Guidelines for Ethical Behavior Relating to Clinical Practice Issues in Neuromuscular and Electrodiagnostic Medicine

American Association of Neuromuscular & Electrodiagnostic Medicine

Abstract

The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) developed guidelines to formalize the ethical standards that neuromuscular (NM) and electrodiagnostic (EDX) physicians should follow in clinical and scientific activities. NM and EDX medicine are medical subspecialties focused on evaluation, diagnosis, and comprehensive medical management, including rehabilitation of individuals with NM disorders. Physicians in this subspecialty evaluate disorders of the motor unit, including muscle, NM junction, axon, plexus, nerve root, anterior horn cell, and the peripheral nerves (motor and sensory). The NM and EDX physician's goal, working with other allied health professionals, is to diagnose and treat these conditions to mitigate their impact, and improve the patient's quality of life. The guidelines are consistent with the Principles of Medical Ethics adopted by the American Medical Association and represent a revision of previous AANEM guidelines.

KEYWORDS: electrodiagnostic medicine, ethics, informed consent, neuromuscular medicine, research

1 INTRODUCTION

The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) developed the following guidelines to formalize the ethical standards that neuromuscular (NM) and electrodiagnostic (EDX) physicians should observe in clinical and scientific activities. NM and EDX medicine is a subspecialty of medicine that focuses on the evaluation, diagnosis, and comprehensive medical management, including rehabilitation of individuals with NM disorders. Physicians working in this subspecialty focus on disorders of the motor unit, including muscle, the NM junction, axon, plexus, nerve root, anterior horn cell, and the peripheral nerves (motor and sensory). The goal of NM and EDX physicians is to diagnose and treat these conditions to mitigate their impact and improve the patient's quality of life. These guidelines were originally modeled after the Code of Professional Conduct of the American Academy of Neurology, are consistent with the Principles of Medical Ethics as adopted by the American Medical Association[1] (Appendix) and represent a revision of previous guidelines of the AANEM. Violation of these guidelines may provide grounds for disciplinary action as outlined in Article 10.0 of the AANEM bylaws and the AANEM's Disciplinary Policies and Procedures.

2 THE PATIENT– PHYSICIAN RELATIONSHIP IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

2.1 The patient-physician relationship

The patient-physician relationship is a key fundamental component of high-quality medical care. The quality of this relationship can impact not only the outcome of the interaction between the patient and physician, but also the outcome of the patient's treatment. The physician has a fiduciary duty to safeguard the interests of the patient first. The physician must practice competently, respect patient autonomy and confidentiality, maintain patient safety, and protect the patient's best interests within the

law.

2.2 Beginning and ending the relationship

Upon the patient's presentation to the EDX laboratory for the study, the physician decides whether to perform an EDX or NM evaluation on a particular patient. The physician should discuss the reason for the evaluation and the methods to be employed with the patient and should not decline the evaluation for discriminatory reasons or on the basis of personal characteristics unrelated to the patient's clinical care. The physician also should not decline an evaluation based on the patient's known or suspected medical diagnosis. The physician should decline to perform an EDX or NM evaluation when the evaluation is unnecessary or not beneficial to the patient.

If the patient has a diagnosis that does not require EDX or NM testing, the physician should recommend canceling the study or give the patient the right to cancel the study (see Section 6.1). If possible, the physician and the referring physician should agree on who should inform the patient (or designated surrogate) of the results of the EDX evaluation.

Once the evaluation has begun, the physician should complete the evaluation process unless the patient ends the relationship prior to completion or if medical contraindications become apparent during the evaluation. Upon completion, the physician should return the patient to the care of the referring physician unless all parties agree that the EDX physician will manage specific conditions. If the patient does not have a referring physician, the physician should address any urgent clinical needs until an appropriate referral can be made.

2.3 Informed consent in clinical evaluation

The physician must obtain verbal or written consent from the patient. When the patient cannot provide consent or lacks decisional capacity, verbal or written consent must be obtained from the patient's appropriate legally authorized representative (LAR), who acts as a surrogate decisionmaker. The physician must disclose information that a reasonable person would need to make an informed medical decision, including benefits and risks of the proposed tests. Consent by the patient or LAR must be voluntary. If a reasonable explanation fails to elicit a patient's consent to undergo the EDX examination, the physician should not undertake the evaluation. The patient may withdraw prior consent; if this occurs at any point during testing, the physician should discontinue the examination. Physicians must comply with applicable state and federal law governing informed consent requirements.

US Food and Drug Administration (FDA) and institutional review board (IRB) rules should be followed when conducting experimental or investigational studies of procedures, pharmaceuticals, or medical devices that involve human subjects (see Section 9).

If the LAR is unavailable and the situation is an emergency, the physician may proceed without consent.

2.4 Patient safety, communication, comfort, and preparation

The physician has a duty to communicate with the patient. Needle electromyography (EMG) and nerve conduction studies (NCSs) should be performed in conjunction with an appropriate real-time history,

physical examination, and diagnostic bedside evaluation.[2,3] This clinical evaluation should include patient identification, medical issues review, and side of body recognition immediately prior to the procedure to ensure patient safety and satisfy the intent of a time out. The objectives of a time out should be fulfilled as part of this normal evaluation process and negate the need for a more formal time out.

The physician should convey relevant information in terms the patient can understand and allow adequate opportunity for the patient to raise questions and discuss matters related to the NM and/or EDX evaluation. Physicians should make every effort to ensure that patients are adequately prepared for the planned NM evaluation and/or EDX procedures and that they are made as comfortable as possible during the examination. Physicians should be attentive to signs of patient discomfort and safety concerns and resolve them before proceeding. Physicians may decide whether to admit family members or significant others into the examination room during testing to provide support. Informing the patient of the findings of the examination should be coordinated with the referring physician (see Section 2.2). Suggestions for changes in clinical management should generally be made to the referring physician rather than the patient unless the referring physician has requested that the physician participate in the direct clinical management of the patient.

2.5 Medical risk to the physician

The AANEM recognizes that physicians have needs and concerns that are relevant for ethical decision-making in the context of patient evaluation. At the same time, physicians should provide appropriate, compassionate care to all patients, including patients with infectious and other communicable diseases (e.g., human immunodeficiency virus or antibiotic-resistant infections). Physicians should not deny care solely because of a real or perceived medical risk to themselves. Physicians must utilize appropriate infection prevention and control precautions during the examination of all patients to minimize their own medical risk.

2.6 Ethical considerations and the management of neuromuscular disease

Specialists providing care to patients with NM disease may encounter situations that raise important ethical questions. Some NM disorders are progressive or debilitating and may impact a patient's autonomy or decision-making capacity. Many NM disorders have limited treatment options, which may lead patients to seek unproven interventions. Others may have effective but costly treatments not covered by insurance or unaffordable to patients. Some NM disorders are known to shorten a patient's life expectancy and may be associated with a challenging final few months of life—leading patients to seek alternatives for end-of-life care. Additionally, genetically diagnosed diseases may raise issues that affect relatives and future decision-making and have social implications.

2.6.1 Discussion of disease implications

Physicians must provide patients with their best diagnostic and management skills during the NM evaluation. They have a duty to discuss openly with their patients the implications of their NM diagnosis and related illnesses. This discussion may require sensitivity and compassion, particularly when the diagnosis is one that will severely affect the patient's quality or length of life. Physician counseling should be honest while allowing patients to maintain a realistic sense of hope. The physician's duty is to help the patient understand, decide upon, and pursue reasonable treatment options, when available, and to help avoid ineffective or futile treatments.

2.6.2 Progressive disorders

For progressive disorders, the physician should be prepared to counsel the patient regarding end-of-life issues. This includes referring the patient to services that help maintain or prolong the patient's autonomy, independence and quality of life. When the patient's NM diagnosis is expected to limit life expectancy, the physician has a duty to provide this information and, if possible, a realistic estimate of life expectancy. The patient has a right to this information to plan appropriately and address end-of-life issues.

2.6.3 Non-Beneficial Treatment

Patients with NM disorders may seek out or request treatments that the EDX physician believes are not medically necessary or ethically appropriate. An EDX physician is not obligated to provide or recommend such treatment. If a patient's treatment preferences conflict with the physician's clinical judgment, the physician should explain the basis for their recommendations and work with the patient, or the patient's surrogate when appropriate, and other treating physicians to resolve the disagreement. If the conflict cannot be resolved and interferes with the physician's ability to provide appropriate care, reasonable efforts should be made to facilitate care by another physician.

2.6.4 Pain management

Pain management is a complex area of patient care with important ethical implications for the physician. Patients with NM disorders may experience significant acute or chronic pain and have a legitimate right to access pain management. Physicians who manage acute or chronic pain in this population should be familiar with available pharmacologic and non-pharmacologic modalities, including the dosing schedules, side effects, and diversion or abuse potential of relevant medications. Physicians should also be familiar with professional guidelines and state or federal regulations related to the use of pain medication or opioid contracts for acute or chronic pain. Physicians who elect not to manage a patient's acute or chronic pain should refer the patient to another appropriate physician or pain management specialist.

2.6.5 Genetics

Novel ethical dilemmas may arise when a NM disease is confirmed through genetic testing. Physicians should provide a balanced approach when interpreting genetic information in the context of environmental factors and phenotypic variability. Physicians should help patients communicate genetic findings and their health implications to extended family members. Resources for genetic counseling should be offered, including preconception and prenatal counseling. Physicians and patients should be aware of legal protections such as the Genetic Information Nondiscrimination Act[4] (GINA) which prohibits discrimination as it relates to employment and coverage for health insurance. Social and financial risks may remain because GINA does not generally apply to life, disability, or long-term care insurance. Physicians should seek expert consultation as it relates to the rapidly evolving field of genetic and epigenetic diagnosis.

3 GENERAL PRINCIPLES OF PATIENT CARE

3.1 Professional competence

Physicians should perform evaluations only within the scope of their training, experience, and competence. The physician should provide care that represents the prevailing standard of care for NM and EDX practice. Physicians should use only standard, well-accepted, published techniques and methods for evaluation and interpretation. Evidence-based techniques are preferred. To this end, physicians should participate in and document regular continuing education. Physicians should maintain current technical skills and obtain adequate experience before introducing new techniques into practice. On occasion, other new or non-standard techniques may be necessary when addressing an unusual clinical problem or conducting a research study. If all or part of the evaluation is considered research, it must conform to the guidelines in Section 9.

3.2 Confidentiality

The physician must maintain patient privacy and confidentiality when performing EDX studies and NM evaluation, as well as in the design and configuration of the examination areas in which they are performed, in accordance with applicable state and federal laws and regulations. The patient's name or other identifying demographic information, or details of the patient's life or illness that could identify the patient, must not be disclosed or published without written permission.

3.3 Patient records

Physicians should maintain complete and accurate medical records for physicians practicing in the US and comply with the Health Insurance Portability and Accountability Act (HIPAA). Physicians practicing outside the US should comply with the applicable privacy requirements of their country. The physician's records should include a statement of the problem and the indications for the NM evaluation and/or the EDX study, description of the findings, assessment of normality or abnormality of these findings, and clinical correlation and diagnostic conclusions. Waveform images should be recorded, reviewed in real time, and, when feasible, retained as part of the medical record to support quality assurance, accreditation review, and responses to payer inquiries or appeals. Waveform submission is not required to bill for appropriately performed EDX studies. In writing reports, physicians are encouraged to follow AANEM's "Reporting the results of NCSs and Needle EMG."[5]

Information within the medical records should be available only to appropriate individuals, including referring physicians, patients, and others (such as LARs) with a valid authorization for release of information signed by the patient. Urgent information should be communicated directly and promptly to the referring physician and appropriately documented in the medical record.

3.4 Professional fees

Physiciana are entitled to reasonable compensation for services based on specified billing procedures, the comprehensive nature of the evaluation, the difficulty of the study, time involved, and the number of procedures performed. The fee structure must be made available upon request to patients, referring physicians, or third-party payers. The physician should bill for and receive compensation only for those services rendered or supervised. The physician must not receive a fee

for making a referral or give a fee for receiving a referral (“fee-splitting”). The physician should not receive a commission from anyone for an item or service ordered for a patient (“kickback”).

3.5 Appropriate services

Physicians should perform a sufficiently comprehensive NM evaluation and/or EDX study to address the clinical issues necessary to establish or evaluate a reasonable differential diagnosis. For the EDX study the physician must be involved in the pretest evaluation (focused history and physical examination) of the patient and the development of the study and should perform only those tests that are medically indicated.[3] Tests selected and procedures used should conform to published guidelines, when available.

3.5.1 Physician has the ultimate responsibility for NCS examinations

The physician must be readily available and must promptly review and evaluate the results of the NCSs in real time.[2] The patient should remain in the examination room until the supervising EDX physician has reviewed the NCS results.

All needle EMG examinations should be performed by the appropriately trained NM or EDX physician, or, in the case of residents or fellows, under the supervision of such a physician.

Except in unusual circumstances, the NCSs and EMG examination of a single patient should be performed on the same day and by the same EDX physician, to promote continuity and consistency.

The evaluation and diagnosis of NM disease may require the use of several specialized laboratory or diagnostic tests. Referral to other specialists should be made if the physician performing the EDX/NM evaluation does not have the appropriate training to conduct the specialized testing. Many of these tests may provide information that can pose ethical dilemmas for the physician as well as the patient.

As the diagnosis and management of NM disease evolves, new ethical questions will continue to arise, especially with whole genome and exome testing, which may identify not only the gene in question but also unexpected gene mutations that may suggest additional disease(s). Society’s views on these topics may shift requiring physicians to remain vigilant.

3.6 Use of artificial intelligence and emerging technologies

Physicians who use artificial intelligence or other emerging technologies in clinical practice remain responsible for the accuracy, appropriateness and quality of care provided. These technologies should be used in accordance with applicable professional standards and in a manner that protects patient privacy and confidentiality, recognizes the potential for bias, inaccuracy, and error, and supports rather than replaces appropriate physician judgment. Physicians should maintain appropriate oversight of technology-assisted clinical decision-making and possess sufficient understanding of the capabilities, limitations and potential risks of technologies incorporated into patient care.[6]

4 PERSONAL CONDUCT

4.1 Respect for the patient

Physicians must treat patients with respect and honesty, with sensitivity to language barriers, sexual orientation, gender identity, sociocultural diversity concerning personal modesty (appropriate use of chaperones), physical pain, and disability. The physician must not abuse or exploit the patient psychologically, sexually, physically, or financially.

4.2 Respect for agencies and the law

The physician should observe applicable laws. The physician should cooperate and comply with reasonable requests from insurance, compensation, reimbursement, and government agencies within the constraints of patient privacy and confidentiality.

4.3 Maintenance of the physician's personal health

The physician should strive to maintain physical and emotional health and should refrain from practices that may impair their ability to provide adequate patient care.

5 CONFLICTS OF INTEREST

5.1 The patient's interest is paramount

When a conflict of interest arises, the physician must attempt to resolve it in the best interest of the patient. Conflicts of interest that cannot be eliminated should be disclosed to the patient. If, after discussing the conflict, the patient does not want to proceed, the physician should not perform the examination on the patient.

5.2 Avoidance and disclosure of potential conflicts

The physician must avoid practices and financial arrangements that would, solely because of personal gain, influence decisions on the types of examinations performed on patients. Financial interests of the physician that could reasonably be perceived to conflict with the patient's best interests or appropriate medical care must be disclosed to the patient.

5.3 Healthcare institutional conflicts

The physician should advocate for appropriate patient care when it is jeopardized by policies of a healthcare institution or agency. The physician should inform the patient when referral restrictions on testing would limit the validity of results.

6 RELATIONSHIPS WITH OTHER PROFESSIONALS

6.1 Cooperation and communication with healthcare professionals

Physicians should cooperate and communicate with other healthcare professionals, including other physicians, nurses, and therapists, to provide the best care possible for patients. Written and oral communication with other healthcare professionals should be carried out in a timely and courteous manner. The communications should provide information that is clinically useful to the referring physician and be as responsive to the referral question as possible.

The physician may supervise and teach fellows and residents how to perform the EDX examination. Effective teaching requires close supervision of trainees during the actual testing and thorough review of the report of the findings before it is sent to the referring healthcare professional.

On occasion, the physician, while evaluating a patient referred for EDX testing, will determine, based on available clinical information, that the patient most likely has a medical problem that is not localized within the peripheral neuromuscular system. The physician should communicate this opinion to the referring healthcare professional with the goal of optimizing further care for this patient. Appropriate actions may include not proceeding with the planned EDX testing and redirecting the diagnostic evaluation.

6.2 Referrals

Typically, referrals to physicians come from other physicians or qualified healthcare professionals. Referrals for NM evaluations and/or EDX testing may come from other healthcare professionals and other non-healthcare professionals, or patients may refer themselves. If the referral did not come from another physician, reasonable efforts should be made to identify the patient's primary care physician so that the results of the NM or EDX evaluation may be communicated to that physician if the patient consents. If the patient has no primary care physician, the physician should refer the patient to a primary physician or specialist if necessary.

If the primary care or referring physician agrees, the physician may actively participate in further evaluation and treatment of the patient's NM condition and may assume primary responsibility for the management of those conditions when appropriate.

6.3 Studies performed on one's own patients — self-referral

Physicians may evaluate and follow patients for clinical, diagnostic, and therapeutic reasons. While providing such evaluation and management, a physician may recommend these patients have EDX or other specialized studies, such as biopsies or ultrasound, to clarify a diagnosis or assist with treatment. Ordering and performing EDX or other specialized studies on one's own patient—when the physician has appropriate training and experience—does not constitute self-referral. Rather, it is an integral component of clinical evaluation and represents appropriate patient care. In many cases, it may be in the patient's best interest for the treating physician, who is familiar with the patient's history and presentation, to perform these studies directly. When considering performing EDX or other specialized studies on a physician's own patient, the physician must keep in mind that there must be a proper indication for the study, consistent with relevant guidelines. The clinical indication, medical necessity and scope of the study should be appropriately documented in the patient's medical record. Some NM and EDX physicians may elect to refer their patients to another qualified physician for specialized or EDX testing, to avoid an actual or perceived conflict of interest. Patients retain the right to request specialized NM or EDX testing by an independent physician without compromising their ongoing clinical care.

6.4 Peer review, utilization review, and quality assurance

The physician should participate in peer review, utilization review, and quality assurance activities to promote optimal patient care.

6.5 Competence of colleagues and impaired physicians

Physicians should not purposely ignore a colleague's incompetence or professional misconduct, thus jeopardizing the safety of the colleague's present and future patients. The physician should strive to protect the public from an impaired physician and to assist in the rehabilitation of impaired colleagues. Physicians should cooperate with peer review processes.

6.6 Expert witness testimony

Physicians, in the public interest, are encouraged to serve as impartial expert witnesses in clinical and technical matters regarding EDX and NM medicine. Expert witness testimony consists of professional opinions that may address the standard of care, nature and extent of disability, causation of injury or illness, the clinical status of the patient, or prognosis. Physicians cannot be required to provide expert witness testimony. Physicians acting as expert witnesses should recognize that deposition and courtroom testimony may be subject to independent peer review.

An expert witness in a medical malpractice action should, at a minimum, meet applicable state legal requirements for expert witness qualifications and the following professional qualifications:

a. Comparable education, training, appropriate certification, and occupational experience in the same field of expertise as the opposing physician.
b. Active medical practice or teaching experience in the same field of expertise as the opposing physician.
c. Active medical practice or teaching experience must have been within 5 years of the occurrence giving rise to the claim.

It is unethical for expert witnesses to provide services under a contingent fee arrangement or to link compensation to the case outcome. Compensation for expert services should be reasonable and commensurate with the services actually rendered.

Physicians providing expert medical testimony should be appropriately knowledgeable and qualified in the medical and scientific issues relevant to the matter. Before providing testimony, the physician should carefully review the relevant medical records, facts of the case and the standards of practice prevailing at the time of the events in question.

Physician expert witnesses should provide testimony fairly, honestly, and impartially and should not act as advocates or partisans in legal proceedings.

6.7 Healthcare organizations

The physician may enter into contractual agreements with managed healthcare organizations, prepaid practice plans, or hospitals. The physician should retain control of medical decisions without undue interference. The patient's welfare must remain paramount.

7 RELATIONSHIPS WITH THE PUBLIC AND COMMUNITY

7.1 Public representation

Physicians should not represent themselves to the public in an untruthful, misleading, or deceptive manner regarding qualifications, credentials, and expertise through statements, testimonials, photographs, graphics, or other means. A patient's medical condition must not be discussed publicly without his or her consent (see Section 3.2).

7.2 Duties to community and society

Physicians should work toward improving the health of all members of society. This may include participation in educational programs, research, public health activities, and the provision of care to patients who are unable to pay for medical services. Physicians should be mindful of society's finite healthcare resources and avoid unnecessary tests and services, while ensuring that resource stewardship does not compromise the appropriate care of an individual patient.

7.3 Existing laws

The physician should obey the laws of the land and refrain from unlawful activities but is strongly encouraged to help produce change in laws that are not in the best interest of patients and society. Physicians must cooperate with legal authorities and processes including honoring reasonable requests from insurers and government agencies, consistent with ethical and legal privacy protections required by law.

8 ALLIED HEALTHCARE PROVIDERS IN THE ELECTRODIAGNOSTIC LABORATORY AND WORKING WITH NEUROMUSCULAR PATIENTS

8.1 Establishing and maintaining patient-allied healthcare provider relationship

Allied healthcare providers, including technologists and advanced practice providers (APPs), play important and distinct roles in the care of patients with NM disorders. Their responsibilities should reflect their education, training, experience, applicable scope of practice, and role within the healthcare team. AANEM supports a team-based model of NM care where APPs collaborate with appropriately trained physicians.[7] While the patient-physician relationship remains the core of all medical care provided, allied healthcare providers are often the frontline staff with whom the patients first interact. Allied healthcare providers should establish and maintain professional rapport with patients.

Allied healthcare providers should always treat every patient in a professional and courteous manner without discrimination or regard to personal characteristics unrelated to the patient's clinical care.

Allied healthcare providers should maintain the patient's right to privacy and confidentiality as defined by the HIPAA laws for US practitioners or by the laws of their country.

Allied healthcare providers should maintain patient safety and follow applicable infection prevention and control standards and requirements.

8.2 Scope of practice

Technologists performing NCSs must work under direct supervision and direction of a physician appropriately qualified in the practice of EDX medicine. While Medicare regulations mandate a physician must provide at least general supervision over certified technologists throughout the performance of NCS testing, it is the position of the AANEM that direct supervision, as defined by Medicare, is recommended for all NCS testing.

Technologists or other allied healthcare providers may explain the EDX testing to the patient. When performing the studies technologists should provide accurate and unbiased electrophysiological studies with patient comfort as their utmost priority. Technologists should perform standard and advanced NCSs in a highly skilled, patient-appropriate manner, recognize normal and abnormal results, and recognize and take reasonable steps to eliminate physiological and non-physiological artifact. The technologist should keep records of studies and take part in the overall maintenance of the lab.

Technologists may not provide the results of NCSs, may not perform or communicate the results of needle EMG, and may not discuss diagnostic or management issues with patients. APPs may evaluate, diagnose, treat, educate, and communicate with patients consistent with their education, training, experience, applicable scope of practice, and role within the care team. APPs may also explain EDX results interpreted by the EDX physician within the clinical context and communicate those results to patients and other members of the healthcare team.[7]

8.3 Professionalism

Allied healthcare providers should demonstrate professional etiquette towards colleagues at all levels of experience, as well as towards physicians, residents/fellows, and other healthcare staff. They should provide high quality, team-based, patient-centered care. Technologists may guide and teach other junior technologists, residents and fellows the skills involved in NCSs.

Allied healthcare providers should maintain required licensure and certification. They should participate in education to ensure knowledge of the most current medical science and technology. Allied healthcare providers are encouraged to attend annual conferences, such as the AANEM meeting, and take part in research and publications.

Allied healthcare providers should maintain patient-appropriate interpersonal skills with patients, laboratory and other allied health personnel.

9 CLINICAL RESEARCH

9.1 Informed consent

Research is an activity designed to develop and contribute to generalized knowledge. All research in human subjects must be approved and in compliance with current IRB rules. Informed consent must be obtained for all research on human subjects. A full disclosure of risks, as well as potential benefits or lack thereof, must be specified. In all circumstances pertaining to research, informed consent must include a written document signed by the subject or legally authorized representative.

The physician or other appropriately identified investigator is responsible for obtaining informed consent from the research subject for any research investigation or clinical trial prior to enrolling the subject in research. If the subject is an active patient of the physician-investigator, the physician must recognize the potential for coercion because of the patient's dependent relationship/position to the physician-investigator. The patient may feel pressured to participate because of the physician-patient relationship. Whenever possible, informed consent should therefore be obtained by an investigator independent of that relationship. Special care should be taken with vulnerable populations, including children, pregnant women, cognitively impaired individuals, prisoners, and others. Opting to participate or not participate in the research should not affect how care is provided to the patient.

9.2 Institutional review

The research project should conform to generally accepted scientific and ethical principles. The physician who participates in clinical research must verify that the research has been approved by an IRB or other comparable body and must adhere to the requirements of the approved protocol. Adverse events or outcomes must be documented and reported to the IRB, Data Safety Monitoring Board, and to sponsoring and regulatory agencies.

9.3 Financial charges to research subjects

When clinical care and research procedures occur in the same setting, the research procedures should be clearly identified and distinguished from clinical care to the research subject following the IRB-approved research protocol. Compensation for research participation should follow applicable study guidelines and IRB approval. Physicians should not bill the patient or the insurer for services already compensated by the study sponsor. All federal, state, and local regulations pertaining to billing for clinical care/services associated with clinical research must be observed to prevent duplicate billing or inappropriate cost shifting.

9.4 Disclosure of potential conflicts

The physician who is paid for testing or examining patients in a clinical research project should inform the patient of any compensation he or she receives for the patient's participation. The amount of compensation for patient testing should be reasonable.

9.5 Reporting research results

Physicians should report and publish research results — both positive and negative findings— truthfully, completely, and without distortion. In reporting research results to the news media, the physician should make statements that are clear, understandable, and supportable by the facts. Physicians should not publicize research results until data has been subjected to appropriate peer review, and accepted for presentation or publication.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

ETHICAL PUBLICATION STATEMENT

We confirm that we have read the Journal's position on issues involved in ethical publication and

affirm that this report is consistent with those guidelines.

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APPENDIX A

AMERICAN MEDICAL ASSOCIATION PRINCIPLES OF MEDICAL ETHICS

Preamble. The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following principles adopted by the American Medical Association are not laws but rather standards of conduct that define the essentials of honorable behavior for the physician.

Principles of Medical Ethics

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
II. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
III. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
IV. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
V. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.
VI. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
VII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
VIII. A physician shall support access to medical care for all people.

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