Oncology Issues

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Developing Mammography Standards—Fast!

IN THE NEWS

DEVELOPING MAMMOGRAPHY STANDARDS—FAST!

Several hundred radiology directors, medical physicists, mammography technologists, and health policy analysts gathered recently to discuss issues that the Food and Drug Administration (FDA) will need to address as it develops and implements standards and regulations for the Mammography Quality Standards Act (MQSA). The FDA-sponsored conference was held in Reston, Virginia, September 20–22, 1993.

"The numbers are daunting," noted FDA's Joseph S. Arcarese who spoke about the immense logistics and aggressive time frame of the Act. "Ten thousand plus facilities need to be certified, a dozen major regulations must be developed, 250 to 300 inspectors must be trained, and a program by which they will be trained must be developed." And all that must be in place by October 1, 1994.

How can FDA certify 10,000 facilities before its upcoming deadline? The 6,000 facilities already accredited by the American College of Radiology (ACR) would immediately become eligible for the new FDA certification, according to Arcarese, who is Assistant Director for Mammography Programs within FDA's Center for Devices and Radiological Health (CDRH). The remaining 4,000 facilities, however, would need to be inspected and certified by late 1994, a task that Arcarese deemed "possible."

"The more facilities that get accredited by ACR, the better," said Arcarese, who explained that it is not FDA's intent to impose an entirely new set of standards.

Congress passed the MQSA with the intent of providing a single, uniform system of quality assurance that would provide for all mammography in the United States to be of high quality. The Act requires that:

- national, uniform quality standards for mammography be developed and promulgated
- facilities receive a federal certificate in order to provide mammography services (To receive the certificate, the facility must be approved by a federally approved, private nonprofit or state organization.)
- facilities undergo periodic review of their clinical images and meet federally developed quality standards for personnel, equipment, quality assurance programs, record keeping, and reporting
- facilities be inspected annually by federal or state personnel to ascertain compliance with these requirements (On-site inspections include an annual survey by a medical physicist and a state or federal inspector, as well as FDA inspection.)
- facilities use only special radiological equipment designed for mammography as opposed to general purpose radiographic equipment
- physicians who interpret mammograms be certified to do so by a specified organization.

The Act also calls for establishing an advisory committee of up to 19 members to guide FDA in developing standards and monitoring the implementation of the whole program.

If facilities do not comply, the MQSA provides for sanctions, including money penalties and suspension of certification. The names of those facilities against which adverse actions have been taken will be published.

LEGAL ROUNDS

Investigational, Or Not?

by John S. Hoff

What treatment is investigational? In this case, the court held that an "off-label" use of an autologous bone marrow transplant (ABMT) to treat a rare form of cancer is not investigational.[1]

The plaintiff was diagnosed with rhabdomyosarcoma of the prostate, which the court said was extremely rare. He had received chemotherapy, and now sought coverage for HDC/ABMT. The insurance plan specifically covered chemotherapy and bone marrow transplants. The insurance company nevertheless denied coverage on the ground that as applied to the patient's tumor, the treatment was investigational because it had not been shown to be effective in that tumor. The court rejected that defense. It observed that because the plaintiff's cancer was extremely rare, it is likely that a "proper" Phase III study would never be conducted. Thus, by definition any treatment for this cancer would be investigational—a result the court would not accept.

The court held that although the treatment was given pursuant to a research protocol, this did not make the treatment investigational because many well-established treatments are administered on protocol. The court also found that the plaintiff's informed consent did not make the treatment investigational, observing in a somewhat cynical fashion that: "We know that the signing of an informed consent document is more for purposes of legal protection against the horde of malpractice claims than an accurate disclosure of medical treatment."

Since the effectiveness of ABMT "is well documented" and has "proven successful against many forms of tumors," including some that are similar to the plaintiff's, the court found it would be wrong not to apply it also to the plaintiff's tumor.

[1] Davis v. SelectCare, Inc. (E.D. Mich., February 8, 1993).

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