

LEARNING OBJECTIVES

1.

To familiarize the reader with the scope of liability and the total payments of federal medical malpractice claims by the Judgment Fund Branch of the Financial Management Service of the Department of the Treasury.

2.

To consider the possible legal ramifications and requisite standard of care when shoulder dystocia is encountered during vaginal delivery.

3.

To highlight legal and medical parameters involving the prescription of hormone replacement therapy for breast cancer survivors.

4.

To acquaint physicians with the national effort to create a central system for reporting medical errors.

5.

To emphasize the importance of autopsies as quality control and risk management tools, and to explain the benefits of autopsies and why the rates have declined drastically.

6.

To explore legal issues raised by the provision of medical information and treatment through the Internet.

7.

To examine the applicable standard of care that courts apply when physicians, such as Family Practitioners, perform procedures often or usually performed by other specialists.

8.

To identify medical-legal liability issues that arise from medication errors.

9.

To review the Armed Forces Institute of Pathology's role as a "people's institute" by furthering public/private knowledge in the years to come.

PAYMENT OF FEDERAL MALPRACTICE CLAIMS

by Richard L. Granville, M.D., J.D.
and Wanda J. Rogers, M.G.A./H.R.M.*



Many health care organizations including agencies within the United States federal government are interested in measuring the number and dollar amount of medical malpractice payments as an indicator of the quality of medical care they provide. If both the number of payments and the total amount of payments can be followed on an annual basis, this data can also provide trending information that is important for the medical-legal community. Such trending is a useful quality control and risk management tool. This article provides an overview of the payment of medical malpractice claims by the federal government. Agency tracking of the number of federal paid claims is not an easy task as there are many legal and medical organizations involved in the resolution of claims. Data provided by the Financial Management Service of the Department of the Treasury serves as an important means of tracking and obtaining this information.

Financial Management Service

The Department of the Treasury consists of Departmental Offices and thirteen bureaus including the U.S. Secret Service, the U.S. Mint, the Bureau of Engraving and Printing, the Bureau of the Public Debt, the Internal Revenue Service and the Financial Management Service (FMS). FMS serves as the financial manager of the federal government. It was originally established in 1974 as the Bureau of Government Financial Operations. In 1984, the name was changed to the Financial Management Service. This name change reflected a new emphasis on achieving greater efficiency and economy in the financial management of the federal government. The mission of FMS is to manage and develop federal financial systems so that the government's cash flows efficiently, securely and effectively. FMS supports other federal agencies by serving as the government's primary disbursing agent of funds in addition to performing numerous other functions. It disburses more than one trillion dollars each year in approximately 860 million non-defense payments, including veterans' benefits, IRS tax refunds, and social security benefits. The

**Director, Financial Accounting & Services Division, Financial Management Service, Department of the Treasury.*

Financial Management Service also tracks certain monetary assets and liabilities and oversees the federal government's central accounting and reporting system.^{1,2}

Judgment Fund

Paying court judgments and settlements is also an important function of the Financial Management Service. Before 1956 most of the judgments against the United States, such as those resulting from contract cases, tax refund cases or personal injury and medical malpractice cases could not be paid from existing appropriations. A specific Congressional appropriation was required for payment.³ In 1956, however, Congress enacted the Judgment Fund Statute that created a permanent indefinite appropriation for the payment of final judgments that are "not otherwise provided for."⁴ The statutory authority for the Judgment Fund is found in 31 USC 1304. Administrative guidance is found in the Treasury Financial Manual, Part 6, Section 3100. The Judgment Fund is managed by the FMS' Judgment Fund Branch.

There were three primary reasons for creating the Fund. First, it would alleviate the procedural burdens of judgment payments. Second, the Fund would allow for payments to be made in a more timely manner. Third, it would reduce the accumulation of interest against the United States, by shortening the period between the date of the judgment and the payment of that judgment.⁵ Congress amended the law in 1961 allowing the Fund to pay Department of Justice compromise settlements in cases of actual or imminent litigation.⁶ Subsequently, smaller administrative claim awards or settlements by an agency such as the Army, Navy or Air Force without the filing of a complaint could also be paid through the Judgment Fund based on various federal statutes such as the Federal Tort Claims Act (FTCA). Generally, FTCA payments of more than \$2500 per claimant can be paid from the Judgment Fund, whereas payments of less than \$2500 are paid from the specific agency's own funds.⁷ Other statutes such as the Military Claims Act⁸ and the National Guard Claims Act⁹ allow for payments of

more than \$100,000 to be paid from the Judgment Fund, with payments less than this threshold amount to be paid directly from agency appropriations.

"... tracking ... the number of federal paid claims is not an easy task"

The Payment Process

The Judgment Fund is available to pay final judgments and awards against the United States. Agency requests for payment must adhere to statutory authority and regulations, and appropriate forms must be fully completed to enable the FMS to determine whether the payment can be appropriately paid from the Judgment Fund. Monies are paid from the Fund only after FMS certification. The criteria for this certification include finality of the payment, certainty of the amount, and the absence of other provisions for payment. The amount of any interest which may be authorized is calculated, as well as offsets from the payment by any known indebtedness to the United States by the judgment creditor.¹⁰ Certification does not involve reviewing the merits of the malpractice judgment or settlement.¹¹

The Judgment Fund review, certification and payment process takes approximately 4 to 6 weeks. An additional 2 weeks is required if the payment is issued by a Treasury Regional Financial Center such as in Philadelphia, San Francisco, Austin or Chicago. When a claim is entered into a database at the Judgment Fund Branch, a "Z" number is assigned for identification purposes. When a federal attorney submits a claim for payment from the Judgment Fund, additional supporting forms may be required, such as Forms 194 and 195. These are Judgment Fund Payment Transmittal letters for litigative awards and administrative awards respectively and are

submitted by the Department of Justice to certify that the claim is final. A litigative award is one in which a settlement or a judgment results from a lawsuit. An administrative award is based on an agency’s settlement authority and generally includes claims settled by the Judge Advocate General (JAG) of the respective military service, in the case of the Department of Defense. There also is a Judgment Fund Award Data Sheet (FMS Form 196) that must be submitted along with the request for payment. This data sheet contains a number of descriptive elements about the claim such as the name of the claimant, the claimant’s file number, the court name, the docket number, a brief synopsis of the facts giving rise to the case, the claimant’s address, the payee names, the name of the plaintiff’s counsel, and the agency that submitted the request for payment. A voucher for payment (FMS Forms 197 and 197A) must be included. All forms are available via the Judgment Fund Website (www.fms.treas.gov/judgmentfund/index.html). After the Judgment Fund Branch has reviewed the claim and certified the request for payment, the voucher is transmitted for payment.¹²

Medical Malpractice Data from the Judgment Fund

Information about the payment of medical malpractice

awards on an annual basis can aid in measuring the medical-legal activity of a given health care organization. The number of payments and the total dollar amounts of those payments are tracking tools used by the Department of Defense (DoD) and other federal agencies in response to various requests from Congress. The Judgment Fund Branch maintains a database of certain elements related to the payment of malpractice cases.

Figure A provides a trend analysis of medical malpractice payments comparing the Department of Defense to all federal agencies. The primary federal health care providers are the Department of Defense, the Department of Veterans Affairs, the Department of Health and Human Services, and the Bureau of Prisons. The majority of cases represent care within the Department of Defense and the Department of Veterans Affairs since they have the largest health care systems. The number of payments has remained relatively stable for the Department of Defense and for all federal agencies between the years 1992 and 1998. There has been no abrupt rise in the number of payments.

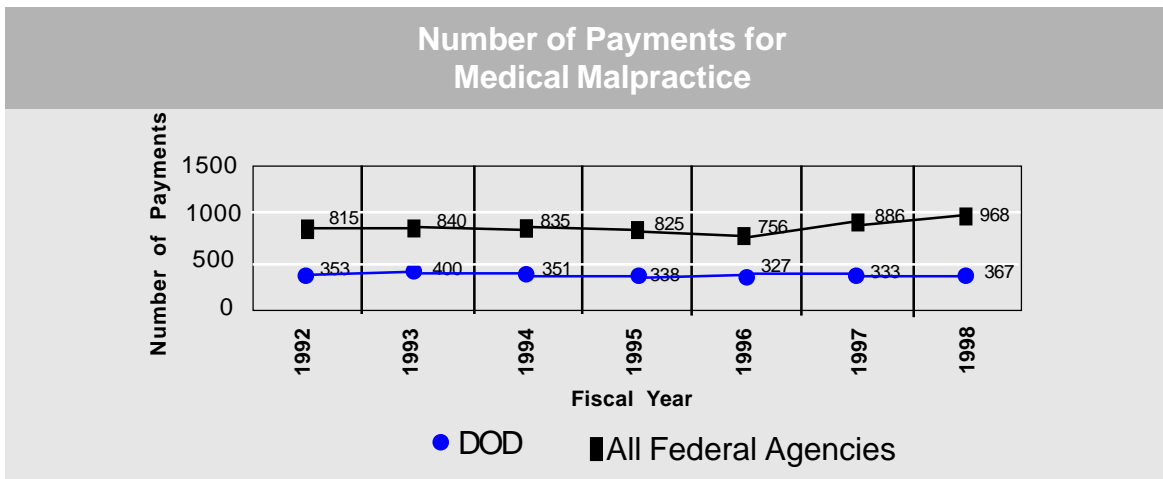


Figure A

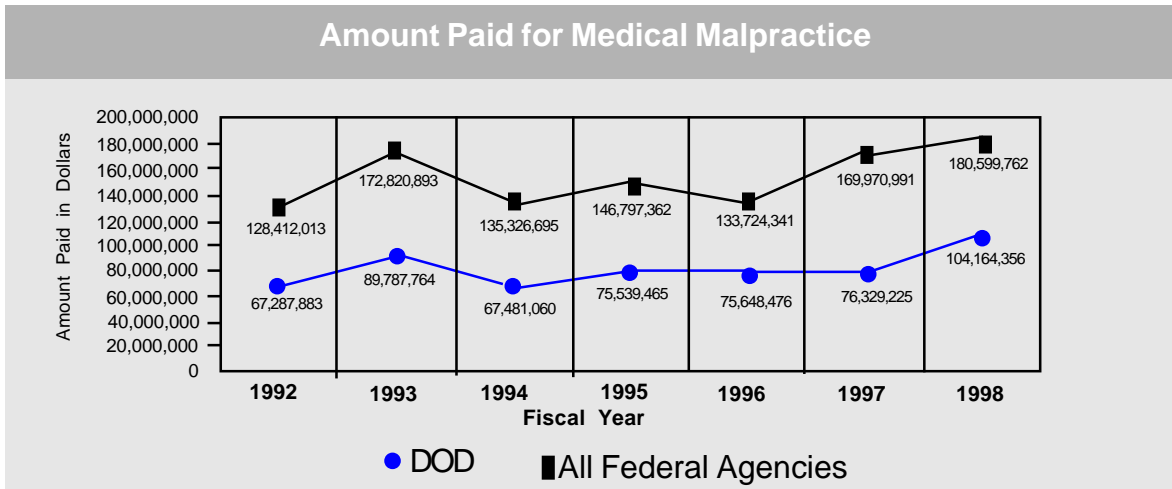


Figure B

Figure B compares the dollar amount of money paid from the Judgment Fund, from 1992 through 1998, on behalf of the Department of Defense and all federal agencies. Smaller payments made by the agencies themselves are not included in these amounts. Here, too, the figures have remained relatively stable. A single malpractice case that results in a very large payment could significantly increase the total amount of money paid, however, so the information must be interpreted cautiously.

In 1998 the Financial Management Service agreed to provide the Department of Legal Medicine (DLM) with a monthly compilation of payments involving the three military services. Using this information, DLM creates monthly reports and submits them to the Army, Navy and Air Force Surgeon Generals' Offices and to the Army, Navy and Air Force JAG Corps.

Additionally, a report is sent by DLM to the Department of Justice. This report is helpful in tracking settlements and awards negotiated by the Assistant U.S. Attorneys, as well as providing follow-up information on closed medical malpractice cases. Such early notification of the payment of these cases is also important for timely reporting to the National Practitioner Data Bank.

Value and Limitations

Accurate medical malpractice data is important to any health care organization, including numerous entities within the federal government. The Judgment Fund claims database is an important source for this information.

As with any other large collection of data, however, certain shortcomings may exist. The agencies' own small payments are not included, and clerical errors may occur at any point in the process. Also, the outcome of a medical malpractice lawsuit can be influenced by a number of factors that do not necessarily reflect substandard medical care such as the aggressiveness of attorneys or the quality of medical records or other evidence. At times it might be more expedient to settle a medical malpractice case than to try it in court.

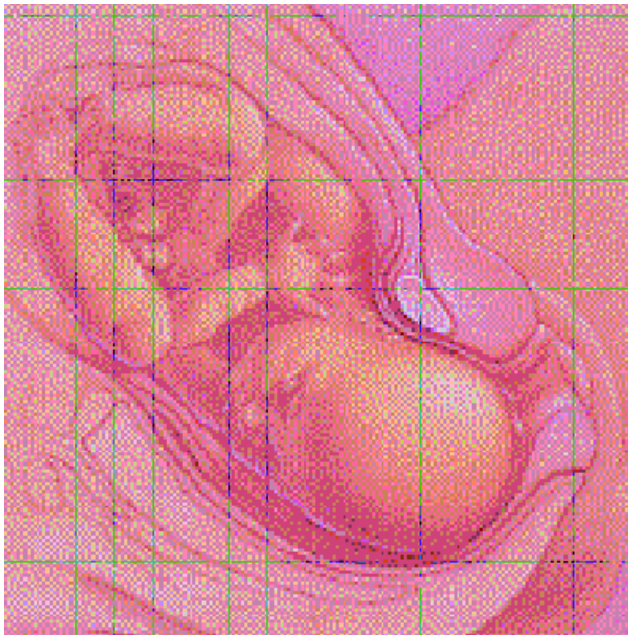
The intrinsic value of the Judgment Fund data remains sound despite its inherent limitations. At present it is the best and most comprehensive source of data regarding the federal government's medical malpractice payments. Federal agencies have a decided interest in obtaining information regarding the number of malpractice payments and the amount paid to support their risk management efforts. The Department of Legal Medicine will continue to collect this data from the FMS Judgment Fund Branch so that it can be used as a risk management tracking tool for the Office of the Assistant Secretary of Defense (Health Affairs), the Tricare Management Activity, and the three branches of the military.

References

1. Department of the Treasury, Financial Management Service—Overview. www.fms.treas.gov/overview.html. Accessed December 30, 1998.
2. Department of the Treasury, Financial Management Service – A Short History. www.fms.treas.gov/history.html. Accessed June 25, 1997.
3. The Judgment Fund. www.fms.treas.gov/judgefund/history.html. Accessed January 1, 1999.
4. 31 USC 1304.
5. The Judgment Fund. www.fms.treas.gov/judgefund/history.html. Accessed January 1, 1999.
6. 28 USC 2414.
7. 28 USC 2672-2680.
8. 10 USC 2733, 2734.
9. 32 USC 715.
10. 31 USC 3728.
11. The Judgment Fund. www.fms.treas.gov/judgefund/history.html. Accessed January 1, 1999.
12. Treasury Financial Manual, Vol. 1, Part 6, Section 3100.

Shoulder Dystocia as a Risk for Obstetric Liability

By Byron C. Calhoun, M.D., Lt Col, MC, USAF,* Roderick R. Hume, Jr., M.D., COL, MC, USA,** and Jennifer L. Walters, J.D.



Shoulder dystocia is described as an obstetric emergency¹ involving the lack of rapid, spontaneous delivery of the anterior shoulder of the fetus. Once shoulder dystocia occurs, it immediately places the pregnant mother and neonate at risk for temporary or permanent injury.² Most physicians or other health care providers who deliver newborns are not familiar with shoulder dystocia due to its unpredictability and infrequent occurrence. What measures should be taken to prevent injury to the newborn and to avoid future medical malpractice litigation if shoulder dystocia occurs? A representative case is presented.

A 33-year-old married black female GO with infertility problems became pregnant with a single fetus after Clomid ovulation induction. Her prenatal course included 15 prenatal visits beginning at her 9th week of gestation. At the time of the initiation of her care she had an ultrasound crown-rump length to date her pregnancy. Subsequent prenatal laboratory values were unremarkable save for an elevated 1-hour glucose tolerance test with a follow up 3-hour glucose tolerance test that was completely normal. An ultrasound performed at 28 weeks showed an estimated fetal weight of 1039 grams at the 50th percentile for gestational age.

**Dr. Calhoun is the Director, Maternal-Fetal Medicine Fellowship Program and Chief, Maternal-Fetal Medicine Services at Madigan Army Medical Center in Tacoma, WA. He is also its Director of the Perinatal Assessment Unit and Assistant Chief of Obstetrical Services.*

***Dr. Hume is the Chief, Department of Clinical Investigations and on the faculty of the Maternal Fetal Medicine Fellowship Program at Madigan Army Medical Center in Tacoma, WA.*

Both doctors are faculty members of the Department of Obstetrics & Gynecology at the University of Washington, School of Medicine, and at the Uniformed Services University of the Health Sciences/ F. Edward Hebert School of Medicine.

The patient did well prenatally. She entered labor and delivery with spontaneous rupture of membranes at 40 weeks gestation at 2:00 AM with an estimated fetal weight by clinical parameters of 7 ½ pounds and a cervical examination of “1 cm dilated/50% effaced/ high station.” Because of her irregular contractions without cervical change and rupture of membranes at term, the patient was placed on pitocin augmentation. She subsequently achieved active labor resulting in complete dilation and began to push approximately 24 hours after admission (1:50 AM the following day). She was “+1” station when she began pushing with her labor epidural in place. The mother underwent an indicated low forceps delivery with 15 degrees of rotation for maternal exhaustion after pushing for 2 hours and 47 minutes. The delivering physicians noted “a mild shoulder dystocia requiring only McRoberts maneuver.” The infant weighed 3730 grams (8 pounds 5 ounces) and had apgars of 7/9 with normal cord gasses.

There was a noted left arm brachial palsy consistent with an Erb’s type that persisted to 1 year of age. The parents brought a case for several million dollars alleging negligence in their child’s care.

Shoulder dystocia complicates from 1-4% of vaginal cephalic deliveries.³ The reported incidence of brachial plexus injuries is between 4-40%.^{4,5,6,7,8,9} Permanent damage is found only in 9-25% of those injuries.^{10,11} Thus, only 1% of shoulder dystocias end up with a permanent injury lasting longer than 1 year. The best way for a physician to avoid the risk of obstetrical negligence due to shoulder dystocia is to know and follow the applicable standard of care.

The best management for shoulder dystocia would be to anticipate and predict certain risk factors, and ultimately to prevent this complication. Such is the first step in managing shoulder dystocia and

avoiding medicolegal action.¹² There have been several risk factors identified, but a combination of them such as macrosomia in the presence of maternal diabetes and obesity consistently confers risk.^{13,14} Pregnant women with gestational diabetes have a two- to six- times increased incidence of babies with shoulder dystocia.¹⁵ However, the use of risk factors to predict patients who will have shoulder dystocia has been disappointing. In fact Acker et al, noted that only 55% of patients with identifiable risk factors had shoulder dystocia.¹⁶

The main problem with any management protocol for shoulder dystocia is that the majority of patients, such as the one in the case above, do not have clear risk factors. This is why it is imperative that a physician, obstetrician, or other health care provider who delivers newborns has a well-managed plan or course of action if shoulder dystocia presents.

The health care provider should immediately ask for obstetric assistance and instruct the mother to discontinue any pushing once shoulder dystocia is diagnosed at delivery. Additionally, any further attempts at vigorous downward traction should cease and no fundal pressure should be applied. This is known to increase the potential for a brachial plexus injury.¹⁷ The use of gentle, downward traction appears to be the standard of care.^{18,19}

The goal of the physician at this point is to free the impacted shoulder as quickly as possible, as a fetus may only endure up to 8 to 10 minutes of asphyxia before permanent neurologic injury occurs. The standard of care demands that the physician know and use certain maneuvers that will relieve shoulder dystocia. These maneuvers will not only facilitate vaginal delivery, but they will also significantly reduce the risk of permanent brachial plexus injury.

There are many maneuvers that are used in delivery, but the literature is sparse regarding the outcomes of

various maneuvers to relieve shoulder dystocia. No maneuvers have been shown to prevent all injuries. The one maneuver known to be effective is the McRoberts maneuver with flexion and slight rotation of the maternal hips onto the maternal abdomen.²⁰ This maneuver is considered the current recommendation for relieving shoulder dystocia.²¹

One important recommendation that is sometimes overlooked by physicians is proper and thorough documentation of the entire pregnancy, especially the delivery. Proper documentation shows the standard of care used, the maneuvers used, and whether or not risk factors were present.²² Good record keeping leads to better obstetrical management, which in turn leads to a decrease in the severity of brachial plexus injuries and thereby reduces the potential for medicolegal action.²³

There can be many legal defenses utilized in litigation for shoulder dystocia cases. The most important argument lies in whether the delivering physician caused the brachial plexus injury. Recently, it has been reported that perhaps labor itself, position of the fetus during labor, uterine anomalies, or increased intrauterine pressures during labor with a uterine abnormality might all predispose to brachial injury without a vaginal delivery and hence a shoulder dystocia.²⁴ Gherman et al, note that it takes about 10 days for muscles to display electromyelo-graphic evidence of denervation.²⁵ If a muscle showed denervation of voluntary motor units, it would give presumptive evidence of an *in utero* insult rather than a result of delivery. Therefore, the use of electromyography early in the newborn period to document possible *in utero* injury is recommended.

Understand that no single risk factor accurately predicts shoulder dystocia, nor does the presence of shoulder dystocia denote any evidence of breach of standard of care. Most shoulder dystocias (99%) will resolve by the age of 1 year, but for those that persist, the delivering health care providers may face malpractice litigation. Careful medical review of this descriptive case

of obstetrical shoulder dystocia at vaginal delivery demonstrates the difficulty in predicting this event. Here the defendant physicians provided thorough, concurrent, written descriptions of the care provided. There were no breaches noted in the medical care of this patient and the standard of care was met. This case study demonstrates the necessity for impeccable documentation of patient care that can be of utmost importance if there is any future medicolegal challenge.

References

1. ACOG Practice Pattern #7. October, 1997.
2. Injuries that may result from a shoulder dystocia include a broken arm or clavicle, strain or stretch of the brachio-plexus nerves resulting in arm or shoulder paralysis, or cerebral hypoxia.
3. Acker DB, Sachs BP, Friedman EA. Risk Factors for shoulder dystocia. *Obstet Gynecol*. 1985;66:762-768.
4. Id.
5. el Madany AA, Jallad KB, Radi FA, el Hamdan H, O'deh HM. Shoulder dystocia: anticipation and outcome. *Int J Gynecol Obstet*. 1991;34:7-12.
6. Gross TL, Sokol RJ, Williams T, Thompson K. Shoulder dystocia: a fetal-physician risk. *Am J Obstet Gynecol*. 1987;156:1408-1418.
7. Gonik B, Hollyer VL, Allen R. Shoulder dystocia recognition: differences in neonatal risks for injury. *Am J Perinatol*. 1991;8:31-34.
8. Gross SJ, Shime J, Farine D. Shoulder dystocia: predictors and outcomes. A five year review. *Am J Obstet Gynecol*. 1987;156:334-336.
9. Graham EM, Forouzan I, Morgan MA. A retrospective analysis of Erb's palsy cases and their relation to birth weight and trauma at delivery. *J Matern Fetal Med*. 1997;6:1-5.
10. Baskett TF, Allen AC. Perinatal implications of shoulder dystocia. *Obstet Gynecol*. 1995;86:14-17.
11. Morrison JC, Sanders JR, Magann EF, Wisner WL. The diagnosis and management of dystocia of the shoulder. *Surg Gynecol Obstet*. 1992;175:515-522.

12. In *Reid v. County of Nassau*, 215 A.D.2d 466, 627 N.Y.S.2d 396 (1995), a jury rendered a verdict for \$3,200,000 after plaintiff contended that defendant should have known that she was predisposed to shoulder dystocia given her history of high-birth-weight babies.
13. Gross et al projected a 27% increase in the total cesarean section rate (from 15.1% to 19.1%) if cesarean sections were done for all fetuses with estimated weights ³ 4000 gms. This would reduce total shoulder dystocias by 42%. (See note 8.)

Another more recent study noted that between 19 and 162 cesarean deliveries would be needed to prevent a single immediate, nonpermanent brachial plexus injury. Others have argued that increasing the estimated fetal weight to 4500 gms for cesarean sections might prove beneficial. However, as yet, no consensus has been reached on this issue due to the increased number of cesarean sections needed to prevent a single case of brachial plexus injury. One projected cost analysis noted that the impact of this policy nationwide would be to cost 8.7 million dollars annually while increasing the number of cesareans by 3,695 to prevent a single permanent injury. (See Rouse DJ, Owen J, Goldenberg RL, Cliver SP. The effectiveness and costs of elective cesarean delivery for fetal macrosomia diagnosed by ultrasound. *JAMA*. 1996;276:1480-1486.)

See also Bahar AM. Risk factors and fetal outcome in cases of shoulder dystocia compared with normal deliveries of a similar birthweight. *Br J Obstet Gynecol*. 1996;103:868-872. Langer O, Berkus MD, Huff RW, Samueloff A. Shoulder dystocia: should the fetus weighing ³ 4000 grams be delivered by cesarean section? *Am J Obstet Gynecol*. 1991;165:831-837. Ecker JL, Greenberg JA, Norwitz ER, Nadel AS, Repke JT. Birth weight as a predictor of brachial plexus injury. *Obstet Gynecol*. 1997;89:643-647.
14. Other risk factors include a history of a macrosomic infant or shoulder dystocia, labor abnormalities, advanced maternal age, excessive maternal weight gain, short maternal stature and postdatism.
15. See generally Acker, *supra* note 3, and note 13.
16. See Acker, *supra* note 3.
17. Bioengineering researchers support the view that large tractions are the cause of a brachial plexus injury encountered during shoulder dystocia, and traumatic injuries cannot happen with gentle or moderate traction. See Allen RH. Understanding the cause of permanent brachial plexus injury: an engineering perspective on shoulder dystocia. Visit <http://www.shoulderdystocia.com/main.html>. Accessed March 31, 2000.
18. See Baskett, *supra* note 10.
19. In *Young v. Louisiana Medical Mutual Insurance Co.*, 725 So.2d 539 (1998), the doctor breached the standard of care by the use of fundal pressure, traction, and a request for the mother to push when shoulder dystocia was encountered. Also, in *Mirazita v. Lauersen*, 1/26/99 NYLJ 4, a plaintiff was awarded \$1.8 million after the jury found that the defendant physician deviated from good and accepted medical practice in failing to diagnose and treat the gestational diabetes, and that he did use excessive traction on the fetus's head.
20. See Acker, *supra* note 3.
21. Gherman RB, Goodwin TM, Souter I, Newmann K, Ouzounian JG, Paul RH. The McRobert's maneuver for the alleviation of shoulder dystocia: how successful is it? *Am J Obstet Gynecol*. 1997;176: 656-661.
22. Examples of recommended documentation include estimated fetal weights by clinical or ultrasound criteria on all deliveries and discussion in the chart about possible primary low transverse cesarean delivery for all nondiabetic infants weighing ³ 4500 gms and all diabetic infants weighing ³ 4200 gms.
23. Not only is documentation important to the care of a patient, but it is also critical evidence in the defense of medical malpractice claims. See Tan MW, Feierstein A. OB/GYN claims: analysis and advice. *Forum*. 1994;15:1-5.
24. Gherman RB, Goodwin TM, Ouzounian JG, Miller DA, Paul RH. Brachial plexus palsy associated with cesarean section: an in utero injury? *Am J Obstet Gynecol*. 1997;177:1162-1164.
25. Id.

LEGAL IMPLICATIONS OF PRESCRIBING HORMONE REPLACEMENT THERAPY FOR PATIENTS WHO HAVE SURVIVED BREAST CANCER

By Brad L. Hilaman, M.D., J.D.*

Almost every practicing physician with mature female patients will eventually face the management problem of controlling the symptoms and effects of menopause in those patients.

While hormone replacement therapy (HRT) is considered a standard treatment option for menopausal symptoms and effects, there are several important contraindications to its use—one of which is a history of breast cancer in the patient. At present, she may have either estrogen or progesterone positive receptors, or both, in the breast cancer tissue, and the concern is that stimulation of these receptors may trigger a breast cancer that appears to be cured. However, according to a recent poll of 418 female breast cancer survivors, 13% were receiving estrogen replacement therapy (ERT) or were consulting with their physician in order to receive ERT. Another 17% had agreed to enroll in a study that planned to place them on ERT.¹ What is the conscientious physician to do if the breast cancer survivor requests HRT or the physician determines HRT is probably the best course of treatment based on the patient's particular problems?

Estrogen Deprivation

Lack of estrogen in women can create a myriad of problems. Estrogen replacement therapy replaces the estrogen that is no longer produced naturally in the body after menopause. Some menopausal patients may present with an array of varying complaints including hot flashes, vaginal dryness, loss of libido, night sweats, poor sleep patterns, and problematic mood swings. Other more serious and unseen effects of menopause include acceleration of atherosclerotic heart disease, development of osteoporosis, and a possible increase in colon cancer. Younger women can experience these symptoms, too, for ovarian failure can occur in pre-menopausal women who receive chemotherapy for breast cancer. Thus both

*Dr. Hilaman is a practicing Obstetrician/Gynecologist associated with Doshier Memorial Hospital in Southport, NC, and is a Consultant to the Department of Legal Medicine.

“... several authors have reported data that suggest ERT use in breast cancer survivors is not absolutely contraindicated.”

pre-menopausal and menopausal women may benefit from estrogen replacement therapy. But what if these patients are breast cancer survivors?

When estrogen replacement therapy is prescribed for female breast cancer survivors of any age, the concern of the prescribing physician is two-fold. Of course there is the question of medical risk to the patient by possibly inducing a negative impact on the disease-free interval of the breast cancer. The physician should also be concerned about medical malpractice if his or her actions are deemed substandard or negligent. Both these concerns can benefit from sound medical practice and a careful review of the pertinent medical literature, as well as a thoughtful discussion of associated risks, benefits, and alternatives with the patient.

The Literature

Large definitive prospective studies are not currently available to show that estrogens are safe to use in breast cancer survivors. However, several authors have reported data that suggest ERT use in breast cancer survivors is not absolutely contraindicated.^{2,3,4,5} Following a pilot study of 41 patients, DiSaia concluded that there was no obvious adverse effect of ERT on breast cancer survivors.⁶ Other researchers followed 43 women on oral ERT for a median of 144 months after cancer diagnosis, and 31 months after initiation of ERT. Although one patient who began ERT 30 months after cancer diagnosis developed a recurrent ER-negative tumor 56 months after initiation

of ERT, the authors concluded that ERT in breast cancer patients does not appear to have a pronounced adverse effect.⁷ In South Africa another prospective study was completed involving 20 women who had been treated 8 to 91 months previously for breast cancer. Premarin and medroxyprogesterone were prescribed. No recurrences were noted during a follow-up period of from 24 to 44 months.⁸ Thus, while results of large prospective studies are needed to fully assure the relative safety of ERT administration after a diagnosis of breast cancer, there is a substantial group of authors advocating its selected use in these patients.⁹

Informed Consent

Informed consent is particularly important in a situation such as this when hormone replacement therapy is contraindicated or relatively contraindicated. Risks and benefits of ERT must be thoroughly and carefully discussed with the patient, and alternative therapies should be presented as well. Whenever a treatment plan has more than one option or is controversial, the legal requirements of informed consent should be fully satisfied not only to protect the clinician but also to aid the patient in making the best possible decision given her particular circumstances.

A full disclosure and review of the material risks associated with the proposed ERT regimen would be required, such as, for example, the possible risk of decreasing the disease-free interval and the possibility of thromboembolic events. A thorough discussion of the benefits of ERT, too, should be set forth so that the patient has as many facts at hand as possible. Non-hormonal alternatives to ERT should be offered by the physician as well. Informed consent discussions should be recorded in the patient's record.

Alternative Therapies

For breast cancer survivors, alternative therapies to ERT include all non-hormonal medications. With the introduction of alendronate, raloxifene and calcitonin nasal spray there are now multiple treatment options

for osteoporosis prevention and therapy. These rely on concomitant treatment with a standard regimen of calcium and vitamin D supplements, and offer bone protection without any of the risks associated with ERT.

For vaginal dryness there are many non-prescription lubricants. When these lubricants are not sufficient, however, the physician may wish to consider topical vaginal estrogen delivery systems or the estrogen-containing ring (Estring) for use in menopausal patients. The systemic absorption in post-menopausal women after the surge seen with the initial application was “virtually indistinguishable from the baseline mean (range 5 to 22 pg/ml).”¹⁰ This low absorption of estrogen from the estrogen ring reduces the risk/benefit ratio making its use worth consideration for treatment of the symptoms of dyspareunia and vaginal dryness.

Treatment of the vasomotor symptoms can be much more difficult without estrogen, despite the increasing number of products available through health food stores that proclaim their ability to treat menopausal symptoms. Ginseng, agnus castus, red sage, black cohosh, dong quai and beth root are examples of some of the herbal products touted to have estrogenic activity. One study of dong quai, however, did not detect effects on vaginal cellular maturation or hot flashes.¹¹ The belladonna compounds (Bellergal S) can be of help without the hormone risk, but can be sedating.¹² Transdermal clonidine in a 100-ug dose can give modest improvement in hot flashes usually with minimal side effects.^{13,14}

Undesirable mood shifts may present as depression, agitation, short temper, or ease of crying. Many of these symptoms can be controlled with selective serotonin re-uptake inhibitors instead of hormones.

Decisions

At the present time there are no completed double-blind studies noting the effects of ERT in breast cancer survivors, but some are in progress. If the non-hormonal agents fail to achieve their intended effects and

the problems associated with estrogen deprivation remain a major concern for the breast cancer survivor, ERT use may be medically justified. Each patient should determine the severity of her vasomotor symptoms, mood swings, and overall quality of life without estrogen replacement. This quality of life assessment should then be compared to the risks of taking estrogen with its effect on breast cancer.

After completion of the informed consent discussion with her physician, it is the patient’s responsibility to make the final decision as to her choice of regimen and to accept or decline hormone replacement therapy. Because of the concerns and risks—both medical and legal—careful documentation in the medical record is warranted. The physician should record not only the attempted alternative therapies, but also evidence of the informed consent analysis and discussion. Once the record is documented, the physician should feel assured that any legal ramifications pertaining to use of ERT in the breast cancer survivor have been satisfied.

“Risks and benefits of ERT must be thoroughly and carefully discussed with the patient, and alternative therapies should be presented as well.”

References

1. Vassilopoulou-Sellin R, Klein MJ. Estrogen replacement therapy after treatment for localized breast carcinoma. Patients responses and opinions. *Cancer*. 1996;78:1043-1048.
2. Eden JA, Bush T, Nand S, Wren BG. A case-controlled study of combined continuous estrogen-progestin replacement therapy amongst women with a personal history of breast cancer. *Menopause J North Am Menopause Soc*. 1995;2:67-72.
3. Cobleigh MA, Berris RF, Bush T, et al. Estrogen replacement therapy in breast cancer survivors: a time for change. *JAMA*. 1994;272:540-545.
4. DiSaia PJ, Creasman WT, Odicino F, et al. Hormone replacement therapy in breast cancer. *Lancet*. 1993;342:1232.
5. Stoll BA, Parbhoo S. Treatment of menopausal symptoms in breast cancer patients. *Lancet*. 1988;1:1278-1279.
6. DiSaia PJ, Grosen EA, Kurosaki T, Gildea M, Cowan B, Anton-Culver H. Hormone replacement therapy in breast cancer survivors: a cohort study. *Am J Obstet Gynecol*. 1996;174:1494-1498.
7. Vassilopoulou-Sellin R, Theriault R, Klein MJ. Estrogen replacement therapy in women with prior diagnosis and treatment for breast cancer. *Gynecol Oncol*. 1997;65:89-93.
8. Guidozi F. Estrogen replacement therapy in breast cancer survivors. *Int J Gynecol Obstet*. 1999;64(1):59-63.
9. Randomized clinical trials are currently underway, assessing the effects of hormone replacement on women with a history of breast cancer. See Pearlstone et al. Hormone replacement therapy and breast cancer. *Ann Surg Oncol*. 1999;6(2):208-217.
10. Estradiol vaginal ring absorption information, phase I study. *Physician's Desk Reference*. 1999;2483.
11. Hirata JD, Swiersz LM, Zell B, Small R, Ettinger B. Does dong quae have estrogenic effects in postmenopausal women? A double-blind, placebo-controlled trial. *Fertil Steril*. 1997;68:981-986.
12. Lebherz TB, French LT. Nonhormonal treatment of the menopausal syndrome: a double blind evaluation of an autonomic system stabilizer. *Obstet Gynecol*. 1969;33:795-799.
13. Nagamani M, Kelder ME, Smith ER. Treatment of menopausal hot flashes with transdermal administration of clonidine. *Am J Obstet Gynecol*. 1987;156:561-565.
14. Goldberg RM, Loprinzi CL, O'Fallen JR, et al. Transdermal clonidine for ameliorating tamoxifen-induced hot flashes. *J Clin Oncol*. 1994;12:158.

PRESIDENTIAL EMPHASIS ON MEDICAL ERRORS: A MAJOR QUALITY ASSURANCE INITIATIVE



by Frank T. Flannery, M.D., J.D., COL, MC, USA

President William Clinton proposed on February 22, 2000 that hospitals undertake a national effort to publicly report medical errors resulting in death or serious injury. The initiative followed the release in November 1999 of a report by the Institute of Medicine, which is part of the National Academy of Sciences. That report found that possibly as many as 98,000 Americans die unnecessarily each year as a result of medical and pharmacy errors.

Responding to a recent report released by the Institute of Medicine, President Clinton proposed a major initiative to publicly report medical errors in an effort to prevent the occurrence of injurious health care mistakes.¹ The proposal also would create an independent federal office to oversee such reporting, with a view toward promoting patient safety by establishing remedial standards to reduce medical errors. Under such a system, error reporting would be non-punitive, in the sense that further legislation would prevent information contained in such reported errors from being utilized against health care providers in possible subsequent malpractice suits.

This proposal followed the release in November 1999 of a critical report by the Institute of Medicine, a part of the National Academy of Sciences. That report estimated that up to 98,000 patients in the United States die needlessly each year as a result of medical errors.² This fatality total far exceeds the number of annual deaths from AIDS, motor vehicle accidents, or breast cancer.³ (See Table 1.) Moreover, these deaths as a result of

medical errors, according to the report, cost the nation almost \$29 billion a year.⁴

In the face of similar losses, the Institute of Medicine Report noted, other sectors of the economy have responded in different positive ways. Responses to rising motor vehicle accident deaths, as well as airline crashes and nuclear reactor disasters, have included carefully coordinated studies which seek to analyze the cause of the incident. This allows for subsequent remedial measures to prevent such future incidents. In medicine, however, no similar central reporting system for medical errors presently exists, resulting in a lost opportunity to prevent future errors.

To highlight the nature of the problem, the report emphasized that medication errors are not only common, but also preventable. In Massachusetts alone, it was noted, estimates are that 2.4 million prescriptions are improperly filled on an annual basis.⁵ Moreover, 88% of these errors involved dispensing either the wrong drug or the correct drug at the wrong strength.

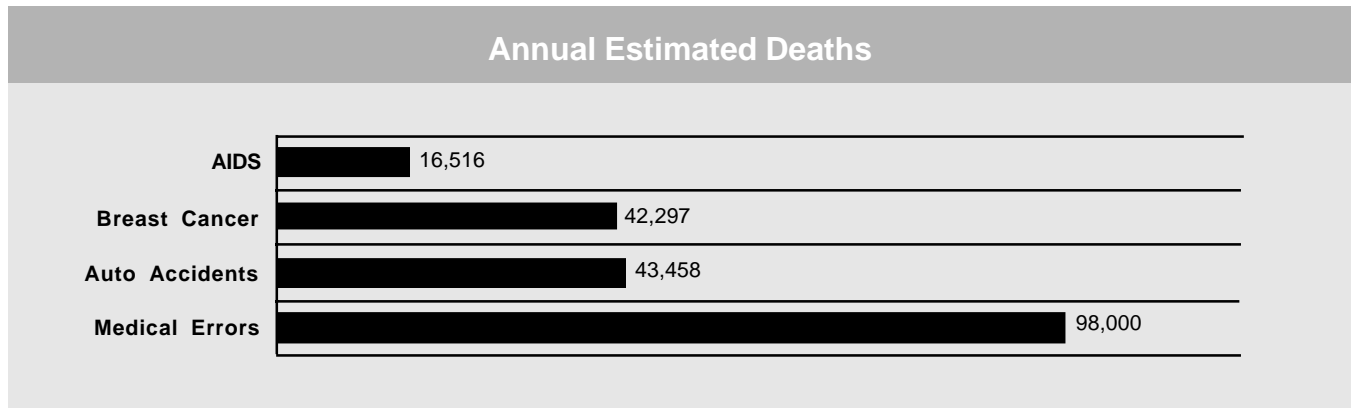


Table 1

Contributing factors included many drugs with similar names, the lack of routine screening for potential adverse drug interactions, and incorrect mathematical dosage calculations, among others.⁶

Many other examples were also given, including improper mechanical operation of an intravenous infusion device. This error, in turn, could have several other contributing factors, namely mechanical malfunction of the apparatus, improper programming of the rate of administration, and negligent monitoring. A misdiagnosis of a medical condition could likewise have several root causes, such as mislabeling of a blood specimen in the laboratory, and negligent reliance on such erroneous data by health care providers.

The President’s proposal for mandatory reporting, however, was not immediately endorsed by all. Dr. Nancy Dickey, past president of the American Medical Association, expressed concern that medical errors would be driven “underground” by any such mandatory system. Her reasoning was that providers would be concerned that mandatory disclosure of medical errors would be followed by increased malpractice litigation. Likewise, a spokesman for the American Hospital Association expressed fear that central medical error reporting would set members of the legal community on widespread “fishing expeditions.”^{7,8}

Most, however, hailed the proposal. In support of the effort, an increase of \$20 million in funding for the

Agency for Healthcare Research and Quality was also announced. The plan is to expend the funds to create a national center to coordinate and fund patient safety research, with a view toward nationwide reduction of preventable medical errors.

Overall, seasoned observers expect that the Presidential emphasis, coupled with substantial funding, will combine to form a lasting effort to identify and analyze recurrent medical errors in both the Federal and private sector. This could allow for a long-term opportunity to construct practical, meaningful strategies for medical error reduction.

References

1. Kaufman M. Clinton seeks medical error report. *The Washington Post*. February 22, 2000:A2.
2. Weiss R. Medical errors blamed for many deaths. *The Washington Post*. November 30, 1999:A1.
3. Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human. Building a safer health system*. Institute of Medicine. Washington, DC: National Academy Press; 1999:22.
4. Weiss, *supra* note 2.
5. Kohn et al, *supra* note 3, page 33.
6. See also page 35 of this publication, *Legal Medicine 2000*, for a comprehensive review of medication errors.
7. Kaufman, *supra* note 1.
8. Id.

Managing Risk Through Autopsies

By Jennifer L. Walters, J.D.

The Greek word “autopsy” means “to see with one’s own eyes.”



Autopsies have always been an important risk management and quality improvement tool for the medical community.¹ Within the last 50 years, however, autopsy rates have declined dramatically, falling nationwide from a high of 50-60% to a low of 5-10%.^{2,3} In some areas of the country, autopsy rates have fallen well below 5%, especially in non-teaching hospitals. One reason for this decline is the number of discrepancies found between the clinical diagnosis and the actual cause of death determined at autopsy. In some of these cases, physicians may be more concerned about the potential for uncovering negligence than they are about the myriad of benefits provided by autopsies.⁴

The ability of autopsies to monitor public health by identifying new diseases and changes in existing ones is an important benefit.⁵ This is especially true when a condition such as hereditary hemochromatosis or cancer is detected at autopsy. Such autopsy results may produce unexpected findings that can actually benefit the next-of-kin. For example, a man was presumed to have died suddenly from intestinal bleeding caused by an ulcer. However, his autopsy showed that he actually died from a small colon cancer that had eroded an artery. When the brother and sister of the deceased were tested for colon cancer, both had pre-malignant polyps that were removed before they turned malignant.⁶

There are two primary reasons why autopsy rates have declined. Some physicians believe that the autopsy has lost its value in today’s high-tech world.⁷ Because of the major advances in technology, more avenues for medical diagnostic testing are now available. The rationale is that since diagnostic tools have improved substantially, the clinical usefulness of autopsies has decreased. However, autopsies can sometimes clarify potential medicolegal issues surrounding death. According to a study completed in 1998, 44% of autopsies revealed a cause of death that had not been previously diagnosed. Two-thirds of those causes were treatable conditions.⁸

Another reason why autopsy rates have declined is that some physicians fear an autopsy might provide medical information that could potentially be used against them in malpractice actions. However, in the study noted above, most of the misdiagnoses indicate a lack of advanced medical technology as opposed to physician

negligence. In fact, “most medicolegal experts believe that thorough postmortem examinations much more often than not provide factual, objective information to the decedent’s families that negate their suspicions and obviate their desire to pursue a medical malpractice lawsuit.”⁹ The autopsy can produce information that might not have been otherwise obtained by advanced diagnostic testing or by a physician’s examination. Thus, the effect of performing more autopsies may actually improve high-tech diagnoses by learning from the discrepancies between the postmortem examination and the antemortem diagnosis.

Every physician should be familiar with state statutes regarding autopsies. Each state has different laws and circumstances under which autopsies may be performed, but in almost all cases an autopsy may be ordered by a coroner or medical examiner if there is suspicion of foul play or a public health concern. When an autopsy is not ordered or required, one may often be performed at the request of the deceased’s family or a physician who has first obtained the proper consent from legal next-of-kin.¹⁰ However, there have been cases where next-of-kin have challenged the performance of an autopsy based on their religious and spiritual objections. The underlying argument is that the possible medical benefits of an autopsy are outweighed by strong cultural beliefs and the emotional trauma of an autopsy.¹¹

Recently, there have been measures taken to increase autopsy rates. The Veterans Health Administration (VHA) amended a directive entitled “The Autopsy as a Critical Component of Quality Management.”¹² The VHA has defined its policy as “permission to perform an autopsy shall be requested in every instance a patient dies while an inpatient at a VHA facility or under the immediate care of a VHA facility (such as during an outpatient or emergency care visit, or during an ambulatory care procedure).”¹³

The VHA’s goal is to increase autopsy rates to 30% for all in-house deaths.¹⁴ Although the directive states that an autopsy should be requested in every death, it

should be recognized that this may not be possible. To maximize the chances of receiving permission, physicians or other medical facility employees should be trained and well-versed in explaining the autopsy procedure and benefits to the next-of-kin. If a physician does not feel comfortable requesting an autopsy, the medical institution should have another employee or “family advocate” request permission.¹⁵

Other suggestions to improve autopsy rates include improving communication between clinicians and families, such as inviting attendings, house staff, and students to attend the actual autopsy and post-autopsy conferences, and communicating the autopsy results to the family as soon as it is available. Altering methods of obtaining consent, altering autopsy procedures, and educating both medical professionals and the public about the value of autopsies have also been suggested.¹⁶

Despite some physicians’ beliefs that the autopsy has lost its value because of improved medical technology, and while others may not request an autopsy for fear of misdiagnosis and negligence implications, there exist, however, many important constructive uses for autopsies. These include improving patient care and safety, educating medical professionals, analyzing potential medicolegal risks, reducing unnecessary litigation, providing public health benefits, and improving quality assurance. As quoted by one scholar, “the most obvious value of the autopsy is quality assurance: to compare the clinicians’ postmortem clinical diagnosis with the precise, anatomical cause of death.”¹⁷

The autopsy remains an important educational tool for the medical community and the public. In order to benefit from autopsies, they must be performed. Physicians must be familiar with state statutes regarding autopsies, and permission to perform an autopsy must be attempted in every instance of death. Autopsies provide quality assurance and improvement for medical institutions, the physicians involved, future patients and family members.

References

1. Zarbo RJ, Baker PB, Howanitz PJ. The autopsy as a performance measurement tool—diagnostic discrepancies and unresolved clinical questions. *Arch Pathol Lab Med.* 1999;123:191-198.
2. Burton EC, Troxclair DA, Newman WP III. Autopsy diagnoses and malignant neoplasms: how often are clinical diagnoses incorrect? *JAMA.* 1998;280:1245-1248.
3. See Peterkin T. Half of Scots autopsies are “unnecessary.” *Scotland on Sunday.* June 20, 1999. 1999 WL 5909444. In this newspaper article it is argued that Scotland’s medical institutions perform too many autopsies because they are ordered to do so by the authorities. “Power to investigate and perform autopsies should be more limited. There should be a requirement to take into account the views of the next-of-kin.” *Id.*
4. Lynn J, Cobbs E, Orenstein J. Autopsy rates and diagnosis. *JAMA.* 1999;281:2184.
5. See Schwartz DA, Herman CJ. The importance of the autopsy in emerging and reemerging infectious diseases. *Clin Infect Dis.* 1996;23:248-254.
6. Gott P. Autopsies provide practical benefits to the living. *The Commercial Appeal.* January 3, 1999; Living Section: Health.
7. Lundberg GD. Low-tech autopsies in the era of high-tech medicine: continued value for quality assurance and patient safety. *JAMA.* 1998;280:1273-1274
8. Nichols L, Aronica P, Babe C. Are autopsies obsolete? *Am J of Clin Pathol.* 1996;110:210-218.
9. Lynn, *supra* note 4. See also Zarbo, *supra* note 1.
10. It is important for a physician to adequately obtain consent to perform an autopsy. There have been many lawsuits brought by the next-of-kin when autopsy consent was wrongfully or mistakenly obtained. See *Scarpaci v. Milwaukee County*, 96 Wis.2d 663, 292 N.W.2d 816 (1980).
11. See generally *City of Boerne v. Flores*, 521 U.S. 507, 117 S. Ct. 2157 (1997); compare *Yang v. Stuermer*, 750 F.Supp. 558 (R.I. 1990), where the court ruled that even though the statute governing autopsies did profoundly impair the plaintiff’s religious freedom, they had no constitutional rights to prevent the autopsy.
12. U.S. Department of Veterans Affairs. The Autopsy as a Critical Component of Quality Management. Washington, DC: Veterans Health Administration; February 26, 1999. VHA Directive 99-004, Change 1. The VHA holds an annual Autopsy Best Practices conference to share ideas and discussions to improve autopsy rates within their medical facilities.
13. VHA Directive 99-004, *supra* note 12.
14. The VHA autopsy reporting form defines “in-house deaths” as deaths of veterans that occur while they are admitted to a VA facility, excluding deaths that occur at home, in a non-VA nursing home, and deaths of veterans who are enrolled at a VA facility but died while admitted to another VA or non-VA facility.
15. At the VHA Autopsy Best Practices Conference on September 15-16, 1999, a suggestion was made to call the employee in the Office of Decedent Affairs who spoke with the families and explained autopsies to them a “family advocate.” This family advocate would be responsible for discussing with the patient’s family the funeral arrangements and death benefits and for requesting an autopsy. The request would then be thoroughly documented in the patient’s file.
16. Lynn, *supra* note 4.
17. Dalen JE. The moribund autopsy. DNR or CPR? *Arch Intern Med.* 1997;157:1633.

A Compilation of Legal Issues Facing Health Care Professionals Who Provide Medical Information Over the Internet

By Jason F. Kaar, J.D., MAJ, USAF, JA*

IN THIS COLUMN, A SENIOR ATTORNEY SHARES HIS INSIGHT ON INTERNET MEDICAL USE AND ABUSE.



These days almost any sort of product, information, or service is available on the Internet, or World Wide Web. A typical user can find airline schedules, toys, gardening tips, books, current news and sports scores, weather conditions, and popular restaurants in Paris, as well as pornography or directions for making a bomb. Electronic commerce (e-commerce) and its related activities now represent more than 500 billion dollars a year and are directly connected to an estimated 2.3 million jobs.¹ One of the fastest-growing areas of e-commerce is in the field of health care and its related industries. While this represents tremendous opportunities for both entrepreneurs and the general public, there are potential pitfalls for those who intend to utilize e-commerce for the delivery of health care or health care information. What follows are some of the issues that face health care practitioners who use or are considering the use of electronic media for business or informational purposes.

**MAJ Kaar is the Brigade Judge Advocate for the Uniformed Services University of the Health Sciences in Bethesda, MD. He serves as Legal Advisor or Consultant to many military organizations.*

Non-Individualized Posting of Health Information

One could argue that web posting of general health-related information for the public to read is similar to publishing articles in medical journals such as the *Journal of the American Medical Association* or the *New England*

Journal of Medicine. Unlike these journals, however, the web is not peer-reviewed. Its postings are not necessarily backed by documented research analyzed by medical authorities, and the reliability of the information presented may be suspect. Moreover, a website's reasonably anticipated audience consists of "average" individuals without the intensive medical background and knowledge of those who usually read professional medical journals.

“...written consent to send sensitive information to the patient via e-mail should be obtained...”

With this in mind, it is recommended that a disclaimer be inserted at least once at the beginning of the website. Such a disclaimer would preferably be set so that before an article could be accessed, the individual user must take overt action (such as clicking on a pop-up box) to acknowledge that the information is for general purposes only and is not intended to deal with a specific situation.²

Interactive Sites

An interactive website contains additional potential problems. While there are variations of interactive sites, generally users type in individualized questions and they receive individualized responses. But who responds? And who does the asking? Has a patient-practitioner relationship been established?

One significant factor that courts have relied on to make such a determination is whether or not a fee is charged to engage the site and obtain a specific answer. If money has indeed changed hands, so to speak, the probability ensues that a court will determine the existence of a patient-practitioner relationship. Once this relationship is established at law, the provider will then likely be subject to all the legalities that apply in face-to-face

encounters. In addition, some jurisdictions claiming dominion over these activities may have additional special rules for telehealth encounters.

If the service is given free of charge, the information provider may be able to avoid the establishment of a patient-practitioner relationship and its ensuing liability. Another method to try to limit the potential for liability exposure is to place a disclaimer, similar to the one found at Reference 2, at the entrance to the site. Thereafter, every response should begin with a statement disavowing a practitioner-patient relationship and recommending that the questioning individual consult his or her own personal health care provider.

Website Review

Whether a provider answers specific questions with preset protocols (as many "ask-a-nurse" hotlines do) or simply places information on the Internet, the website should be regularly reviewed and its information updated. It is always best to include the date of the review or update on the site as well.

Linked Goods and Services

Often when we think of health care deliverers we think in terms of physicians and nurses, but especially in telemedicine we need to broaden our frame of reference. We need to look beyond this small professional grouping to see what else is offered and by whom.

Currently, one of the most popular medically related websites is drkoop.com, originated and named after former United States Surgeon General C. Everett Koop. Presently on this site, along with a myriad of other health-related subjects, is an advertisement for and a link to a mail-order pharmacy that promises to provide prescription drugs at a discount. A quick review of several state pharmacy laws suggests that this could pose a licensing problem. As an example, the Commonwealth of Virginia requires that any person who engages in "the practice of pharmacy" by dispensing "drugs within this Commonwealth" must be li-

censed in Virginia.³ Based on the wording of the statute, mail order and internet pharmacies that ship their products into Virginia may be “dispensing,” and therefore may be required to be licensed in Virginia. Failure to be licensed may subject the pharmacy to potential criminal and civil sanctions.

Interstate Problems

Traditionally the regulation of health care in the United States has been a function of state government. As early as 1888, the U. S. Supreme Court recognized the ability of states to determine who could practice medicine within their borders and under what conditions.⁴ But which state controls what happens over the Internet? Where is the practice of medicine (or pharmacy as discussed above) occurring? Is it the location of the health care provider or the location of the patient? If it is occurring where the patient is, and the patient is in a different state from the health care provider, that health care provider might be practicing medicine without a license.

If the practitioner is deemed to have practiced medicine without a license, does his or her medical malpractice cover what the courts have declared to be an illegal act? All these are valid issues to consider.

Intrastate Regulations, Too

At first blush, it would appear that a health care practitioner located and licensed in one state providing direct care and treatment for someone also in that same state via the Internet would be free from regulatory difficulties. This is not the case, however. Dr. “Y,” a California osteopath who specialized in hair transplantation, decided to conduct hair loss consultations and recommend baldness treatments over the Internet. In order to sell the hair-growth pill Propecia, Dr. Y undertook online consultations at a price of \$50, whereby the “patient” would check off various blocks on an online form, perhaps along with some additional information. Such interaction, coupled with \$150 for a 3-month supply of Propecia and \$6 for postage,

was all that was needed to obtain this potentially dangerous substance.⁵

“The website should be regularly reviewed and its information updated.”

After an undercover agent filled out the appropriate online form and paid the required fees, Dr. Y was charged with gross negligence by California Medical Board authorities for violating state codes by prescribing dangerous substances without first conducting a “good-faith medical examination.”⁶ In his defense, Dr. Y stated that while it is true the “patients” completed the online forms themselves, he reviewed each form and wrote back and forth via electronic mail (e-mail) to the “patients” to determine their specific needs.

California authorities seem to have taken the position that a physical exam must be appropriately performed in person, and not over the Internet. The California Deputy Attorney General handling the case stated: “Over the Internet, the patient is the one who is diagnosing his condition.”⁷ Viewing this case as a whole it leads one to conclude that had Dr. Y originally seen the patient in person and then followed up via e-mail or other internet interaction, the situation probably would have been viewed in a much different light.

State laws are not the only obstacles to practices such as Dr. Y’s. The U. S. Department of Justice’s Office of Consumer Litigation has been looking into Internet-based health care, specifically when it involves the dispensing of prescription drugs. It is the opinion of the Justice Department that under the provisions of the Safe Food, Drugs and Cosmetics Act, the issuance of a prescription without a valid medical examination violates the Act, subjecting the provider to criminal and civil penalties.⁸

Online Medical Records

Online access to personal medical information is a concept that is beginning to catch on throughout the high-tech medical community.⁹ The notion is that all health care providers and patients with Internet access (a continually growing number) will be able to review and maintain their individual medical records so that valuable information would not be overlooked in the future. Patients would wear or carry medical information identification bands (much like medical alert bands) with the name of a particular website and the specific password needed to access their medical records. In an emergency or in the event the patient was unable to provide answers to pertinent medical questions, health care professionals could access his or her complete medical record, allowing them to dispense with needless tests and more quickly identify and treat the underlying medical condition.¹⁰

While this concept has a lot of promise, problems with Internet security need to be addressed and alleviated. An individual's privacy could be violated by the accidental or intentional release of the password. There is also the likelihood that a hacker could access an individual's medical records and either remove important information or add false information, thus endangering the individual involved.

Keep That E-Mail

The ability to communicate with others via e-mail has proven to be a great link between people all over the world. Because of the relative ease of use, an increasing number of health care practitioners are communicating with their patients using e-mail to answer medical questions and provide advice. While this is a beneficial use of time and technology, it must be remembered that in many ways it is just like any other consultation, and therefore copies of all e-mail messages and related information should be made part of the patient's permanent record. It is also important to remember that additional people (typically a spouse, children and

perhaps even employer or co-worker) may have access to a patient's e-mail account, so written consent to send sensitive information to the patient via e-mail should be obtained in advance.

Is It Legal?

In September 1999 an unknown individual posted for sale on eBay.com—an electronic online auction site—what was advertised as a “fully functional kidney.”¹¹ The sale of human organs is a violation of U.S. federal law punishable by up to 5 years in prison and a \$50,000 fine.¹² Bidding on the kidney reached \$5.75 million before eBay terminated the listing.

Still more bizarre is the website posted in October 1999, ronsangels.com. It proclaims that it is the “only web site that provides you with the unique opportunity to bid on eggs from beautiful, healthy and intelligent women.” Bids may start from \$15,000 to \$150,000 in \$1000 increments.¹³ Assuming the legitimacy of the “egg auction,” it should be noted that this practice appears to be legal at the present time.

Federal Responses

In June 1999 the Federal Trade Commission launched what it calls “Operation Cure.All,” a campaign to curb fraudulent health claims on the Internet.¹⁴ Prime targets were identified as those Internet activities that made “unsubstantiated health claims.” In addition, the Department of Health and Human Services has established a website (<http://www.healthfinder.gov>) as a gateway for reliable health-related information. Certainly this site can assist curious Web surfers to filter information, but it cannot do the job by itself.

The Clinton administration has proposed that online pharmacies (like traditional ones) must be approved by the Food and Drug Administration (FDA) before they can lawfully operate. According to FDA Commissioner Jane E. Henney, M.D., fines up to \$500,000

could be assessed for dispensing drugs without a prescription or operating without an FDA certification.¹⁵

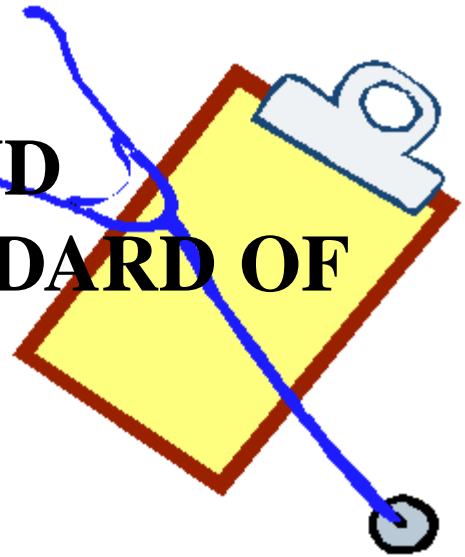
As the Internet and its health care applications evolve, rules pertaining to them and their uses will also evolve. Until such time as lawmakers and the courts assist in providing needed clarity to these rules and regulations, it is important for health care providers who integrate the Internet into their practice to evaluate the potential problems that may lie ahead. Keep in mind that it is always best to seek the advice of an attorney knowledgeable in this aspect of the law and to periodically determine if there is any legal or Internet update that may impact your use of the “net” to provide medical information.

9. See, e.g., <http://www.personalmd.com>.
10. See <http://www.drkoop.com/aboutus/products/pmrtdour/printable.html>. Accessed October 7, 1999.
11. Online bidders offer millions for human kidney. *Reuters News Service*. September 3, 1999.
12. 42 USC 274e.
13. See <http://ronsangels.com> where a sperm auction is also presently available with a minimum bid of \$15,000. Accessed February 23, 2000.
14. FTC tackles fraudulent Internet health claims. *Reuters News Service*. June 24, 1999.
15. Greider L. Assuring the safety of drugs sold online. *AARP Bulletin*. February, 2000;41:2.

References

1. Nathan S. Internet economy soars 68%. *USA Today*. October 27, 1999:1A.
2. Such a disclaimer might read: “The information contained on this site is for general health information only. It is not medical advice. Never substitute any information or advice from the Internet for bona fide health care. You should consult with your health care provider before undertaking any action based on information or advice found here or elsewhere on the Internet. We do not warrant, represent, or endorse the accuracy or reliability of any information, products, advertisements, or links downloaded or accessed from this website.”
3. VIRGINIA CODE ANN. § 54.1-33.
4. See *Dent v. West Virginia*, 129 U.S. 114 (1888), in which West Virginia’s licensing requirements are upheld.
5. Propecia carries possible side effects including possible liver damage and may cause damage including malformation in male fetuses if a pregnant woman touches the raw substance.
6. McKee M. Hair today, gone tomorrow. *The Recorder/Cal Law*. June 17, 1999.
7. *Id.*
8. Comments by Mr. Eugene Thirof, J.D., Office of Consumer Litigation, United States Department of Justice, before the National Conference on Legal and Policy Developments, October 13, 1999, at the Hart Senate Office Building, Washington, DC.

FAMILY PRACTICE AND THE REQUISITE STANDARD OF CARE



By George F. Fuller, M.D., COL, MC, USA* and
Frank T. Flannery, M.D., J.D., COL, MC, USA

Family practice is still a relatively new medical specialty. Its comprehensive scope and widespread growth have challenged traditional concepts of medical liability and the requisite standard of care. Eventually a distinct family practice standard will probably evolve. In order to predict what that standard will be, it is useful to examine the origins of the specialty and the treatment accorded family practitioners and other generalists by various courts.

Traditionally, general practitioners were held to a lower standard of care than specialists. General practitioners were legally required to exercise reasonable care defined as that standard of care practiced by other reasonably prudent general practitioners in the same or similar circumstances.¹ Specialists, on the other hand, were expected to exercise that higher degree of skill and learning possessed by specialists in similar circumstances.² Additionally, specialists were the first to be held to a “national standard” rather than a local one reflecting the national basis of medical education and practice as distinct from local community practices.³

The American Academy of General Practice was founded in 1947, and in 1971 the name was changed to the American Academy of Family Physicians.⁴ This change reflected the reorientation of primary health care in which family doctors were increasingly providing comprehensive health care to the public. Family practice has emerged as a comprehensive specialty that covers a wide spectrum of health problems affecting patients of both sexes and all ages. The specialty integrates the biological, clinical, and behavioral services in providing comprehensive care for all family members.⁵

In 1969, the American Board of Family Practice was officially recognized as the twentieth medical specialty, and today all candidates for Board examination must have completed 3 years of training in a family practice residency program

*Assistant Professor, Department of Family Medicine, Uniformed Services University of the Health Sciences, F. Edward Hebert School of Medicine; Fellow, American Academy of Family Physicians; Diplomate, American Board of Family Practice; Staff Physician, White House Medical Unit, Washington, DC.

accredited by the Accreditation Council for Graduate Medical Education (ACGME).⁶ Currently, family practitioners receive formal training and practice in areas in which general practitioners rarely ventured, such as dilatation and curettage, performance of high-risk obstetrics and Caesarean sections, colposcopy, colonoscopy, esophagoduodenoscopy, graded exercise testing and sophisticated orthopedic treatment.⁷ These procedures add substantial risk to the clinical encounter and easily fall within the domain of “specialized care.”

Legal Interpretations

Such broad practice parameters utilized by today’s family physician challenge traditional notions of separate standards of generalist and specialist, and court results to date have been inconsistent. For example, in the case of *Chapel v. Allison*,⁸ a general practitioner in Montana treated an injured patient who had been kicked by a horse. An X-ray showed a comminuted tibia fracture, to which the physician applied a long leg cast. Removal of the cast several months later revealed a varus deformity necessitating a subsequent osteotomy to straighten the bowed leg. The question at law was whether the physician should be held to the standard of the generalist or the orthopedic specialist. The court recognized that this injury clearly fell within the area of orthopedics, but nonetheless held that this defendant and other general practitioners should only be held to the standard of other reasonably competent general practitioners – not to the standard of an orthopedic surgeon.⁹

An analogous result was reached in the case of *Birmingham v. Vance*¹⁰ in which a general dentist performed a root canal normally performed by specialists in endodontics. The plaintiff attempted to introduce the specialist’s testimony, but the court rejected it stating that general dentists should only be held to the lower general practitioner standard. To this Michigan court, it did not matter that the defendant was “performing procedures regularly conducted by specialists.”¹¹

Other courts have reached different conclusions. In the case of *Simpson v. Davis*,¹² the court stated that if a physician practices as a specialist, he can be held to the higher standard of the specialist even if he is not formally trained and not board certified in that specialty. Furthermore, another court in *Simone v. Sabo*¹³ held that the practice of treating diseases normally handled by specialists amounts to the physician holding himself or herself out to the public as a specialist. Even if a generalist knew that the patient could have benefited from specialty care, this could result in the generalist being held to the higher specialist standard.¹⁴ Under this theory, treating disease processes normally treated by specialists will result in physicians being held to the higher standard.¹⁵

An interesting case with specific reference to family practice is the recent Rhode Island case of *Sheeley et al v. Memorial Hospital et al*¹⁶ in which a family practice resident performed an episiotomy that subsequently resulted in a rectal-vaginal fistula. In the ensuing malpractice suit, the defendant attempted to exclude the expert testimony of a board-certified obstetrician/gynecologist arguing that the specialist was not qualified to testify about the standard of care pertaining to family practice residents. The court ruled the testimony to be admissible since the focus in any malpractice case should be the procedure, such as the episiotomy in this case. The expert would not have to be trained in the defendant’s specialty, but must only be familiar with and trained in the performance of the actual procedure. Under this reasoning, any expert in family practice or in another specialty may testify as long as they have training and experience in the specific procedure in question.

Managed Care

Some commentators argue that as family practitioners increasingly assume the “gate-keeping” function in managed care, the standard of care should be explicitly redefined. In other words, because family practitioners and other primary care providers in a managed care

environment are under cost containment restraints, they are obliged to perform services traditionally provided by specialists to whom patients were formerly referred.¹⁷ Some would therefore argue that a new, more realistic standard of care should be applied to the managed care physicians in order to relieve them of the higher specialty standard of care. Under this theory it is unfair to hold generalists to specialty standards while at the same time discouraging them from freely seeking specialty consultation as they had in the past. As of the present, however, no court has adopted this theory.

Currently, it is reasonable to assume that family practitioners will usually be held to a standard established by expert testimony and that this testimony will be given by both fellow family practitioners and specialists familiar with the actual procedure or treatment. As previously stated, family practice is still a relatively new specialty, and it may take several more years of appellate judicial opinions to more clearly define an actual family practice standard of care. Both the medical community and the legal community await these decisions.

References

1. *Lawless v. Calaway, et al.*, 24 Cal.2d 81, 147 P.2d 604 (1944).
2. *Hall v. Hilbun*, 466 So.2d 856 (Miss. 1985).
3. *Bates v. Meyer*, 565 So.2d 134 (Ala. 1990).
4. American Academy of Family Physicians. 1999 Facts about Family Practice. Available at www.aafp.org/facts. Accessed February 11, 2000.
5. *Id.*
6. Marquis Who's Who, The Official ABMS Directory of Board Certified Medical Specialists 1999, page 947.
7. *Supra* note 4.
8. 785 P.2d 204 (Mont. 1990).
9. *Id* at 210.
10. 516 N.W.2d 95 (Mich. App. 1994).
11. *Id* at 99.
12. 219 Kan. 584, 549 P.2d 950 (1976).
13. 37 Cal.2d 253, 231 P.2d 19 (1951).
14. *Sinz v. Owens*, 33 Cal.2d 749, 205 P.2d 3 (1949).
15. *Belk v. Schweizer*, 268 N.C. 50, 149 S.E.2d 565 (1966).
16. 710 A.2d 161 (R.I. 1998).
17. Friedland B. Managed care and the expanding scope of primary care physicians duties: a proposal to redefine explicitly the standard of care. *JL Med & Ethics*. 1998;26:100.



Medication Errors

By Georgia A. Martin, J.D., Ph.D., MSN

Health care professionals have almost unlimited opportunities to make medication errors. With more than 8,000 drugs to choose from, the most educated of professional health care providers make medication errors, and somewhat less experienced providers such as physician assistants compound the problem.¹

The Institute of Medicine's report, *To Err is Human*, indicated that 2.5 billion prescriptions were filled during 1998. In hospitals, approximately 3.75 billion drugs are administered annually to inpatients. In one large teaching hospital, the medication error rate was estimated to be 3.13%. Although most medication errors are not serious, acknowledged medication errors killed 7,391 people in 1993.²

Medication errors are caused by numerous factors. Common causes include sleep deprivation, mental lapses, fatigue, inadequate knowledge of drugs, inadequate knowledge of a patient's existing medical conditions, use of multiple drugs, allergies, deviations from medication rules and procedures, faulty drug identification, transcription and handwriting errors, and dosage errors. Other causes include infusion pump/parenteral administration errors, inadequate monitoring, faulty drug stocking or delivery methods, preparation errors, lack of standardization, or confusion about a patient's identity.³

Legal Issues Regarding Medications Errors

Approximately 30% of all malpractice claims involve drug-related injuries. An average payment of \$99,721 was made for 2,195 out of the 6,646 claims reported to the Physician Insurers Association of America during the period 1985 through 1992.⁴ Anyone who manufactures, sells, distributes, prescribes, dispenses, or administers drugs, as well as the health care facility that employs them or places the medication in their formulary can be sued for subsequent patient injuries.⁵

Theory of Liability

Health care providers sued for medication errors generally incur liability under the theory of negligence. Negligence is a tort that relates to an injury caused by conduct that deviates from a “standard of care.” Medical malpractice is a type of negligence that denotes an injury to a patient caused by a health care provider’s conduct that deviates from a professional standard of care. In a malpractice claim of a medication error, a jury assesses a health care provider’s behavior to determine whether it adhered to the professional standards of practice required by both his profession and the law. In determining the strengths and weaknesses of the case, the plaintiffs and defendants often will hire expert witnesses with similar experiences and training to analyze the medical records and determine whether the health care provider’s actions were within acceptable standards of practice.

“Teaching patients about their medication also helps to prevent medication errors.”

Malpractice Defenses

Defenses are legal justifications to escape alleged liability from lawsuits. Medical malpractice claims for medication errors are seldom defensible and frequently result in substantial payments for resultant patient injuries. The traditional defenses to lawsuits for patient injuries caused by medication errors include lack of proximate causation, bad outcome or other explanations for patient injuries, contributory and comparative negligence, statute of limitations, and the Federal Tort Claims act that specifically protects federally employed health care providers from liability.⁶

Another defense deserving mention is the “learned intermediary” doctrine. Under this doctrine, drug

manufacturers claim to fulfill their duty to warn consumers about the hazards associated with their products by warning physicians of known risks, side effects, and contraindications. Except for a number of limited exceptions, it is the physician’s sole responsibility to interpret the scientific/medical information supplied by the manufacturer regarding potential risks and benefits of prescription drug therapy. Despite the warnings included on the package inserts, the physician or prescriber determines which warnings to give the patient during the informed consent process. The doctrine implies that the manufacturer has accurately and completely informed the physician of all the risks associated with a particular drug. Some courts have refused to enforce the doctrine when the manufacturers’ warnings to the physicians were inadequate or defective. A warning may be defective if it did not disclose safety and efficacy data to the Food and Drug Administration that should have been included in the product labeling. The adequacy of the warning depends on what risks were included on the label, whether the warnings were conveyed to the physician in an appropriate manner under the circumstances, or whether the risks were downplayed during aggressive marketing campaigns.⁷

Informed Consent

Malpractice claims for medication errors frequently allege that the patient was inadequately educated about a medicine – for example, its risks, its side effects and what to do if they occur, or the consequences of failing to take the medication appropriately.

Prior to administering new medications, as with all other procedures or treatments, a health care provider must obtain the patient’s informed consent. Informed consent involves the disclosure of the material risks, benefits, and alternatives to a medication, procedure, or treatment to a patient. The adequacy of this disclosure often forms the basis of informed consent litigation. The majority of states use the “reasonable practitioner” standard to determine the degree of disclosure required. This standard requires a practitioner to disclose the

information that most practitioners in similar circumstances would disclose. Most of the remaining states use the “reasonable patient” standard that requires the practitioner to disclose the information that a reasonable patient in similar circumstances would want to know. A few states use the “subjective patient” standard that requires the practitioner to disclose the information that a particular patient would want to know. The courts do not generally accept this standard, however, because it is too susceptible to manipulation.⁸

Traditional informed consent components include a discussion of the following: 1) the medical problem necessitating a proposed medication, treatment or procedure; 2) an explanation of the therapy’s purpose, description, and probable outcome; 3) likely benefits; 4) probable complications, any temporary pain, or discomfort; 5) probable permanent results, disfigurement, disability, scarring, and required care and related medical costs; 6) known, anticipated, or foreseeable material risks to include possible death; 7) alternative procedures and treatments and their known side effects, risks, and benefits to include no treatment at all; and 8) the consequences and rights of the patient to refuse or withdraw consent for any reason. Risks that usually need not be disclosed are commonly known risks or remote risks unless the risk is significant to the patient.

When obtaining informed consent use words, phrases, and language the patient understands. Completely document all discussions of informed consent in the medical record because these records may be used as evidence at trial. Include how much time was spent in the discussion, what was discussed, and whether written information was provided. Allow opportunities for the patient to ask questions. Evaluate the patient’s level of understanding by asking the patient questions and through the use of a check sheet maintained as a permanent part of the medical record.

Case Reviews

In *Harris County Hosp. Dist. v. Estrada*,⁹ a medical resident prescribed Bactrim for a 73-year-old patient.

The patient immediately had a reaction and died 16 days later. The patient’s family sued the physician, the hospital, and the nursing, clerical and pharmacy staff. Prior to trial the resident settled the claim against him for \$230,000. At trial it was learned that the defendants relied on a computer generated Medication Administration Record (MAR) which listed “no allergies” for the patient. The defendants failed to thoroughly review the patient’s medical records for allergies or check the MARs for any inconsistencies. The court concluded that the defendant health care providers had failed their responsibilities to verify the appropriateness of the patient’s prescriptions and to bring potential problems to the attention of the prescriber. The plaintiffs were awarded \$350,000 in damages.

“Approximately 30% of all malpractice claims involve drug-related injuries.”

In *Pellerin v. Humedcenters, Inc.*,¹⁰ a patient was admitted to a hospital’s emergency department complaining of chest pain. Following an evaluation by a staff physician, an intramuscular injection of Demerol and Vistaril was given in the patient’s left hip. The patient sued when the site became irritated, painful, and red. At trial 10 years later, the defendant health care provider could not remember giving the injection. The patient’s medical records indicated that the defendant had signed the medication administration sheet, but she failed to document the time, location, or the injection technique. This lack of documentation allowed the jury to conclude that the injection had been administered improperly. The patient was awarded \$90,000 for damages.

These cases illustrate that standards of practice for medication administration require health care providers to thoroughly assess the appropriateness of the proposed medication and thoroughly document its administration.

In the first case, the failure of the defendant health care providers to assess for allergies caused the death of the patient. In the second case, the failure of the defendant to document the time, location, and injection technique led to a large award for the patient injuries.

Risk Management: Prevention of Medication Errors

Computer-based patient safety systems are being used by several hospitals to reduce medication errors. Researchers warn, however, that computers are not error-free, but instead create their own unique mistakes. Some hospitals have reduced their error rates by eliminating drugs with similar names, by standardizing drug orders, and by revamping the processes for ordering, dispensing, administering, and monitoring drugs. Programming errors associated with computerized patient controlled analgesia (PCA) machines have been reduced by making user instructions short, clear, and easy to understand. Additional PCA related errors could be reduced at night by decreasing the rates of machines that are infusing narcotics, and by frequently monitoring vital signs, oxygen saturation, capillary refill, and patient responsiveness.¹¹

Studies have shown that putting pharmacists on patient care teams in medical intensive care units reduced errors in prescribing medications anywhere from 66% to 77%.¹² In addition, pharmacists can help prevent medication errors by maintaining adequate stock levels of drugs on patient care units, and ensuring that health care providers order their patients' drugs during regular pharmacy hours whenever possible.

“Computer-based patient safety systems are being used by several hospitals to reduce medication errors.”

Some classes of drugs and some specific drugs have been identified as having a higher potential for adverse drug reactions (ADRs). The classes in which most errors occur are antimicrobials (40%), cardiac, steroid, non-steroidal anti-inflammatory, and surgical drugs. Common drugs with a high potential for ADRs include insulin, heparin, opiates, patient-controlled analgesia, and potassium chloride. It has been estimated that medication errors in hospitals can be reduced by 33% by preventing errors in these medications alone.¹³

Teaching patients about their medications also helps to prevent medication errors. Patients should familiarize themselves with the colors and shapes of all their medicines so they can spot unfamiliar medications and question health care providers when in doubt. Suggest that patients purchase a drug reference book for home use and provide them with Internet addresses of sites related to medications. Teach patients to keep updated written records of their prescription and nonprescription medications and of any adverse reactions to individual drugs and dyes used during diagnostic testing. Instruct patients to use one pharmacy, to ask for written information about each of their prescriptions, to review the information with their pharmacist, and to ensure that their pharmacist has a computerized list of all their current medications to include over-the-counter drugs, allergies, and chronic conditions.

Never assume that health care providers are knowledgeable of the medications they administer or that patients are knowledgeable of the drugs they take. Legally, health care providers are responsible for understanding the medications they prescribe, dispense, or administer. They must know the dosage ranges, possible adverse effects, toxicity levels, indications, and contraindications. They are responsible for clarifying incomplete or ambiguous orders, for following routine safeguard procedures, and for notifying the primary health care provider of potential problems. Improving health care while preventing medication errors and their attendant expenses and subsequent liability

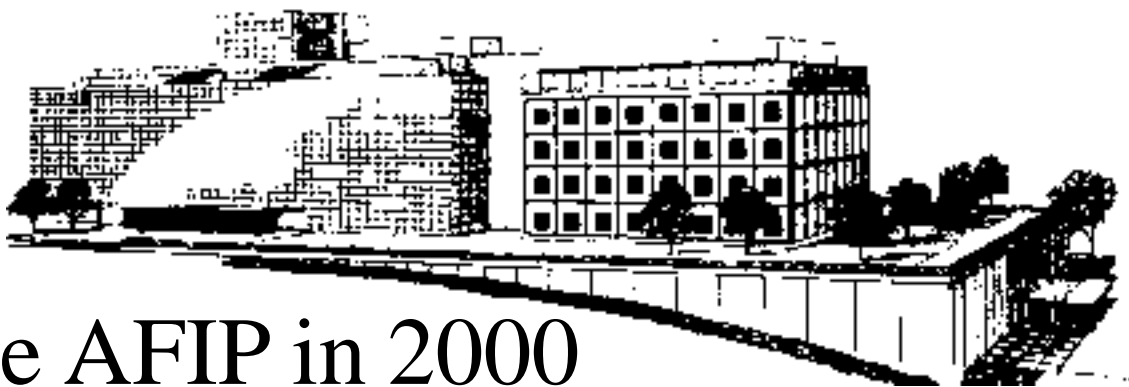
requires an extensive knowledge of medications and due diligence in prescribing, dispensing, and administering medications. Good communication among all health team members, thorough documentation, patient assessment, and patient education for both prescription and over-the-counter medications are additional requirements.¹⁴

Currently, there is no nationwide mandatory requirement to report medication errors. However, they may be voluntarily reported to the Institute for Safe Medical Practice — United States Pharmacopeial Convention Medication Error Reporting Program at (800) 233-7767, and to the FDA MedWatch program at (800) FDA-1088.¹⁵

8. Mawn SV. Informed consent. *Legal Medicine Open File*. 1994;94-2:1-6.
9. *Harris County Hosp. Dist. v. Estrada*, 872 S.W.2d 759 (Tex. 1993).
10. *Pellerin v. Humedcenters, Inc.*, 696 So.2d 590 (La. 1997).
11. Bates DW. More than 80 percent of medication errors eliminated by computerized physician order entry system. Available at <http://www.annenber.net/mederrors/html/announcement.html>. Accessed March 12, 2000.
12. Leape LL, Cullen DJ, Dempsey Clapp M, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA*. 1999;282:267-270.
13. *Supra* note 4.
14. Smith, *supra* note 5.
15. Kohn et al, *supra* note 2, pages 74-86.

References

1. Lesar TS, Briceland LL, Delcours K, Parmalee JC, Masta-Gornic V, Phol H. Medication prescribing errors in a teaching hospital. *JAMA*. 1990;263:2329-2334.
2. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human. Building a Safer Health System*. Institute of Medicine. Washington, DC: National Academy Press;1999:27-34.
3. Leape L, Bates D, Cullen D, et al. Systems analysis of adverse drug events. *JAMA*. 1995;274:35-43.
4. Physician Insurers Association of America. *Medication Error Study*. Washington DC: Physician Insurers Association of America;June,1993.
5. Smith MJ. Pharmacological update: new medications and the preventable adverse drug events initiative. *J Leg Nurse Cons*. 1999;10:22.
6. Benjamin DM. Defenses in professional negligence. Available at <http://www.channel1.com/users/medlaw/index.htm>. Accessed October 28, 1999.
7. Benjamin DM. The learned intermediary doctrine for physicians, dentists and other prescribers. Available at <http://www.channel1.com/users/medlaw/prm/learned.htm>. Accessed October 28, 1999.



The AFIP in 2000

By Jill E. Thach, J.D.

“And so I dedicate this building to the conquest of disease so that mankind, more safe and secure in body, may more surely advance to a widely shared prosperity and an enduring and just peace.” Dwight D. Eisenhower, President of the United States, 26 May 1955.

At the apex of the Cold War, the Armed Forces Institute of Pathology (AFIP) building in Washington, DC was thus dedicated, according to a large bronze plaque just outside the front entrance. A huge fortress had been built with underground tunnels and no windows. Apparently, those windowless occupants could sense the importance of their mission, however, for in this new millennium AFIP is notably famous around the world for its expertise in clinical, anatomic, and forensic pathology and a broad range of pathology-related sciences.

Leading the way is the new Director of the Armed Forces Institute of Pathology, Navy Captain Glenn N. Wagner. Captain Wagner’s career has allowed him an association with AFIP for more than 20 years, and he has served in a variety of capacities including a pilot, flight surgeon, aircraft field investigator, Assistant Chief Deputy Medical Examiner, Director of the Office of Strategic Planning, and now Director.

Captain Wagner has trained with the Navy Seals and Marine Recon, survived Air Assault and “Special Ops” training, worked as a homicide detective, and taught medical students as a Clinical Professor of Pathology at the Uniformed Services University of the Health Sciences School of Medicine. He is also a recognized authority in forensic pathology, aided by his background in medicine, law enforcement, fire fighting and emergency medical services, and his ability to reconstruct disasters such as those at Ruby Ridge, Waco and Gander (for which he earned the Legion of Merit award). He is licensed to practice medicine in several states, and continues to see patients on a regular basis as an osteopathic physician.

Captain Wagner, describing himself as a “known commodity” who “loves the Institute,” terms the AFIP a “people’s institute”—not simply a military or governmental entity. He believes in making pathology and forensic medicine relevant to the general population.

To this end, in 1998 pathologists in the AFIP's Center for Advanced Pathology consulted on more than 100,000 cases involving more than 90,000 patients. This patient population came from around the globe, military and civilian alike. Through the American Registry of Pathology (ARP), AFIP provides global access to the world citizenry, a unique quality for a Department of Defense medical entity. In return, AFIP receives access to a global population and specialized geographic pathology, infectious disease, environmental and toxicologic threats, as well as epidemiology of malignancies. ARP is a non-profit organization formally recognized by an Act of Congress in 1976. For a fee, civilian pathologists can utilize the expertise of AFIP pathologists. Fees for consults range from \$100 (using general diagnostic slides) to \$1950 (for a DNA synthesis). The combined department median turn-around time for diagnosis using slides is less than 4 working days, with a longer turn-around for special procedures and stains.¹

Aside from pathology consultations, the AFIP offers a multitude of educational opportunities worldwide. These range from 3-year veterinary pathology residencies, to fellowships in different pathology specialties, to more than 30,000 annual hours of Continuing Medical Education (CME).²

Of course research is vital at the Institute. New technologies and methods are continually under development including RNA and DNA tests,³ additional immunostains and complex toxicologic assays. Telepathology advances continually are explored and utilized. AFIP staff are involved in microbial genetic fingerprinting and developing vaccines against bioterrorism agents. Of particular relevance is the research on combat casualty prevention from body armor, and on footwear that can better protect against devastating injuries from landmines.

The National Museum of Health and Medicine is another important part of AFIP and the successor of the founding entity of the Army Medical Museum.

While in the past the Museum-Institute was located on the National Mall in Washington, DC, it is now integrated into the main AFIP building on the Walter Reed Army Medical Center campus.

The Museum exhibit area of approximately 16,000 square feet houses both anatomical specimens and medical devices as well as visiting exhibits and public health programs. The bullet that killed President Abraham Lincoln is included in the collection, as are old medical and dental instruments, and preserved human organs and body parts. The Museum strives to preserve, collect and interpret objects, specimens, photographs and documents that chronicle the history and practice of medicine over the centuries. The public is welcome to visit the Museum free of charge.

Despite calling the AFIP a people's institute, Captain Wagner has a real fondness for the animals who enrich people's lives and a keen appreciation for the work and dedication of AFIP's veterinarians and veterinary pathologists. The Department of Defense utilizes, studies, or cares for many types of working animals including dolphins and sea lions in Southern California, manatees in Florida, military horses in Washington, DC, and service dogs working throughout the United States and overseas. The AFIP is at least peripherally involved in much of this animal work, and offers a preceptorship through its Department of Veterinary Pathology at the National Zoo in Washington, DC where AFIP veterinary fellows and residents work hand-in-hand with National Zoo experts on challenging cases.

The AFIP is intimately involved in extensive animal research that can ultimately benefit mankind. For example, some animal vaccines have evolved into human vaccines. Research into zoonotic diseases has helped with additional research in AIDS, plague, malaria and tick-induced illnesses. Also, because bio-markers that can first be found in animals can often later be found in humans, veterinary researchers have tracked working dogs from Desert Storm (along with

camels, goats and wild cats found in that region) in hopes of better treating ill servicemembers who served in that campaign.

Captain Wagner has many hopes for this Institute, but high on his “wish list” for AFIP is a new building large enough to house all departments under one roof or at least on the same campus. Funding and plans continue

to evolve, however, and at this point in time ground breaking is not imminent.

While the fate of a new facility remains uncertain, the AFIP’s mission is clear—a continuing dedication to conquering disease through treatment, education and research so that people everywhere can share peace and prosperity in this year 2000 and beyond.

References

1. See http://www.afip.org/consult/Standard_Consultation/standard_consultation.html and then “Diagnostic Fee Schedule” and “Diagnostic Turn-Around Time.” Accessed April 6, 2000. Using Telepathology, fees begin at \$50 although they can be waived for various reasons. No fee is charged for VA or military treatment facilities. See <http://www.afip.org/telepathology/faq.html>. Accessed April 6, 2000. See also AFIP’s website at www.afip.org for additional information.
2. The Department of Legal Medicine annually publishes *Legal Medicine*, offering 5 CME credits. See www.afip.org/legalmed/lmof.html to access previous issues of *Legal Medicine*.
3. Kaar JF. New applications for old DNA. *Legal Medicine*. 1999:15-18.