LEGISLATIVE, LEGAL, AND REGULATORY ISSUES

Interpretation of Echocardiographic Data: Are Physicians and Sonographers Violating the Law?

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When a sonographer renders diagnostic interpretations from echocardiographic data, the possibility exists that state statutes concerning the unauthorized practice of medicine may be violated. Problems likely exist in this regard when the sonographer renders such interpretations without proper physician interaction or when the physician delegates such responsibilities to the sonographer. In such situations the physician may be guilty of aiding and abetting the unauthorized practice of medicine. Such practices may also violate various reimbursement rules and policies. Given such a situation, even the rendering of preliminary results by sonographers without appropriate supervision by the physician may be in violation of various state statutes and rules governing reimbursement procedures. (J Am Soc Echocardiography 1988;1:95-9.)

Many members of the American Society of Echocardiography remain concerned that cardiac sonographers may be placed in the position of rendering diagnostic interpretations of echocardiographic data. The official policy of the Society concerning this matter is contained in “The Report of the American Society of Echocardiography Committee on Education and Training of the Echocardiographer.” It states the following:

“Although the echocardiographer (cardiac sonographer) must be knowledgeable about the various cardiac abnormalities in order to produce diagnostic echocardiograms (including Doppler) he/she should not be placed in the position of rendering clinical interpretation of results.”

Concern exists within the echocardiographic community that such practice of rendering diagnostic interpretations may be construed as placing the sonographer in the position of practicing medicine without a license. The purpose of this article is to elaborate further on the problem as it may be manifested in everyday practice, describe potential risks for the sonographer, and discuss possible solutions. Although the American Society of Echocardiography has not rendered further official statements of policy or ethics on this matter, ideally the information contained herein will assist the membership in understanding the various issues involved.

In addition to the concerns presented below, it should be well recognized that if a physician employs a sonographer and specifically delegates the authority for interpretation of echocardiographic data to the sonographer, risks may exist. For example, if a question of liability arises consequent to the sonographer’s activities and if the delegation of responsibilities violated state law, this would likely be taken into account by a jury in assessing physician negligence.

PROBLEM

In general, there are two major settings where potential difficulties could arise from the expansion of the sonographer’s role into the unlawful practice of medicine. One area involves having no system for responsible physician review; the other is where such a formal system for physician review exists but is misused.
The most obvious manifestation occurs when a sonographer willingly submits diagnostic interpretive data that are entered into the patient's clinical record without responsible physician review. This might occur when the sonographer practices in a mobile or other service, rendering interpretations with full recognition of the fact that there is no physician (or at least not a competent one) to review the reliability of the interpretation. In these cases it appears that the sonographer is most likely to assume the role of interpreter voluntarily.

It appears, however, that sonographers may not only be providing interpretive data when a system exists for final review of data by a responsible physician before the generation of a final diagnostic report but also when the physician review is nominal, and the decision by the sonographer is routinely “rubber stamped.” In this setting the problem is usually manifest in a less obvious way. For example, a sonographer may be called for a preliminary report and thus deliver diagnostic interpretive data orally or in writing that are then used for further clinical decision making. Where a formal mechanism for physician review exists but actual physician review is nominal or nonexistent, it appears that the sonographer may be assuming the role of interpreter under duress or may be participating in such practices without full awareness of the potential legal or ethical risks.

There are obviously many other clinical settings where variations of this potential problem may be manifest, and it is not within the purview of this discussion to present every possible setting where such risks to the sonographer occur. The two examples set forth above are likely to be familiar to almost every member of the Society in some form.

We have not conducted a systematic study of the extent to which such practices exist. We are, however, well aware of the concern about such practices from sonographers and physicians alike.

SONOGRAPHER’S ROLE

Clearly the proper practice of cardiac sonography requires a rather detailed knowledge of various disease processes for the proper conduct of an ultrasonic examination of the heart. During the course of practice it is likely that most conscientious sonographers acquire a fund of knowledge that may tempt them to apply it to the clinical decision-making process by rendering interpretive data.

The proper roles for various allied health professionals in the acquisition of diagnostic information appears well described. Cardiac sonography is one of the many allied health professions in which a detailed knowledge of disease processes is a requisite for proper performance of one’s duties. For example, in the varied field of medical laboratory technology there are many levels of competence and practice. In the course of practice in this profession a technologist may be called on to collect and prepare a peripheral blood smear and inspect and count the number of different cells present. During this analysis the technologist may recognize that an unusually high number of white blood cells may be present, which suggests that the patient has leukemia. Although the technologist may well recognize the existence of leukemia, in this setting the technologist's role is to perform the laboratory analysis and analyze the results. It is the physician's role to assign the proper diagnosis, as it is the diagnostic information on which further clinical decisions are based.

There are parallels to this situation in the practice of cardiac sonography. The sonographer may be called on to perform an examination in which an oscillating target is seen on the aortic valve in a febrile patient with aortic insufficiency. In this setting it appears that it is the sonographer's role to obtain the necessary information and describe the abnormality present. It is the physician who interprets the data and renders the diagnosis of valvular vegetation.

There are certain other allied health professionals such as nurses and physician's assistants who may render and perhaps even act on certain diagnoses. Proper practice of these professions still requires direct physician supervision somewhere in the course of patient care. Unlike cardiac sonography, the practice of these professions requires certification of competency and licensing, which in some cases delineates the activities that are permitted under the allied health professional's license.

Many physicians and sonographers have indicated that there is great pressure on cardiac sonographers to render diagnostic rather than descriptive data. Except in the most obvious situations in which there is no physician coverage, most sonographers and physicians are unlikely to be aware of the potential for legal and ethical conflict in this area. With increasing pressure on sonographers to provide such information as preliminary reports, the role of the physician and the sonographer in providing diagnostic interpretive data for patient care requires further analysis.
PRACTICE OF MEDICINE WITHOUT A LICENSE

The fundamental issue complicating the sonographer's reporting of diagnostic impressions is the potential for practicing medicine without a license. Although laws vary from state to state, it is quite clear that the unsupervised rendering of a diagnosis by a sonographer may violate such statutes.

In some states both the sonographer and the physician may be at risk. Statutes that preclude the unauthorized practice of medicine vary significantly from state to state; the applicable state codes for California, New York, and Texas are included in this article (Appendix).

In general, most statutes pertaining to the regulation of the practice of medicine do not define specifically what shall constitute a violation; instead, they use only general terms prohibiting the "practice of medicine" without a license. Generally, the practice of medicine has been said to have the following necessary elements:

1. Diagnosis of the patient's symptoms to determine what disease of infirmity he is afflicted with
2. Determination and prescription of the remedy or treatment to be used in attempting to cure the patient

When a person without a license performs acts that constitute the practice of medicine, he or she is not relieved from liability by the fact that he or she performs those acts as an assistant to or under the direction and supervision of a duly authorized practitioner, unless the state statute specifically indicates that such supervised activities are permitted, or unless the physician's involvement is so extensive that the interpretation can be said to be that of the physician. Furthermore, as a general rule, an individual who aids and abets another in practicing medicine without a license is subject to penalties, even if he or she is licensed to practice.

Review of general information related to the practice of medicine without a license, as well as the state-specific information for Texas, California, and New York, strongly suggests that when test results are interpreted by sonographers, the sonographers may be guilty of practicing medicine without a license. At least when the sonographer's interpretation is not independently verified, the employing physician or physicians responsible for supervising the sonographer's activities may also be guilty of aiding and abetting an individual without a license in the practice of medicine. Depending on the state, the sanctions involved may include loss of license, criminal penalties, or both.

IS REIMBURSEMENT AFFECTED?

A physician who delegates to a sonographer the responsibility of interpreting an echocardiogram or fails to directly supervise a sonographer who performs the technical component of such services may be in violation of Medicare reimbursement rules. Part B of the Medicare program reimburses services rendered directly by physicians to the patient. Physician services, within this context, include diagnosis, therapy, surgery, and consultation, including the interpretation by a physician of a test result, such as an echocardiogram. However, Medicare does not cover, as "physicians" services, interpretation of echocardiographic data by sonographers.

Moreover, the "technical" component of the echocardiogram is not covered unless directly supervised by a physician. The services of a technician in performing an echocardiogram are covered as "supplies furnished "incident to" a physician's professional services." "Incident to a physician's professional services" means that the services must be furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness. Such services are commonly furnished in physician's offices and are generally either rendered without charge or are included in physician's bills.

To be covered as services "incident to a physician's services," the services of a nonphysician must be rendered under the physician's direct supervision by employees of the physician. Direct personal supervision does not mean that the physician must be present in the same room with his or her sonographer. However, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the technician is performing services. Moreover, if auxiliary personnel perform services outside the office setting, their services are considered "incident to" physician services and therefore are reimbursable only if there is direct personal supervision by the physician.

Exceptions to the direct supervision requirement are made for certain services provided to homebound patients and services in rural health clinics; however, these exceptions do not appear to be applicable to, for example, mobile scanning units.
WILL CANONS OF ETHICS AND STANDARDS OF PERFORMANCE HELP?

A canon of ethics is a statement of a principle of good conduct, such as, “only a licensed physician will review and interpret test results.” Canons usually are based on voluntary compliance, and failure to abide by a given canon of a professional society could result in having one’s membership in the society terminated. An additional benefit of canons of ethics is that they may offer members of the society a given higher standard of practice, which is deemed desirable to the individual or the community.

Standards of performance promulgated by a professional organization constitute a statement of acceptable practice. As such, they may be accorded widespread recognition and compliance by those within the profession and therefore may have significant anticompetitive effects.

Both the adoption of standards of performance and the adoption of canons of ethics may carry significant antitrust implications, yet they may be lawful, provided they are objective, accurate, valid, and accepted in the profession.

ROLE OF AMERICAN SOCIETY OF ECHOCARDIOGRAPHY

The Society is evaluating many available options in dealing with these issues pursuant to our goal of providing excellence in the performance of ultrasonic studies of the heart. Overall, the Society remains in a position to monitor these potentially unlawful practices as they affect patient care and the practice of medicine. Ideally, this article may serve to inform the membership of potential areas of risk that may exist. In addition, the Society will continue to evaluate the possibility of developing a voluntary canon of ethics within the bounds of antitrust legislation and to determine what other action, if any, is necessary to ensure that the services provided for patients are in compliance with the highest standards of quality, and are in compliance with the laws.

REFERENCE


APPENDIX

Unauthorized Practice of Medicine
Rules in selected states

Texas

The Texas Medical Practice Act defines “practicing medicine” as follows:

A person shall be considered to be practicing medicine within this act:

a) who shall publicly profess to be a physician or surgeon and shall diagnose, treat, offer to treat any disease or disorder, mental or physical, or any physical deformity or injury by any system or method or to effect cures thereof; or

b) who shall diagnose, treat or offer to treat any disease or disorder, mental or physical, or any physical deformity or injury by any system or method and to effect cures thereof and charge therefore, directly or indirectly, money or other compensation

(Texas Medical Practice Act Article 4495[b] Section 1 03[b] [B]).

Additionally, the Texas Medical Practice Act, Article 4495(b), Section 3 06(d) (1) notes that a person licensed to practice medicine has the authority to delegate to any qualified person acting under the physician’s supervision any medical act that a reasonable and prudent physician would find is within the scope of sound medical practice to delegate. Such delegation is predicated on the person being able to properly and safely perform the act in its customary manner and not in violation of any statute. The person must not hold himself or herself out to the public as being authorized to practice medicine. The ultimate decision, whether an act constitutes the practice of medicine and whether a particular medical act may be delegated by a physician, rests with the Texas State Board of Medical Examiners. The Texas Code cites the failure to adequately supervise the activities of those under the supervision of the physician as grounds for licensure denial. Additional contributing factors include delegating professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience, or licensure to perform the responsibility or acts; as well as aiding and abetting the practice of medicine by any person, partnership, association, or corporation not duly licensed by the Board to practice medicine. It would therefore appear that the Texas Medical Practice Act may be violated when physicians are failing to adequately supervise cardiac sonographers and are inappropriately delegating the responsibility for interpreting test results.

California

Section 2038 of the California Medical Practice Act de-
defines the use of the words “diagnose” or “diagnosis” to include the following:

... Any undertaking by any method, device, or procedure whatsoever, and whether gratuitous or not, to ascertain or establish whether a person is suffering from any physical or mental disorder. Such terms shall also include the taking of a person’s blood pressure and the use of mechanical devices or machines for the purpose of making a diagnosis and representing to such person any conclusion regarding his or her physical or mental condition.

The California courts have concluded that diagnosis itself is a part of the practice of medicine. Additionally, the California courts have held that one who is not licensed to practice medicine or surgery cannot legally perform acts that are medical or surgical in character. The practice of medicine without a license in the State of California is a misdemeanor.

Analysis of the relevant California statutes indicates that a strong case could be made that the interpretation of test results by a technician constitutes the “diagnosis” within the meaning of the California law and may therefore violate the statute. No specific reference was made in the California statute regarding the physicians’ responsibility to supervise technicians, although such responsibility is implied.

New York

The New York Medical Practice Act defines the practice of medicine as “diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition” (N.Y. Medicine Law no 6521 [McKinney 1985]). New York case law has noted that the following factors should be considered in determining whether a person has violated restrictions on the practice of medicine:

1. Whether there was a diagnosis determining a disease, infirmity, or physical condition
2. Whether a remedy or treatment was prescribed
3. Whether the act performed by the defendant was such as to endanger the public health and
4. Whether the defendant invaded the territory of the profession by specific actions solely within the province of a duly trained and knowledgeable medical practitioner.

In applying these factors, where a sonographer interprets echocardiograms without adequate physician involvement, the sonographer has arguably “invaded the territory” of the physician. On the basis of this analysis, under some circumstances, sonographers who interpret echocardiograms could be held to have violated the applicable statute by practicing medicine without a license. The physicians who employ the sonographers could, under New York law, be guilty of professional misconduct, as the New York statute sets forth within its definition of professional misconduct “permitting, aiding, or abetting an unlicensed person to perform activities requiring a license,” New York Medicine Law no 6509 (McKinney 1985).