarding the ending of a life, vocabulary that is sufficiently procedurally and morally specific should be employed to facilitate meaningful discussion and avoid confusion. The term “aid-in-dying” is far too vague and associates too many ethically diverse actions to be truly useful or enlightening in either political or medical discussion.

The author gratefully acknowledges the support of the Foundation Brocher, Geneva, Switzerland, in the preparation of this article. The Foundation Brocher is a nonprofit institute dedicated to the study of ethics and law in medicine and science. Part 2 in the Spring issue will discuss current laws regarding physician-assisted suicide and euthanasia, and ethical questions facing physicians.

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Dr. Marijuana, Inc., is IN

By *Jesse Oehler*

It is a laid-back California coastal town like so many others. A slight ocean breeze of optimal temperature soothes the bronzed, sun-soaked skin of easygoing locals who play beneath 300-plus annual days of sunshine. As California's great coastal route eases into one of the city's main thoroughfares, the diverse signs of the California lifestyle become apparent.

Businesses buzz with activity: a pet shop, a local eatery, a hardware store and a discount clothes outlet. Day laborers linger outside the local lumberyard, hoping today will bring work for cash. Young surfers, surfboards saddled

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aside classic beach cruisers, head eagerly west toward that elusive perfect wave. A homeless man, a drifter and a drug addict occupy their respective corners, confident in the charitable natures of passersby and daily commuters.

Upon arrival in this vibrant community, it is easy to miss a small white house with green trim just off the freeway. It is an unimposing structure, invisible to many who pass by every day. But for a steadily increasing number of patrons, and for the culture of California—ever a national trendsetter—this little business office reflects one of the most fundamental changes in law and attitude in decades. For a year I was office manager of this California medical marijuana clinic.

In 1996 the state of California passed Proposition 215, otherwise known as the Compassionate Use Act of 1996. It used simple, straightforward text, to “ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use ... has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS ... and other illnesses for which marijuana provides relief.”

The ambiguous law permits a physician to provide “oral or written approval or recommendations” for the use of medical marijuana; the physician would not be punished for doing so, so long as no other laws were violated.

At first federal agents routinely busted up medical marijuana operations, claiming that California was in direct violation of federal law, despite the 10th Amendment, which provides that powers not granted to the federal government

Dr. Marijuana (cont'd)

or prohibited to the states by the Constitution are reserved, respectively, to the states or to the people.

Citizens had a range of emotions, ranging from outrage to relief; most were confused as to the exact definitions and limitations of the use, obtainment and prescription of marijuana. The Compassionate Use Act, Senate Bill 420, was passed into law in California in 2003 to address these problems. Its overall effect was to clarify and to better define the parameters of Proposition 215. The bill authorized a voluntary state ID card program and a uniform procedure for issuing medical marijuana recommendations.

The office where I worked was owned by a businessman and a doctor, neither of whom I met during my entire stint as an employee there. All business between my employers and me was conducted via phone and email. In this way I was hired, paid and instructed in my work. The doctor hired a physician's assistant to perform evaluations of patients and to justify or deny the marijuana recommendation.

I was provided a stamp to reproduce the doctor's signature at the bottom of the recommendation letter, before we sent clients off to a marijuana dispensary we worked with closely. When questions were later raised regarding use of a stamp, a local doctor was hired to come once a week and pre-sign 100 or so blank letter templates. The next week the same doctor reviewed the recommendation letters that had been produced and signed the next 100 templates. After her review, all patient documents were scanned and uploaded to the computer, and the hard copies were destroyed. I deposited income in a bank account.

The owners were opening new offices at a fast rate. In the time that I worked for them they opened two more nearby offices. It was rumored that they would be moving on to Colorado shortly, following the legalization there. The fee for our service was \$100, but was not charged if the client did not receive a recommendation letter.

During my year I only saw two patients denied recommendation. One had made the mistake of saying he suffered from bipolar disorder, and the other said that she was schizophrenic. In neither case is marijuana advised. (But clients were often alerted by literature online, or word of mouth, not to divulge this sort of information during their evaluation.)

I was paid a \$1-per-patient bonus on top of my normal generous rate of pay. I would often make \$20 in bonuses during the business day from noon to 6 p.m. Monday–Saturday. Similarly, the physician's assistant was paid a \$15 bonus for each successful recommendation.

Dr. Marijuana (cont'd)

My routine at work was simple. I had a laptop, a printer and a scanner. I would open the office and let patients in (there would almost always be a line outside the door to start the day). The waiting area was one large room with the physician's assistant's office off to one side.

I would take a copy of the patient's California ID, the first and most basic requirement for consideration for medical marijuana "prescriptions." I would present the patient with a generic form for information such as name, phone number, medications taken, and what the patient's complaint was. Much information, such as address and email, was not filled out, nor did we require it.

The patient was then ushered in to the physician's assistant's office for evaluation while I would prepare the recommendation letter. This was an official-looking document that had a physician's statement describing benefits possibly attributable to marijuana, and recommending its use in this client/patient. The ID was scanned and copied to the form. At the bottom were a line for the doctor's signature and a line for the patient to sign. Lastly, a pressure-embossed seal was placed at the bottom of the letter, which would be ready for the patient's signature about 10 minutes into their evaluation.

There was an expectation that all patients would be given a recommendation. In the rare case that a patient was denied, their physician's review sheet would be filed away as incomplete, and their letter would be shredded. Whenever there was a denial, a call would invariably come from the boss in Southern California with an inquiry as to why this patient had not been given a letter.

After the patient exited the practitioner's office, I would take their \$100 and give them their letter with directions to the nearest marijuana dispensary. I would then log on to an official online medical marijuana patient database, and enter in the information of each patient who had been issued a recommendation. Each patient had an identification number, and each letter displayed a phone number and a website by which one could confirm the legitimacy of the recommendation letter. Marijuana dispensaries throughout California could confirm the client identity or the validity and term of the "prescription" via the website, or by calling our office. We provided one-year recommendations, with half off for patients who renewed at our office.

Police officers could also call or go online to verify the certificate, or could call our office. The complete database was only accessible to our doctors, the owners and me. It was not made public, and could not be seen by government agencies or police.

Our patient base was very broad, and to say the least, the terms "seriously ill" and "chronic pain," qualifying conditions outlined in the medical marijuana

legislations, were very broadly interpreted. Patients came from all walks of life, and with all kinds of conditions. Government workers, drifters, parolees, gang members, drug dealers and grandmothers would all come for our service. There were men and women of every race, age and condition. Parents came in with 16-year-old children where both parent and child received recommendation letters—the parents would sign for the children. If a patient had an ID or suitable proof of California residency, they were most of the way to legalized marijuana.

In my experience the most common patron was a 20-something with “back pain” or “headaches.” We required very little evidence of a patient’s condition, and sometimes none at all. A bottle of prescription pills, an X-ray report, or a handwritten note from a doctor sufficed.

I have mixed feelings about my involvement in the medical marijuana industry. At times I felt very good about helping patients who were clearly sick or in pain. These sometimes were people with AIDS, cancer, or multiple sclerosis. These patients would have tears in their eyes that peered at us from behind stacks of medical records, as they expressed their gratitude that we could provide this service to them, thankful for medicine allowing them to sleep, to stomach food, and to be able to focus on something other than their pain or other disease symptoms.

I felt dirty when a pack of 21-year-olds came in, 10 strong, having just made a two-hour road trip from another city, all with “headaches,” “knee pain,” “insomnia,” and “intense back pain.” As they emerged triumphantly from the evaluation and waited for their friends, some would make calls, joyfully informing them that “Yes! It really works; can you make it down here?”

What I have written here is not an exposé; it is simply an attempt to describe a small part of the process where marijuana, like alcohol and tobacco, becomes an industry. Don’t imagine this was a poorly run business. We always followed the letter of the law exactly, because the California medical marijuana industry is operated for profit, where foolish management leads to business failure.

I have no strong opinions about how our business was conducted, because it was all done within the confines of the law. I felt saddened when I saw people abuse the law, but I have no illusions; this happens whenever laws are made. It seems to me that if marijuana were legalized, competition would lower prices, tax revenue would increase, and perhaps crime and abuse of the law would diminish. But that will be decided by the people of California, as it should be.

Cannabis' Regulatory Void,

Or, How Did We Become "Gatekeepers" Without a Gate?

By Donald Lyman, M.D., Chair of Sierra Sacramento Valley Medical Society Public and Environmental Health Committee

The article by Jesse Oehler that precedes this one relates his work in a local marijuana dispensary. He describes the workings of an awkward and perverse non-system in which we physicians are named as the authorizing access point for retail purchase of medical cannabis.

We physicians stand in an unhappy situation. On one side is the Drug Enforcement Administration (DEA), which declares that there is no medical utility to cannabis, and therefore is keeping it as a Schedule I prohibited substance ("illegal"). On the other side, California and 15 other states have decriminalized use of cannabis. This means that the state of California has declared that it will not enforce the federal declaration of the illegality of cannabis—the "feds" will have to do that themselves.

This article by Dr. Lyman is adapted from a 2011 white paper prepared by the Legalization and Taxation of Marijuana Technical Advisory Committee of the California Medical Association entitled "Cannabis and the Regulatory Void: Background Paper and Recommendations" and appears in the January/February 2012 issue of SSV Medicine, published by the Sierra Sacramento Valley Medical Society. Copyright © 2012, SSV Medicine.

We California physicians are authorized to "recommend" (not "prescribe") cannabis to patients with no state penalties for that action. A stand-alone recommendation for cannabis is protected under federal constitutional First Amendment free-speech rights and under California state statute. All this notwithstanding, if a physician advises the patient to break federal law, or participates in such illegal acts, then he is at risk of federal legal action under that law.¹ In reality, most of the cannabis that physicians "recommend" probably is used for non-medical purposes. And in truth, cannabis travels to the buyer from production to consumption on a totally unregulated track.

The California Medical Association (CMA) recently has adopted as policy a call for "legalization" and strict regulation of cannabis (not prohibition!). Its intention is twofold: to protect both the public and physicians from the abuses we see in the Oehler article, and to address the legitimate anxieties of those who favor continued strict prohibition.

Cannabis' Regulatory Void (cont'd)

So, where is all this going? Here are current status descriptions and future projections on what is likely to come. We physicians seem “parked” in the position as gatekeepers to cannabis as this non-system of access evolves.

Current Status

What's missing is a regulatory system (the “gate”) upon which we can depend to assure ourselves, our patients, and the public that the cannabis itself is “safe” and effective. Where did the stuff come from? Is it pure or contaminated with pesticides, herbicides, fecal material, and such? What is its strength? How much is toxic? What medical effects are documented and preferential to those of other drugs or procedures? I found one cannabis shop with a lollipop for sale listed as “Two Doses.” So what is one dose?

The CMA policy calls for a regulatory system to protect us all. While the press has referred to this as “legalization,” it is really a call for re-scheduling by the DEA—a regulatory action—with subsequent research upon which to base rational regulatory schemes. We can't get the research done while cannabis is listed on Schedule I, which includes drugs or other substances that have a high potential for abuse and for which no prescriptions may be written. Such substances have no currently accepted medical use in the United States, and there is a lack of accepted safety for their use under medical supervision. Moreover, they are subject to production quotas by the DEA. Other Schedule I substances are heroin and lysergic acid.

The CMA has produced two documents to help us navigate to some resolution of this conundrum. First, the Council on Scientific Affairs earlier this year issued a practice advisory on Physician Recommendation of Medical Cannabis.² It is consonant with similar guidelines by the California Medical Board and the California Attorney General. Second, a Technical Advisory Committee (TAC) produced a white paper entitled “Cannabis and the Regulatory Void,” which recommends steps to move this agenda forward.¹

The TAC assumed that the cannabis issue is traveling on a trajectory much like alcohol prohibition did a century ago: that is, it is a freely available substance nationally despite its federal illegality. As was the case with alcohol near the time of repeal of Prohibition, we now see that state after state is decriminalizing the use of cannabis.

Also like the situation with alcohol, we currently are witnessing an “Al Capone-like” crescendo of violence related to gang control of the substance. While most of the visible parts of this crescendo are in Mexico, it is now also happening with more frequency in the United States.

Cannabis' Regulatory Void (cont'd)

So why is the CMA acting so forcefully now? It is a reaction to a distribution non-system that is floridly out of control, and yet one in which physicians are being drawn into playing a major role. Indeed, there is a growing concern by many physicians that more of us are being asked to act as gatekeepers while our knowledge of medical cannabis remains grossly inadequate. Current federal policies are resulting in harm, with an escalation of violence both here and in Mexico. Importantly, there is a concomitant increase of public repudiation of those policies.

What Is to Happen Next for Medical Cannabis?

For medical cannabis, the TAC recommends that the CMA take an active leadership role in joining with the 15 other state medical societies to petition the DEA to reschedule cannabis. For the past half century the DEA has functionally ignored such petitions. If the petition were granted, the CMA would also champion federally funded research into the uses and dangers of cannabis.

Let's briefly review the differing Schedules. Schedule II drugs have a high potential for abuse and may lead to severe psychological or physical dependence, but they have a currently accepted medical use in treatment. However, with such deployment there are severe restrictions, as with morphine and topical cocaine. Thus they are only available by prescription, and distribution is carefully controlled and monitored by the DEA. Schedule III drugs have a currently accepted medical use, but also a potential for abuse that is less than those of Schedules I and II (still may lead to moderate or low physical dependence or high psychological dependence). They also are available only by prescription; however, unlike Schedule II drugs, refills are permitted. Examples are ketamine, buprenorphine, thiopental and hydrocodone/codeine when compounded with a non-steroidal anti-inflammatory drug (such as Vicodin or Tylenol 3). Schedule IV drugs have a low potential for abuse and a currently accepted medical use, while abuse may lead to limited physical dependence or psychological dependence (such as benzodiazepines and phenobarbital).

The likelihood that the DEA would respond to a coalition of state medical societies is probably proportional to: a) the number of states that have decriminalized cannabis (now 16), and b) the public response to any violence in the drug wars among gangs in the United States and Mexico. As these actions unfold, the TAC recommends that we sustain our physician role as gatekeeper.

What Is to Happen Next for Non-medical Cannabis?

For non-medical (recreational) cannabis, the TAC calls for either: a) a federal regulatory scheme similar to alcohol and tobacco, or b) federal permissive authority for states to regulate cannabis until the feds get their act together.

Cannabis' Regulatory Void (cont'd)

Realistically, neither of these are politically likely outcomes. Therefore, the TAC implies that a fallback option would be for the feds to simply ignore states with such regulations and passively let them function. Colorado already has taken this step.

In the next few years we are likely to see more propositions on the California ballot regarding cannabis. We also are likely to see state legislative actions, in California and elsewhere, to set up regulatory schemes to get this matter under some control. The TAC's white paper is intended to give the CMA a road map to help guide policy decisions that protect both the public and physicians.

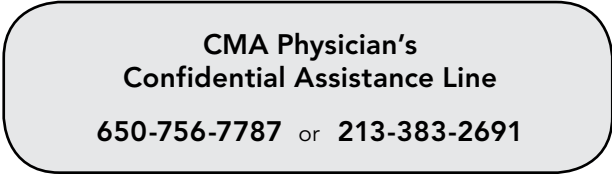
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Website Information of Interest

The Attorney General Physician Guidelines: http://medicalmarijuana.procon.org/sourcefiles/Brown_Guidelines_Aug08.pdf

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Arthur E. Guedel Memorial Anesthesia Center

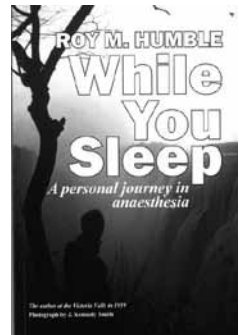
Interested in a Good New Book? A Visit to the Guedel Results in One!

*By Selma Calmes, M.D., President,
Board of Trustees, Guedel Memorial Center*

Interested in a new book that's fun to read? Retired anesthesiologist Roy M. Humble's book, *While You Sleep: A Personal Journey in Anaesthesia* (Melrose Books, Cambridgeshire, U.K., 2011), is a wonderfully entertaining read focused on anesthesia. It came into being after his visit to the Guedel Memorial Center in San Francisco, to see the Richard Gill curare collection. The visit got him thinking about his life in anesthesia, and thus this book. Because of the book's special interest to anesthesiologists, this article will review it and discuss why anesthesiologists might enjoy it.

The Guedel's collection of items related to the history of anesthesia is often used by researchers. As with any historic library, the researcher has to get written permission to use images, such as pictures of equipment; must give credit to the Guedel Center in the publication; and then must provide a copy of the publication to the library. Guedel images in the last few years have appeared in publications from Australia to England, in anesthesia journals and in textbooks. Dr. Humble used a picture from the Gill collection in his book. We wouldn't have known about this book of personal memoirs except for the requirement to send us a copy of the publication.

When the book arrived, the cover looked interesting, so I read it. I loved it. Dr. Humble has had an amazing life while practicing medicine on three continents. He was born in Scotland and attended Glasgow University and Dublin's Rotunda Hospital. He was then a junior medic in the British Army in Egypt and Libya. After traveling in Zimbabwe, he became a family doctor in Kenya. As Africa's political changes began, he and his wife decided to return to England. He had been doing anesthesia since medical school graduation, in addition to his medical practice, and he decided to specialize in anesthesia. Anesthesia training in London led to a consultant anesthetist position in Dumfries, Scotland. In 1969, he moved to Edmonton, Alberta, Canada.



Guedel Center (cont'd)

Most chapters have interesting ties to anesthesiology. His early experience as a tonsillectomy and adenoidectomy patient, the state of anesthesia during medical school and his days in Africa, and the situation for anesthesia (no blood gases, no ICUs, etc.) as he began specialty training are all handled with a precise understanding of the hazards of those times and the progress that we've made. His descriptions of many challenging patients will remind most anesthesiologists of their own similar situations and bring back many memories.

Two things make this book especially attractive: its structure and the style. The book is divided into two parts: his early life, medical training and early practice, and his later life once he began specializing in anesthesia. Each section has numerous short chapters with intriguing titles ("The Day God Came to Call," "Four Men in a Car," "The Flying Death"). Each chapter can stand alone. But Dr. Humble's style is the book's greatest attraction. He is generally lighthearted and very humorous, but turns dead serious in many areas, especially when patients die due to anesthetic or surgical care.

Reading this book will bring back many memories of life as an anesthesiologist to most of us. For recent graduates, it is a good tale about what anesthesia was like in the early days; it also vividly illustrates the strong qualities (including humor) of those who tried to move anesthesia forward in the early days. This is a delightful read. Because of the short chapters, it is especially good for before-bed reading. The book also serves to recognize anesthesiologists and their accomplishments—its back cover quote begins: "When thanking your surgeon after a successful operation, do you ever spare a thought for the individual who brought you safely through that surgery?" We're fortunate Dr. Humble visited the Guedel and decided to write about his life in anesthesia.

This book is available on Amazon.com.

CSA Website www.csahq.org

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April 19-22, 2012

**CSA Spring California Anesthesia Seminar
(Formerly CSA Annual Meeting)
The Ritz-Carlton Laguna Niguel
Dana Point, CA**

October 29-November 2, 2012

**CSA Fall Hawaii Anesthesia Seminar
Mauna Lani Bay Hotel & Bungalows
Kona, Hawaii**