



PRF NEWS

Covering Practice and Risk Management Issues for Physicians

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New Guidelines for the Treatment of Elevated Cholesterol Levels

BY STEPHEN J. SCHEIFELE, M.D.

New clinical guidelines for the testing and management of cholesterol have been issued by the National Cholesterol Education Program Expert.* These evidence-based guidelines, referred to as Adult

Treatment Panel III, focus on primary prevention for patients with risk factors for the development of coronary heart disease (CHD) and identify LDL as the major target of cholesterol-lowering therapy.

Because primary prevention offers the greatest opportunity to reduce CHD, ATP III emphasizes the role that obesity, physical inactivity, and an atherogenic diet play in the development of CHD. A program of therapeutic lifestyle changes (TLC) includes:

- Reductions in total fats to < 35% of total calories (saturated fats <7% of total calories)
- Increased physical activity
- Weight control (waist circumference <40 in. for men, <35 in. for women)

Adults should have a fasting lipoprotein profile every 5 years starting at age 20. Based on an assessment of risk for CHD using the Framingham scoring algorithm, patients are stratified into three groups with differing therapeutic goals and intensity of risk-reduction therapy. CHD Risk Prediction Score Sheets for men and women are available on the Internet at <http://www.nhlbi.nih.gov/about/framingham/riskabs.htm>. The home page for the Framingham Heart Study is <http://www.nhlbi.nih.gov/about/framingham/>.

The Framingham score estimates the risk of developing CHD

within 10 years based on the patient's:

- Age
- Blood pressure
- HDL level
- LDL level
- Cigarette smoking
- Diabetes

High Risk patients have a >20% risk of developing CHD within 10 years based on the Framingham score, existing CHD or other atherosclerotic disease, or diabetes. The therapeutic goal for High Risk patients is a LDL <100.

Moderate Risk patients have a <20% risk of developing CHD within 10 years based on the Framingham score. The therapeutic goal for Moderate Risk patients is a LDL <130

Low Risk patients have a <10% risk of developing CHD within 10 years based on the Framingham score. The therapeutic goal for Low Risk patients is a LDL <160

Although TLC should be the initial therapeutic approach to CHD risk-reduction, LDL-lowering drugs may be necessary for High Risk patients whose LDL target goals are unmet. Treatment options include:

- Nicotinic acid (brand name: Niacin) is available

over the counter. A lot of people cannot tolerate Niacin because of a side effect, which is flushing (hot flashes).

- Statins (HMG-CoA reductase inhibitors) are the most widely prescribed class of cholesterol lowering drugs. They are known by the following brand names: Lipitor, Zocor, Mevacor, and Pravachol. Contraindicated in patients with liver disease, patients taking statins must have their hepatic enzymes monitored. Side effects include myopathy, liver dysfunction and abdominal discomfort. One statin, Bacol, was withdrawn from the market on August 8 because of a link to rhabdomyolysis.
- Hormone Replacement Therapy was thought to reduce the risk of CHD in postmenopausal women.. However, recent clinical trials have cast doubts about HRT's effectiveness. ■

Dr. Scheifele is board secretary of the PRF-RRG.

* An Executive Summary of ATP III can be found in JAMA, May 16, 2001-Vol 285, No. 19.

PRF NEWS

Avoiding Delay in Diagnosis of Breast Cancer

BY MICHAEL L. SMALL, MD

Delay in diagnosis of breast cancer is the one of the most common antecedents to malpractice litigation because physicians sometimes forget these five basic principles:

1. Any breast abnormality detected by mammography or physical exam is cancer until proved otherwise.

An abnormal mammographic finding can be a DENSITY or a CALCIFICATION.

If the finding is a DENSITY, biopsy should be performed if the density:

- Is new
- Has indistinct margins
- Appears stellate
- Appears more dense than surrounding breast parenchyma
- Contains calcifications
- Distorts overlying skin or nipple

If the finding is a CALCIFICATION, biopsy should be performed if the calcifications are:

- New
- Clustered
- Branched or rod-shaped
- Associated with a density
- Pleomorphic

2. In the presence of a palpable nodule, a negative mammogram means nothing.

Ten percent of breast cancers are not detected by mammogram. Of particular concern are nodules that are:

- New
- Firm
- Dominant
- Associated with overlying skin or nipple retraction
- Associated with axillary adenopathy.

3. A needle biopsy is only definitive if it is positive.

A negative needle biopsy can reduce the chance that a lesion is malignant to 5% or less, but that small but real false negative rate must be discussed with the patient and this discussion recorded in the patient's chart.

4. Any abnormality not excised or biopsied must regress or remain stable over at least two full years of careful observation.

5. The patient must be informed of the abnormality and of your concern regarding cancer.

Although the decision regarding biopsy versus observation is made by the patient, your degree of concern needs to be clearly articulated and those discussions clearly documented.

If you listen to the patient, talk with (not to) her, and have her participate in the decision making process while you worry about every abnormality and record every discussion in the chart, not only will you reduce your risk of malpractice litigation, but you will have a patient who feels she is a respected participant in her own health care. Finally, and most importantly, you may improve her chances of cure if the abnormality turns out to be breast cancer. ■

Dr. Small is a member of the PRF-RRG.

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Avoiding Delay in Diagnosis of Breast Cancer

By following five basic principles, the physician can minimize risk of litigation stemming from delay in diagnosis of breast cancer.

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Legal Cases Illustrate Errors in Breast Cancer Diagnosis

Two California cases involving breast cancer underscore the importance of careful diagnostic procedures. The cases were reported in the January 1998 Professional Liability Newsletter.



HAVE IDEAS FOR RISK MANAGEMENT EDUCATION?

The Risk Management & Education Committee is seeking member input and involvement. They are looking for newsletter topics of interest, authors for articles, and members who want to serve on the committee. Minimum time is required. Please call June Riley, PRF Executive Director, at (415) 921-0498 or send an e-mail message to june@prfrg.com. ■

CASE 1. DELAYED DIAGNOSIS

A 36-year-old woman visited a Los Angeles County clinic because she found a lump in her left breast. A physician's assistant saw the patient and referred her to a radiologist for a screening mammogram. The radiologist diagnosed fibrocystic disease.

Three weeks later the patient returned to the same physician's assistant, saying that the mass was now larger. The PA referred the patient to Olive View Medical Center, a county institution.

About 10 days later a part-time internist at Olive View saw the patient and agreed with the radiologist's diagnosis. Believing there was no need for a second mammogram, the internist did not schedule a follow-up appointment.

Eight months later the patient returned to Olive View. This time a fine-needle aspiration biopsy was performed, which resulted in a diagnosis of cancer and led to a radical mastectomy seven weeks later. Because there were positive axillary nodes, the patient was given chemotherapy. She died four and a half years later at age 42.

The patient's son brought suit against Los Angeles County. After a 10-day trial, a jury deliberated two days before returning a \$250,000 verdict in favor of the son.

During the trial the plaintiff claimed the internist casually managed the breast lump by accepting the radiologist's diagnosis of fibrocystic disease, not ordering a repeat mammogram and not scheduling the patient for further evaluation. The defense pointed out that the patient waited six months before returning to Olive View, but she was notably unsophisticated about medicine and she did not speak English. Because of the patient's contribution to the delay in diagnosis, the jury reduced the verdict to \$100,000.

David S. Rubsamen, MD, LLB, newsletter editor, commented that it appeared that because the Olive View clinic was so busy, the internist did not have the time to "pause and reflect on the possible significance of the patient's lesion."

CASE 2. INSUFFICIENT DIAGNOSTIC INVESTIGATION

A 32-year-old woman saw a family physician at a local community health center after she found a lump in her right breast. The physician ordered a mammogram that was read as negative and was referred to a general surgeon. The surgeon learned that the patient's sister had surgery for a breast malignancy at age 34 and

recommended a core-needle biopsy with the aid of ultrasound, which was read as negative. The surgeon told the patient he did not feel it was necessary to do an open biopsy but offered to do it if she wanted. The patient declined.

The patient received no further medical care until six months later when she returned to the surgeon after the lump had doubled in size. An excisional biopsy revealed a malignancy and the patient underwent a radical mastectomy, chemotherapy and breast reconstruction surgery.

The woman sued the general surgeon on the grounds that an excisional biopsy should have followed the negative core-needle biopsy largely due to the family history of breast cancer. Before details of a Pomona jury's \$356,289 verdict were stipulated, the case settled for \$330,000.

Dr. Rubsamen notes that enough diagnostic investigation should be performed to satisfy the due-care standard. In this case the jury agreed with the plaintiff's expert witness, who said that a negative mammogram and a negative needle biopsy was insufficient investigation, considering all the factors in the case. ■

When to Call the PRF Office

BY REUBEN A. CLAY, JR., MD

Because physicians are sometimes uncertain about when they should call the PRF office for assistance, here are answers to some commonly asked questions about malpractice issues.

1. What should I do if I receive a notice of intent to sue?

If you receive a notice of intent to sue, call the PRF office immediately.

A notice of intent to sue, commonly referred to as a 90-day notice, may come in the form of a formal letter from an attorney representing the patient, or a seemingly informal letter sent by the patient. While a 90-day notice does not always result in a legal action, it should definitely be looked upon as a potential suit.

At that time PRF will request that you send copies of the following: 1) the 90-day notice; 2) a management report; 3) a signed arbitration agreement, if one exists; and 4) any pertinent medical records. At this point nothing else needs to be done.

2. What should I do if I am served with a summons and complaint?

If you are served with a summons and complaint, call the PRF office immediately.

A summons and complaint must be responded to within 30 days of receipt of service. The Chair of the Patient Care and Management Committee and the PRF office staff will work with you to assign suitable counsel to your case. If you have not already provided all the information noted above, PRF will request that you do so. Once the arrangements have been made and an attorney has been assigned to your case, the attorney will contact you directly. PRF will send

the attorney a letter of engagement, and the attorney will notify opposing counsel that he or she is the attorney of record in the matter and respond to the summons and complaint.

3. What should I do if I receive a deposition subpoena to produce medical records?

If you receive a deposition subpoena to produce medical records, call the PRF office immediately.

Contact the PRF office and fax a copy of the subpoena. A subpoena to produce medical records should be accompanied by a Notice to Consumer or Employee. This notice allows the individual 30 days to object to the production of their medical records. It is important that these records not be released prematurely, i.e., before the patient has the allowable time to object. Please speak with the staff at the PRF office, who have access to expert legal advice to ensure that you respond to the deposition subpoena appropriately.

4. I am not a named defendant, but I have been deposed. What should I do?

If you receive a deposition subpoena relating to a matter where you are not a named party to the action, call the PRF office.

It is fairly common for a physician or other allied health professional to receive a deposition subpoena relating to a matter where they are not a named party to the action. It is the policy of

PRF to provide legal representation to its insureds in these circumstances. Counsel will meet with you and prepare you for the deposition. Your appointed attorney will also attend the deposition with you. It is in your best interest to be represented by counsel whenever you are deposed, and as a PRF insured you are provided with this benefit.

5. Where do I get arbitration agreements? Do I have to pay for the agreements and/or the delivery charge?

As a PRF insured, arbitration agreements are provided at no cost to you. PRF pays both the cost of printing the agreements and the cost of shipping them. Arbitration agreements are available in English, Spanish and Chinese. Whenever you need a supply of arbitration agreements, simply call **Lasting Impressions Printing at (925) 686-1509**, tell them that you are insured by PRF, and request the desired quantity and language. The arbitration agreements will be shipped directly to you. ■

Dr. Clay is chair of the Patient Care and Management Committee of the PRF.



WHEN TO WRITE THE PRF OFFICE

You must notify the PRF office in writing **when-ever there is a significant change regarding your practice**. For example, an insured must communicate in writing with the PRF office when:

- There is a new or changed practice location, phone and/or fax number
- The insured wishes to change type of coverage (e.g., from OB/GYN to GYN)
- A physician and/or allied health staff member joins or leaves the practice

Be sure to **clearly state the effective date of the change** in every written communication. ■