

CHARACTERISTICS OF DEPARTMENT OF DEFENSE MEDICAL MALPRACTICE CLAIMS: A Quality Management Tool

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The Department of Defense (DoD) continues to be a leader in the area of malpractice data collection and trend analysis for the purposes of risk management under the National Quality Management Program. This has proven to be useful to the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) in supporting quality management efforts such as external review. Malpractice data has highlighted high-risk areas requiring study by other programs such as the DoD Civilian External Peer Review Program (provider focused) in the past and now Special Studies (best practice focused), and has also been useful as a benchmark for comparing DoD results with the private sector.

This article represents an update regarding the DoD medical malpractice database, called Tort-2, which is maintained by OASD(HA) with the assistance of the Department of Legal Medicine, Armed Forces Institute of Pathology.¹ Tort-2 is part of the Defense Practitioner Data Bank. Since 1991, the Department of Legal Medicine has monitored and summarized the contents of this database. The aggregate information has proven useful in responding to congressional inquiries as well as various requests for statistical data by the services and even the media. In mid-1998 the database contained approximately 4,580 entries—information abstracted from medical malpractice cases resolved between 1988 and 1998 involving DoD medical treatment facilities. Claims are resolved or closed when final legal action has been taken. An initial report describing the data collection process and the entries from the first 1,544 closed malpractice claims was presented in this publication in 1992.² The tables and figures in this article which refer to the Defense Practitioner Data Bank reflect all cases both paid and unpaid.

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This medical malpractice database was created in 1988 by OASD(HA) as part of its quality assurance program.^{3,4} As a quality assurance document, it is protected from disclosure by statutory law concerning medical quality assurance activities.⁵ Medical malpractice claims are generally filed at the local Judge Advocate General (JAG) office, and data for Tort-2 is generally collected in the risk management department of the medical treatment facility. This information is then forwarded to the respective Office of the Surgeon General where additional items of information are collected.

The data collection effort differs somewhat among the three military services, but a thorough process of malpractice claims review exists within the office of each Surgeon General. Two or three reviews of each malpractice case are undertaken at various levels up to and including the Surgeon General's Office. Data is then collected from various entities in the Department of Defense, the Department of Justice, the Department of the Treasury, and previously the General Accounting Office. More than 100 military treatment facilities and their respective JAG offices are involved in this data collection effort as well. Cases proceeding to litigation are managed or monitored by the Torts Branch of the Civil Division of the Justice Department. However, more than 90% of their cases are delegated to one of 93 federal offices of the United States Attorney throughout the country.

Given the large scope of information coming from numerous independent federal entities, it is not surprising that Tort-2 data collection can be difficult. Since it is a closed case database, data collection cannot be completed until a malpractice case has been concluded, which may take several years. Because of the difficulty in subsequently obtaining detailed medical and legal information from prior malpractice incidents, the data within Tort-2 is at times incompletely reported. Some fields are nearly 100%

complete while others are only 50% complete. This results in different sums for specific data elements and reduces the total number of complete reports. Comparison with JAG databases, which comprise both open claims and closed claims databases, often is not possible because of the extensive review process which occurs after JAG closure of a case; however, Tort-2 still represents an extremely large and useful collection of medical malpractice cases. In the future, with the advent of the Centralized Credentials Quality Assurance System version 2.0, a new DoD database anticipated to deploy in 1999, it is expected that malpractice data collection will be more complete and that this will significantly improve the capability to produce malpractice rates and identify liability trends.

Other Sources of DoD Malpractice Data

Department of Defense malpractice claims are initially managed by the local office of the Staff Judge Advocate. Each of the three military Claims Services maintains a central database and can quickly ascertain the approximate number of claims filed per year. It can be seen from Table 1 that the total number of malpractice claims filed has remained relatively stable at approximately 1,000 per year. Likewise, the DoD rate of claims is relatively steady in the range of 7 to 9 claims per 100 physicians per year. This compares favorably with the St. Paul Fire and Marine Insurance Company rate of 12 to 16 claims per 100 private sector physicians per year. However, exact comparison with private sector claims experience is difficult for a number of reasons. The most obvious reason is that the Feres Doctrine which precludes active duty service members from filing a malpractice claim necessarily affects the DoD rate. If active duty members were permitted to file such claims, the DoD rate would no doubt increase although the actual percentage is difficult to determine. Approximately 20% of the patient population is active duty.

DoD MALPRACTICE CLAIMS RATE COMPARED TO PRIVATE SECTOR (Claims/100 Physicians)

| Reporting Year | Number of DoD Claims Filed ¹ | Number of DoD Physicians ² | DoD Rate ³ | Private Sector Rate ⁴ |
|----------------|---|---------------------------------------|-----------------------|----------------------------------|
| 1990 | 1131 | 14,996 | 7.5 | 12.4 |
| 1991 | 958 | 14,225 | 6.7 | 13.0 |
| 1992 | 1014 | 15,711 | 6.5 | 13.8 |
| 1993 | 995 | 14,912 | 6.7 | 14.4 |
| 1994 | 1067 | 14,625 | 7.3 | 14.1 |
| 1995 | 1068 | 13,383 | 8.0 | 16.7 |
| 1996 | 1250 | 12,744 | 9.8 | 16.0 |
| 1997 | 1095 | 13,347 | 8.2 | 15.8 |

Table 1

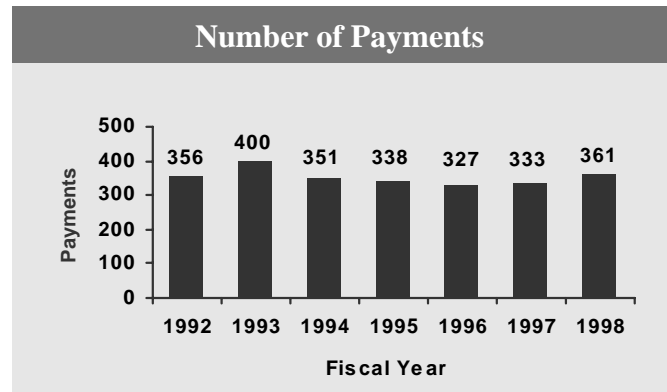
¹SOURCE: Army, Navy, and Air Force Judge Advocate Corps Claims Service

²SOURCE: U.S. Medicine, Federal Market Facts (includes military and DoD civilian physicians)

³Number of claims per 100 DoD physicians

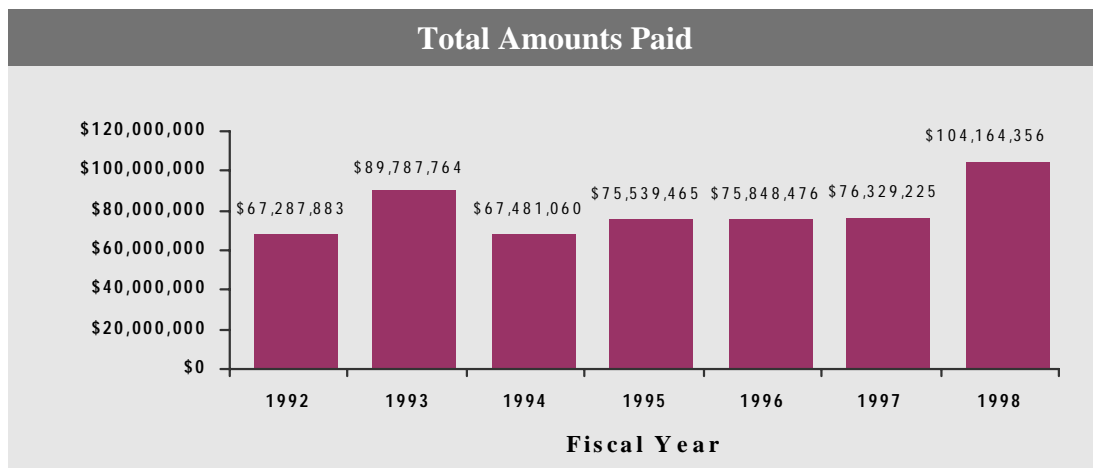
⁴Number of claims per 100 private sector physicians; SOURCE: Physicians and Surgeons Update: 1998 Midyear Report from the St. Paul Fire and Marine Insurance Company

Another source of malpractice information is the Judgment Fund Branch of the Financial Management Service of the Department of the Treasury. This entity pays most judgments and settlements against the United States and is a reasonably good source of the number of DoD malpractice payments. Figure 1 indicates that there are approximately 350 annual medical malpractice payments made by the Department of the Treasury. Administrative settlements up to \$2,500 under the Federal Tort Claims Act for care in the United States and settlement amounts up to \$100,000 under the Military Claims Act for care in overseas military facilities are not paid by the Judgment Fund.



SOURCE: Judgment Fund Branch, Financial Management Service, Department of Treasury

Figure 1



SOURCE: Judgment Fund Branch, Financial Management Service, Department of Treasury

Figure 2

Figure 2 depicts the total monetary amount paid per year from the Department of the Treasury's Judgment Fund Branch for medical malpractice by the Department of Defense. The average annual amount paid has remained relatively stable at approximately \$75 million.

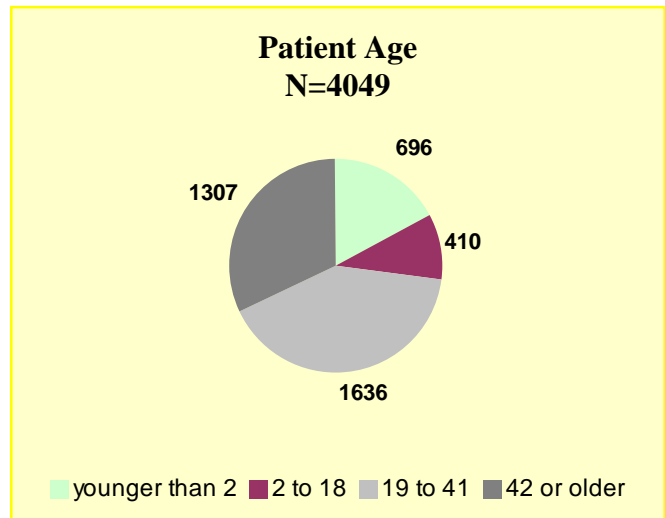
Patient Characteristics

Tort-2 contains a number of clinically relevant patient fields which are useful in characterizing DoD malpractice claims. Information includes patient age, gender, and injury severity.

Concerning patient age, 17% of the closed malpractice cases in Tort-2 involved patients less than 2 years old. Ten percent fell into the 2- to 18-year-old group, and the remainder were more than 18 years of age as depicted in Figure 3. Sixty-one percent of the patients were female; 39% were male. This difference in gender is not surprising because of the Feres Doctrine that bars active duty service individuals, who are primarily male, from suing the federal government. The majority of patients who file malpractice claims (54%) are dependents of active duty service members. Retired military account for 16% and dependents of retired service members account for another 16% of the claimants. A small percentage of claims are filed by active duty service members but are denied because of the Feres Doctrine. Concerning the severity of injuries suffered by patients in malpractice cases within the Department of Defense, 16% had no injury, 81.6% suffered some degree of injury, and 2.3% died.

Claims Characteristics

Medical malpractice cases within the federal sector proceed through an administrative phase and perhaps a litigation phase, as stated earlier. Most cases are resolved in the administrative phase. Only about 20% of DoD malpractice cases are resolved in the litigation phase. In the initial administrative phase, the respective military JAG office investigates and either denies the claim or settles it administratively.



SOURCE: Defense Practitioner Data Bank

Figure 3

Claims can be denied for a number of reasons. First, the statute of limitations may have passed, precluding payment on the claim. The statute of limitations in the federal sector is 2 years from the time that the claimant knew or should have known of the injury and its cause. Some claims are filed by active duty service members as noted above and are barred by the Feres Doctrine. The majority of claims are denied because they are non-meritorious or do not satisfy the four elements of negligence: duty, breach, causation and injury. If a claim is denied, the claimant has 6 months within which to file suit in federal court. The claim then proceeds as a complaint in the litigation phase and is handled by the Department of Justice. Once again at this new level, attorneys can settle the malpractice case or allow it to proceed to trial, resulting in a judgment for either the plaintiff or for the United States.

Table 2 illustrates the legal outcome of the medical malpractice cases within the database. Approximately one-quarter of malpractice cases (23%) are settled administratively. More than one-third of the cases are denied as non-meritorious. Among those few cases that finally proceed to trial, more than half (57%) result in a decision for the United States. The

| Legal Outcome N=4223 | | |
|------------------------------------|-----------------|------------|
| | Number of Cases | Percentage |
| Settled Administratively | 964 | 22.8% |
| Denied: Dismissed | 109 | 2.6% |
| Denied: Statute of Limitations | 137 | 3.2% |
| Denied: Feres Barred | 305 | 7.2% |
| Denied: Non-Meritorious | 1537 | 36.4% |
| Litigation: Decision for Plaintiff | 157 | 3.7% |
| Litigation: Decision for U.S. | 207 | 4.9% |
| Litigation: Settlement by D.O.J. | 504 | 11.9% |
| Other | 303 | 7.2% |

SOURCE: Defense Practitioner Data Bank

Table 2

| Primary Allegation* N=4176 | | |
|-------------------------------|-----------------|------------|
| | Number of Cases | Percentage |
| Diagnosis Related | 1696 | 40.6% |
| Surgery Related | 858 | 20.5% |
| Treatment Related | 584 | 14.0% |
| Obstetrics Related | 531 | 12.7% |
| Medication Related | 217 | 5.2% |
| Miscellaneous | 96 | 2.3% |
| IV and Blood Product Related | 77 | 1.8% |
| Anesthesia Related | 71 | 1.7% |
| Monitoring | 26 | 0.6% |
| Biomedical Equip/Prod Related | 20 | 0.5% |

*Act or Omission Codes adopted from the Harvard Risk Management Foundation

SOURCE: Defense Practitioner Data Bank

Table 3

Department of Justice settles approximately 11.9% of all closed medical malpractice cases within the overall DoD database.

Tort-2 contains many prior determinations of the standard of care at various levels of review, including determinations arrived at by the military treatment facility itself and the local JAG office, as well as determinations from the appropriate Office of the Surgeon General. Each Surgeon General evaluates the standard of care as either being met, not met or indeterminate. Surveying these statistics, of 4,164 cases in the database, 2,868 (68.9%) met the standard of care. A total of 1,063 (25.5%) did not meet the standard of care, and 233 (5.6%) were indeterminate. An indeterminate evaluation is usually made because of inadequate medical records for review.

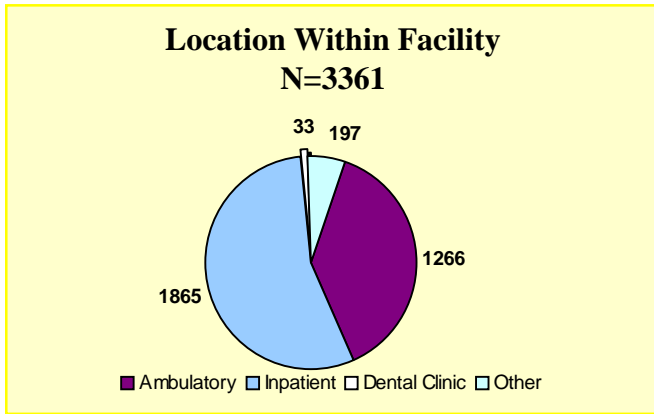
Various codes for the primary medical malpractice allegation were created for Tort-2 and analysis of 4,176 entries is reported at Table 3. Approximately 40% of the cases in Tort-2 are diagnosis related, 20% concern surgery, and 14% relate to treatment. Obstetrics cases account for 12.7% of the total. A minority of cases involved medications, intravenous fluids and blood products, anesthesia, monitoring or biomedical equipment. Examples of specific diagnosis-related acts or omissions include failure to diagnose a disease or condition, misdiagnosis of an existing condi-

tion, improper performance of a diagnostic test, delay in diagnosis, or failure to obtain informed consent. Surgery-related claims include allegations related to retained foreign bodies, operations on the wrong body part, improper performance of surgery, unnecessary surgery, a delay in surgery, improper management of a surgical patient, and failure to obtain informed consent for surgery. Treatment-related allegations include failure to treat, improper performance of a treatment or procedure, improper management of a course of treatment, premature end of treatment or failure to seek consultation. Obstetrics-related allegations include failure to properly manage pregnancy, improper performance of vaginal delivery, improper performance of cesarean section, delay in delivery, improperly managed labor and failure to identify and treat fetal distress.

Facility and Provider Characteristics

Figure 4 illustrates the location within the medical treatment facility where the incident occurred. Of 3,361 cases, 55% involved inpatient care. Approximately 38% were related to ambulatory care, and 1% involved the dental clinic.

Attribution of the malpractice is not surprising: primary providers headed the list. Fewer than 10% of all cases filed attributed malpractice to facility, management, or system problems.



SOURCE: Defense Practitioner Data Bank

Figure 4

The profession of the primary provider was collected in 2,103 malpractice entries. Statistics show the provider was a physician in 90.1% of cases, as illustrated in Table 4. A physician assistant was the primary provider in only 2.1% of cases, and a registered nurse was involved in only 1.2% of cases. Among physicians involved in 1,870 malpractice

| PRIMARY PROVIDER PROFESSION* | | |
|------------------------------|-----------------|------------|
| N=2103 | | |
| | Number of Cases | Percentage |
| Physician (MD, DO) | 1895 | 90.1% |
| Physician Assistant | 45 | 2.1% |
| Dentist | 44 | 2.1% |
| Registered Nurse | 26 | 1.2% |
| Nurse Anesthetist | 22 | 1.0% |
| Nurse Practitioner | 21 | 1.0% |
| Nurse Midwife | 18 | 0.9% |
| Clinical Psychologist | 13 | 0.6% |
| Podiatrist | 10 | 0.5% |
| Optometrist | 9 | 0.4% |

*Professions of the most involved providers in the case
SOURCE: Defense Practitioner Data Bank

Table 4

| DIAGNOSTIC GROUPS | | |
|---------------------------------------|-----------------|------------|
| N=4058 | | |
| | Number of Cases | Percentage |
| Perinatal Period | 676 | 16.7% |
| Neoplasms | 556 | 13.7% |
| Digestive System | 386 | 9.5% |
| Blood & Blood Forming Organs | 385 | 9.5% |
| Symptoms/Signs/Ill-Defined Conditions | 337 | 8.3% |
| Respiratory System | 322 | 7.9% |
| Endo/Nutritional/Metabolic/Immunity | 315 | 7.8% |
| Genitourinary System | 244 | 6.0% |
| Nervous System & Sense Organs | 144 | 3.5% |
| Congenital Anomalies | 134 | 3.3% |
| Pregnancy/Childbirth/Puerperium | 127 | 3.1% |
| Skin & Subcutaneous Tissue | 124 | 3.1% |
| Circulatory System | 84 | 2.1% |
| Musculoskeletal & Connective Tissue | 70 | 1.7% |
| Mental Disorders | 65 | 1.6% |
| Infectious & Parasitic Diseases | 53 | 1.3% |
| Injury & Poisoning | 36 | 0.9% |

SOURCE: Defense Practitioner Data Bank

Table 6

| PRIMARY PROVIDER SPECIALTIES* | | |
|-------------------------------|-----------------|------------|
| N=1870 | | |
| | Number of Cases | Percentage |
| Obstetrics/Gynecology | 435 | 23.3% |
| Surgery | 290 | 15.5% |
| Family Practice | 189 | 10.1% |
| Internal Medicine | 179 | 9.6% |
| Pediatrics | 126 | 6.7% |
| Orthopedics | 101 | 5.4% |
| General Medical Officer | 88 | 4.7% |
| Radiology | 64 | 3.4% |
| Emergency Medicine | 51 | 2.7% |
| In Training | 45 | 2.4% |
| All Other Specialties | 302 | 16.1% |

*Specialties of the most involved physician in the case
SOURCE: Defense Practitioner Data Bank

Table 5

cases, it is not surprising that the most common specialty was obstetrics/gynecology with 435, or 23.3% of the entries as seen in Table 5. Surgery was the second most frequent specialty with 15.5% of the recorded incidents. Family practice ranked third (10.1%) while internal medicine was fourth (9.6%). General medical officers accounted for fewer than 5% of the cases, and radiologists were involved in only 3.4% of the malpractice cases.

Table 6 shows a range of diagnostic groups involved in DoD medical malpractice cases. Almost one-third (30.4%) of malpractice cases involve the diagnostic

| MOST FREQUENT SPECIFIC DIAGNOSES N=3903 | | |
|---|--------------------|------------|
| | Number of Cases | Percentage |
| Malignant Neoplasm, Female Breast | 76 | 1.9% |
| Malignant Neoplasm, Trachea, Bronchus, Lung | 51 | 1.3% |
| Other Fetal/Placental Problems Affecting Mothers Management | 48 | 1.2% |
| Pain and Other Symptoms Associated with Female Genital Organs | 45 | 1.2% |
| Acute Myocardial Infarction | 34 | 1.2% |
| Ectopic Pregnancy | 31 | 0.9% |
| Normal Pregnancy | 29 | 0.7% |
| Intrauterine Hypoxia and Birth Asphyxia | 26 | 0.7% |
| Acute Appendicitis | 24 | 0.6% |
| Early or Threatened Labor | 24 | 0.6% |

SOURCE: Defense Practitioner Data Bank

Table 7

groups of the perinatal period and neoplasms. The digestive system is involved in approximately one-tenth of cases, and the blood and blood forming organs are involved in another tenth of cases. The ten most frequent specific malpractice case diagnoses are shown in Table 7. The diagnoses are coded using the ICD-9 Clinical Modification System, and the titles reflect the nomenclature used in that textbook. The most frequent diagnosis, malignant neoplasm of the female breast, accounted for slightly less than 2% of the cases in the database. Cancer of the lung was the second most frequent diagnosis at only 1.3%. Acute myo-

cardial infarction accounted for 1.2% of the cases. Ectopic cases (0.9%) and appendicitis (0.6%) were seen even less frequently.

Payment Information

Table 8 illustrates the relative distribution of small and large malpractice payment amounts. Of 4,580 cases in the database, 1,661 (36%) were paid cases. On the lower end, a total of 18% of cases were paid for less than \$10,000 each, and accounted for only 0.4% of dollars paid. At the other extreme, only 10% of cases were paid for more than \$500,000 each, but these accounted for 65% of the total dollars paid.

| AMOUNT PAID N=1661 | | | |
|--------------------------|-------------------------|----------------------|---------------------------------|
| Amount | Percentage of Claims | Sum | Percent of Total Amount Paid |
| \$0-10,000 | 18.3% | \$1,691,036 | 0.4% |
| \$10,001-25,000 | 20.8% | \$7,021,126 | 1.7% |
| \$25,001-50,000 | 10.5% | \$7,094,103 | 1.7% |
| \$50,001-100,000 | 13.4% | \$17,833,181 | 4.3% |
| \$100,001-200,000 | 15.5% | \$40,954,062 | 10.0% |
| \$200,001-500,000 | 11.6% | \$66,589,999 | 16.2% |
| \$500,001-1,000,000 | 5.0% | \$63,045,094 | 15.3% |
| \$1,000,001-12,000,000 | 4.8% | \$206,919,590 | 50.3% |
| Total Amount Paid | | \$411,148,191 | |

SOURCE: Defense Practitioner Data Bank

Table 8

Value and Limitations of Malpractice Data Analysis

The Government Accounting Office report on DoD medical malpractice in 1987 stated that better use of malpractice data could improve the quality of medical care.⁶ There are a number of ways in which this can be accomplished. First, high-risk areas with frequent claims such as obstetrics or surgery can be targeted for remedial attention. Second, lessons learned from the study of individual malpractice cases can reduce the future incidence of such cases by educating health care practitioners regarding medical error. Third, comparisons with other health systems or insurance companies can roughly measure the quality of a health care system. The number of claims filed, the number of claims closed, or the number of claims paid are recognizable milestones that can be followed over time. A periodic report card containing these measurements certainly has some value for comparing not only individual facilities but also the entire DoD health care system. It should be remembered, however, that malpractice data is less than perfect. Initially, the data itself is difficult to collect. In some instances even paid cases contain acceptable medical care but are settled for other reasons. Nevertheless, a malpractice database represents a series of complaints against the system over

time with an accompanying number of errors by practitioners or system problems.

Future Directions

The most prominent initiative which will significantly improve the collection of medical malpractice data by DoD is the Centralized Credentials Quality Assurance System (CCQAS).⁷ This system will allow malpractice data to be collected and electronically transmitted from the medical treatment facility to a central database administrator at the Armed Forces Institute of Pathology for access by the military services and DoD. This will dramatically increase the speed of data collection for malpractice analysis and eliminate the current more cumbersome methods. Secondly, the Department of Legal Medicine will continue to utilize other federal databases in analyzing malpractice data. These databases include those maintained by the Department of Justice, the Department of the Treasury, and the three military service JAG databases. Future comparisons with civilian data from the National Practitioner Data Bank as well as large private insurers, such as the St. Paul Fire and Marine Insurance Company, will be facilitated resulting in more timely and useful risk management analysis.

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NEW APPLICATIONS FOR OLD DNA



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In the 17th century when Anton van Leeuwenhoek first looked through his microscope and found what he later described as “little animals,” it was impossible for him to know the future importance of his discovery and that it would lead to opening the secrets of deoxyribonucleic acid.¹ Over the course of the last decade, and especially the last year, deoxyribonucleic acid (DNA) has become the most important tool in forensic science. From the bloody glove, to the remains of the Unknown Soldier, to President Jefferson’s offspring, DNA has become the gold standard on which the legal system and medical community are making determinations. This three-foot strand of 46 chromosomes (twenty-three from each parent) is present in every cell of a person’s body. Because of the nature of DNA, it is different in every person with the possible exception of identical twins. It is estimated that the odds against duplication are from one in a billion to one in one hundred billion.² (It is important to note that the world population is approximately six billion.³)

Courts are accepting DNA evidence in both criminal and civil proceedings with increasing frequency. It can virtually eliminate an accused from being a suspect, or it can link an individual to a crime. Paternity and child support issues keep DNA laboratories busy with more than 200,000 tests per year,⁴ and as the O. J. Simpson trial showed us, all that is needed is a drop of blood to perform the analysis.⁵ As long as the material is present, it can provide the answer, and the fact that an item has been washed or left as decaying bone fragments⁶ will not in and of itself invalidate the test.

Beyond the court system, DNA has provided definitive answers where none were available before. At the Armed Forces Institute of Pathology (AFIP), DNA testing performed in 1995 provided positive identification of the remains of Tsar Nicholas II who was executed and buried in an unmarked grave following the Russian Revolution and disproved Anna Anderson's claim to be Anastasia, his daughter. In 1998 through use of DNA testing, the AFIP identified the remains of the Vietnam Unknown Soldier enshrined at Arlington National Cemetery as those of Air Force 1st Lt. Michael Blassie. While this case received the most publicity, it was in fact only one of approximately 100 such cases in which the AFIP was able to identify previously unidentifiable service member remains.⁷

DNA testing has also helped attain a better understanding of our past. In November 1998 it was reported that DNA testing had established a possible familial link between Thomas Jefferson and the youngest son of his slave, Sally Hemings.⁸ This same study also showed that there is no genetic link between President Jefferson and Hemings' older children.⁹

DNA Types and Identification Techniques

Different types of DNA can be used for analysis including nuclear (chromosomal) and mitochondrial DNA. Mitochondrial DNA passes directly from the mother to the child without interference or input from the father; thus, individuals can be traced back to a common female ancestor, but not to a common male ancestor. Mitochondrial DNA (mtDNA) testing is one of the newest types of DNA testing.

Techniques used to identify DNA include restriction fragment length polymorphisms (RFLP) and polymerase chain reaction or PCR. The RFLP method looks at the length of the strands of a person's nuclear DNA and establishes a specific pattern of tandem repeats which differs for each individual.¹⁰ Several thousand cells and long stretches of DNA in perfect condition are required for the RFLP tests

which can take about a month to complete. Using the PCR method, scientists are able to create a "biological copy machine" that mimics the method in which mtDNA is produced. PCR tests require just several days, need DNA from just a few cells, and can be accurate even if the DNA is somewhat degraded.¹¹ This is particularly helpful in situations where only a few older remains are left as with the Russian Tsar and with Lt. Blassie.

The technique used to compare DNA samples is called "gel electrophoresis." DNA samples are mixed with enzymes that break up the DNA strands and are then placed on one end of a gel slab. An electrical current is passed through one end of the gel to the other dragging the DNA segments with it. Smaller shorter segments move faster and farther than the larger longer fragments. This results in a separation of the sizes, and a pattern is established when the current is turned off. Pre-identified, lightly radioactive pieces of DNA are applied to the samples for the purpose of binding to specific sequences and establishing DNA markers. These markers (several of which are typically used in a test) ultimately are recorded on x-ray film which produces a record for comparing different samples. The more markers used, the more reliable the test.¹²

Legal Basis for Accepting DNA and Other Scientific Evidence

As early as 1923 courts struggled with the relevance and admissibility of "scientific evidence." In *Frye v. United States*,¹³ the court chose not to allow the results of a systolic blood pressure deception test (an early version of the polygraph) deciding that only evidence generally accepted by the scientific community (not experimental) would be admissible. Over the years the *Frye* test became the standard for the rest of the federal court system as well as for many of the state court systems.

The U.S. Supreme Court revisited *Frye* recently in *Daubert v. Merrill Dow Pharmaceuticals, Inc.*,¹⁴ and *General Electric Company, et al. v. Joiner*.¹⁵ In

Daubert the court refused to allow admission of in vitro and in vivo animal studies purporting to show the drug Bendectin caused birth defects in humans. In doing so the court recognized the importance of animal studies but found that those offered by the plaintiff were not sufficiently related to the case at hand. In the *General Electric* case, the plaintiff claimed the cancer he contracted was the result of exposure to polychlorinated biphenyls (PCBs) considered to be health hazards instead of his personal cigarette smoking. In support of his claim, he attempted to submit four studies none of which paralleled his situation. Once again the court found that the evidence was not sufficiently relevant to the case at hand.

Based on this short history of scientific evidence in federal civil cases, is DNA evidence admissible? It certainly can be if it is sufficiently related to the case at hand, properly collected, and reliably prepared.

Civil and Criminal Cases

In certain civil arenas, DNA testing has taken on a life of its own, creating a mini-industry. Typical clients involved in custody disputes include men both disputing and fighting to establish paternity and “black-haired dads who wonder why their kids sport carrot tops.”¹⁶ Beyond the realm of familial identification, defense lawyers have attempted to show that a plaintiff’s claimed injuries were not the result of their client’s actions, but rather were a result of the plaintiff’s own genetic defects. For example, in 1993 an obstetrician defended a malpractice case involving a severely retarded child by asserting that the child was born with the rare genetic disorder Angelman’s Syndrome. Turning the tables, in litigation involving claims that benzene exposure had resulted in leukemia, defendants demanded the plaintiff produce DNA evidence of benzene-induced chromosome damage.¹⁷

Because of the higher standard of proof required by the criminal justice system, DNA testing made its

debut in criminal cases primarily as a means to exclude an individual from an event (i.e., it could not have been the accused who attacked the victim for the DNA could not have been his), and has freed numerous individuals who have been wrongly convicted of crimes.^{18,19} As the science of DNA matching has obtained wider acceptability and testing procedures have improved, DNA is more frequently being used to connect individuals to crimes using either the victim’s or the perpetrator’s DNA. Most notable is the State of California’s attempt to link O.J. Simpson with his former wife’s murder.²⁰

Future Implications

Obviously the process of testing and analyzing DNA samples has become regularly accepted practice within the scientific community and, as such, based on both the *Daubert* and *General Electric* decisions, we can expect to see an increase in the use of DNA evidence in the legal system. However, this is not to say that DNA results will automatically determine the outcome of a case. Questions regarding the collection of samples will arise, as will questions regarding the specific tests performed and number and selection of genetic markers used. Once these questions are answered, the battle will ensue over the accuracy of the probability of the result. Assuming that answers to all these questions support admission of the DNA test results, it will be but one piece of evidence—albeit a very strong piece—used to make a legal decision.

See References on Next Page

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BREAST DISEASE DIAGNOSIS: MAKING THE SAME OLD ERRORS, OVER AND OVER AGAIN

by **RAYMOND B. WEISS, M.D.***

IN THIS COLUMN, A SENIOR CONSULTANT SHARES HIS MEDICO-LEGAL INSIGHT WITH FELLOW CLINICIANS.

Those who cannot remember the past are condemned to repeat it.
George Santayana, 1910

Breast cancer is a common disease; approximately 180,000 new cases will be diagnosed in 1999. In addition, its incidence has risen steadily over the past 50 years. It can occur in any adult woman, it is laden with emotion and sexual connotation, and it is the single disease most feared by women. Although approximately 44,000 women will die of this malignancy in 1999, about 67,000 (52% more) women will die of lung cancer, and the number of deaths from lung cancer in *both* sexes will exceed by 20,000 those occurring from breast, prostate, and colon/rectum cancers *combined*. It is breast cancer, however, that sends shivers down the spines of women everywhere and attracts the most media and national attention.

With all the focus on breast cancer, physicians should be especially wary of the many implications of this disease and approach a breast complaint with heightened consideration and concern. Unfortunately, too many physicians fail to take heed of the pitfalls in the diagnosis of this cancer and continue to make errors, as evidenced by the fact that it is the second most common initiator of medical malpractice suits *overall* and the most common and expensive one related to a delay in the diagnosis of a cancer.¹ Over

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my 28-year career in the subspecialty of medical oncology, I have observed numerous instances of physicians displaying exactly the opposite of "heightened concern" for a breast complaint by failing to follow accepted practice in evaluating such symptoms, with ultimate adverse consequences for themselves, their insurance carriers and their patients. The failure to diagnose breast cancer with a resultant delay in treatment can be devastating. Physicians who fail to be mindful of the implications of this emotion-laden disease and who fail to follow well-established procedures in assessing breast symptoms will continue to add malpractice caseloads to the DoD or to their private insurance carriers.

This article will review several physician errors so that other physicians who see adult female patients will be reminded not to make the same blunders. The one fact to keep in mind whenever a woman presents with a breast symptom is that cancer is the worst diagnosis one can make involving this organ, so the question should always be, "Does this woman have cancer?" With the high incidence of this disease, the answer is too often, "Yes, she does."

Who Gets Breast Cancer?

The question seems simplistic, but it is not. Any adult woman beyond the age of puberty can develop this cancer. Physicians sometimes forget breast cancer can occur in women in their 20s and approach the assessment of a breast complaint by women in their 20s or early 30s with the notion that the patient is too young to have cancer. Obviously the disease is uncommon in this age group, but the youngest woman I have seen with breast cancer was only age 18 when she was diagnosed, and I have cared for a number of breast cancer patients in their 20s and early 30s. Women in these younger age categories still deserve proper evaluation of a new breast symptom. Few physicians fail to understand that breast cancer can be hereditary, especially now that two germline mutations related to breast cancer (*BRCA1* and *BRCA2*) have been identified. When the woman with a breast symptom relates a history of her mother or

sister having the disease (especially if it occurred in the premenopausal age group), most physicians are aware of the greater risk of breast cancer in this family. Only about 10% of newly diagnosed breast cancer, however, has a hereditary context. The great majority of women who develop breast cancer either have no such family history or only a remote relative (for example, a grandmother) who had it.

In addition to family history, there are other categories of risk for breast cancer. Women who have had any significant total amounts of radiation to the thorax may develop it. It was recognized by the 1960s that women who had tuberculosis treated from the 1930s to 1952 with repeated induced pneumothoraces, accompanied by frequent (weekly) chest fluoroscopy, had a significant risk for subsequently developing breast cancer, as did women treated with breast irradiation for acute postpartum mastitis. Although most of these patients have died, today there is a new category of women who present a similar high risk. This new group consists of women treated for Hodgkin's disease with thoracic irradiation before the age of 30, particularly between the ages of 10 and 16. Such women have a standardized incidence ratio of 75 for developing breast cancer compared to the average woman, and an estimated actuarial incidence of breast cancer reaching nearly 35% by age 40.² In fact, women with this history have such a significant risk for developing breast cancer, it is recommended they pay greater attention to early diagnosis techniques such as breast self-examination, semiannual physician examinations, and screening mammograms.

Another high-risk category for developing breast cancer includes women who have already had one breast cancer. Over their lifetimes they have approximately a 10% chance of a second cancer in the contralateral breast. Another, but less well-known and much less common relationship of breast cancer with other neoplasms is one with meningioma.³ Women who have had a meningioma removed should be considered at risk for breast cancer.

Benign breast diseases (fibroadenoma, sclerosing adenosis, duct papilloma, etc.) are common, but the only benign breast conditions associated with increased risk for developing cancer are atypical hyperplasia and lobular neoplasia. Both conditions are usually diagnosed only when breast tissue is biopsied for some unrelated reason, and both are correlated with a probability of developing cancer in *either* breast of four to five times the rate in the general population. The risk tends to increase the younger the woman is diagnosed with these conditions, particularly when premenopausal. If a family history of breast cancer is also associated with atypical hyperplasia, the risk for subsequent breast cancer increases even more.

Age is a well-known risk factor for cancers, and this holds true for breast cancer. The incidence increases significantly after menopause. The use of post-menopausal estrogen replacement medications also produces an increase in the risk of breast cancer particularly if the total use of the hormonal agents exceeds 5 years.⁴ There are additional hormone-related risk factors for developing breast cancer such as early menarche, late menopause, nulliparity, age greater than 30 for the first pregnancy carried to term, and obesity in postmenopausal women. These factors should always be considered in assessing new breast symptoms.

There are some aspects of breast disease that are *not* associated with an increased risk for developing cancer. These are presence of breast implants, presence of pathologically-diagnosed fibrocystic disease, and use of oral contraceptives.

Evaluating a Breast Symptom

The first step in evaluating a new breast symptom (a “lump,” pain, nipple discharge, skin change, change in breast or nipple contour, etc.) is to consider risk factors for the disease as described above and establish a risk profile. The second consideration, which should never be forgotten, is that the only means of reliably diagnosing this cancer is by invasive tissue diagnosis. A systematic approach to the workup will

reduce the risk of missing the diagnosis when cancer is present.

The History

After obtaining information about the various potential risk factors described above, the patient should be asked about the duration of the symptom, the relation to menses if the patient is premenopausal, and the possibility of pregnancy. Such information should be recorded in the office notes with details. I have seen office notes of physicians who are being sued that consist of only the complaint “breast lump” with the next item being only a brief record of the physical findings.

A particularly noteworthy facet regarding the history is that the presence of pain does not mean either the presence or the absence of cancer. I have seen physicians tell patients that cancer is painless, and therefore the fact that the lump was painful meant it was not cancerous. Cancer is more often painless, but cancer can produce pain also. The history of a nipple discharge, especially a bloody one, would seem intuitively to be a likely sign of cancer, whereas it is more often the symptom of a benign duct papilloma. Nipple discharges may be galactorrhea and indicate some hormonal imbalance rather than cancer. However, nipple discharges can occur with cancer also.

The Physical Examination

There are many textbooks and other guides for conducting a breast examination, so directions for this aspect of breast evaluation will not be discussed here. If a woman presents with the complaint that she has discovered a breast “lump” or “thickening” (and approximately 75% of breast cancer is diagnosed after discovery of a mass by the patient herself), the first step is for her to demonstrate what she feels and where she feels it. The lesion should be characterized as to consistency, location, and size. Often a picture sketched in the records can provide important information for future use. The regional node-bearing areas also should be examined and the findings recorded, something too often neglected by the careless physician. The breast should be observed

carefully for skin retraction, nipple abnormalities, and skin color changes.

When the patient presents with a self-discovered "lump," the physician is sometimes unable to perceive any abnormality which can present a dilemma. In this situation I have seen physicians make the error of assuring the patient nothing is wrong because nothing can be palpated. Simply reassuring the patient in this situation can be fraught with danger. Follow-up examinations at intervals of several weeks may allow the patient-detected abnormality to be better defined, and, of course, there is always the option of sending the patient for a second-opinion consultation.

Uncommon physical findings, but ones I have seen lead to malpractice suits when not properly recognized, are the presence of skin irritation and desquamation around the areola which usually means Paget's disease, a breast condition often indicative of an underlying cancer. Physicians sometimes fail to recognize this condition and its cancer association while treating the problem with various corticosteroid creams as an eczema. Another misdiagnosis I have seen physicians make is to label a swollen, painful, erythematous breast as "mastitis" and treat with antibiotics. If the patient is not lactating and nursing, an infectious mastitis is extraordinarily unlikely. Such a physical finding is indicative of inflammatory breast cancer, a particularly aggressive variant of breast cancer.

The consistency of the breast may vary in premenopausal women, especially during the luteal phase of ovulation when the breasts may be nodular and have greater tenderness than usual. It is legitimate to have the patient return for a re-examination soon after the next menses to allow a more accurate assessment of the physical findings.

Radiographic Assessment

A mammogram should be performed, as part of the assessment process, for any woman who presents with a palpable mass, "lump," or "thickening." The

purpose of the mammogram is to determine if there are indeed any obvious signs of cancer in either breast. If possible, previous mammograms should be retrieved and compared to the present study. Masses, asymmetries, skin edema and indentations, and microcalcifications can be identified that may assist in the assessment of the breast symptom, and cone compression films may provide additional help in evaluating a mammographic abnormality. However, it must never be forgotten that a mammogram is *not* a diagnostic test for cancer. False-negative mammograms occur with an incidence varying from 5% to 20% (in young women this figure can even increase to 30%), depending on the age of the patient, the quality of the films, and the experience of the radiologist who interprets them. Premenopausal women usually have dense breast tissue, and a cancer may be present within such tissue on mammography and yet be totally undetectable. Infiltrating lobular carcinoma may have diffusely infiltrated the breast as seen at mastectomy, yet the mammogram is still read as being "negative" by even experienced radiologists who know the subsequent diagnosis. One *absolutely never* orders a mammogram, gets a "negative" report, and stops with the evaluation there. Although most physicians would not do such a thing, I have personally observed several dozen instances in my oncology career where a physician did exactly that to the ultimate dismay of the patient, himself, and the malpractice carrier. The point cannot be emphasized too much that a mammogram is *not* a diagnostic test; it is a diagnostic aid that is subject to fallibility.

Breast ultrasound may be an additional and useful tool for determining whether a breast abnormality is cystic or solid. However, as with mammography, a sonogram is not an infallible tool either. False negatives can also occur.

Tissue Acquisition

Despite the frequency of breast cancer, when breast masses are biopsied more benign lesions are found than malignant ones. However, there is nothing about the history, the risk factor assessment, or the physi-

cal examination that can exclude a diagnosis of breast cancer. Although some very experienced physicians can claim expertise in predicting whether a breast symptom is due to benign or malignant disease,⁵ such is not true for most clinicians. I have too often seen a physician dismiss a mass newly perceived by the patient as being nothing more than “fibrocystic disease.” Notwithstanding the fact that it has been argued this condition is not even a disease, it is not a diagnosis one can make by clinical examination alone. A new breast “lump” in any woman is a cause for concern, and this fact is especially true for postmenopausal women.

Fine-needle aspiration (FNA) and fine-needle aspiration biopsy (FNAB) are tests that probably should be performed only by those physicians adept in the process, and referral to a specialist is appropriate. FNAB is a more involved diagnostic process that requires both a clinician and pathologist skilled in the technique. Ultrasound and mammographic guidance may assist in obtaining meaningful tissue from the correct site, but false negative results can occur up to 30% of the time.

Biopsy is the gold standard test for diagnosing breast cancer, and whenever one is dealing with a new breast symptom, the need for ultimate biopsy should be borne in mind. The approach of “triple diagnosis”^{6,7} using the combination of careful physical examination, mammography and perhaps ultrasonography, and FNAB will allow one to miss very few true cancers. If the breast lesion being assessed is suspicious for cancer by any of these means, open biopsy is indicated.

Summary

With delay in the diagnosis of breast cancer being such a frequent source of malpractice litigation, physicians evaluating new breast symptoms must take special care in the assessment process. A profile for risk of developing the disease should be developed. The medical history should be fully explored and recorded in the medical record. Careful physical examination should be performed with attention to

the consistency of the breast, skin and nipple abnormalities, and presence or absence of regional lymphadenopathy. If the patient feels something that the physician cannot confirm, re-examination in 2 or 3 weeks and perhaps examination by a consultant would be in order. Mammography should be done, but a “negative” report should never be the basis for stopping the assessment process there. Ultrasonography may give additional information. The final step is tissue acquisition through FNA, or preferably FNAB, and ultimately a biopsy. The careful physician will not contribute to an adverse outcome for the patient by inordinately delaying diagnosis of a breast cancer, and the malpractice carrier will not add another case to the national statistics on medical litigation.

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OPTIMIZING A MEDICAL MALPRACTICE SETTLEMENT

by Donald B. Suss, J.D. and John J. Luke, Jr.*



Physicians are often bombarded with information about the reasons for malpractice suits, the actual mechanics of the litigation process, and various ways to avoid the problem. Rarely, however, do physicians hear anything about what happens during the settlement discussions regarding monetary awards. Besides an outright cash payment, an alternate vehicle exists known as a structured settlement which incorporates periodic payments over the course of the claimant's life. Such an arrangement has real potential not only to avoid dissipation of funds and safeguard the injured party's future assets, but also to ultimately reduce the overall cost of malpractice payments. This article will examine the theory and operation of this financial vehicle.

Is there a way to better manage the uncertainty and expense of medical malpractice litigation? Is there a proven way to avoid the risk of a huge plaintiff's verdict? Can an acceptable solution be offered which satisfactorily addresses the cost of a medical professional's time and the collateral damage inflicted on the medical professional and the affiliated medical institution? Is there a way to provide a thoughtful, reasonable plan which recognizes a claimant's future needs in a cost effective and tax beneficial manner? The answer is a conditional "yes." It is conditional because only knowledgeable, experienced structured settlement specialists have the resources, the skills, the infrastructure and

logistics to provide the resolution framework. These professionals are trained to ask the right questions, go to the right sources, compile and extrapolate disparate data in the right way, and design and articulate needs-based plans which are right for the claimant's long term well-being. The positive end result is the expeditious resolution of an often contentious, distracting and unproductive chapter in the lives of medical professionals.

What is a Structure?

A structured settlement is any resolution of a case in controversy which incorporates periodic payments as a component of the settlement. A structured settle-

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ment of a medical malpractice personal injury claim generally enjoys an income tax exclusion pursuant to Internal Revenue Code Section 104(a)2 which states:

“... gross income does not include ... the amount of any damages (other than punitive damages) received (whether by suit or agreement and whether as lump-sums or as periodic payments) on account of personal physical injuries or physical sickness.”

This language was added by the Small Business Job Protection Act of 1996 signed into law on August 20, 1996 (Pub. L No. 104-188).

Periodic payments specified during the negotiation of a malpractice settlement can take many forms. Any combination of payments can be present in a structured settlement, including the following:

- payments for the life of one person with or without a specific time period guaranteed
- payments for the longer of two joint lives with or without a specific time period guaranteed
- payments for a specific period of time guaranteed
- payments of single lump sums either guaranteed or life contingent
- payments monthly, quarterly, semi-annually or annually
- payments level, increasing by a specified simple or compound amount, or increasing at the Consumer Price Index

Understanding the Transaction of the Structured Settlement

The obligation to make the periodic payments would be funded by the purchase of an annuity contract is-

sued by a life insurance company or the purchase of United States Government obligations. The self-insured defendant, or the insurance carrier, would either purchase and own the qualified funding asset on its own or arrange for a transfer of the obligation to make the periodic payments to a third party by way of a qualified assignment pursuant to Internal Revenue Code Section 130. Most self-insured entities and insurance carriers do not want to own the funding assets, so they can completely close the file and release all financial reserves.

In a typical structured settlement involving the purchase of U.S. Government notes and bonds as the funding assets, the qualified assignment is to a trust which has been established to purchase these securities. In this instance, the grant of a security interest to the claimant in the purchased U.S. Government securities is essential for the penultimate security of this transaction.

The Structured Settlement Advocacy Argument

The focus in the structured settlement design should be centered on the anticipated future needs of the claimant. The view is one defined in “future values.” A review of ongoing medical needs and an understanding of familial responsibility and estate concerns results in a rational settlement design illustrated in future dollars. Multiple cash flows are targeted to meet anticipated needs.

The cash flow can be designed with built-in increases in order to reduce the impact of price inflation. Periodic lump sum payouts are also used as a contingency to offset the impact of possible price inflation.

A unique feature of a structured life annuity is that the claimant cannot outlive the payments. This is the only financial product which will continue to pay as long as an individual is alive. This solution is especially compelling when extensive skilled or custodial care is projected in the life plan documentation.

Also, in the structured life annuity, the transfer of mortality risk to a life insurance company is further enhanced in substantial personal injury cases through an analysis of the claimant's medical condition. Any aspect of the claimant's medical history which may reduce life expectancy will result in an increased benefit for the same available dollars.

There is a social benefit of a structured settlement, in that the periodic payments cannot be accelerated, and, thereby, there is no risk of dissipation as there is with all-cash settlements. The funds of the structure are under professional management, prudently diversified, and administered to make payments on the promised dates which are, of course, income tax-excluded under IRC 104(a)2.

A Cynic's Retort to Structured Settlement

While the design of a structured settlement is infinitely flexible during the negotiation stage, once a settlement is implemented the program is inflexible in that the periodic payments cannot be accelerated, deferred, increased or decreased by the recipient of such payments (Internal Revenue Code Section 130(c)(2)(c)). Such lack of liquidity is usually addressed by including a lump sum cash component in the settlement. "Up front cash" becomes a part of the settlement so there are funds available for unforeseen contingencies, payment of legal expenses incurred, or the satisfaction of a (usually negotiated) lien.

While the risk factor of a structured settlement is extremely low,¹ there still exists some risk that less than 100% of all scheduled payments will be made due to insurance company insolvency. This minimal risk is managed by analyzing data from third-party, professional reporting organizations. The major independent insurance rating reports can be obtained from A.M. Best, Standard and Poors, Moody's, Duff & Phelps, and Weiss. An analysis of these ratings, as well as the underlying investment portfolios of the structured annuity entities

should be undertaken as part of a fiduciary "due diligence." A structured settlement consultant and The National Structured Settlement Trade Association, Washington, D.C., can be effective resources in the creditworthiness review and analysis.

Further, in cases with very substantial settlement funds, investment risk can be ameliorated by designing the settlement with multiple funding assets. Structured annuity funds can be placed among several different life insurance companies, and some payments could be derived from a separate trust funded with U.S. Treasury obligations. Further diversification also could include a "settlement preservation trust" funded with a tax-free municipal bond or bank investment grade corporate bond mutual fund wherein the custodian and corporate trustee is a major financial institution.

The Estate Impact of the Structured Settlement

Although payments from a structured settlement are federal income tax excluded, the value of the structured settlement is inclusive in the estate. One can avoid expenses and delays of probate of estate, however, by specifying the names and relationship of primary and contingent beneficiaries at settlement. If no beneficiary is specified, then the estate will become the beneficiary of specified, future payments, and the estate must be administered until the final payment is made even if that is well into the future.

Beware of the structured settlement which provides for a long deferred period before the annuity commences and a long term certain guaranteed period. The Internal Revenue Service has clearly indicated in a recent series of rulings that it will seek to include in the claimant's estate the present value of the term certain guaranteed payments remaining at the claimant's death. (Note that the present value of a structured settlement with a long deferral period and a long term certain guaranteed period will increase until the payments commence. For example, the present value of a life annuity paying \$5,000 per

month with a 40-year term certain guaranteed period for a female, age 5, which commences at age 18, is approximately \$480,000. Should the claimant die precisely at age 18, the present value of the 40-year term certain which is about to begin is approximately \$940,000). It may be prudent to consider the use of life insurance to pay potential estate taxes for the substantial personal injury recovery. Life insurance premiums can be paid out of the upfront cash, or a cash flow can be incorporated into the structured settlement for the payment of the premiums.

Dangers in Negotiating All-Cash Settlements

From the perspective of the insured (defendant), negotiating solely on cash value of the case significantly restricts the extent of settlement negotiations, and rarely permits a focus on the claimant's future needs (expressed in future values). A structured settlement which addresses future needs and future payments to meet identified needs utilizes an annuity or bond trust which is funded with discounted dollars.

Additionally, future value benefits often "bridge the gap" between plaintiff demand and the insured/defendant "reserve" or "authority" funds. When the formalized, detailed plan is presented to the claimant, there is a greater likelihood of meaningful dialogue with the settlement consultant who is not perceived, necessarily, as an adversary.

From the claimant's perspective and that of counsel to claimants/plaintiffs, as well as society in general, the danger of an all-cash settlement is dissipation of the funds. This usually occurs because of imprudent expenditures, unsophisticated business dealings, inappropriate investments and, perhaps, inappropriate and unwise grants and loans to family and friends. Further, cases that involve those with ongoing need for at-home or institutionalized medical care can exhaust invested cash because of poor market experiences and taxation of investment income and gains.

This is in contrast to the available alternative of the structured annuity which can be designed to pay out specified tax-excluded income as long as the claimant is alive.

The Value-Added Professional Settlement Specialist

Settlement specialists are experienced in claims, insurance, law, economics and financial planning. This knowledge and acumen, along with a commitment to creative and responsive solutions, has proven instrumental in the successful conclusion of thousands of demanding claims. Settlement specialists use their substantial resourcefulness and positive approaches to reach early and favorable settlements for all parties and the unfortunate physician who finds himself or herself involved in a malpractice suit should bear in mind the benefits of such an arrangement.

Reference

1. National Structured Settlement Trade Association, 1982-1992 data, surveyed 200,000 settlement annuities with total premiums of more than \$25.4 billion. The percentage of settlement annuities not performing at 100% was .0015% of all settlement annuities contracted, and the default on total premiums written over the period was .000113%.



MEDICAL LEGAL ISSUES IN THE EVALUATION OF THE FEBRILE PEDIATRIC PATIENT

by James G. Zimmerly, M.D., J.D., M.P.H., LL.D (Hon), COL, MC, USA (RET)*

Fever in a child is a frequent presenting complaint in both pediatric clinics and emergency departments. While the vast majority of fevers may be due to relatively benign viral conditions, otitis media and other causes, serious illnesses including pneumonia, sepsis, meningitis and urinary tract infections may also present with a fever.¹ Unrecognized and untreated these conditions can result in the child's death or significant permanent disability, with resulting liability for the physician.

The three cases that follow resulted in litigation. Enough detail is presented to permit the reader to consider whether or not appropriate standards of care were met, and also to consider obvious weaknesses in the defense of each case. Two cases resulted in deaths and one in significant permanent disability.

Case 1

At 8 p.m. on the evening of 23 November, 8-month-old Joshua L. presented to H. Hospital emergency department with a history of fever of 103.7°F, vomiting and failure to eat all day. The infant had been well on 22 November, and the mother denied diarrhea. The recorded rectal temperature in the emer-

gency department was 99.3°F and the weight was 23.9 lbs. Joshua had a wet diaper and the mother asserted that he could retain juices. The discharge diagnosis was "probable gastroenteritis," and Tylenol was prescribed for the fever.

According to the patient's mother, the subsequent temperature remained between 102°F and 103°F despite Tylenol. When she presented him to another hospital's emergency department at 7:25 p.m. on 24 November, she described a lethargic infant who was unable to retain clear liquids. That emergency department recorded rectal temperature was 97.9°F, the respiratory rate was 44, pulse 116 and weight 22 lbs. Additional history of a cough was elicited. Diagnosis was "URI with fever and

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cough.” Directions for continued Tylenol use plus Erythromycin were given. The infant was discharged at 7:35 p.m., 10 minutes after check-in.

Because of continued fever and lethargy plus “diarrhea all day” the mother returned the infant to the second hospital on 25 November at 9:20 p.m. Temperature was 103.1°F, pulse 180, respiratory rate 32, and weight 22 lbs. Diagnosis was “acute gastroenteritis” and according to the mother, the emergency department physician advised that since it takes more than 24 hours for the antibiotics to work, she should return home. The mother refused and insisted on a pediatric consult. The on-call pediatric resident examined the infant and scheduled admission. Shortly thereafter the infant began seizing.

After a thorough work-up and appropriate treatment, the infant was discharged on 11 December. Discharge diagnoses included H. flu meningitis and sepsis, dehydration, lacunar brain infarct, right hemiparesis and left lower lobe pneumonia.

Case 2

On 3 July, 3-year-old Elizabeth J. developed a fever with an axillary temperature of 103°F. Despite acetaminophen the fever persisted throughout the evening and at 4 a.m. on 4 July, the axillary temperature was 104.6°F. After the patient vomited her Tylenol, the mother took her to the hospital emergency department, arriving at 5:11 a.m. on 4 July. Her recorded vital signs on arrival were temperature of 103.3°F, pulse 120, and respiratory rate 36. Elizabeth was evaluated by the emergency department physician at 5:30 a.m. and discharged home at 5:40 a.m. with a diagnosis of “viral syndrome.” She was to return “as needed.” Over the next 2 days, the patient languished at home, accepted fluids but had no appetite, and continued to take Tylenol for the fever. No other specific symptoms developed. At 4 a.m. on 6 July, the patient expired at home and autopsy confirmed

a streptococcus pneumoniae infection with sepsis, meningitis and right lower lobe pneumonia.

Case 3

On 15 January, 4-month-old Adolpho T. was taken to the emergency department of a local hospital with a history of fever as high as 103°F, poor oral intake, crying without producing tears, and coughing for the past several days. Three days previously the infant had been started on Suprax and Ventolin syrup for bronchitis by the family pediatrician. Vital signs on admission to the emergency department recorded a rectal temperature of 103.7°F, pulse of 152, and respiration rate of 36. The emergency department physician ordered a chest X-ray, CBC, chemistry panel and blood culture. The chest X-ray was normal. The blood work was canceled after the technicians were unable to obtain a specimen, and intravenous hydration was also canceled. The physician diagnosed “bronchitis” and directed the mother to discontinue the Suprax and begin Bactrim pediatric suspension. In addition, Pediaprofen was prescribed for fever and clear liquids were encouraged. The mother was directed to call the pediatrician for an appointment in 2 days.

On 16 January, the parents found the infant unresponsive with a high fever. Adolpho was returned to the hospital in full arrest with a rectal temperature of 101.1°F. Autopsy reported the cause of death to be severe bronchiolitis and early bronchopneumonia. Cultures for causative organisms were negative.

All three of the aforementioned cases were settled after discovery and prior to trial despite credible, experienced pediatricians as defense expert witnesses. After weighing the factors, the defense in each case decided that a negotiated settlement was preferable to the uncertainty of a trial where damages were significant and documented treatment marginal at best and substandard at worst.

Medical Overview

More than 300 articles have been published in journals in the past 35 years concerning the management of febrile children. Practice guidelines for the management of febrile children have been published and are to a large degree underutilized. The immediate medical concern is about fever of recent onset in children who have no adequate explanation for the fever either by history or by physical examination. These high fevers without localizing signs may be caused by the prodrome of a viral infection or by serious illnesses such as pneumonia, meningitis, sepsis, gastroenteritis or urinary tract infections.²

To start with, accurately measuring the temperature and prescribing treatment to allay the discomfort of fever is expected, but trying to identify the cause of the fever is more important. Adding to the nebulous complaint is the fact that parents often do not accurately measure temperature. In children under 3 years of age, aural temperature measurement often used for home monitoring is inaccurate—off by an average of 0.6°C when compared to rectal temperatures. Also, pre-hospital treatment may result in a relatively normal temperature upon arrival in the emergency department.³

“Approximately 15,000 children are diagnosed with meningitis annually . . .”

The etiology of bacterial meningitis varies with the age group to a large extent. Infants less than 1 month of age are most commonly affected by group B streptococcal organisms followed by *Escherichia coli* and *Listeria monocytogenes*. All other bacterial organisms are far less common pathogens in infants. Children 1 to 3 months of age are in a transition stage immunologically and are susceptible to all of the aforementioned bacteria, plus *Haemophilus influenzae* type B, *Neisseria meningitidis*, *Streptococcus pneumoniae* and oth-

ers. In children more than 3 months of age, the most common affecting organisms used to be *Haemophilus influenzae* type B, but cases requiring hospitalization have been markedly reduced (from 50 per 100,000 to 3 per 100,000) due to routine use of the specific vaccine. Immunization to H. flu type B typically begins at 2 months of age.⁴ *Neisseria meningitidis* and *Streptococcus pneumoniae* are other common pathogens in the young child. All three organisms are encapsulated and the encapsulation may result in added resistance to normal host defenses.

Approximately 15,000 children are diagnosed with meningitis annually in the United States. Physical results range from complete recovery to extensive neurological damage, deafness, blindness, paralysis, loss of portions of extremities, to death in up to 10% of the cases. Malpractice settlements and awards can be high and are not uncommonly in the several million-dollar range.

While early diagnosis is essential to reduce morbidity and mortality, early diagnosis can be elusive. The early signs and symptoms often mimic benign conditions that are much more common. Whereas late stage meningitis can be diagnosed by less skilled practitioners, early disease can stump the best clinician. Laboratory tests can be nonspecific and may even be normal in early disease.

The physician may sense a dilemma: miss the diagnosis and the resultant damages to the patient may be huge, to say nothing about the effect of litigation on one's practice, or perform a thousand-dollar work-up on every febrile child and run the risk of criticism in the current managed care environment. With cost containment programs growing, clinical justification will be increasingly required for all laboratory tests.⁵ This is not to suggest, however, that an extensive work-up is either required by law, or is good medical practice in the case of most febrile children.

So how does the physician sort out the patients who require an extensive work-up? One way is to be aware of various risk factors. Febrile infants less than 1 month old usually require hospitalization. Between 1 and 3 months, the risks of bacteremia and meningitis are high, increased when compared with older infants.² Native Alaskans, Native Indians, and African-Americans, especially with sickle cell disease, are also at increased risk. Children who are immunologically compromised or undernourished are at added risk. A basilar skull or cribiform plate fracture adds risk. Direct extension of a bacterial infection from a site adjacent to the meninges, such as ear, sinuses or mastoids rarely causes meningitis. The seeding of the meninges from the bacteria in the blood stream is usually the mechanism. Bacteremia with *Haemophilus influenzae* and *Neisseria meningitidis* more often leads to meningitis than bacteremia with *streptococcus pneumoniae*.

Bacteremia is common following trauma, infections and even dental brushing, but in most instances the normal healthy host defenses overwhelm the bacteria. If the bacteria overwhelms the host, the result is sepsis or focal infection. Therein lies part of the problem in diagnosing early bacterial meningitis. Bacteremia is often occult and children do not always appear very ill. Occult bacteremia, most commonly *streptococcus pneumoniae*, occurs in 5% of febrile children between 6 and 24 months of age.⁶ In addition, urinary tract infections occur in 7.5% of febrile children under 1 year of age⁷ and pyuria may be caused solely by high fever in 9% of children.⁸

The clinician then must discriminate between the benign illness and the potentially serious illness. It has been estimated that the predictive value of a thorough history and physical examination will enable the physician to detect serious illness in 80% of the cases. This article is about the other 20%.

Is there any predictive value of the temperature that can assist in identifying early cases of potentially serious illness? The occurrence of bacteremia in a

patient whose temperature is less than 102°F is close to 1%, while the incidence of bacteremia rises to 20% in patients whose fever exceeds 105°F. Since up to 10% of bacteremic patients will develop meningitis, it follows that a high fever can be an ominous sign if it were not for the fact that the vast majority of high fevers are due to viral illness. Studies have attempted to relate bacteremia to elevated white blood counts which might be a better prognostic measurement but for the fact that elevated WBCs can occur in viremia as well as in bacteremia.

The studies that have measured this relationship have found that a WBC below 10,000 is associated with a bacteremia in 1% of the cases while a WBC of greater than 20,000 is associated with bacteremia 20% of the time. Should the patients in Cases 1, 2, and 3 have had their WBC measured, with blood cultures started if the WBC was elevated? All three patients had high fevers reported by the mothers, and two were confirmed in the emergency department. All three patients had vomiting and lethargy described by the mothers. Vomiting is a common but sometimes serious problem; possibly an early sign of meningitis. True lethargy is a rare and usually ominous clinical finding necessitating comprehensive evaluation. Most children will have three or more illnesses with fever in each of their first 3 years of life. Most are viral. Most resolve without treatment. The combination of fever, lethargy and vomiting, however, does suggest greater toxicity and more potential for serious disease.

If only it were that simple. While an elevated WBC may be suggestive of a bacteremia, of what significance is a low WBC? An extremely low WBC may be due to a viral illness 99% of the time; the remaining 1% may be on the verge of septicemia. In cases similar to the previous three examples, experts have testified that when WBCs showed an increase in the number of band cells a bacteria was favored. While toxic granulation, Dohle bodies and an increase in juvenile neutrophils may favor bacteremia, all can be seen in viral illness as well.

In infants between 1 and 3 months of age with a temperature greater than 102°F, low risk has been defined in one study as “appearing well,” a normal CBC, and a normal urinalysis. Other physical findings such as playfulness, being able to be calmed by the mother, and eating well may help the clinician decide about ordering a lumbar puncture to obtain spinal fluid for analysis.⁹

“Every febrile infant or child is a potential malpractice claim.”

What help are other tests short of a lumbar puncture? An elevated ESR is not diagnostic. A C-reactive protein has a positive predictive value of 3%. Blood cultures may be positive 90% of the time, but only after 24 hours or more, and low sample amounts decrease the positive rate. Blood cultures should be considered in cases where the likelihood of bacteremia is high, such as young children with a temperature more than 102°F, a WBC above 15,000, or a toxic appearance, or infants less than 3 months old with an abnormal temperature, either high or low. A new technology, polymerase chain reaction amplification of bacterial DNA, has been reported to be a potential rapid indicator of generalized sepsis in the neonatal intensive care units, offering a glimpse into the future of potential rapid screening of febrile infants.¹⁰

Lumbar puncture will definitely identify an infection of the central nervous system, but in an early viral meningitis the WBCs in the spinal fluid can be predominantly polymorphonuclear cells usually associated with bacterial infections. Lumbar punctures are indicated whenever the physician suspects meningitis and in most febrile infants younger than 3 months of age. Does the presence of a seizure in a febrile child mandate a lumbar puncture? Not necessarily. The threshold of suspicion may be lowered, however, but

lumbar puncture is not always required merely because of the seizure. Children who have febrile seizures are at risk of developing meningitis at the same rate as febrile children who do not have seizures.

Early in the course of bacterial meningitis, the CSF may be normal. It may be necessary to repeat the lumbar puncture in 3 to 6 hours for infants or 12 hours for older children, or at any time if the child deteriorates clinically. You treat the patient, not the test. This is difficult to do if the patient has been sent home to be observed by the family. Blood cultures may detect an infecting organism, even on some occasions when the CSF culture is sterile. In one large study of bacterial meningitis, 90% of meningococcal cases, 90% of Haemophilus influenzae cases, and 80% of pneumococcal meningitis cases had positive blood cultures.¹¹

Thus, the diagnosis of early meningitis is not patently obvious in many cases, and ultimately may depend on the clinical judgment of a seasoned physician with a low threshold of suspicion. Pediatricians can easily claim to possess the requisite training and experience to assess acutely ill children. Emergency physicians claim to provide the majority of care to acutely ill and injured children in the United States and also claim to possess the background and experience.¹² One state surveyed the preparedness of 90 hospitals to treat pediatric emergencies. It discovered that 45% of the emergency department personnel had no pediatric experience and 52% had no continuing education credits in pediatrics.¹³ This is surprising since pediatric patients comprise a significant percentage of patient visits to emergency departments.

The following three aphorisms are always valid:

1. Good medical practice reduces the risk of litigation.
2. Some cases of bacterial meningitis and/or sepsis will be missed under the best of care, but these cases can be reduced in number.
3. Every febrile infant or child is a potential malpractice claim.

The primary care physician, regardless of specialty, must maintain a high index of suspicion. If the physician does not consider the diagnosis, he or she will not make the diagnosis. If sepsis or meningitis is considered, then it must be ruled out. The work-up must include a thorough history, a thorough physical examination and appropriate supporting laboratory tests. The history should include the child's behavior over the past several hours and days. Recent antibiotic treatment may mask clinical signs.¹⁴ The physical examination may not disclose any "classic" signs of meningitis in early stage disease, and the younger the child, the more nonspecific the clinical signs.¹⁵ On occasion the only sign of early meningitis or sepsis may be a fever, and in infants even the fever is variable. In fact, the early physical examination may be rather unremarkable. Up to 10% of infants with meningitis may appear clinically well on first examination.¹⁶ Appropriate laboratory work-up should be determined by the history and physical examination.

A parent's description of the child's condition must not be discounted for the parent will know when the child is not behaving normally. The physician's 10-minute examination is a mere snapshot in time to be weighed against the parent's observations over hours and days. The physician should spend time with the patient in the initial examination and re-examine the child prior to discharge. There should not be a prolonged "waiting time" in well-run emergency departments, but instead an "observation time" for noting changes in condition. In Case 1 and 2, the infants were both discharged within 10 minutes of the time that the examining physician first saw the patient, and less than 30 minutes after signing in to the emergency department. A little observation time could have been very helpful in the defense of these cases for failure to document improvement while the patient is under observation is a frequent finding in cases proceeding to litigation.

Physicians' discharge instructions should be thorough and clear to the parents. Both oral and written instructions are appropriate and customary. "Return prn" (as needed) does not signal much concern for the patient. More definitive instructions, with specific time frames based on a change in condition, can prove more meaningful and can enhance defensibility.

Case Discussion

In Case 1, the emergency departments recorded normal temperatures in the 8-month-old patient, whereas the mother insisted that the temperature ranged from 102°F to 103°F at home. This is a common scenario: the medication given at home has taken effect. The recorded weight of the infant decreased from 23.9 lbs on the first visit to 22 lbs on the second visit 24 hours later. Is this significant? The defendant physician claimed that the weights were not accurate. Why not? And why record the weights if they are not accurate? Should a weight loss of 8% during a 24-hour period be of concern in an infant?

The infant in Case 3 presumably died from a respiratory syncytial virus infection. Each year this virus is responsible for approximately 90,000 hospitalizations and 4,500 deaths in infants and young children in the United States.¹⁷ Activity peaks in the months of January and February.¹⁸ Case 3 occurred in January. Most of these infections attack infants aged from 2 to 6 months; Adolpho was 4 months old.

Should the physician in Case 1 have contacted the emergency department that examined the infant 24 hours earlier? Should the physician in Case 3 have contacted the pediatrician who began treatment of the infant for bronchitis 3 days previously? The truly outstanding physician will contact previous health care providers or facilities and most emergency physicians will personally establish follow-up treatment by contacting the patient's pediatrician. Remember that prior treatment with antibiotics may mask the

presentation of meningitis. One study estimates that 30% to 50% of patients have received antibiotics prior to a diagnosis of meningitis.¹⁹

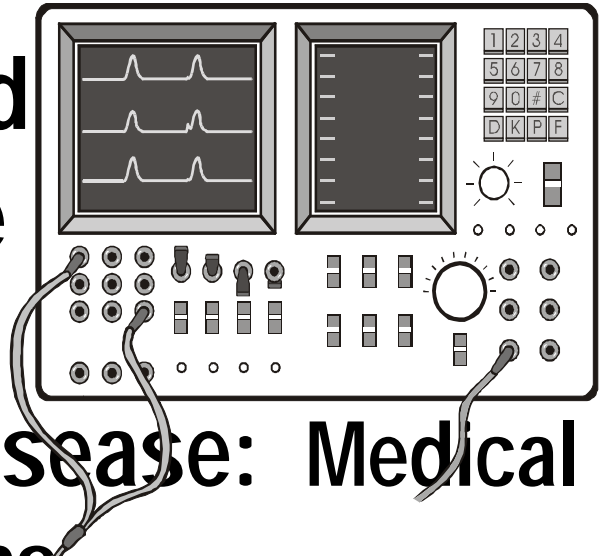
Based on the foregoing cases and the accompanying discussion, it is apparent that evaluation of the febrile child presents unique risk management con-

cerns. Failure to diagnose or a delay in diagnosis of pediatric meningitis, pneumonia, or other serious infectious entities can have catastrophic medical and financial consequences. In an evaluation of the febrile child, there is no substitute for a healthy index of suspicion coupled with a thorough history and physical and appropriate diagnostic testing.

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Ultrafast Computed Tomography in the Diagnosis of Coronary Artery Disease: Medical and Legal Implications



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Heart disease remains the leading cause of patient mortality, and the failure to diagnose coronary artery disease presents a major medical-legal liability risk. Ultrafast Computed Tomography is a newer diagnostic tool with current utility and the potential for growing medical acceptance as part of the “standard of care” with concomitant legal implications.

Despite its declining incidence over the past four decades, coronary artery disease (CAD) continues to be the major cause of death among Americans.¹ The failure to promptly diagnose and treat myocardial infarction also remains a frequent allegation in medical malpractice claims. In emergency medicine missed myocardial infarctions account for at least 10% of malpractice cases.² In terms of monetary losses, myocardial infarction cases often prove to be extraordinarily expensive. Because of the catastrophic consequences often following a “missed MI,” the dollars paid in subsequent settlements or

successful lawsuits have been among the highest, accounting for 25.4% of all dollar losses in emergency medicine alone.³

With this background it is understandable that physicians are haunted by the spectre of the “missed MI.” In addition to a meticulous patient history and physical and a healthy index of suspicion, resort to accepted, appropriate diagnostic tests is mandatory. Recent technological advances have provided us with new diagnostic modalities, among them Ultrafast Computed Tomography (UFCT). While this imaging technique is new and has limitations, it also pos-

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sesses important diagnostic potential. Physicians should be aware not only that this diagnostic tool exists, but also that eventual general acceptance of this or other diagnostic modalities by the medical community in specific circumstances can bring this testing into the realm of the "standard of care" which the law demands.

Over the years there have been numerous studies to identify the factors that predict the probability of patients dying from CAD. The unpredictability of this disease has been highlighted in a classic study which demonstrated that 52% of individuals whose death was attributed to heart disease died without previous symptoms.⁴ This illustrates the importance of developing an effective diagnostic tool to identify the presence of CAD. Ideally this tool should be highly sensitive, highly specific, non-invasive, easily accessible, and low cost. At present there is no effective non-invasive method which meets these requirements.

There has been a historically well-recognized association between the presence of coronary calcium with atherosclerotic disease.⁵ Because of this association, the use of ultrafast computed tomography (UFCT) to detect coronary calcium is now offered as a possible non-invasive test to detect the presence of CAD.

Historical Diagnostic Modalities

The current standard test for the detection of CAD is stress electrocardiography (ECG). This procedure requires the patient to have the ability to exercise and to have a near-normal baseline ECG, and it requires the presence of a physician who is well trained in stress ECG testing. After all of these qualifications are met, stress ECG is less than a fully reliable diagnostic test for CAD, with sensitivity of detecting CAD reported to range from 14% to 88%.⁶

Fluoroscopy of coronary calcification has also been shown to have low sensitivity and specificity. The

reason for this may be the false positive readings that are obtained due to the interference caused by the spine, lung nodules, aortic plaque, and other non-coronary calcium deposits.⁷

Conventional computed tomography has been suggested as a modality to detect coronary calcium, but there are a number of drawbacks to this method as well. Slow scanning times make this procedure long and costly. In addition motion artifacts, caused by patient movement and breathing, lead to missing and overlapping segments in the final image.⁷

Ultrafast Computed Tomography

The use of UFCT to detect the presence of coronary calcium, however, has shown promising results. UFCT is performed with a high-resolution UFCT scanner using 100ms exposure time. Images are obtained at the same point in diastole using ECG triggering. During one 30-second breath hold, twenty to forty 3-mm-thick images are obtained. After each scan the machine is moved to create a sequence of images to be obtained from the aortic root through the left ventricle.^{6,7,8}

There have been a number of studies evaluating the correlation of UFCT detected coronary calcium and angiographically diagnosed CAD. One of largest studies to date is the multicenter study performed by Budoff et al.⁶ The study population consisted of 710 patients from 6 centers across the United States. The patients in this study population underwent coronary angiography for suspicion of CAD and had ultrafast CT within 3 months after the angiogram. The results of this study are summarized in Tables 1 and 2.

The data from this study demonstrate a number of important findings: first, the increasing sensitivity and positive predictive value of UFCT with age in identifying obstructive CAD as shown in Table 1. This is important because the prevalence of calcium found in CAD lesions increases with age. The absence of calcium detected by UFCT is

| Detection of Obstructive Coronary Lesions by UFCT | | | |
|---|-----|----------|-----|
| | Age | | |
| | <40 | 40 to 50 | >50 |
| Sensitivity | 68% | 84% | 99% |
| Specificity | 74% | 53% | 34% |
| Positive Predictive Value | 59% | 69% | 73% |
| Negative Predictive Value | 81% | 72% | 98% |

Table 1

highly accurate in excluding obstructive CAD in patients above age 50. In addition the number of calcified vessels detected by UFCT has an increasing positive predictive value for the detection of obstructive CAD as shown in Table 2. Patients with one calcified vessel have an 84% chance of having obstructive coronary artery disease, and pa-

UFCT in Gender Differences and Lesion Differences

A study by Devries, et al evaluated the effect of gender differences on the ability of UFCT to detect significant coronary calcium.⁹ In this study 70 men and 70 women undergoing coronary catheterization and UFCT within a 9-month period were studied to determine the effects of age, gender and the relationship of detected coronary calcium and angiographic results.

In analyzing the data, they found that the sensitivity of coronary calcium for the detection of angiographic disease in the same vessel was 48% for women less than 60 years old, 70% for women more than 60 years old, while the sensitivity was 72% for men less than 60 years old and 79% for males more than 60 years old. The specificity of these groups were all statisti-

| Prediction of Obstructive CAD by Number of Calcified Vessels on UFCT | | | | |
|--|-------------|-------------|-----|-----|
| Number Calcified Vessels | Sensitivity | Specificity | PPV | NPV |
| 1 | 92% | 54% | 84% | 71% |
| 2 | 76% | 78% | 90% | 55% |
| 3 | 56% | 88% | 93% | 43% |
| 4 (LM, LAD, CX, RCA)* | 20% | 98% | 96% | 31% |

*Left Main, Left Anterior Descending, Circumflex, and Right Coronary Artery.

Table 2

tients with four calcified vessels have a 96% chance of having obstructive disease.

Finally, this study demonstrates that with a high calcium score (a computed number used to quantify the amount of calcium found with UFCT) and a prediction of multivessel calcium by UFCT, there is an 80% prevalence of obstructive multivessel disease regardless of patient age. Using this as a benchmark for identifying CAD in high-risk patients, UFCT could become a powerful non-invasive diagnostic tool.⁶

cally similar. This result suggests that younger women have a different pattern of coronary calcification than do older women and men, possibly due to the effects of estrogen on coronary calcium deposits. Younger women are less likely to have calcium deposits associated with coronary lesions than are older women and men of all ages. This study shows the reduced benefits of scanning younger women with UFCT for the detection of CAD.⁹

Another distinction was the difference in the detection of obstructive CAD (luminal narrowing of

³70%) and angiographic disease (luminal irregularities of <70%). The negative predictive value of UFCT was found to be 94% for obstructive CAD versus 76% for luminal irregularities.⁷ Therefore, UFCT is very good at ruling out high grade lesions and is less effective as a diagnostic tool for detecting lesser grade lesions.

Unanswered Questions Concerning UFCT

One of the first questions regarding UFCT concerns the actual method in which it is performed. The scan is obtained using 3mm slices through the left ventricle. Questions have been raised as to whether this method is the most accurate. Reducing the slice diameter to 1mm has been suggested to be more precise in detecting coronary calcium that might be smaller but significant. This modification in the methods, however, would increase the scan time and would negate the ability to make scan runs in one patient breath.^{7,8}

Another question concerning UFCT is its use in clinical medicine. With the promise of possible cost savings in UFCT scans, clinical cardiologists and primary care physicians may both be tempted to use this modality for the diagnosis of CAD in all cases. As the published data shows, however, there is tremendous variability in the sensitivity, specificity, positive predictive value, and negative predictive value of UFCT depending on age and sex. This complex and limiting data must be made known to maximize the diagnostic value of UFCT. If this data is not understood, this modality may be inappropriately used in diagnosis of patients who have been proven to gain no benefit from UFCT.

Finally, UFCT has been shown to be most effective in ruling out obstructive coronary lesions. The lower negative predictive value for luminal irregularities means that even though a patient can be ruled out for obstructive coronary artery disease he may not be able to be ruled out for lower grade obstructions.

Because of this limitation, further definitive data must be generated on the difference between stenoses of ³70% and those of <70%. The prognostic value of the determination of less than or greater than 70% stenosis must be made clear for UFCT to become a definitive noninvasive test for CAD.⁹

Legal Implications

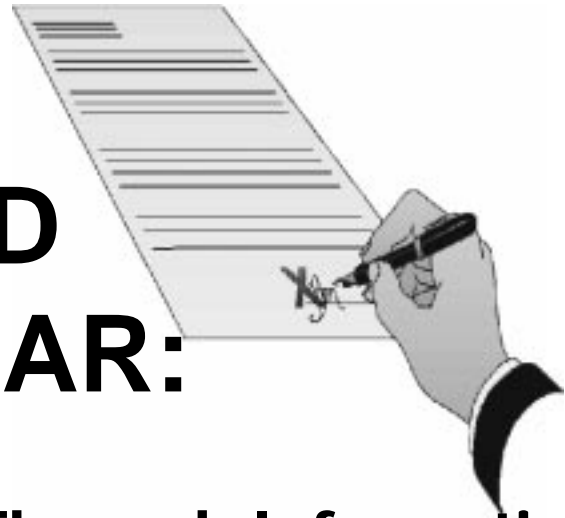
Because of these many unanswered questions concerning the efficacy of UFCT, this modality is not yet considered part of the standard of care routinely utilized by physicians in cardiac diagnosis. In fact, recent articles in the *New England Journal of Medicine* point to the fact that while UFCT appears very promising, more studies are required to define its exact role as a diagnostic tool.^{10, 11} Generally the law looks for scientific consensus and "general acceptance" of tests and procedures within the medical community before holding that the omission of the test represents negligence.¹² As technology progresses and other physicians in similar circumstances are found to utilize specific diagnostic resources, the courts are prone to find the omission of that test to be negligence. For example, in *Forrestal v. Magendatz*¹³ the court found an obstetrician negligent for failing to employ ultrasound, x-ray pelvimetry, and electronic fetal monitoring since all tests were available at the obstetrician's hospital, he knew how to use them, and they were routinely being utilized by other obstetricians in similar localities. Precedent even exists for imposing liability in the absence of routine utilization of a safer, better practice, if it can be shown that an entire industry or profession utilized a less effective test and should have embraced the newer, more efficacious method.

In any case, UFCT provides an excellent illustration of a new diagnostic test with evolving applications. Presently, it remains to be seen if UFCT will eventually gain general acceptance in certain circumstances, with attendant legal liability attaching for its omission.

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INFORMED CONSENT AND THE PAP SMEAR:



Avoiding Malpractice Through Information

by Kent E. Harshbarger, M.D., J.D., CPT, MC, ILARNG*

Primary care providers, cytotechnologists, and pathologists are being subjected to claims of professional negligence in the collection and interpretation of cervical cytology specimens at an alarming and ever increasing rate. This process continues to jeopardize the availability of the Pap smear because the increasingly large damage awards, low reimbursement, increasing government regulation, and the possibility that laboratories may be required to make large capital expenditures for new automated technologies are forcing many laboratories to discontinue the service. In an effort to reduce liability, many authors have suggested obtaining a patient's informed consent prior to obtaining a Pap smear. This paper examines the history and development of the doctrine of informed consent and explores the legal effects of obtaining a patient's informed consent prior to obtaining a Pap smear.

Historically, pathologists have enjoyed a relatively protected position in the arena of medical malpractice litigation. Many reasons have been offered to explain this liability protection, but most notably pathologists generally have no direct patient contact and generally are not involved in high-risk procedures. Another factor leading liability away from the laboratory is the delay or extended time period between the diagnosis and the discovery

of any error. Additionally, a pathology malpractice case can be relatively costly to litigate. The interpretation of cytologic or histologic specimens and their explanation to a lay jury can require an expensive "battle of the experts," and the often conflicting expert opinions can create confusion about the applicable medical standard of care. These factors combined to create a deterrent to legal actions against pathologists.

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Today, however, pathologists, insurance companies, and their attorneys have come to realize that any perceived protections were illusory. Pap smears and cytology practices in general have become rapidly growing areas of potential liability for pathologists. A recent article, citing the experience of the Doctors' Company, noted that cervical cytology claims are more costly than the average pathology claim and the number of claims has at least doubled since 1988. Cervical cytology claims represented almost 30% of the total claims against pathologists in 1995, with the total indemnity paid for cervical cytology claims nearly 40% of the total paid for all claims against pathologists in 1995.¹

An increase in liability is naturally followed by the efforts of risk managers and quality assurance managers to reduce that liability. The College of American Pathologists recently devoted an entire conference to define and emphasize the trends in liability.² Also, the International Academy of Cytology published a summary of recommendations from their task force on medicolegal affairs with respect to Pap smears and liability.³ One idea that has been receiving attention is the doctrine of informed consent and its application to cervical cytology.⁴ One laboratory now requires a signed informed consent form prior to interpreting a Pap smear.⁵ This article explores the history and development of the doctrine of informed consent and provides a brief analysis of its use with Pap smears.

One laboratory now requires a signed consent form prior to interpreting a Pap smear.

History and Development

The current doctrine of informed consent imposes a legal duty upon physicians to provide adequate disclosure of the medically recognized risks, benefits, and alternatives to any proposed diagnostic or therapeutic medical procedure so their patients can make informed decisions and give informed consents to

those procedures. This doctrine is entrenched in all fifty states as well as the District of Columbia. It rests on several specific legal premises including the idea that touching without consent is battery, that treatment without consent is a violation of the provider's fiduciary duty to the patient, and that the patient has a right to self-determination or autonomy.⁶

Historically, physicians maintained the position of patriarchal authority and courts provided them great deference. Patients did not question their doctor's treatments or methods. This deference began to erode as medical science grew. Hospitalization, aseptic technique, and improvements in anesthesia made it possible for larger, more extensive surgeries that naturally carried increased morbidity and mortality. Courts were forced to recognize the flaw in patriarchal deference when highlighted by the helplessness associated with anesthesia. Furthermore, they realized some patients would not want to take the increased risks associated with these new and developing procedures. The early cases, decided around the turn of the century, focused mainly on simple consent. In *Pratt v. Davis*,⁷ the patient's husband had consented to only one operation and the court determined a battery had been committed when the surgeon extended the procedure to include a "second" operation without consent. *Schloendorff v. Society of New York Hospital*⁸ memorialized the notion that tort law, specifically battery, can apply to physician-patient relationships.

The doctrine remained unchanged until 1960 when the courts finally took note that the requirement for simple consent only disguised the patriarchal deference used in the eighteenth century. Courts had empowered patients by requiring their consent for diagnosis and treatment; however, the rule did not provide or require any basis or knowledge to help make that choice. Many patients, then and now, simply relied upon and trusted the expertise of their doctor. The first case to expand the simple consent theory was *Natanson v. Kline*,⁹ which held that a

physician had to disclose enough information to allow the patient to understand the recommended treatment before obtaining a patient's consent. The duty to disclose arose out of a physician's fiduciary duty to the patient created by the disproportionate level of knowledge and experience.

This subtle change created a massive switch in legal direction. The applicable body or theory of law changed from an intentional tort, namely a battery, to a cause of action based more closely on the tort law of negligence. The court now focused on the specific information the physician passed on to the patient, and compared the information required for disclosure to that which would be expected from the average reasonable medical professional similarly trained and in similar circumstances.¹⁰ The standard is the same one used in medical malpractice or other professional negligence claims to determine if the standard of care has been breached. This is known as the "professional" standard and is currently the rule followed in just over half the jurisdictions.¹¹

This standard, however, did not gain universal acceptance and controversy developed over its application. Many argued that patients could only be protected by a standard which focused on the needs of the patient and not on what the medical establishment believed to be important. The next leading case to refine the standard of disclosure, *Canterbury v. Spence*,¹² suggested the "prudent patient" standard which remains the minority approach.¹³ It requires the disclosure of all information that would be "material" to a reasonable person in the patient's position when faced with a similar decision. The debate over how to protect patients grew even larger when the courts of Oklahoma and West Virginia removed the "reasonable person" requirement from the standard.¹⁴ To fulfill their duty under this third standard, providers must tailor their disclosure to the individual patient's needs based on that particular patient's values, knowledge base, and concerns.

During the 1970s many state legislatures took the debate away from the courts and enacted statutes to

codify the common law. These laws further modified the requirements for the use of informed consent by specifying in which cases it was required, what documentation was required, and how much information should be exchanged. Three states (Hawaii, Louisiana and Texas) completely changed the process by creating "Medical Disclosure Panels."¹⁵ Since state legislatures have created great diversity in the requirements and methods by which the doctrine of informed consent is satisfied, each physician is encouraged to become familiar with the relevant statutes in his or her jurisdiction.

A patient can also waive the right to informed consent.

Elements, Defenses, and Analysis

An allegation of malpractice based on the lack of informed consent rests on the idea that an injury occurred without consent. The patient did not "accept the risk." A patient so injured must establish the standard four elements of a negligence claim as modified for informed consent cases. These elements include the following: 1) a provider's specific duty to disclose particular information; 2) a breach of that duty because the information was not disclosed; 3) the occurrence of an injury; and 4) the failure to disclose the information caused the injury. The last element, causation, can be further divided into two necessary components. First, the patient must show that if the required information had been provided he or she would have forgone treatment or elected to proceed with an alternative method. The second component requires that the injury was the direct result of the medical care provided and the particular risk was known or reasonably should have been known to be associated with the patient's medical care.¹⁶

The establishment of these elements does not always signal liability. The courts recognize specific instances where limited or no disclosure is necessary

and desirable. One obvious instance is where a particular patient already knew or should have known the risks or alternatives. In some jurisdictions, a patient can also waive the right to informed consent; however, the physician must clearly document the waiver including the patient's desire to undergo treatment regardless of the risks. The patient must understand she has a right to the information and decline it without pressure. Thus, the waiver must also be an "informed waiver."

Emergencies, by definition, require prompt decisive action precluding the discussions necessary to obtain an informed consent. Also, courts recognize that most "reasonable patients" would not forgo the emergency treatment and therefore the element of causation is not met. There are times when courts may mandate treatment, which removes the need for informed consent, such as the drawing of blood alcohol or the removal of trace evidence. Finally, the need for disclosure is removed when the mere act of revealing the material information alone will cause harm to the patient's recovery or cause undue stress that derails therapy. This exception is known as the "therapeutic privilege." Again, the use of this defense requires clear documentation in the medical record including the reasons for withholding relevant information. The decision should be supported with opinions from professional peers if possible.

Relevance to Pap Smears

The doctrine of informed consent and its use as a defense to professional negligence in cervical cytology lawsuits has appeared in recent articles, and some authors have regarded it as being of limited value.¹⁷ This opinion seems to discount several factors. First, as illustrated by one author,¹⁸ the majority of suits tend to follow a "script" which includes many claims of negligence, only one of which is the lack of informed consent. Second, patient education can take place by helping to remove the public notion that cervical cytology is 100% accurate. Finally, the process helps strengthen the physician-patient relationship through cooperation, which may reduce the likelihood of later legal action.

A false negative diagnosis will be better understood by the patient and thus remove some of the motivation to consult an attorney.

False negatives can and do occur in the absence of negligence.

The entire process serves to shift the burden of risk of potential or expected complications from the physician to the patient, once she has agreed to proceed despite the possibility of disclosed dangers. In the case of Pap smears, the patient has formally accepted the fact that there is a recognized error rate and false negatives can and do occur in the absence of negligence. The physician, of course, will remain liable for care provided in a manner that falls below the appropriate and reasonable standard of care with respect to the actual cytologic slide interpretation, its processing, and reporting. However, well documented informed consent allows the defense to show the jury that, while unfortunate, mistakes do happen without fault, and therefore there should be no liability. Arguments that emphasize the patient's responsibility for follow-up care and repeat testing become much stronger.

Documentation of informed consent is invaluable at the time of trial. In a case involving a claim of negligence and lack of informed consent, a court noted that in the state of Washington a signed consent form is prima facie evidence of informed consent.¹⁹ This means that once the form is introduced by the defendant physician at trial, the plaintiff must produce evidence to rebut the idea that she consented to the testing. In the case of Pap smear litigation, the jury would hear from the defense that the patient consented, knowing that false negatives could occur even in the best laboratories. Plaintiff would then have to demonstrate to the jury how the alleged diagnostic error fell outside those errors which could be expected and predictable.

The doctrine of informed consent can provide physicians needed protection from liability associated with cervical cytology and Pap smears. Physician liability cannot result from harm caused by expected or predicted dangers once the patient has agreed to proceed after knowing those risks. Many observers have discounted the legal protections afforded by informed consent because most malpractice cases will also center on allegations of substandard care resulting in unexpected injuries. However, it is clear that proper informed consent can limit liability by providing needed education regarding the limitations associated with screening, as well as shift the burden of known risks to the patient. Also, it can assist in the development of trust and encourage patient participation in decision-making. These factors often combine to make the patient less likely to initiate a lawsuit. If a lawsuit is ultimately brought, well documented informed consent forces the patient to differentiate between those errors that were the result of true screening failures and those caused by negligence.

For these reasons, the doctrine of informed consent should encourage physicians to discuss openly and honestly the limitations of cervical cytology. Many laboratory tests, including screening tests like the Pap smear, are not capable of a "yes/no" answer. In the profession's rush to extort the virtues of mass screening, it chose not to emphasize that the Pap smear is a test incapable of 100% sensitivity for fear some women would forgo this valuable test altogether.²⁰ Taking the time to educate patients will help emphasize the value of repeat testing and will place some responsibility on the patients once they are involved with the decision-making process. Proper repeat testing can greatly reduce the possibility of missing treatable disease, which again lowers the chance of a lawsuit.

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