



AMERICAN COLLEGE OF SURGEONS

SURGERY NEWS

Public Disclosure Is Already Law in Some States

BY JOYCE FRIEDEN
Elsevier Global Medical News

When it comes to public disclosure of drug company payments to doctors, how much your patients know depends on where you live—at least for now.

Although no federal law has yet been passed, “six states and the District of Columbia have already passed disclosure legislation,” Jennifer Colapietro, director of pharmaceutical and life sciences advisory services at PricewaterhouseCoopers, said during an audioconference sponsored by Harvard Health Policy Review and Rx Compliance Report.

Currently, California, Nevada, Vermont, Minnesota, Maine, and West Virginia all have disclosure laws in effect; Massachusetts has recently passed a law, but it doesn’t take effect until next year, she said.

State disclosure laws vary greatly, said Chris Armstrong, investigative counsel for the Senate Finance Committee, where Sen. Chuck Grassley (R-Iowa) is the ranking member. For example, only two states capture device payments, and only a few release the information to the public, he said.

In addition to the laws already in effect, “there are 12 pieces of legislation filed so far, including 3 in Texas.

This issue is gaining traction; over the next few years, there will be a lot of growth in this area.”

Maine state Rep. Sharon Anglin Treat (D-Hallowell) agreed that the laws vary, with only Minnesota’s law disaggregating the data so the public can see what each physician is paid.

“States such as Maine and West Virginia also require reporting on [pharmaceutical] advertising and marketing, including direct-to-consumer television ads, whereas Vermont doesn’t collect that information,” said Ms. Treat, who also is executive director of the National Association on Prescription Drug Prices, a nonprofit group formed by state legislators concerned about prescription drug costs.

The answer, according to Mr. Armstrong, “is to have a single, clear, robust, and reasonable federal rule.” On that point, the Physician Payments Sunshine Act (S. 301) was introduced first in 2008 by Sen. Grassley and reintroduced this year; it would require drug companies to submit a report to the U.S. Health and Human Services secretary detailing any payments made to physicians, as well as any food, gifts, trips, product rebates, admission to medical conferences, or any other compensation deemed appropriate. The reports would be available online.

Mr. Armstrong said that the federal legislation is not

intended as a “floor” for state laws. “One person had the idea that if Iowa passed a law saying that companies had to disclose their payments twice a year—rather than once a year [as in] in our bill—that’s okay. But that’s not our intent. Any requirements that [necessitate] a duplication of that reporting on the state level are preempted.”

On the other hand, “that’s not to say Iowa couldn’t require reporting of payments to organizations or other prescribers,” Mr. Armstrong continued. “Because those are types of payments not in [the scope] of our bill, those aren’t preempted at all.”

In anticipation of a federal law, three pharmaceutical manufacturers—Pfizer Inc., Merck & Co., and Eli Lilly & Co.—have already announced plans to develop payment databases.

On another federal front, John T. Bentivoglio, a lawyer in Washington, noted that the HHS inspector general’s office has taken an increasing interest in making pharmaceutical companies disclose their physician payments, with biopharmaceutical manufacturer Cephalon Inc. becoming the first company (in September 2008) to sign a corporate integrity agreement (CIA) requiring disclosure of physician payments. “The early trend is that such disclosure requirements will be included in future CIAs,” he said. ■

Doctor-Patient Communication Key to Avoiding Lawsuits

BY DAMIAN McNAMARA
Elsevier Global Medical News

MIAMI BEACH — Hospitalists are most likely to be targeted by malpractice claims that involve alleged informed consent issues, standard of care, or errors resulting from poor communication.

Physicians still win more than half of malpractice cases, Dr. Franklin A. Michota Jr. said at a meeting on perioperative medicine sponsored by the University of Miami. Lawsuits are inevitable, he said. “I am estimating that 30%-40% of you in the audience have been sued.”

In general, surgeons are sued about once every 4 years, anesthesiologists every 5 years, and internists every 7-10 years. Hospitalists, as part of the perioperative team, are sued as often as surgeons, said Dr. Michota, director of academic affairs for the department of hospital medicine at the Cleveland Clinic.

Poor communication is the leading reason physicians get sued, Dr. Michota said. “Sometimes it doesn’t matter if you do everything right. If you don’t talk to the patient, you are going to get sued.”

Hospitalists can lower their risk by staying alert to the most common reasons for lawsuits, shown in three malpractice cases presented by Dr. Michota and Matt Donnelly, chief counsel at the Cleveland Clinic.

The first case was a 65-year-old man referred for preoperative stress testing before total knee arthroplasty. He had a history of coronary artery disease and marked limitation of activity on the Duke Activity Status Index; he also had chronic obstructive pulmonary disease, hypertension, and prior abdominal aortic aneurysm repair. Dobutamine stress echocardiography was performed with a target heart rate of 132 bpm. During the test, the man complained of shortness of breath and chest pain, and the test was stopped. He went into ventricular tachycardia, then ventricular fibrillation, and died despite resuscitative efforts.

Mr. Donnelly noted that how informed consent was obtained was central to this case. Was it obtained by the referring physician a few weeks before the stress test or on the test day? Was death as a potential outcome discussed with the patient as part of the informed consent process? Was there appropriate monitoring during the test?

“I don’t remember a time when I referred someone to a stress test where I told them they could die. I do now,” Dr. Michota said.

A lawsuit can be filed even if the patient signed a consent form in the stress testing laboratory, Mr. Donnelly said. A plaintiff’s attorney might question whether the patient understood the risks, for example.

Standard of care issues are illustrated by a case of a 75-year-old man with rectal cancer. He had a remote cardiac history but presented for surgery with good functional capacity on the Duke Activity Status Index and no symptoms. Surgery was uneventful, but he developed hypotension in post anesthesia; he improved the next morning. Bleeding occurred 2 days later and he was returned to the OR, where he experienced cardiac arrest. He was revived but died 2 weeks later. An autopsy revealed myocardial infarction as the cause of death.

“The complaint was he did not have a proper cardiac work-up,” Dr. Michota said. Mr. Donnelly commented that the patient’s cardiac condition was well controlled and “was way in the past.” One of the main issues in the case was the question of whether an ECG should have been performed, Mr. Donnelly said.

Hospitalists could be involved in such a case if they do a preoperative evaluation and do not order an ECG, even though it is not recommended in this scenario by the American College of Cardiology or American Heart Association, Dr. Michota said.

A third case showed the importance of documentation and communication. A 67-year-old man went for a consultation after developing shortness of breath after a laminectomy. He was started on full-dose low-molecular-weight heparin, his symptoms resolved, and his work-up was negative. The consultants signed off without stopping the LMWH. The man was discharged to a rehabilitation unit and did well until postoperative day 7, when he developed urinary retention and could not move his legs. Then the LMWH was stopped, and he underwent emergency surgery to evacuate a spinal hematoma. He never fully recovered his neurologic function.

“This case was interesting because once the docs involved realized what happened, they got nervous and started finger-pointing,” Dr. Michota said. Each surgeon thought the other was going to stop the LMWH. “Interestingly, the hospitalist in the case made a notation in the chart after the neurologic injury occurred, but dated the entry as before the fact. Doctoring the medical record never plays well to the jury—it is a clear sign of guilt!” ■



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Women Do Worse With Abdominal Aortic EVAR

BY BRUCE JANCIN
Elsevier Global Medical News

TUCSON, ARIZ. — Women who undergo endovascular abdominal aortic aneurysm repair have significantly greater 30-day morbidity and mortality, compared with men, according to an analysis of the American College of Surgeons National Quality Improvement Program.

The explanation for the gender disparity in outcomes is likely in part the higher preoperative risk level among women undergoing endovascular aneurysm repair (EVAR) for an abdominal aortic aneurysm. Also, women appeared to undergo longer, more technically challenging operations, Dr. Nick N. Abedi said at the annual meeting of the Southern Association for Vascular Surgery.

But even after researchers controlled for these and other differences in a multivariate analysis, female sex remained

an independent risk factor for 30-day mortality, conferring an 85% increased relative risk, according to Dr. Abedi of the University of Kentucky, Lexington.

He reported on all 3,801 patients in the ACS National Quality Improvement Program registry who underwent EVAR with prospective data collection during 2005-2007 at 173 participating academic and community hospitals.

Women made up 17.5% of the study population. Their 30-day mortality rate of 3.5% was nearly double the 1.8% rate in men. Overall morbidity at 30 days, with 21 potential complications recorded under the quality improvement program's protocol, was 18.1% in women who underwent EVAR, compared with 10.5% in men.

Bifurcated repairs with one docking limb accounted for 43% of the procedures, bifurcated with two docking limbs 34%, tube grafts 9.5%, unibody repairs

5.7%, aortouni-iliac/femoral 4.4%, and iliac 3.7%.

The major gender differences among patients undergoing EVAR include the following:

► **Preoperative factors.**

Female EVAR patients were significantly older than the male patients, with mean ages of 74.8 and 73.6 years, respectively. Women were more likely to have a history of chronic obstructive pulmonary disease, by a margin of 23% to 17.8%. They were also more likely to be current smokers, and tended to have more extreme body

mass indexes. Women had a threefold higher rate of heart failure 30 days prior to surgery, and they had more angina. Yet they were significantly less likely than men to have a history of

cardiac surgery (14.5% vs. 27%) or coronary angioplasty (15.5% vs. 20.6%).

► **Intraoperative variables.**

Emergency EVAR was performed in 6.8% of women and 4.3% of men. Women experienced longer operative times—a mean of 183 minutes, compared with 162 minutes for men. Women received an average of 0.89 intraoperative transfusions, a rate more than twice that in men.

“The higher intraoperative transfusion requirements and longer operative times suggest that EVAR is more difficult in women than men,” Dr. Abedi observed.

► **Postoperative factors.** A return trip to the OR was necessary for 9.3% of women and

4.8% of men. The 3.5% incidence of superficial wound infection in women was nearly twice that in men. Graft failure occurred in 2.3% of women and 1.1% of men. Ventilation for more than 48 hours was implemented in 4.5% of women, compared with 2% of men.

The average length of stay was 5.2 days in women undergoing EVAR, compared with 3.7 days for men.

Abdominal aortic aneurysms account for roughly 45,000 deaths annually in the United States, Dr. Abedi noted.

Discussant Dr. J. Gregory Modrall, an ACS Fellow with the University of Texas at Dallas, noted the higher rates of pulmonary risk factors and lower rates of cardiac interventions in women despite a background of cardiac disease similar to men. He speculated that greater efforts to improve surgical fitness could make for better EVAR outcomes in women. ■



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DR. ABEDI

Adjuvant CRT Tames Node-Positive Pancreatic Cancer

BY DAMIAN McNAMARA
Elsevier Global Medical News

PALM BEACH, FLA. — Adjuvant chemoradiation therapy was associated with an overall survival benefit for patients with resected pancreatic adenocarcinoma, but the advantage was significant only among those with node-positive disease, according to a large, multicenter study.

“Adjuvant chemoradiation therapy should be reserved for patients with lymph node-positive disease, regardless of their resection margin status,” Dr. Nipun B. Merchant said at the annual meeting of the Southern Surgical Association.

The role of chemoradiation therapy (CRT) remains controversial, said Dr. Merchant, an ACS Fellow who is also a gastrointestinal surgical oncologist at Vanderbilt University Medical Center, Nashville, Tenn.

Approximately 80%-85% of pancreatic cancer patients present with advanced disease. After surgical resection, median survival ranges from 11 to 20 months (Ann. Surg. 2007;245:566-72; Ann. Surg. Oncol. 2006;13:1201-8). The 5-year actual survival is estimated at 12% in one study (World J. Surg. 2009;33:104-10).

Dr. Merchant and his associates retrospectively assessed 708 patients treated at one of seven institutions in 2000-2006. A total of 402 (57%) had surgery only; 255 patients (36%) also received adjuvant CRT; and 51 (7%) received adjuvant chemotherapy only. The researchers restricted their primary analysis to the 402 patients who received no CRT and the 255 who received CRT. Half of the 402 patients had lymph node-positive disease, and half were lymph node negative. Median follow-up was 17 months.

Overall survival was a median 14.5 months for the no-CRT group compared with 20 months for the CRT group. The longer survival associated with CRT, however, was significant only among the 160 patients with node-positive disease in the CRT group and not the 201 with node-negative cancer. ($P = .001$). Overall survival was also significant, although less so, for the 89 patients who had an R1 resection and CRT compared with 84 who had an R1 resection without CRT ($P = .038$).

“Mean survival was 20 months in the combined therapy group, which is significantly better than surgery alone, emphasizing the importance of multidisciplinary therapy,” said discussant Jason Fleming, an ACS Fellow and a surgical

oncologist specializing in pancreatic cancer at the University of Texas M.D. Anderson Cancer Center in Houston.

But Dr. John S. Bolton, another discussant, noted that the therapy was not standardized. “It does not make sense that it would not also affect the lymph node-negative patients, so there may be other factors involved,” said Dr. Bolton, an ACS Fellow and chair of surgery at Oschner Health System in New Orleans.

A meeting attendee asked why the lymph node-negative patients fared significantly worse with CRT. “I would be hard pressed to see if anyone has an answer to that,” Dr. Merchant said.

“This is a well-done study that has prompted many additional questions and issues,” said Dr. Charles Yeo, a discussant who brought up the issue of cost. “Our pancreatectomy charges and postoperative recovery charges are often dwarfed by the cost of neoadjuvant agents and outpatient radiation charges,” said Dr. Yeo, an ACS Fellow who is also professor and chair of surgery at Jefferson Medical College, Philadelphia.

He asked if the cost of CRT could be expressed in terms of quality-adjusted life years.

“We could do that from this study, but

it's not done yet,” Dr. Merchant replied.

Dr. Yeo also asked why 5-fluorouracil (5-FU) was the primary chemotherapy agent used in this study and how many patients received another agent, such as gemcitabine.

“Unfortunately, patients received adjuvant therapy at outside centers, so we could not confirm the type in all cases—for example, if it was 5-FU alone or if gemcitabine was included,” Dr. Merchant replied.

The ability to stratify patients by lymph node and margin status and evaluate patients “in a modern time period” are strengths of the study, Dr. Merchant said, while the retrospective design and the fact that adjuvant therapy was not standardized are among its limitations. However, he pointed out that many of the shortcomings of his study are characteristic of all research—including randomized studies—in adjuvant therapies for pancreatic cancer.

Differences in outcomes between adjuvant chemoradiation therapy and chemotherapy alone must be further evaluated on the basis of randomized studies that stratify pancreatic cancer patients according to lymph node status, he concluded. ■