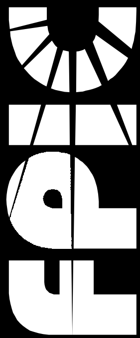

Preventive Action

LIABILITY ISSUES RELATED TO STROKES

In 1998 over 158,000 people died from strokes, the third leading cause of death in the United States[1]. More than 700,000 individuals are newly diagnosed with strokes annually[2]. The costs associated with strokes are staggering, with estimates to exceed $40 billion every year[3].

The following case presents a medical malpractice suit that could have been prevented.

Case One: *Over the course of several years, a male patient was diagnosed with hypertension, memory loss, short-term change in vision, and short-term numbness/weakness on one side of his body. The patient was seen by an internist and several neurologists during this time, but was not treated for these symptoms. At the age of 49, the patient suffered a massive stroke. After the stroke, he was unable to work and unable to care for himself independently. He was placed on Coumadin and had no further strokes.*

Suit was brought against the internist and the neurologists because of failure to diagnose and properly respond to an at risk patient. The plaintiff's attorney claimed that had the patient been properly diagnosed and started on anticoagulant therapy, the stroke would have been avoided. An economist testified at the trial that the estimated costs of lifetime care and lost income were valued at $1.5 million. The jury agreed and awarded the plaintiff $2.5 million, $1.5 million for lost earning potential and $1 million for pain and suffering. The amount of the award in this case reflected not only the severity and nature of the patient's injury but the relatively young age of the patient.

The issue in this case is the physician's failure to address the patient's risk factors.

The next case illustrates what may happen when a patient is placed on anticoagulation therapy but then is not properly managed.

Case Two: *An elderly patient was diagnosed with atrial fibrillation in 1985. His physician started him on anticoagulation therapy at that time. In 1988, he underwent a minor surgical procedure. The Coumadin was discontinued three days prior to surgery and heparin was given instead. The heparin was stopped and the Coumadin restarted the day he was discharged from the hospital. The patient experienced no adverse effects from the procedure or medication management.*

Two years later, the patient underwent the same type of procedure. This time his surgeon had him stop taking the Coumadin five days before the surgery and not restart it until five days after the surgery. The patient did not take Coumadin for a total of 11 days, the longest period since 1985. No other anticoagulation therapy was ordered as a replacement during this period. On the eleventh day, he was admitted for right-sided weakness and slurred speech. He was diagnosed with a massive stroke and died a month later from associated complications. From the information uncovered about the case, there is no reason to believe that the patient would not have had an uneventful course as before if his medications had been properly managed. The court awarded the patient's spouse $300,000.

The high indemnity in these two cases is consistent with indemnity patterns for stroke claims reported in the Physician Insurers Association of America (PIAA) Data Sharing Project. Since 1985 the average payment for claims related to strokes was more than 60% higher than the average indemnity for all claims.

A higher percentage of patient deaths was reported in stroke claims than in all claims reported to the Data Sharing Project.

Men accounted for 53% of claims and 57% of indemnity. However, the percentage of male claimants for all claims reported to PIAA was significantly lower, (44.6%).

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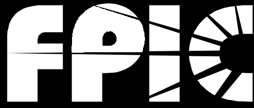
The Quarterly Risk Management Newsletter for Policyholders of FPIC

Summer 2001



FPIC publishes Preventive Action on a quarterly basis as a service to its policyholders. Information in this publication does not establish a standard of care, nor is it a substitute for legal advice. The information and suggestions contained in this newsletter are generalized and may not apply to all practice situations. FPIC recommends you obtain legal advice from a qualified attorney for a specific application to your practice. The information should be used as a reference guide only.

For comments, questions, or to obtain additional copies contact the FPIC Risk Management Department at 800-741-3742, ext. 3016.

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LIABILITY ISSUES RELATED TO STROKES

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Claims resulting from stroke management occurred in the hospital 72.8% of the time. These claims account for 64% of paid claims but more than 75% of the indemnity paid. Within the hospital, the patient's room was where the incident was most often reported, in 32.5% of claims and 43.3% of deaths. The highest average indemnity, $372,249, was claims that occurred in the emergency department.

The specialty with the most stroke claims reported was Internal Medicine. Internal Medicine had an average indemnity of $238,694. The average indemnity payment for General and Family Practice was $168,501, 30% less than Internal Medicine. However, General and Family Practice had a higher payment ratio, 40.9%. Neurology had the highest average indemnity for stroke claims at $488,833.

The American Academy of Neurology gathered information on stroke patients in its 1998 member survey. The survey showed that 52% of neurologists who responded were providing extended or long-term treatment to stroke patients. The survey showed that from 1991 to 1998, the number of neurologists performing or interpreting MRIs increased from 7.8% to 17.4%. The interpretation of CT scans also increased from 8.4% to 16.3%. This shift in practice trends brings with it the liability issues previously associated solely with radiology.

The two misadventures with the highest total indemnity were failure to Supervise/Monitor and Improper Performance of a Procedure. According to the AHRQ, treatment with warfarin for patients with atrial fibrillation may prevent over 40,000 strokes a year. Some physicians may be reluctant to place patients at risk of stroke on anticoagulation therapy, such as warfarin, because of the amount of monitoring and follow-up required. Warfarin treatment has become the standard of care for prevention of strokes in patients with atrial fibrillation. Warfarin is a narrow therapeutic index drug, with a small window for beneficial effects and very harmful effects outside of that window. It presents similar problems encountered by insulin-dependent patients. As with insulin users, treatment noncompliance can have significant adverse effects. Patient education and effective communication are essential elements for patients on long-term medication therapy, including warfarin treatment.

STROKE CLAIMS BY MISADVENTURE

Misadventure	Amount
No Medical Misadventure	$239,575
Diagnosis Error	$200,202
Failure to Supervise or Monitor	$255,246
Improper Performance	$426,418

Warfarin treatment has become the standard of care for prevention of strokes in patients with atrial fibrillation.

The anticipated increase in the incidence rate of strokes will likely translate into an increase in medical malpractice cases involving stroke.

Strategies for Risk Reduction for Strokes

- Identify patients at risk for stroke according to established clinical standards.
- Document why a patient at risk of stroke was or was not placed on anticoagulation therapy.
- Educate patients about the implications of anticoagulation therapy.
- Document patient education.
- Establish written procedures for monitoring patients on anticoagulation therapy and follow them.

More information on stroke prevention and treatment can be found at www.cdc.gov/nchs and www.ahrq.gov or by contacting FPIC's Risk Management Department at 800-741-3742, ext. 3016

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REDUCING RISKS IN ANTICOAGULATION THERAPY WITH PROCESS-OF-CARE PROGRAMS

Anticoagulation therapy with warfarin has proven to be highly effective in reducing the incidence of atrial fibrillation (AF)-related stroke and the risk of recurrent thrombosis and pulmonary embolism (PE) in patients with deep vein thrombosis (DVT). Results from supporting clinical trials are highly persuasive. Warfarin has demonstrated a reduction in the incidence of AF-related stroke by 84% in women, 60% in men, and 68% overall.[1]

In addition, with six months of therapy instead of six weeks, warfarin has demonstrated nearly a 50% lower recurrence of DVT/PE after a first episode of venous thromboembolism.[2] In a subsequent study, patients with an average of 12 months of therapy showed a 95% relative risk reduction for recurrent idiopathic venous thromboembolism after a first episode of idiopathic DVT/PE.[3]

Also significant, according to Louis D. Fiore, MD, Assistant Professor of Medicine, Boston University School of Medicine, and Director of the Special Coagulation Laboratory, Boston VA Medical Center, are recent refinements in anticoagulation process-of-care programs. By combining lower intensity therapy (INR range 2-3), monitoring methods, and careful patient selection, such programs have increased the safe and effective use of warfarin in patients with AF and DVT/PE. This is important for physicians to know when considering warfarin therapy. Physicians' concern about bleeding may result in their inappropriately minimizing the proven protection against thrombosis. With the cost of malpractice insurance already so high, physicians may find the possibility of increased litigation and higher insurance costs another reason to avoid warfarin therapy.

"It's a physician's dilemma," Dr. Fiore said. "Failure to treat increases the risk of a poor clinical outcome, but using warfarin in this population carries its own risks…."[4]

Up-to-date anticoagulation process-of-care programs can help address this dilemma. In a study at a university-affiliated anticoagulation clinic (AC), the medical records of more than 300 patients were examined to assess the impact of the process-of-care programs implemented in the AC for anticoagulation control, patient outcomes, and costs of hospitalization and emergency department visist.[5] Statistically significant improved AC patient outcomes were demonstrated versus patient outcomes with unusual medical care[5]:

	AC	UMC*
Significant bleeding event rates (per patient-year)	8.1%†	35.3%
Thromboembolic event rates (per patient-year)	3.3%‡	11.8%
Incidence of warfarin sodium-related events (per 100 patient-years)		
· Hospitalizations	5.0%†	19.0%
· Emergency room visists	6.0%†	22.0%

*Usual medical care

†P<.001

‡P<.05

In this study, the establishment of an AC improved anticoagulation control, reduced bleeding and thromboembolic rates, and annually saved more than $162,000 per 100 patients in reduced hospitalizations and emergency room visists.[5]

Recently, FPIC became aware of the availability of HeartFirst™ (formerly known as CoumaCare℠). Offered by DuPont Pharmaceuticals Company, HeartFirst™ is a new comprehensive patient management program, which presently includes the area of anticoagulation. HeartFirst™ is also a process-of-care program designed to give support to large physician group practices and anticoagulation clinics by providing an assortment of tools to assist in the management of patients receiving Coumadin® (Warfarin Sodium tablets, USP) Crystalline.

More than 2,000 medical offices and clinic settings, which serve hundreds of thousands of patients throughout the U.S., are presently using the various anticoagulation management services encompassed by CoumaCare℠. Such services include patient management system software, patient education tools, patient education forums, office support materials, CME materials, clinical offerings and symposia, web sites, and patient newsletters.

Failures in care entailing the use of anticoagulants can be a factor in malpractice claims attributed to adverse drug events. Adopting a process-of-care program, such a HeartFirst™, is an excellent means of improving the process of care, which may reduce failures to a minimum.

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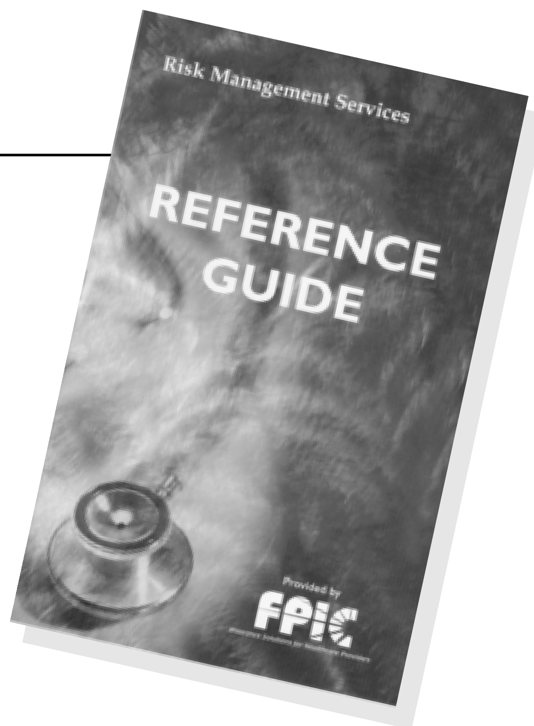
RISK MANAGEMENT REFERENCE GUIDE AVAILABLE

In addition to the many services provided by FPIC's Risk Management Department, a booklet entitled, *Risk Management Services Reference Guide* is available. The booklet can be obtained free of charge by calling the Risk Management Department at 800-741-3742, ext. 3016.

The *Reference Guide* contains five general sections designed to assist in avoiding claims, what to do when a claim is made, the phases of the lawsuit, and how to terminate the doctor/patient relationship.

Below is a sample section of the *Reference Guide.*



Medical Records Do's & Don'ts

Do's

- Record the patient's name on each page of the chart.
- Document all contacts with the patient. Include all telephone calls and all services rendered. Document all prescription refills.
- Chart the complete date (day, month, and year) on each chart entry. Initial and date each chart entry.
- Use black ink. It is best for photocopying purposes.
- Write legibly. Print each chart entry.
- Chart all information immediately (delays lead to inaccuracies).
- Describe clearly in each chart entry:
  - Mode of contact (i.e., telephone call, visit, etc.)
  - Reason for contact
  - Procedures done, or information/advice given
  - Outcome of contact
  - Follow-up taken
- Fill in every blank. Record negatives as well as positives.
- Use only "standard abbreviations"
- Chart precise amounts. Be particularly careful to accurately place decimals.
- Correct any error or mistake in charting by drawing a single line through the incorrect portion, then initial and date the correction.
- Identify, date, and sign any additions or corrections to the chart.
- Record an emergency contact mechanism for the patient and next of kin.

Don'ts

- Never use "liquid paper" or "white out," scribble over, cut off or in any way obliterate a chart entry which has been made.
- Don't chart subjective comments about the patient (i.e., "Patient is crazy"). Instead, quote the patient's words, "I'm Napoleon Bonaparte," which describes the behavior instead.
- Don't chart names without describing their function in relation to the patient's future care. Chart "Referred to Bob Jones, MD for allergy testing." NOT "Referred to Bob Jones."
- Don't chart information that is not pertinent to the future care of the patient.
- Don't file a chart until it has been checked for completeness.
- Never alter records after a suit has been filed. DO NOT correct, clarify, add to, change, or modify an entry in any way.

NEW SURVEY SHOWS BIG GAINS IN PHYSICIAN INTERNET/WEBSITE USE

According to a new Harris Interactive poll, most physicians now go online on a daily basis, and two out of every five doctors work in practices that have websites, up from just over a quarter thirteen months earlier. The full version of this article, complete with tables and statistics, can be found in http://harrisinteractive.com/about/vert_healthcare.asp. (*BW Healthwire* via *Newsedge*)

REDUCING RISKS IN ANTICOAGULATION THERAPY WITH PROCESS-OF-CARE PROGRAMS

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To find out more about Coumadin® (including the full Prescribing Information) and new HeartFirst™, call 1-800-4PHARMA (1-800-474-2762), or visit www.coumadin.com or www.coumacare.com web sites.

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MALPRACTICE AWARDS ON THE RISE

According to recent data from *Jury Verdict Research*, jury awards in medical malpractice claims increased 7% in 1999 despite a 2% decline in the number of plaintiff verdicts returned over the same period. The median medical malpractice award climbed to $800,000 in 1999, up from $750,000 the previous year. Noteworthy is the number of $1 million-plus verdicts returned. Approximately 45% of the jury awards returned in 1998-1999 were in the one million-plus range, as opposed to 39% of those verdicts returned in 1997-1998.

LEGAL QUESTIONS

What is a deposition

A deposition is testimony that is given under oath before a court reporter. Depositions are important in the preparation of a case for trial. Depositions also freeze testimony and can be used to impeach your credibility if you deviate from them later. They are used to discover the facts of the case and to uncover additional witnesses. Depositions are also used to narrow the issues of the case.

What to do when you receive a summons and complaint?

Immediately notify FPIC by calling the Claims Department at 800-741-3742, ext. 3293. If you are served, FPIC only has a limited number of days in which to assign a defense attorney and prepare a response to be filed on your behalf. It is important to not discuss the case with the patient, the patient's attorney, other physicians involved in the care and treatment of the patient, or a hospital representative. You should gather and secure the patient's records immediately.

Are physicians required to provide patients an itemized bill?

Yes. Physicians are required, upon request, to submit to the patient. The patient's insurer or the administrative agency for any federal or state health program under which the patient is entitled to benefits and an itemized statement of the specific services rendered and the charge for each, no later than the physician's next regular billing cycle that follows the fifth day after the rendering of professional services. This cannot be conditioned upon prior payment of the bill.

What to expect after receiving a summons and complaint?

You will receive a letter from FPIC advising you of the assignment of your case to a defense attorney. If an attorney was assigned during the pre-suit phase, that same attorney will usually handle your defense. If you do not have an attorney, you will be contacted by an FPIC field representative to arrange a meeting to discuss your medical records and care of the patient. The assigned attorney may join in the meeting. You should be prepared by reviewing the records and developing counter arguments to the allegations contained in the complaint.

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