AMERICAN ACADEMY OF NEUROLOGY
ETHICS, LAW AND HUMANITIES COMMITTEE

ETHICAL DIMENSIONS OF NEUROLOGIC PRACTICE

A Case-Based Curriculum for Neurology Residents

PILOT PROJECT

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American Academy of Neurology

Ethics, Law and Humanities Committee

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INTRODUCTION

Goals of This Curriculum

The ethical dimensions of medical practice have grown exponentially over the past 50 years. The last 25 years have been marked by an explosion in the numbers and variety of ethical issues that affect neurologists in their treatment of the patient with neurologic diseases. Dating from the early brain death and termination of treatment court cases, neurologists have played a central role in the identification of ethical issues, the assessment of patients for whom ethical issues were being discussed, and carrying out care based upon ethical as well as scientific and clinical principles.

The American Academy of Neurology has recognized the importance of educating neurologists in the ethical dimensions of practice. It has accomplished this educational function in a variety of ways, including courses at the annual meeting, the development of position papers and practice parameters, and the development of training materials. This workbook is designed to help prepare neurologists-in-training for the ethical issues that may confront them during their residencies and will confront them in practice.

The goal of this curriculum is to enhance the care of patients with neurologic disease by improving the ability of neurologists-in-training to identify ethical issues and appropriately manage those issues.

How to Use This Curriculum

This curriculum uses a case based approach to explore ethical issues that arise in the care of patients with neurologic disease. The curriculum is intended as a whole, and the cases are arranged in a manner that ensures that the learner will face core ethical issues (e.g., competence) early in the curriculum. It is suggested, therefore, that the curriculum be pursued as a whole, although the use of a single case or other portion of the curriculum may, at times, be useful.

The cases were prepared by members of the Ethics and Humanities Subcommittee of the American Academy of Neurology. Each case begins with a core set of learning objectives. The instructor should be aware of these objectives and use them to guide discussion. These objectives should not preclude the learners from pursuing other related issues, and one can anticipate that such pursuits will occur particularly when the casebook case is supplemented by discussion of a similar case that forms part of the common group experience. In order not to forestall other issues from arising, the faculty facilitator may wish to distribute learning objectives at the end of the case. The cases are intended to introduce ethical questions in the context of frequently encountered neurologic conditions. All names are fictitious.

After the learning objectives you will find the case itself. These cases are intended to provide the primary structure for learning. The cases are prepared so that they can be easily reproduced and distributed to an entire group.
Following each case is a proposed outline for ethical analysis of the case. Ethical analysis is a systematic process, and this outline can help students learn one system for decision-making. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds), *Introduction to Clinical Ethics*. University Publishing Group Inc., Frederick, Md. 1995. While this is only one of several systematic approaches to ethical analysis, we have used it to form the infrastructure of case discussion in this case book. For most cases, the entire analysis will be appropriate. For some of the cases, only certain elements are used.

Following the proposed outline for ethical analysis are comments organized in the same fashion as the outline. These comments have been prepared by the case author and are intended to help the faculty facilitator guide discussion, identify issues, and identify resources. The comments provide additional perspectives of the author, and are not intended to be completely comprehensive on the topic. Where available, AAN practice parameters and guidelines are included.

Case authors have also suggested references. References are included to expand upon the analysis of the case. They are not intended to be comprehensive nor necessarily supportive of one position or another on the issue under discussion. Some cases conclude with a section entitled “Instructional Suggestions”; in this section, the case author provides insights on teaching methods that have proved useful in the past.

The nature of the faculty facilitator for this curriculum merits comment. A facilitator who has formal training in bioethics and familiarity with the clinical issues in the cases is desirable, although having such a facilitator may not be possible in all settings. The facilitator should be a thoughtful person comfortable with diverse opinions and capable of enhancing group process even through difficult discussion. Issues that arise in this curriculum are by their very nature emotionally charged. Once can anticipate that the group participants will have a variety of religious, cultural, economic, and lifestyle backgrounds. There may be significant disagreement about particular issues. Discussion, even heated discussion, during sessions of this curriculum is not to be frowned upon. In fact, thoughtful disagreement may enhance the residents’ better understanding of their own beliefs and biases, as well as enhance their ability to understand the diverse perspectives held by patients. The facilitator’s role in keeping the group focused on issues and arguments, not personalities; in modeling tolerance for diverse opinions; in insisting upon rigor in the ethical analysis; and in maintaining a collegial atmosphere is very important. Consequently, the facilitator should be carefully chosen.
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). Introduction to Clinical Ethics, University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment
   1. What is the patient’s medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient’s preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
CODE OF PROFESSIONAL CONDUCT

PREFACE

The Ethics and Humanities Subcommittee of the Practice Committee of the American Academy of Neurology developed the Code of Professional Conduct to formalize the standards of professional behavior for neurologists members of the Academy. The primary goal of the Code is to promote the highest quality of neurologic care. The Code is framed to outline the set of professional standards that neurologists must observe in their clinical and scientific activities.

The Code embodies traditional medical ethical standards dating from the time of Hippocrates as well as more contemporary standards. It includes general principles of medical ethics and provides their application to the specific demands of neurologic practice. The Code is delineated to be generally consistent with the American Medical Association Code of Medical Ethics and the American Medical Association Current Opinions of the Council on Ethical and Judicial Affairs.

The Code is written in relatively broad language. It is designed to be a dynamic instrument that can grow and change in response to future developments in the practice and science of neurology. While ethical principles do not change with time, developments in science, technology, and clinical practice may lead to a change in application of these ethical principles.

The Code outlines the standards of professional conduct for Academy members. Violations of these standards may serve as the basis for disciplinary action as provided in the Bylaws of the Academy.
1.0 THE NEUROLOGIST-PATIENT RELATIONSHIP

1.1 The Practice of Neurology
The profession of neurology exists primarily to study, diagnose and treat disorders of the nervous system. The neurologist-patient relationship forms the foundation for neurologic care.

1.2 Fiduciary and Contractual Basis
The neurologist has fiduciary and contractual duties to patients. As a fiduciary, the neurologist has an ethical duty to consider the interests of the patient first. As a party to an implied contract, the neurologist has a duty to practice competently and to respect patients' autonomy, confidentiality, and welfare.

1.3 Beginning and Ending the Relationship
The neurologist is free to decide whether or not to undertake medical care of a particular person. The neurologist must not decline a patient on the basis of race, religion, nationality, or gender. Once the relationship has begun, the neurologist must provide care until care is complete, the patient ends the relationship, or the neurologist returns the patient to the care of the referring physician. If the neurologist justifiably desires to end the relationship, and if continued neurologic care is appropriate, he/she should assist in arranging care by another neurologist.

1.4 Informed Consent
The neurologist must obtain the patient's consent for tests or treatment. The neurologist should disclose information that the average person would need to know to make an appropriate medical decision. This information should include benefits, risks, costs, and alternatives to the proposed treatment. If the patient lacks medical decision-making capacity, the neurologist must obtain informed consent from an appropriate proxy.

1.5 Communication
The neurologist has a duty to communicate effectively with the patient. The neurologist 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 treatment.

1.6 Emergency Care
In an emergency situation, the neurologist should render services to the patient to the best of his/her ability. While obtaining informed consent is desirable before beginning treatment, the neurologist should not delay urgently needed treatment because of concerns about informed consent.

1.7 Medical Risk to the Physician
A neurologist should not refuse to care for a patient solely because of the real or perceived medical risk to the neurologist. The neurologist should take appropriate precautions to minimize his/her medical risk.

1.8 Medical Decision-Making
The patient has the ultimate right to accept or reject the neurologist's recommendation about medical treatment. The neurologist should respect decisions made by patients with decision-making capacity and by the lawful proxy of patients who lack decision-making capacity. If the neurologist cannot honor the patient's or proxy's decision, the neurologist should seek to
2.0 GENERAL PRINCIPLES OF NEUROLOGIC CARE

2.1 Professional Competence
   The neurologist must practice only within the scope of his/her training, experience, and competence. The neurologist should provide care that represents the prevailing standards of neurologic practice. To this end, neurologists should participate in a regular program of continuing education.

2.2 Consultation
   The neurologist should obtain consultations when indicated. The neurologist should refer patients only to competent practitioners and should assure that adequate information is conveyed to the consultant. Any differences of opinion between the neurologist and consultant or between the neurologist and their referring physician should be resolved in the best interest of the patient.

2.3 Confidentiality
   The neurologist must maintain patient privacy and confidentiality. Details of the patient's life or illness must not be publicized.

2.4 Patient Records
   The neurologist should prepare records that include relevant history, neurologic findings, assessment, and plan of evaluation and treatment. Patients are entitled to information within their medical records.

2.5 Professional Fees
   The neurologist is entitled to reasonable compensation for medical services to or on behalf of patients. The neurologist should receive compensation only for services actually rendered or supervised. The neurologist must not receive a fee for making a referral ("fee-splitting") or receive a commission from anyone for an item or service he/she has ordered for a patient ("kickback"). The agreed upon division of practice income among members of an organized medical group is acceptable.

2.6 Appropriate Services
   The neurologist should order and perform only those services that are medically indicated.

3.0 SPECIAL CATEGORIES OF NEUROLOGIC CARE

3.1 The Dying Patient
   The neurologist should strive to relieve the suffering of dying patients. The neurologist should respect the expressed wishes of dying patients about life-prolonging therapy, including lawful advance directives.

3.2 The Profoundly Paralyzed Patient
   The neurologist should attempt to enhance the independence and communication of profoundly paralyzed patients. Patients with advanced degrees of paralysis who retain decision-making capacity should be encouraged and assisted to participate in decisions about their medical care including decisions about withdrawing life-support.
3.3 The Demented Patient
   The neurologist should define a course of treatment which respects the wishes expressed by
   the patient before dementia had impaired decision-making capacity. If such wishes are not
   ascertainable, the neurologist should be guided about appropriate treatment by the patient's
   lawful proxy.

3.4 The Patient in a Persistent Vegetative State
   The neurologist managing the patient in a persistent vegetative state should follow the
   provisions of lawful advance directives for medical care and, in their absence, the health care
   decisions of a lawfully authorized proxy.

3.5 The Brain-Dead Patient
   The neurologist should determine brain death using accepted tests and techniques. The
   neurologist should be mindful that some patients may have religious or other strongly held
   objections to the concept of brain death. Compassionate management in these situations is
   desirable.

4.0 PERSONAL CONDUCT

4.1 Respect for the Patient
   The neurologist must treat patients with respect, honesty, and conscientiousness. The
   neurologist must not abuse or exploit the patient psychologically, sexually, physically, or
   financially.

4.2 Respect for Agencies and the Law
   The neurologist should observe applicable laws. Because agencies may impact on patients' 
   welfare, the neurologist 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 Neurologist's Personal Health
   The neurologist should strive to maintain physical and emotional health. The neurologist
   should refrain from practices that may impair capacities to provide adequate patient care.

5.0 CONFLICTS OF INTEREST

5.1 The Patient's Interest is Paramount
   Whenever a conflict of interest arises, the neurologist must attempt to resolve it in the best
   interest of the patient. If the conflict cannot be eliminated, the neurologist should withdraw
   from the care of the patient.

5.2 Avoidance and Disclosure of Potential Conflicts
   The neurologist must avoid practices and financial arrangements that would, solely because of
   personal gain, influence decisions in the care of patients. Financial interests of the neurologist
   that might conflict with appropriate medical care should be disclosed to the patient.

5.3 Dispensing Medication
   The neurologist may dispense medication, assistive devices, and related patient-care
items as long as this practice provides a convenience or an accommodation to the patient without taking financial advantage of the patient. The patient should be given a choice to accept the dispensed medication or device or to have a prescription filled outside the neurologist's office.

5.4 Health-Care Institutional Conflicts
The neurologist generally should support his patient's medical interests when they are compromised by policies of a health-care institution or agency. Physicians employed by healthcare institutions should represent the patient's medical interests and serve as their medical advocate to the institutional administration.

5.5 Conflicting Ethical Duties
While a neurologist ordinarily must respect a patient's confidentiality, there are circumstances in which a breach of confidentiality may be justified. When the neurologist is aware that an identifiable third party is endangered by a patient, the neurologist must take reasonable steps to warn the third party. When the neurologist is aware that members of the general public are endangered by a patient, the neurologist must take reasonable steps to advise responsible public officials or agencies of that danger.

6.0 RELATIONSHIPS WITH OTHER PROFESSIONALS

6.1 Cooperation with Health Care Professionals
The neurologist should cooperate and communicate with other health care professionals, including other physicians, nurses, and therapists, in order to provide the best care possible to patients.

6.2 Peer Review
The neurologist should participate in peer review activities in order to promote the best care possible of patients.

6.3 Criticism of a Colleague
The neurologist should not unjustifiably criticize a colleague's judgment, training, knowledge, or skills. Neurologists should not knowingly ignore a colleague's incompetence or professional misconduct, thus jeopardizing the safety of the colleague's present and future patients.

6.4 Legal Expert Testimony
The neurologist called upon to provide expert medical testimony should testify only about those subjects for which the neurologist is qualified as an expert by training and experience. Before giving testimony the neurologist should carefully review the relevant records and facts of the case and the prevailing standards of practice. In providing testimony, the neurologist should provide scientifically correct and clinically accurate opinions. Compensation for testimony should be reasonable and commensurate with time and effort spent, and must not be contingent upon outcome.

6.5 Health Care Organizations
The neurologist may enter into contractual agreements with managed health care organizations, prepaid practice plans, or hospitals. The neurologist should retain control of medical decisions without undue interference. The patient's welfare must remain paramount.
The Impaired Physician

The neurologist should strive to protect the public from an impaired physician and to assist the identification and rehabilitation of an impaired colleague.

RELATIONSHIPS WITH THE PUBLIC AND COMMUNITY

Public Representation

The neurologist should not represent himself/herself to the public in an untruthful, misleading, or deceptive manner. A patient's medical condition must not be discussed publicly without the patient's consent.

Duties to Community and Society

Neurologists 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. The neurologist should be aware of the limitation of society's health care resources and should not squander those finite resources by ordering unnecessary tests and ineffective treatments.

CLINICAL RESEARCH

Institutional Review

The neurologist who participates in clinical research must ascertain that the research has been approved by an Institutional Review Board (IRB) or other comparable body and must observe the requirements of the approved protocol.

Disclosure of Potential Conflicts

The neurologist who is paid for treating patients in a clinical research project should inform the patient of any compensation the neurologist receives for the patient's participation. The compensation for patient treatment should be reasonable in amount. The neurologist should not bill the patient or the insurer for services already compensated by the study sponsor.

Individual Patient Experimentation

The neurologist who begins a patient on an experimental therapy that has not been approved as a valid clinical study by an IRB should obtain informed consent from the patient.

Reporting Research Results

The neurologist should publish research results truthfully, completely, and without distortion. In reporting research results to the news media, the neurologist should make statements that are clear, understandable, and supportable by the facts. Neurologists should not publicize results of research until after the data have been subjected to appropriate peer review.

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Portions of this Code were modified from the following codes of professional ethics and professional conduct:


Approved PC 02/93
Approved EB 02/93

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I. Learning Objectives

At the conclusion of this case, neurology residents will:

1. be able to define and explain the following terms and concepts: truth telling, disclosure, therapeutic privilege, paternalism, confidentiality of medical records.
2. be able to discuss applicable state law and institutional rules regarding confidentiality of medical information.
3. have increased ability to sensitively communicate information in a way that avoids euphemisms and half-truths.
4. be aware of his/her responsibility to communicate with patients with respect, honesty, and sensitivity.
II. Case

Ms. JA is a 24 year old woman, a law student in her final year, who developed blurred vision in her right eye. After several days, her vision deteriorated so much that she could not read her textbooks, and her eye became painful upon movement. Her family physician referred her to an ophthalmologist who, in turn, referred her to a neuro-ophthalmologist, Dr. JM, who made a diagnosis of acute retrobulbar neuritis. Without giving a specific medical diagnosis, Dr. JM told the patient that she had an inflammation of the optic nerve and suggested a course of intravenous methylprednisolone, which he explained should reduce the swelling of the nerve and restore her sight.

Dr. JM happened to be a friend of the patient’s parents. Later that afternoon, when the patient’s father called to inquire about his daughter, the doctor told him that JA had optic neuritis and that this might be the first evidence of multiple sclerosis (MS), and consequently Dr. JM was going to obtain a neurological consultation. The father urged the doctor not to tell his daughter, arguing that she was about to take her final exams. He feared that the news would upset her, causing her to fail the exams. Furthermore, she already had prospects of a job with a law firm, and he feared that they might not hire her if they thought she had the potential for subsequent illness.

Ms. JA went to the library, and between the Internet and books, concluded that the inflammation of the optic nerve was optic neuritis, and discovered the possible relationship to MS. She recalled that several years earlier she had experienced numbness of one leg, which had lasted for several weeks, but for which she had not sought medical attention. She decided not to tell the doctor because she was concerned that Dr. JM might be asked to provide a medical report and her job chances might be jeopardized if he confirmed the diagnosis.

Over the subsequent weeks, Ms. JA’s vision improved, and she was successful in her examinations. When she began her new job, she completed information for a health insurance package. When asked about her past health, she did not report her visual or neurological symptoms. Her vision returned to normal.

Ms. JA had no further difficulties over the subsequent year. When she became romantically involved with one of her colleagues in the law firm, she debated whether or not she should tell him about her medical history.
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I. Assessment
   1. What is the patient’s medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient’s preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments
(by Robert F. Nelson, MD)

A. Assessment

1. What is the patient’s medical condition and prognosis? What treatment options exist?

The patient has acute optic neuritis, and probably because of multiple sclerosis. Strictly speaking, the diagnosis of multiple sclerosis requires the occurrence of more than one attack and at the time of her presentation there appeared to have been only one episode. However, the patient recalled that she had had previous neurological symptoms. Thus, the optic neuritis was probably the second event, and the criteria for the diagnosis were met. Had the ophthalmologist and the patient been more forthright, further tests such as an MRI or CSF studies might have been carried, which would have helped to confirm the diagnosis.

The prognosis is unpredictable, but certain statistics may give some idea of the possibilities. For example, there is a 33% chance that the disease will remain benign for at least 10 years; although there is a 10-20% chance that the disease may be progressive from its onset, in the great majority of cases it will consist of relapses and remissions for the first decade. After that, 40% of cases will become secondarily progressive, and only 45% will continue the pattern of relapses and remissions. Relapses may occur at a rate of 0.1 to 1.15 per year (0.4/year).

The treatment option of the acute optic neuritis includes high dose methylprednisolone. Patients with early symptoms and signs of MS may benefit from ongoing treatment with various forms of interferon or with copolymer, which may reduce the likelihood of subsequent attacks by up to one third. Patients should be told about such treatment options and about the possible adverse effects that they should weigh against the potential benefits. By not revealing the diagnosis the physician is preventing the patient from making informed decisions about her own health care.

2. Who is the appropriate decision maker?

The appropriate decision maker in this case is the patient herself. She is adult and presumably competent. The father is not the decision maker in this case, and the physician was in error to give him information. In this situation, the physician decided not to disclose certain information to the patient, and disclosed information to another, apparently without the patient’s consent.

3. What are the patient’s preferences?

It may be valuable to discuss whether or not the patient would have preferred full disclosure at the time of initial visit. As the case progresses, it is clear that the patient preferred to keep some information about prior symptoms a secret. This was because of fear that she had MS, and she thought that if this was confirmed it might jeopardize her career and her chance for obtaining insurance.

4. What are the preferences of her family or surrogate decision makers?

It is important to stress that the preferences of the family are not relevant in this situation.
The father did not want his daughter to be told the doctor’s suspicions. The father is acting in a very paternalistic fashion, which might be understandable but is inappropriate.

5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?

The patient’s father has an interest in his daughter’s well being and success in life. As noted above, this may lead him to treat her inappropriately. The neuro-ophthalmologist had a conflict in that he wished to comply with his friend who happened to be the father of his patient. The law firm might wish to know of her health status before they hired her. The insurance company surely would wish to be informed of her diagnosis. Ms. JA’s significant other may wish to know of her medical condition, particularly if they are contemplating marriage.

The physician may wish to inform the patient of others’ interest in knowing this information, and perhaps, her interest in having other people know. He should inform her that insurance billing rules may make it impossible to keep certain diagnosis confidential, if the medical care will be billed to insurance. Although the physician should encourage the patient to disclose information herself, the physician should not disclose the information. The physician’s first responsibility is to his patients, and he acted inappropriately in telling her father of her illness (unless he had consent from the patient to discuss it with him).

6. Are there institutional, legal or other factors which need to be considered?

Most states and health institutions have laws or standards relating to the disclosure of confidential information by physicians. Neurology residents should be aware of these laws and standards. With regards to the patient’s situation, her failure to answer questions truthfully on a health insurance contract might result in limited coverage or voiding of the contract.

B. Identification of the Ethical Problem(s)

7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)

Major ethical issues in this case include disclosure of information by the physician to the patient’s father without her consent, and failure to fully disclose information to the patient. Being truthful with patients demonstrates that the physician respects their autonomy. Lying, incomplete disclosure, and deception may have resulted from physician paternalism, and attempting to act in the patient’s best interest, but are nonetheless inappropriate. This case may afford an opportunity to discuss when nondisclosure is appropriate, mechanisms of staged disclosure, etc.

Breaching the patient’s confidence also demonstrates a lack of respect for her autonomy. The physician could get her consent to speak to family. Note that the physician has contributed to a situation of secret-keeping within the patient’s family as well.

The patient herself also withheld information from the physician and her insurance company. Pelligrino and Thomasma have suggested that truthfulness and disclosure in relating the medical history (to physicians) is one of the virtues of the good patient, important so that appropriate diagnosis, work up, and therapy can proceed.
8. **What ethical considerations are most relevant?**
   Autonomy, truthfulness, disclosure, deceit, beneficence, paternalism.

9. **Are there analogous cases?**
   Many neurologists will have treated patients with MS or another neurologic disease and will have experienced similar dilemmas regarding telling patients of the diagnosis and working with families who wish information kept from patients. An oft-quoted survey by Elian and Dean (1985) demonstrated that most patients with MS wish to be informed about the diagnosis, although there are some who do not. A more recent study by Mushlin (1994) showed that those who were certain of their diagnosis of MS experienced an enhanced quality of life compared to those who were uncertain; knowing the diagnosis appears to give a sense of empowerment.

10. **What are the relevant guidelines for clinicians regarding the problem(s)?**
    Several societies, including the British Society of Rehabilitation Medicine and the Multiple Sclerosis Society of Great Britain and Northern Ireland, have published guidelines for imparting the diagnosis of MS.

C. **Decision Making and Implementation**

11. **What are the ethically acceptable options?**
    The physician should determine early on how much information the patient is interested in receiving. Patients should not be forced into accepting unwanted information, but neither should the physician's paternalistic urges result in patients not having appropriate information that they would wish to have. It is also inappropriate for physicians to hide behind medical jargon and euphemistic terms that obfuscate an issue rather than enlighten patients.

12. **What justifications can be given for the ethically preferred resolution of the case?**
    Withholding information is often excused by implying that it is in the patient's best interests. The term 'therapeutic privilege' describes a situation in which the physician withholds information when it is believed that providing the information might be detrimental to the patients health. In most cases, the patient should be provided with enough information to make wise health decisions.

    Patients may not always want to know the truth. However, physicians must never presume that patients do not want to know. If they do so, they may act out of benevolence, but in a paternalistic way that overrides the respect for the patient's autonomy.

13. **How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?**
    Physicians should disclose pertinent information to patients, and not disclose information to others without the consent of the patient. Hopefully, the patient will inform her physician of her previous neurological symptoms and her suspicions and concern that she may have MS. The physician may advise the patient to make others aware of her diagnosis, if confirmed, but it is not the physician's role to force this decision.
Many companies have health plans, disability insurance and other benefits that apply to all employees. In some instances, new employees must fill in an application and may be rejected on the basis of their health. It is incumbent on applicants to fill the forms out honestly. Applicants may have to sign a waiver allowing the company to ask for medical reports from treating physicians. It is expected that physicians will provide truthful information. Physicians may feel an obligation to their patients to couch the information in favorable terms. Professionalism demands that the forms be filled in honestly. Some physicians may sense a conflict between their duty to the patient and their duty to society as represented by the company. However, truthfulness is an important principle that underlies all social interactions.

IV. References


I. Learning Objectives
At the conclusion of this case, neurology residents will:
1. be able to define and explain the following words and concepts: Huntington's disease, autosomal dominant genetic transmission with complete penetrance, predictive DNA tests, positive and negative predictive value, autonomy, self-determination, genetic counseling, trinucleotide repeat number.
2. understand the importance of a given trinucleotide repeat value in the HD DNA test.
3. be able to counsel the at-risk relative of an HD patient about the meaning of the DNA test.
4. be able to refer patients with DNA tests for psychological and genetic counseling.
5. practice the ethical guidelines for use of the HD DNA test, including: that tests should not be performed on minors; that third parties may not order patients' tests; that strict privacy and confidentiality regarding test results must be maintained; and that every tested patient should be enrolled in a program of pretest and post-test psychological and genetic counseling.
6. recognize that adult patients at risk for HD have a right to know whether they carry the HD gene, and respect that right.
7. understand the need for ethical guidelines in the use of predictive genetic testing to prevent harm from occurring to the tested patient.
II. Case

A 26 year old man sought neurological consultation to determine whether he was at risk for developing Huntington’s disease (HD). His mother was found to have HD twelve years ago at the age of 38 and now was profoundly demented and living in a nursing home. The mother’s father and paternal aunt had died of HD several decades earlier. The patient had no symptoms of HD, but, like his two asymptomatic younger sisters, he was anxious about the possibility of developing HD.

Upon further evaluation, the patient informed the neurologist that he was engaged to be married but that his prospective in-laws strongly opposed the marriage unless the patient underwent genetic testing and was found not to have the HD gene. The patient expressed certainty that he could not possibly carry the gene because he felt normal and had no symptoms. Nevertheless, he was ambivalent about undergoing genetic testing because he was not sure he really wanted to know for certain whether he was destined to develop HD.

The results of neurological examination were entirely normal. The neurologist informed the patient that there was no way of knowing with certainty whether he was destined to develop HD except by performing the genetic test. Yet the neurologist was uncertain about how to proceed in this case because it was the prospective in-laws rather than the patient who were most eager for him to undergo genetic testing for presymptomatic identification of HD.
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). Introduction to Clinical Ethics, University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment
   1. What is the patient's medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient's preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
   11. What are the ethically acceptable options?
   12. What justifications can be given for the ethically preferred resolution of the case?
   13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments
(by James Bernat, MD)

A. Assessment
1. What is the patient's medical condition and prognosis? What treatment options exist?

The patient clearly is at risk for developing HD. There is a definite family history of an affected parent with HD. Because HD is inherited as an autosomal dominant trait with complete penetrance, the patient has a 50% chance of having inherited the HD gene and developing the disease. Most patients become symptomatic in their thirties or forties and die after a mean disease duration of 17 years. Treatments for HD may suppress the choreiform movements, but no treatment for HD alters its progressive dementia or its inexorably fatal course.

Numerous tests have been proposed for the presymptomatic diagnosis of HD. The test with the greatest positive predictive value (PPV) and negative predictive value (NPV) is that which tests for the HD gene. It has been estimated that, for the genetic test, both the PPV and the NPV are in the 99% range. Therefore, unlike all of the previously proposed predictive tests, the genetic test is a highly reliable predictor of developing HD.

2. Who is the appropriate decision maker?

Surrogate decision making in HD becomes necessary as the disease progresses because dementia worsens and patients lose their decision making capacity. Early in the course of the illness, advance directives should be executed in anticipation of this complication. No surrogates are necessary for testing in the presymptomatic stage if the patient is competent and is an adult.

3 & 4 What are the patient's preferences? What are the preferences of the family or surrogate decision makers?

Presymptomatic testing for HD should be performed only voluntarily at the request of an at-risk patient. It should neither be ordered by others nor its ordering coerced by others, such as in this case. It should not be ordered on minors who cannot give valid consent.

5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?

In this case, the prospective in-laws insist that genetic testing negative for HD be a condition for approving their daughter's marriage. These third-party interests conflict with those of the patient, who is not certain that he wishes to know whether he is destined to develop HD later in life. A similar situation exists when prospective employers or insurers demand that at-risk patients be tested. It is not ethically justifiable for third parties to require the performance of a genetic test against the will of the patient.
6. Are there institutional, legal, or other factors which need to be considered?
No institutional or legal requirements mandate presymptomatic testing in this circumstance.

B. Identification of the Ethical Problem(s)

7 & 8 What are the ethical problems in the case? (If appropriate, rank by magnitude.)
What ethical considerations are most relevant?

The ethical problems presented by presymptomatic genetic testing for HD include the following: 1) who should be tested? 2) how should permission for testing be obtained? 3) is the test safe? 4) is the test accurate? and 5) how can the potential problems associated with receiving the tests results be minimized?

It is widely accepted that all presymptomatic testing should be voluntary. Patients at risk for developing HD may wish to learn their fate in advance. Most studies have shown that 75 to 85% of at-risk patients would choose to be tested if a safe and accurate test were available. Studies of HD genetic programs have shown a reduction in patient anxiety even among those who tested positively, because they are no longer uncertain about their future. If at-risk patients are fully informed about the test, are not coerced into taking it, and if the test results remain confidential, they should be allowed to be tested if they wish.

Permission for testing is based on informed consent. Patients undergoing testing therefore need 1) to have adequate decision making capacity; 2) to receive adequate information about the test; and 3) not be coerced into having the test. Adequate information in this context includes the risk of developing HD if the test result is positive or negative, the availability of pretest and post-test psychological counseling irrespective of the results of testing, and genetic counseling.

The genetic test is entirely safe and requires only a blood sample. This is in contrast to the controversial levodopa provocative test, which has been criticized, among other reasons, because it may cause an earlier onset of the symptoms of the disease and because the results of the test are immediately obvious to the patient and anyone observing the patient. Unlike the genetic linkage test used before the gene test, blood specimens from family members are not required. The extremely high accuracy of the genetic test was discussed previously.

Problems associated with the test may include severe depression or suicide if the test is positive. There are even complications of negative testing, including the "survivor guilt complex." These problems can be minimized if the testing program provides adequate pretest and post-test counseling as a requirement of being tested. There is clear evidence that resolving the prognostic uncertainty itself leads to reduced levels of anxiety in at-risk patients, even among those who test positive for the gene.

9. Are there analogous cases?
The most closely analogous cases are those involving requirements by employers
or insurers for genetic testing. Genetic testing mandated by employers without patient consent was judged to be inappropriate in nearly all instances by the American Medical Association Council on Ethical and Judicial Affairs (7). Similarly, genetic testing as a condition of health insurance without patient consent was judged to be unethical by the Task Force on Genetic Information and Insurance of the National Center for Human Genome Research (8).

10. **What are the relevant guidelines for clinicians regarding the problem(s)?**

Guidelines for the ethical use of predictive tests in HD have been proposed by the Commission for the Control of Huntington's Disease (9), the Huntington's Disease Society of America (10), the International Huntington Association (11), and the United Kingdom Huntington's Disease Prediction Consortium (12). These guidelines emphasize voluntariness, confidentiality, safety, absence of coercion, the availability of psychological and genetic counseling. These guidelines prohibit testing on minors.

C. **Decision Making and Implementation**

11. **What are the ethically acceptable options?**

The neurologist should discuss the risks and benefits of testing with the patient. If the patient decides to proceed, the testing should be performed in a setting in which pretest, post-test, and genetic counseling are provided. When available, the testing should be performed in a comprehensive HD program in which experienced counselors are available and close follow-up is part of the testing protocol. The neurologist should explain that all presymptomatic genetic testing must be voluntary.

12,13 **What justifications can be given for the preferred resolution of the case? How is a satisfactory resolution to this case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?**

The patient must decide whether to capitulate with his future in-laws and undergo testing or to refuse and face the consequences. The opinion of the fiancé should also be considered. The physician should not order the test unless it is clear that the patient has given his free and informed consent. This case illustrates one of the limits on autonomy: that many decisions cannot be free from constraints from others and that the concept of truly "voluntary" or "autonomous" choices may represent only an ideal.

IV. **References**


In clinical practice, neurologists may order tests that yield genetic data about patients or members of their families. Tests can, for example, identify a disease-specific gene or disclose a biochemical abnormality thought to be genetically determined or influenced. Many of these tests are generally accepted and widely performed (e.g., tests of phenylketonuria or sickle-cell disease, measuring of cholesterol or lipoprotein levels) and engender little controversy. Other tests may identify genes that predict severe and untreatable neurologic disease (e.g., Huntington’s disease) or that suggest vulnerability to such a disease (e.g., Alzheimer’s disease). Tests in this latter category have profound implications for patients and their families and merit careful consideration before ordering.

Neurologists are now receiving advertising and other materials that encourage “genetic testing” of their patients. Among other things, these materials may assert that new molecular techniques enable reliable identification of carriers of genes for particular neurologic diseases or of genotypes that predict susceptibility to such diseases. Although molecular diagnostic technologies are undeniably powerful and increasingly accurate, the information they reveal can generate various problems. For example, testing a patient may be of little or no predictive value if family members are not tested as well. Also, unless a variant genotype absolutely predicts clinical disease (as in Huntington’s disease), identifying that genotype may have little utility. Indeed physicians or genetic counselors may find that attempting to explain an “abnormal” genotype of uncertain predictive value may only confuse or upset patients or their families. Moreover, once a result of a genetic test that predicts disease or significant susceptibility is entered into a person’s medical record, an evident risk is that health insurers, employers, or others will gain access to it and use it in ways that adversely affect the person’s welfare. Although medical records are legally protected as confidential documents, patients sometimes, willingly or unwittingly, allow others access to their records to obtain reimbursement for medical expenses or to claim other benefits.

For these reasons, among others, the Genetics Task Force of the American Academy of Neurology’s Practice Committee recommends to neurologists that they consider the following points in weighing a decision whether to order genetic testing for patients or family members suspected of harboring genes that cause or increase susceptibility to major neurological disorders.

The following points should be considered:

1. Predictive power of the test. Neurologists should understand what a positive or negative genetic test implies with respect to probabilities that a patient, family member, or potential offspring has or will develop a particular neurologic disease. In this regard, a neurologist should appreciate the predictive power of a particular genotype, distinguishing among genotypes that foretell disease with a high degree of certainty (Huntington’s disease), those that suggest a possibly heightened susceptibility to a disease (apoE4), and their positive predictive power.

2. Counseling. Sensitive and informed counseling provides patients and families a foundation for decisions about testing for serious neurologic disorders. Therefore, before ordering a genetic test in such a setting, neurologists should either possess the training and experience to provide competent counseling about the test and its implications or take steps to ensure access to a qualified genetic counselor. In most situations, genetic testing for major neurologic disorders should not be performed until adequate counseling has been afforded. In the case of predictive testing for Huntington’s disease, for example, psychological counseling by appropriately trained persons is essential before testing and after results of testing are disclosed.

3. Informed consent. As to diagnostic testing, the doctrine of informed consent asserts that physicians must disclose to patients information that is material to a decision about testing and that consent to testing must be informed and voluntary. Therefore, before ordering a genetic test for a major neurologic disorder, neurologists should ordinarily establish that a patient or lawful surrogate is capable of comprehending relevant disclosures and capable of exercising informed choice. If these conditions exist, the neurologist or collaborating genetic counselor should disclose why the test is recommended, the predictive weight of the test, the potentially adverse consequences of a positive test (e.g., extreme emotional distress, stigmatization, loss of health insurance or
employment), the benefits of enhanced knowledge about genotype (whether test is positive or negative), and any negative consequences of not testing (e.g., transmission of a detectable disease-associated genotype to offspring). Once there has been adequate counseling, documented disclosure of material information, and voluntary agreement to testing by a competent patient or lawful surrogate, neurologists are ethically justified in ordering a genetic test that may diagnose, predict, suggest vulnerability to, or exclude a major neurologic disorder. Neurologists should not order genetic tests of this sort at the request of members of patients’ families or other third parties (e.g., insurers, employers) without the express written consent of a patient or lawful surrogate.

4. Confidentiality. Test data confirming that patients or family members carry genes that indicate or predict susceptibility to major neurologic disorders are highly sensitive. Accordingly, neurologists who obtain such data should implement rigorous measures to ensure their confidentiality and should never disclose such data to third parties without explicit written authorization from tested personal or their lawful surrogates.

Acknowledgment
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The Genetics Testing Task Force: H. Richard Beresford, MD; James L. Bernat, MD; Mitchell F. Brin, MD; John H. Ferguson, MD, Chair; Jay H. Rosenberg, MD; Russell D. Snyder, Jr, MD.

Note. This statement is provided as an educational service of the American Academy of Neurology. It is not intended to include all possible proper methods of care for a particular neurological problem or to exclude any specific alternative therapies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

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Learning Objectives
At the conclusion of this case, neurology residents will:
1. have experience in identifying ethical issues related to health care financing mechanisms.
2. have considered the scope of the neurologist's duty to disclose to patients financial or other incentives that may influence the type of care that is offered or provided.
3. have explored the limits of a neurologist's duty to accommodate to a patient's preferences for how care is provided, especially where these preferences are in conflict with generally accepted standards of practice or the neurologist's own values.
4. understand the importance of knowing their own state's legal requirements reporting, or maintaining confidential, communicable diseases and high risk behaviors of their patients.
5. have considered physician behavior in situations where the duty to protect confidentiality may conflict with a physician's desire, or obligation, to warn third parties who are at risk.
6. have considered their individual attitudes about situations where legal and ethical obligations appear to be in conflict with each other.
II. Case

Samuel Smith is a 41-year-old computer specialist who has been referred by his primary care physician, Dr. Richard Blue, to Dr. Alice White, a neurologist, for evaluation of a recent seizure and an abnormal finding on a CT scan. Mr. Smith became Dr. Blue's patient when he began work for a new employer. Both Dr. Blue and Dr. White have contracts with WeCare, the managed care plan in which Smith is enrolled, and WeCare has approved the referral. Dr. White's contract with WeCare calls for reimbursement on a discounted fee-for-service basis; she is eligible for a year-end bonus if she achieves the status of "efficient providers" for any particular year. One criterion for this designation is "prudent" ordering of diagnostic and treatment measures for plan enrollees.

Mr. Smith has HIV disease. Prior to the seizure, he had been doing well on triple-therapy that includes 2 protease inhibitors. Over the months preceding the seizure, he began a new full-time job as a computer troubleshooter, regained weight that he had previously lost, and his plasma HIV-RNA titres are now undetectable. Smith engages in sexual activity, including an ongoing heterosexual relationship with a woman who is employed by one of his company's clients, and occasional homosexual activity with various partners at a private club. He always uses condoms in heterosexual activity, but only "sporadically" in his homosexual activities. He has not told any of his sexual partners of his HIV status.

Smith has not informed his current employer of his HIV status. He did not tell Dr. Blue he has HIV disease, but did inform Dr. White because of a concern the seizure "might have something to do with HIV." Mr. Smith is currently relying on his salary and accumulated savings to pay for his antiretroviral drugs that are being prescribed - at a discounted rate - through an HIV clinic at a public hospital. The only health insurance claims he has submitted to WeCare have been for a visit to Dr. Blue after he had his seizure and for the subsequent CT scan.

On examination by Dr. White, Smith appeared generally well, was afebrile and had no abnormal neurological findings. The brain CT films that are available reveal an enhancing 2- to 3-cm. lesion in the right frontal lobe and suggests a smaller nonenhancing lesion in the left temporal lobe. A waking EEG in White's office was normal. White has informed Smith that the seizure was probably caused by one of the brain lesions; that the differential diagnosis includes lymphoma, toxoplasmosis or TB; and that toxoplasma serology may offer clarification. White did not propose performing a spinal tap or MRI of the brain, but recommended to Smith that he begin taking a "first line" anticonvulsant such as phenytoin, carbamazepine or divalproex. Smith has informed White that "I don't want any tests that might tip off my employer or anybody else that I have HIV."

He also has told White that if he concludes that Smith's has HIV-related brain disease, "I want you to give me a medicine that will stop my seizures but which, if I take enough of it, I could use to kill myself." Smith explains that he can't endure the thought of living with an illness that "will affect my mental functions or ability to work."

What ethical issues are presented? How should Dr. White proceed in his care of Smith.
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II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
   10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
   11. What are the ethically acceptable options?
   12. What justifications can be given for the ethically preferred resolution of the case?
   13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments
(by H. Richard Beresford, MD, JD)

A. Assessment
1. What is the patient’s medical condition and prognosis? What treatment options exist?
   The patient is HIV infected, and probably has AIDS. He has a new diagnosis of seizure disorder, with incomplete evaluation. Important elements to discuss are the patient’s desire to forego tests that may alert others to the fact that he is HIV positive. Particularly coupled with the physician’s incentives to limit diagnostic tests and treatment, how does this impact decisions about certain noninvasive or minimally invasive diagnostic testing (e.g. spinal tap, toxoplasma/CMV serology) that might allow a more certain diagnosis of the brain lesions?

2. Who is the appropriate decision maker?
The appropriate decision maker in this case is the patient, Mr. Smith.

3. What are the patient’s preferences?
The patient’s preferences are for adequate work-up, but with strict maintenance of confidentiality about his HIV status. He has clear preferences that his primary care physician, employer, insurance company, and sexual partners not be informed of his HIV status.

4. What are the preferences of the family or surrogate decision makers?
   There are no family or surrogate decision makers that are relevant in this discussion. This may provide an opportunity, however, to discuss the importance of physicians discussing advance directives with patients with AIDS-related illnesses. An advance directive, like a durable power of attorney for health care, may allow the patient to identify a surrogate decision maker who will make medical decisions on the patient’s behalf should the patient become incompetent at a later time.

5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   Areas to be discussed may include the interest in the primary care physician in having full medical information about this patient from the consultant; the interest of Mr. Smith’s sexual partners in knowing his HIV status; the interests in both physicians in minimizing costs of patient care.

6. Are there institutional, legal or other factors which need to be considered?
   Residents should identify what laws and professional standards exist, in your particular jurisdiction, about the confidentiality of medical information and duty, if any, to report transmissible diseases. Note that in some jurisdictions the professional standards which encourage disclosure of unsafe sexual practices are in conflict with laws which preclude such disclosure.
B. **Identification of the Ethical Problem(s)**

7. **What are the ethical problems in the case? (If appropriate, rank by magnitude.)**

Ethical issues relate to confidentiality of information, and ethical tensions created for physicians by payment mechanisms for health care. Specific problems related to the first area include: should Dr. White inform Dr. Blue of Mr. Smith's HIV status; what disclosure is necessary for payment for health care; should the care provided to Mr. Smith be dictated by his concerns about disclosure; how should Dr. White handle Mr. Smith's unsafe sexual practices in terms of counseling Smith and potentially notifying others. Specific problems related to the second area include: how Dr. White handles the incentives to limit diagnostic testing of Mr. Smith; whether this impacts his discussion with Smith of the limits Smith wishes to put on testing; whether White informs Smith of the potential for bonus which exists in the health plan; whether White discusses pertinent legislation which may protect Mr. Smith from discrimination related to his HIV status.

The case also raises the issue of physician assisted suicide, and if time allows, this may be entered into. Note that this is covered more fully in another case in this casebook.

8. **What ethical considerations are most relevant?**

**Patient Autonomy.** Two important dimensions of the autonomy principle are that a patient is entitled to receive from a physician enough relevant information to enable an informed choice about care, and that the physician will respect a patient's right of self-determination. The vignette raises questions that implicate both dimensions. Examples include the following. What more should White tell Smith about diagnostic possibilities, potential tests or treatment options, or financial considerations that bear on how much testing or treatment is offered? Does respect for Smith's right of self-determination include complying fully with the limits Smith has set on testing or treatment?

Does respect for Smith's right of self-determination also include nondisclosure of the danger Smith's conduct poses for his sex partners - even if applicable law does not explicitly require that confidentiality be breached in the particular circumstance? If the law provides no clear guidance and White decides that a nonconsensual breach of confidentiality is appropriate, how should he proceed? Should he first try to prevail on Smith to warn his sexual partners? Should he try to identify the partners and warn them himself? Should he inform a state or local health department or the police of the perceived danger?

Finally, does respect for Smith's right of self-determination include prescribing a potentially lethal quantity of an anticonvulsant when White has reason to believe that Smith harbors suicidal thoughts?

**Beneficence.** The fiduciary dimension of the beneficence principle suggests that a physician must put the best interests of patients ahead of all other concerns, even if doing so conflicts with the interests of the physician or others. A physician who cannot satisfy this obligation should ordinarily withdraw from the professional relationship and assist his or her patient in finding another care giver. However, before such an impasse is reached, it is appropriate to consider what are the "best interests" of a patient. The term is obviously not
self-defining, and much can turn on whether it is measured by objective or subjective criteria. Thus, what dispassionate third parties might regard as in a patient's best interests may not jibe with the patient's own conception.

In this context, pertinent questions raised by the vignette include the following. To what extent should White agree to accept Smith's conditions on tests, treatment or processing of any insurance claims? Should White inform Smith that he - White - may receive a bonus if he is determined to be a "prudent" deployer of medical resources? Should White decline to care for Smith if Smith is unwilling to undergo tests that the physician recommends or if Smith refuses to accept treatment that the physician believes is optimal? How far should White go in negotiating with Smith before withdrawing from his care? In deciding whether to perform a lumbar puncture to clarify the nature of Smith's brain lesions, is it appropriate for White to take into account the risk that he might become infected with HIV if he inadvertently sticks himself with a local anesthetic or spinal needle during the procedure? Should White take into account the possibility that Smith might lose his job and attendant benefits, or incur social stigma, by reason of any nonconsensual disclosures White might make about Smith's medical condition?

Should White pass along to Smith any information he possesses about laws [e.g. antidiscrimination laws, the new federal health insurance portability statute] that might protect Smith against adverse actions by his employer or WeCare? Does White, as a physician, have any obligation to gather such information because of its potential value to his patients?

How should White respond to a request from Smith about how much of an already prescribed anticonvulsant it would take to cause death? Assuming Smith becomes "terminally ill" [high probability of death within 6 months despite the best available treatment] and is experiencing pain that is controllable only with high doses of opiates, should White prescribe a dose of opiates that he has reason to believe may be fatal in an effort to achieve better pain control? Must he inform Smith before prescribing such a dosage?

**Justice.** The concept of "justice" is amorphous, but presumably embraces notions of principled allocations of societal resources and individual entitlement. It thus encompasses both distributive concern and equitable rights. In the context of the case, "justice"-oriented questions might include the following. In developing a plan of care for Smith, should White take into account the potentially high costs of a comprehensive effort to precisely determine the nature of Smith's brain lesions or to provide optimally effective treatment, or weigh how these costs might impact on the managed care plan's ability to provide services for the benefit of its other enrollees?

In order to justify a breach of confidentiality, is it appropriate for White to rank the interests of Smith's "consensual" sexual partners in avoiding infection higher than the interests of Smith in maintaining confidentiality about his HIV status? Does White owe any duty to Smith's employer to protect the employer from financial or other consequences of Smith's attempts to conceal his medical condition? Or from adverse consequences that might flow from Smith's risky sexual conduct involving an employee of one of the firm's clients?
9. Are there analogous cases?

10. What are the relevant guidelines for clinicians regarding the problem(s)?

C. Decision Making and Implementation
11. What are the ethically acceptable options?

12. What justifications can be given for the ethically preferred resolution of the case?

13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?

IV. References


5. New York Public Health Law, section 2782 [confidentiality and disclosure provisions re HIV-infected persons]

6. Doe v Roe, 599 NYS 2d 350 {NY Sup Ct, App Div 1993}[strict enforcement of section 2782, supra, against a physician for nonconsensual but good faith disclosure]

7. Burt RA. The Supreme Court speaks: not assisted-suicide but a constitutional right to palliative care. New Eng J Med 1997;337:1234-1236


V. Instructor Comments

This vignette presupposes a curriculum which allocates only a few hours to ethics since, within the confines of a single case, several different “ethical” issues are raised. In a fuller curriculum, the case could be greatly simplified and could, for example, focus on the tension between preserving patient confidentiality and protecting the safety of third parties.
THE ETHICAL ROLE OF NEUROLOGISTS IN THE AIDS EPIDEMIC

Report of the Ethics and Humanities Subcommittee

Nineteen hundred ninety-one was not only the end of the first year of the Decade of the Brain, but the end of the first decade of the acquired immunodeficiency syndrome (AIDS) epidemic. After 10 years marked by a growing understanding of the human immunodeficiency virus (HIV) and the diseases it causes, the AAN feels that this is an appropriate time for neurologists to reflect on the magnitude of the epidemic and its implications for each of us in our practices and teaching and scientific careers. As neurologists and neuroscientists, we now appreciate that HIV directly invades the nervous system early in the course of infection, producing virus-related disease that may be quite independent of the degree of immune suppression, just as it results in CNS tumors and opportunistic infections that are important late markers of immunological change. Thus, HIV infection produces neurological disease throughout its course, and neurologists have an important contribution to make to the understanding of the disease, to the care of infected patients, to society's response to the needs of those involved, and ultimately to whatever success we will have controlling the epidemic nationally and throughout the world.

In 1990 the cumulative death toll from AIDS reached 100,777 in the United States, with 30,196 deaths in that year alone. The cumulative case total for adults and adolescents reached 152,231. In 1989, the Centers for Disease Control (CDC) predicted 365,000 diagnosed cases of AIDS by 1992 with 263,000 cumulative deaths. If these predictions are accurate, we should see nearly 215,000 newly diagnosed cases of AIDS in the next two years with perhaps as many as 165,000 deaths -- a near tripling of the current rate.

AIDS in 1989 was the second leading cause of death among young American men (aged 25-44). In 1988, it was the eighth leading cause of death among comparably aged women but is now surely in the top five. As impressive as these numbers are, it is still thought that AIDS surveillance identifies only 70 - 90% of cases, so even these numbers are underestimates of the problem in this country. AIDS is also increasingly a disease of the poor and underprivileged. This is not merely because the combination of acquired disability and the need for expensive medical care impoverishes many victims, but because spread of the disease has been disproportionate among the racial and ethnic minority groups that constitute the bulk of America's urban underclass.

It is estimated that there are two million HIV-infected people in all of the Americas and more than three million infected in Africa -- perhaps six million worldwide. Furthermore, under-reporting is a great problem in the Third World, with perhaps only 6% or 7% of an estimated 600,000 cases of AIDS reported in Africa.

The AIDS epidemic presents a challenge to neurologists to examine the most important medical, ethical, and social issues of our time. We are prompted to think about the preventability of the disease and what we can do individually and collectively to diminish its enormity. We must appreciate the terminal nature of the illness and determine how we can help patients cope with the inevitability of early death. Thus, we need to understand the legal and ethical validity of advance directives -- whether they be living wills or durable powers of attorney for health care -- and promote their use. We must help to increase awareness of AIDS as a dementing illness, which requires us to confront both the problems of obtaining informed consent from patients who may be incapable of understanding the requirements of their care and the problems of withholding or withdrawing care from patients when pertinent advance directives are lacking. The AIDS epidemic also highlights the problems of the maldistribution of care in America and the lack of adequate health care insurance for a large and needy segment of our population.
It is important for all of us to remember that the AIDS epidemic is a worldwide problem requiring new levels of international cooperation in the areas of epidemiology and therapeutics. At the same time, we must realize that AIDS is altering the entire character of neurological practice in some parts of our country through changes in patient demographics and marked changes in disease prevalence. For many of us, primary tumors are no longer mostly gliomas, meningitis is no longer mostly streptococcal, and neuropathy is no longer mostly diabetic. With these changes come challenges to our training programs and our traditional expertise.

Finally, we must also recognize that our more recently acquired abilities to slow the course of the illness with antiretroviral therapy and to effectively treat many opportunistic infections have also altered the complexion of the epidemic. This prompts the need to reassess many ethical issues where previous consensus was built around the lack of effective treatments. For example, given the possibility of treatment, should we consider mandatory screening of high risk populations? And should we continue the accelerated evaluation and release of promising new medications at a time when we have some that are effective? Or is this the time to slow down and insist on more complete demonstrations of efficacy and safety?

Because in its tenth year the AIDS epidemic continued to present us with these growing challenges, the AAN strongly encourages all neurologists to:

1) Provide appropriate, compassionate care to HIV-infected patients who present for that care and not deny care to anyone by reason of the diagnosis of HIV infection. Furthermore, as physicians we must not abandon such patients when we are unable to retard the progression of their illness; but must continue to work to ameliorate their suffering.

2) Work to diminish discrimination against HIV-infected patients and to minimize public fears of contagion by providing scientifically grounded information about the modes of viral transmission and the risk of exposure.

3) Share the burden of providing care broadly rather than compound the disadvantages of AIDS patients by transferring them disproportionately to public hospitals or other institutions already overburdened and undersupported in the care they provide the poor and uninsured.

4) Learn and practice appropriate precautions in the examination of HIV-infected patients and in the obtaining and handling of tissue from such patients to minimize the risk of transmission of the virus to ourselves and others.

5) Promote the development of advanced treatment directives, durable powers of attorney for health care, or other mechanisms to guide care in the setting of terminal illness.

6) Support public health measures of known importance in limiting the spread of the virus including public education about disease transmission, the use of condoms, non-sharing of needles by IV drug abusers, and the disclosure of HIV status by infected patients to others whom they might place at risk.

7) Promote understanding of HIV infection by direct participation in research or by supporting research at local, state, and national levels.
Furthermore, as neurologists we recognize the special contribution we can make by:

1) Developing and maintaining expertise in the recognition and treatment of the neurological manifestations of HIV disease and educating non-neurologists in these areas.

2) Developing and promulgating an appropriate awareness of the diagnostic implications of dementia in AIDS patients and of the other neurological complications of HIV infection.

3) Analyzing some of the behavioral and subjective manifestations of AIDS so that they may be properly managed as either signs and symptoms of organic involvement or emotional responses to the illness.

4) Accurately advising about prognosis in patients with nervous system involvement -- neither promoting false hope nor fostering therapeutic nihilism.

5) Applying special knowledge and experience that neurologists may have in the management of acute and chronic pain in the setting HIV disease.

6) Developing and maintaining appropriate educational programs at the medical school, residency, and post-graduate levels concerning the neurology of HIV disease.

Note: The above is intended to serve as an interim report. The American Academy of Neurology is currently studying the issue of testing health-care workers and other issues that have recently gained importance. Additional statements are forthcoming.

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurological problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

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*The Ethics and Humanities Subcommittee is grateful to Dr. Richard Foa who drafted this report.

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(3/3/93)
I. Learning Objectives
At the conclusion of this case, neurology residents will:
1. understand the ethical and legal dilemmas of prescribing opioids for chronic non-malignant (CNP) pain, and the evaluation, documentation, and monitoring requirements for the use of opioids in this condition.
2. understand the importance of knowing the legal and regulatory status of prescribing opioids in CNP in the resident's own state and locality, and the required documentation to support it.
3. understand the necessity for self-assessment and continuing education to competently manage CNP, using nonpharmacologic and pharmacologic methods.
4. be able to describe options for appropriate referral to pain management and addiction specialists.
II. Case

An orthopedic surgeon, Dr. Jackson, asks you to evaluate and take over the pain management of Mr. Jones, a 48 year old unmarried man followed until recently by Dr. Williams, a retired senior partner. Dr. Williams had been prescribing hydrocodone. Last Saturday night, Mr. Jones ran out of medication and came to the hospital emergency room (ER) seeking a refill. Dr. Blake, cross-covering orthopedics, refused to authorize narcotics over the phone for a patient whom he did not personally know. Dr. Harris, the ER attending, told Mr. Jones that the best she could do was to provide 20 acetaminophen with codeine to “tide him over” until Monday. Mr. Jones refused that offer with obscenities, angrily protesting that he needed hydrocodone “up to 4 times a day to get by,” and dismissing codeine as “totally worthless” for his chronic pain.

Unsettled by reports from the ER, Dr. Jackson felt uncomfortable about writing scripts for strong narcotics for a patient he believed he hardly knew himself. He wanted the patient to be seen by a “good neurologist who might pick up something that’s been missed, or maybe know of a new ‘wonder drug’.”

Mr. Jones’ back problems began at age 27, soon after he started work as a long distance truck driver. While loading his truck, he experienced sudden excruciating low back and bilateral leg pain caused by a severely herniated L4-L5 disc. Surgery by Dr. Williams had relieved most of the back pain and all of the leg pain, leaving him for several years with mild intermittent low back pain particularly with “long hauls” cross-country. Subsequently, this pain became more intense and continuous with less provocation. Six years ago, he had a life-threatening upper GI bleed requiring multiple transfusions, attributed to overuse of aspirin and nonsteroidal, and to alcohol abuse. He joined Alcoholics Anonymous and has been abstinent from alcohol ever since. His weight and smoking have increased. Past medical history is noteworthy for hypertension, moderate obesity and a 2 pack-per-day (50 pack-year) cigarette habit. He denies ever having used intravenous drugs.

Three years ago, while helping to unload a truck, Mr. Jones lost his balance and twisted his trunk, triggering immediate incapacitating lumbar pain, paroxysmal “electric shocks” superimposed upon new numbness and tingling within the left S1 dermatome, and weakness, particularly when standing on his left toes. Pain was unrelieved by 2 weeks of strict bed rest, oxycodone, and muscle relaxants. An EMG study showed a severe, acute, and chronic left S1 radiculopathy, superimposed upon mild bilateral chronic L5-S1 radiculopathies. Lumbosacral MRI showed herniation of the L5-S1 disc with a large fragment compressing the left S1 root. Three weeks after the injury, Dr. Williams performed L5-S1 discectomy and fusion without apparent complication. Despite postoperative physical therapy, Mr. Jones reported gradually increasing lumbar pain and burning dysesthetic pain in a left S1 distribution.

Over the ensuing year, his left foot became cooler and dusker in color, with the spread of burning pain over his entire foot up his calf to the knee. The touch of sheets and socks on his foot became unbearably painful. He consulted several local orthopedic surgeons and neurosurgeons who found no further surgical indications, underwent several courses of physical therapy that he believed made the pain worse, and briefly attended a pain clinic but found that sympathetic and regional nerve blocks provided no or transient pain relief. A number of adjuvant analgesics failed to relieve his “reflex sympathetic dystrophy,” including amitriptyline, fluoxetine, carbamazepine
and mexilitene. Finally, Mr. Jones returned to Dr. Williams who had performed both of his back operations; Dr. Williams prescribed hydromorphone, which provided reasonable partial relief. Mr. Jones was able to retrain, and returned to work part-time as a warehouse inventory manager, a "desk job" at the local office of his trucking company.

Mr. Jones is a physically imposing, alert, attentive man wearing a back brace, walking stiffly with a cane and favoring his left leg. Your general exam reveals a long, well-healed nontender midline lumbar scar, and a cool puffy mottled left foot, which he is exceedingly reluctant to allow you to touch. Neurologic exam is normal throughout, except for left ankle give-way in all directions because of pain with resistance. The left ankle reflex is absent, the right reduced. Plantar reflexes are flexor. Vibration and pinprick are poorly tolerated over the entire left foot, where light touch causes burning.

Pending further work-up, you write Mr. Jones a new prescription for hydromorphone. Later the same week while in the ER seeing another patient, you encounter Dr. Harris, the ER attending who had offered Mr. Jones acetaminophen with codeine. She heard that you are now in charge of his pain management, and she sympathizes. She mentions that the regional affiliated hospital ERs and pharmacies are compiling a metro-wide database to thwart "doctor shopping" and illegal narcotic diversion, and she suggests this might help you "keep tabs" on Mr. Jones.
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). *Introduction to Clinical Ethics*, University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment
   1. What is the patient’s medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient’s preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
   10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
   11. What are the ethically acceptable options?
   12. What justifications can be given for the ethically preferred resolution of the case?
   13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments
(by Glenn A. Mackin, MD)

A. Assessment

1. What is the patient's medical condition and prognosis? What treatment options exist?

The patient has a complicated "failed back syndrome" after 2 lumbar operations, manifested by severe persistent lumbar pain and "neuropathic" symptoms in a left S1 radicular distribution that evolved into a chronic regional pain syndrome (or CRPS-II) involving the distal left leg. This condition has been unresponsive to a variety of analgesics, therapy and pain clinic interventions, including sympathetic and regional blocks. He has risk factors for chronic back pain, including his former occupation as a long-distance truck driver, obesity, and cigarette smoking. He has gained significant partial relief over the past 18 months from hydromorphone, a Schedule II "strong" opioid for chronic nonmalignant pain (CNP).

Although the patient must be considered "physiologically dependent" on opioids, at risk for withdrawal symptoms if they are abruptly discontinued, they have evidently reduced his pain and improved his function to enable him to return to work part-time. Aspirin and nonsteroidal anti-inflammatory drugs (NSAID) cannot be used because of past gastritis. Given his past history of alcohol abuse and the belligerent behavior he exhibited in the ER, the possibility of "psychologic dependence" (addiction) and potential for diversion to nonprescribed uses must be seriously considered by any physician providing opioid scripts (thus the ER physician's suggestion that his name be entered into a local database for monitoring purposes, critiqued below). However, there is no evidence of other drug abuse, self-medication unrelated to severe pain, hoarding drugs or obtaining opioids from multiple physicians, or ongoing alcohol abuse. His disruptive behavior in the ER is best viewed, as discussed several paragraphs below, as "pseudoaddictive" behavior superficially mimicking—but not the same as—behaviors of a psychologically dependent addict, reflecting his physical dependence and experience with past multiple failed analgesic attempts.

Several definitions may be useful. Neuropathic pain should be distinguished from nociceptive pain, which refers to pain especially musculoskeletal attributable to ongoing stimulation of pain-sensitive nerves by inflammation, compression, and other mechanisms. Treatment of nociceptive pain relies upon salicylates and NSAIDs as mainstays. By contrast, neuropathic pain is nerve-based (e.g., diabetic neuropathy, postherpetic neuralgia), where the "sustaining mechanism for the pain is inferred to involve aberrant somatosensory processing in the peripheral or central nervous system"(1).

Treatment of neuropathic pain commonly involves "adjuvant analgesics" which are non-opioid medications whose principle indications are not pain relief per se, and whose analgesic range often uses a relatively low dose range. Common examples include tricyclic antidepressants (TCA) including amitriptyline and nortriptyline; serotonin reuptake inhibitors (SRI) including fluoxetine and paroxetine; some antiepileptic drugs (AED) including carbamazepine, phenytoin, valproic acid and gabapentin; antiarrhythmics such as lidocaine and mexilitene; antispasticity agents such as baclofen; and sometimes major tranquilizers such as pimozide. True analgesics
such as topical capsaicin and narcotics of various strengths may also be used. Many physicians adopt an "analgesic ladder" approach to pain management, often using salicylates and NSAIDs, occasionally selecting from a short list of favored adjuvants such as amitriptyline for chronic use, reserving "weak" opioid mixtures (e.g., acetaminophen with codeine) for brief courses of strictly limited quantity for acute severe pain, and rarely if ever using "strong" opioids (e.g., hydromorphone) (2). Published guidelines for an "adequate" drug trial for each analgesic empirically tried include candid discussion of the need for trial and error, drug titration one at a time, initiating with smallest-size available oral tablet, increasing every 3 to 7 days as tolerated and required, close communication between patient and staff weekly or biweekly, and increasing until satisfaction or intolerable side effects are reported. Historical analgesic trials must be deemed inadequate and inconclusive if dose increase was curtailed short of intended analgesic level for reasons other than intolerance, or if intolerance followed too-fast titration or too many drugs being used simultaneously (3). The goal of analgesic trials, individually and in combination, is to provide partial, incremental analgesia when a cure is not possible (4).

CRPS is a new term for a subclass of neuropathic pain syndromes traditionally termed "causalgia" and "reflex sympathetic dystrophy" (RSD), which often but not invariably follow as subacute sequela of trauma and other conditions (5). Neurologist Weir Mitchell used "causalgia" to describe a syndrome including severe burning pain in the hand after major partial injury to the brachial plexus during the Civil War. The diagnostic weight of different physical and diagnostic signs observed in various combinations in the "syndrome" varies greatly among authorities, but by definition, causalgia or CRPS-II requires an identifiable nerve lesion usually in a "named" peripheral nerve, plexus or root structure. The pain is severe, persistent, and usually burning in quality, including hyperalgesia (minimal stimulus evokes disproportionate pain), allodynia (innocuous stimulus like touch changes to noxious dysesthesia such as burning), and hyperpathia (temporal summation of repeat stimuli into crescendo pain); and is associated with varying amounts of edema; cutaneous changes of color, temperature, sweat, and nail growth ("trophic changes"); stiffness; local osteoporosis; and eventual fixed contractures. The pain sustaining mechanism is controversial, some implicating sympathetic efferents at certain stages, thus advocating sympathetic blocks for diagnosis and treatment. Others vigorously argue for a significant psychological sustaining mechanism. A similar constellation of symptoms and signs, not associated with an identifiable nerve lesion, constitutes RSD or CRPS-I. Meaningful use of CRPS (or RSD/causalgia) terminology entails making a distinction between causalgia and RSD, and therefore demands a neurologically sophisticated examination, imaging, neurodiagnostic and other studies.

CNP is chronic pain not associated with a malignancy. It encompasses many types of moderate to severe chronic pain syndromes, including neurogenic (painful polyneuropathies, zoster, trigeminal neuralgia and other facial pains, CRPS), intractable headache, spinal pain (including "failed back syndrome"), arthritis, burns, sickle cell, AIDS related, and pelvic pain. Designating these syndromes as chronic nonmalignant pain distinguishes them from cancer associated pain, where recent experience with opioids in cancer centers has established for them a more accepted role in the medical community and more secure standing in law and regulations.
Ponenoy has extensively reviewed experience with opioids for cancer pain (6,7), and has proposed one of several sets of guidelines (8) for long-term opioids in CNP, and has published the most detailed of several competing sets of proposed guidelines for prescribing opioids for CNP (9-14). The problem is that there are no universally agreed-upon, evidence-based criteria for selecting what segment of the CNP population is appropriate for long-term opioids, and what outcome measures to use to assess efficacy and safety. Lessons from cancer experience include a favorable balance between benefits of reduced pain and improved function and risks of major organ toxicity (none) and addiction (0% - 11%, most series note a few percent), stable dose levels absent a change in disease process, lack of "ceiling" dose with narcotics, and manageable side effects (constipation). The key distinction is that physical dependence (physiologic potential for manageable abstinence or "withdrawal" syndrome after sudden discontinuation) attends all chronic courses of opioids; exposure alone rarely causes psychologic dependence or addiction (psychologic and behavioral syndrome including loss of control over use, compulsivity; and continued use despite harm). A high level of caution and early referral to a specialist in addiction medicine is certainly warranted in the medically, ethically, and legally difficult situation of past substance abusers (15). Finally, Ponenoy has published empiric behavioral criteria that he considers "relatively predictive" for distinguishing between "pseudoaddictive" behaviors reflecting physical dependence and past experience with past inadequate pain trials (e.g., demanding a specific drug and dose) and psychologic dependence "addiction" (e.g., stealing, forging or repeatedly "losing" scripts; "shopping" for scripts among several physicians and filling them at several pharmacies).

Concerning the patient in question, if indicated imaging and neurodiagnostic studies fail to disclose a correctable lesion presumed to be the "pain generator", and if careful review of past records concludes that all reasonable and adequate non-opioid analgesic trials to control his pain and restore function have failed, then continuing opioids may be appropriate.

2. Who is the appropriate decision maker?

The patient. Careful mental status examination should be performed with particular focus to detect a confusional state or inattentiveness that would preclude valid informed consent. Consideration of historical and behavioral clues of past or current psychologic addiction, or compulsivity regarding opioid use, is important to ensure that consent is truly volitional.

3. What are the patient's preferences?

The patient clearly wants an ongoing supply of hydromorphone for pain control, which he has found through experience provides him partial relief enabling him to return to work (analgesia plus function without disabling sedation or constipation). He also has a reasonable expectation that his physician will honor the physician's professional "fiduciary" duty (16) to grant appropriate primacy to patient interests, and the traditional professional norm to reduce suffering. In addition, he has a reasonable expectation that his physician will tell the truth and disclose all relevant medical alternatives for his well being. In this regard, willful withholding of relevant information about the admittedly controversial and difficult option of chronic opioids for CNP, deliberately underdosing any opioids, or driving the patient away via communicated disinterest, while simultaneously neglecting to refer for definitive pain management, is wrong. (17)
wayward practitioners (including inappropriate prescriptive practices). State governors appoint board members, whose qualifications vary considerably from state to state. There is considerable diversity in the language of different states' HPAs, each requiring interpretation, ranging from encouraging to threatening. No systematic analysis exists state-by-state; the individual physician is responsible for understanding the applicable regulations in his or her own jurisdiction. It is therefore at the state level that physician uncertainty is most intense concerning the boundaries of permissible opioid prescribing practices. One "chilling effect" is physician uncertainty over what indications, duration, and overall volume of opioid prescription will create a "high profile" for state (and federal) regulators, triggering a license-threatening and potentially criminal investigation.

Some states have recently adopted detailed guidelines for ongoing prescription controlled substances for chronic nonmalignant pain. A few all but prohibit it (20). Most are in the middle, limiting dosing beyond "usual and recommended" dose ranges and durations, imposing restrictions on dose units unrelated to indication (e.g., to 120 pills irrespective of potency), restrict opioids to specific indications, limiting phone refills to emergencies, restricting who may pick up prescriptions, impose onerous records keeping rules, and establishing multiple-copy prescription programs (MCP, "triplicate forms"). In the ten states currently with MCP laws, one copy goes to the state police or drug enforcement agency. The tighter the restrictions, the harder a time patients have in locating pharmacies (operating under their own regulations) that stock strong narcotics such as hydromorphone, oral morphine, or methadone-class drugs. (21)

B. Identification of the Ethical Problem(s)

7. What are the ethical problems in this case? (If appropriate, rank by magnitude)

A well-documented feature of contemporary medical practice is the widespread undertreatment by physicians of moderate to severe pain, through underdosing or outright withholding. Particularly vulnerable populations include women, the elderly, and minorities. To withhold or fail to refer for the sole remaining class of analgesics that might relieve a patient's refractory CNP for no reason other than undue fear of causing iatrogenic addiction abdicates the physician's traditional role in relieving suffering and effectively tolerates avoidable disability.

It must be noted that opponents of opioids for CNP argue for a less biomedical and more biopsychosocial model of pain management, that shifts the locus of responsibility for CNP control from physician prescribing to patient responsibility for modifiable factors, especially habitual and psychologic or behavioral (here weight reduction, smoking cessation, and perhaps biofeedback or other nonpharmacologic modalities of treatment), where the explicit goal is to minimize the amount of opioids actually prescribed. (22,23)

The ER physician's well-meaning recommendation to verify compliance by entering the patient's name on a metro-wide computer database for the use of affiliated hospitals carries heavy risks of breach of confidentiality of highly sensitive information without the patient's knowledge or consent by employers, and by third parties with no compelling need to know. A much better strategy is to enter into a formal "contract" with the patient, specifying that there will be just one prescribing physician, specified amounts for well-documented indications, the possibility of
defined "rescue" doses or hospitalization for exacerbations, but no refills for "lost" scripts and immediate termination of the "contract" for repeated documented noncompliance. It is appropriate for the dispensing physician emergency room to have a copy of the opioid contract that spells out conditions for emergency refills for exacerbation. This must be kept strictly confidential by all ER staff permitted to access it on a "need to know" basis.

Practicing physicians including many neurologists tend to justify their reluctance to prescribe opioids for CNP by invoking practical and ethical considerations in varying proportions. Commonly heard practical considerations include lack of training, experience, interest and especially, time to devote to pain control. However, given the accessibility of recent publications, continuing education programs and pain clinics, it is highly disingenuous and inappropriate for physicians to remain naive of modern pain management techniques just to avoid attending to the time-intensive special needs of patients with CNP.

Ethical arguments against opioids in CNP include nonmaleficence (do no harm) and justice (sensitivity to societal considerations including the public health interest in addiction control, potential investigation of medical licenses for perceived wrongdoing, and the police interest in crime control). Close analysis reveals that the nonmaleficence argument against opioids in CNP is really a double-edged sword. First, narcotics pose essentially no risk of organ toxicity, and side effects such as constipation are easily managed. The principle of "double effect" that justifies unintentional deaths due to respiratory depression in the context of palliative care in inapplicable to probably most CNP situations because the disease process underlying the pain therein is less likely to be life-threatening. This difference creates a duty for physicians responsible for prescribing narcotics for CNP to be particularly scrupulous assessing and adjusting for co-morbid factors and concurrent medications that could contribute to dangerous respiratory depression.

Second, concern about creating new additions or reactivating old ones in CNP is not dispositive, even if one concedes that there may be more psychopathology in the CNP population rather than the cancer population and that rates of de novo addiction in the latter are not trivial. A prerequisite for patient candidacy for opioid therapy is the capacity to give valid informed consent recognizing a small but definite risk of addiction and willingness to comply rigorously with ideally, a detailed written treatment contract. Rather than an all-purpose veto for narcotics in CNP, the finite possibility of addiction confers a duty upon each treating physician to control the amount of narcotics prescribed, monitor carefully for emerging addictive behaviors and refer promptly to addiction medicine specialists.

Third, the criticism is well taken that reduced cognitive function and functional performance are themselves disabling and may negate any beneficial analgesic effects of opioids. However, this concern merely creates another duty for the prescribing physician to possess the training and commitment to carefully monitor the functional effects along with the analgesia during long-term opioid administration, (24) and to institute proper corrective actions when either outcome measure is adversely affected. Actually sedative effects aren't the exclusive reason that opioids may impair cognitive function. Paradoxically, insufficient and erratic dosing may promote development of "mini-withdrawals" that lead to quiet impairment of performance
or distressingly "pseudoaddictive" behaviors. (6) In essence, the problem of functional impairment reiterates the need for good training in pain management and opioid pharmacology.

Moreover, unnecessary undertreatment of pain by physicians despite available alternatives, causes identifiable harms. First, undue fear of respiratory depression, addiction, functional impairment and justice concerns that effectively block patient access to needed treatment tolerates pain in a way that shirks a physician's beneficence-based duty to promote the well-being of each patient. Honorable individual physicians may disagree about the relative merits of a "biomedical" approach to opioids in CNP (that extrapolates from the favorable cancer experience with opioids) and a "biopsychosocial" approach (that favors functional treatment bolstering individual responsibility and minimizing opioid use), but this does not absolve them of a duty to secure for the patients some reputable treatment. Second, the categorical withholding of opioids when all other reasonable attempts at analgesia have failed, tolerates and sustains potentially remediable disability due to pain. It may restrict the patient's freedom to pursue the fullness of life, and to take pleasure in it. Third, deception even with beneficent motives constitutes unjustifiable paternalism and is morally wrong.

The relevant and legitimate desires of patients with CNP who enter into fiduciary relationships with physicians are to obtain relief safely and competently. While a physician may conscientiously decide that, on balance, the medical literature does not support opioids in CNP, the provides no warrant to mislead the patient through silence or excessively negative verbal framing of this option. There is, in fact, enough basis in the literature to at least discuss it as an alternative, and to disclose - along with any personal reservations - the names of reputable physicians who use it. Deliberate withholding of information about opioids for significant intractable CNP directly violates the patient's autonomy interest in making an informed choice among clinically relevant and legitimate alternatives. It is every bit as important to grant the patient the opportunity - as a matter of truth-telling and consent - to decline opioids for CNP as it is to accept them. It is unethical for a physician to withhold this information when doing so promotes a personal monetary interest in an invasive or neurodestructive procedure.

Fourth, the physician's justice-based duty to take the broader interests of society into account in decision making does not contradict or trump his or her beneficence-based duty to the patient with CNP. Bernat defines the physician's duty to society as follows: "The ethical good that a patient accrues from the patient physician encounter is of paramount importance, but it must also be balanced against the harm other patients may sustain as an inevitable byproduct of the encounter."(18) Provided that the conscientious physician concludes that there is no reasonable alternative to opioid therapy of a specific patient's CNP, that there are no countervailing medical or psychosocial risk factors, and provided that the patient has given valid informed consent and promised to faithfully adhere to the therapeutic contract, then society and other individuals in it incur no meaningful, direct or inevitable risk of harm. Physicians should be aware of the potential conflict of interest between their personal aversion to assuming possible risks in prescribing opioids for CNP, and specific patients' claim for exactly that treatment for their otherwise-intractable pain.
8. **What ethical considerations are most relevant?**

The traditional medical principle, primum non nocere, is as usual highly informative in this clinical context. The physician's obligation of beneficence to the patient is critical. Provided the physician takes care to exclude treatable causes, exhaust all other reasonable methods of analgesia, document indications and outcome measures (analgesia and function) clearly, institute a therapeutic "contract", and refer where necessary to monitor for addictive behaviors and ongoing needs, the ethical imperative supports treating CNP with opioids within the limits of one's training, professional experience, and practical capabilities. If the physician cannot provide this care, consultation with appropriate experts in pain management is appropriate.

9. **Are there analogous cases?**

Opioid "contracts" governing prescription dispensing in cancer, sickle cell, AIDS.

10. **What are the relevant guidelines for clinicians regarding the problem(s)?**

Guidelines for opioid "contracts" and identification of "addictive" behaviors as proposed by Portenoy and others. Federal and state laws and regulations governing CNP.

C. **Decision Making and Implementation**

11. **What are the ethically acceptable options?**

The decision should be to treat within the limits of one's capabilities or refer to a reputable comprehensive pain management center, psychologist, or psychiatrist (as appropriate) or addiction specialist. Communicated disinterest or frank abandonment are not ethically acceptable.

12. **What justifications can be given for the ethically preferred resolution of the case?**

The principle justifications are beneficence, patient autonomy, and confidentiality.

13. **How is a satisfactory resolution of the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?**

The decision should be taken in the context of frank discussion with the patient, including relevant consultants. Every physician should be able to do this, and should also have knowledge of governing laws and regulations. Neurologists may have a special responsibility to patients with CNP, even as modern neuroscience unlocks pain mechanisms, specifically to ensure a complete evaluation for a remediable correctable lesion, to prescribe and monitor the effects of psychoactive medications within the limits of one's ability, and to remain available to consultants, to monitor the patient and look for changing disease or new lesions when opioid requirements inexplicably increase. Hospital or legal counsel may be helpful for guidance in difficult situations. Ethics consultation and judicial review are normally not needed in this setting.

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I. Learning Objectives
At the conclusion of this case, neurology residents will:
1. be able to define and explain the following terms and concepts: vegetative state, persistent vegetative state, permanent vegetative state, minimally conscious state, durable power of attorney for health care.
2. Be able to describe various forms of surrogate decision making, including a general hierarchy of decision-making authority.
3. Understand and be able to describe the differences between withholding and withdrawing treatment, and suicide.
II. Case

A 25 year-old woman sustained massive anoxic brain damage. Her initial post-anoxic course was characterized by seizures and the need for tracheotomy and assisted ventilation. Over the next several months, she evolved into a vegetative state, with fluid and nutrition eventually provided through a jejunostomy tube. She was transferred to a nursing home from the acute care hospital.

Her condition did not change significantly over the next five years. Her husband requested that the jejunostomy tube be removed; he was supported in this petition by her parents and other family members. The nursing home refused this request. The matter went to a superior court; a court-appointed guardian ad litem agreed with the family’s decision. In the sixth year of her vegetative state, the superior court (after a bedside visit and a seven-day trial) approved removal of the feeding tube.

The nursing home appealed this decision to the state supreme court. Four neurologists examined the patient during the process of consideration by this supreme court: two of them agreed with the diagnosis of a persistent vegetative state, whereas the other two observed and recorded behaviors that they interpreted as evidence of some preservation of cognitive ability. The court concurred with the diagnosis affirmed by the first two, finding that there was “clear and convincing” evidence that the woman was in a persistent vegetative state. On the other hand, the court disagreed with the finding of the superior court (that there was similar “clear and convincing evidence that, if competent, the woman “would not want to have her life artificially prolonged in that condition”), concluding instead that her earlier statements were “remote, general, spontaneous and made in casual circumstances” and, as such, were not “sufficiently specific” to be regarded as “clear and convincing.” Nevertheless, the supreme court held that the family could use their “substituted judgment” to make the decision that they believed the patient would have made, had she been competent. Further, this court required the nursing home to participate in this process, despite their request not to.

In the month after this decision by the supreme court (more than seven years since the woman had entered the vegetative state), requests were made at several levels for those decisions to be reviewed; all were denied. After completion of the appellate process, the woman was transferred to a hospital, her jejunostomy tube was removed, fluid and nutrition were discontinued, and she died some days later.
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   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments
(by Michael P. McQuillen, MD and Robert M. Taylor, MD)

A. Assessment

1. What is the patient's medical condition and prognosis? What treatment options exist?

Consciousness consists of two aspects: alertness, dependent on the integrity of the brainstem ascending reticular activating system (ARAS), and awareness, the content of consciousness, dependent on the integrity of the cerebral cortex. To be conscious, one must have preservation of both alertness and awareness.

The vegetative state is defined as the condition of being awake (or alert) but unaware and results from the loss of cortical function with preservation of the function of ARAS (2). It must be distinguished from several related neurologic conditions. Coma, a sleep-like state of unconsciousness, results from loss of function of the ARAS. The locked-in syndrome results from destruction of the descending pontine efferent pathways, resulting in a patient who is conscious (i.e., both alert and aware) but has very limited behavioral capacity to demonstrate that awareness, often limited to vertical eye movements. Patients with severe dementia have very limited awareness but remain alert.

After an acute neurologic injury, resulting in coma, most patients either die or quickly recover consciousness (although often with cognitive impairment). However, some will evolve into a vegetative state. If the vegetative state persists for a month or longer after the original neurologic insult, it is called a persistent vegetative state (PVS). Patients with progressive dementia, such as those with end-stage Alzheimer's disease, may also evolve into PVS. Extensive evidence supports the determination that the condition of PVS is permanent, within reasonable medical certainty, if it persists for three months after anoxic brain injury, for one year after traumatic brain injury, or for one month in patients with degenerative neurologic disease. Thus, if this patient were indeed in a persistent vegetative state, after five years, that state would have to be considered permanent.

Nevertheless, making the diagnosis of persistent or permanent vegetative state may be problematic, as demonstrated by the split in neurologic opinion in the case. Despite such a highly publicized example as this case, the Multi-Society Task Force on PVS asserted that the possibility that a person in PVS retained awareness but showed no evidence of it was "sufficiently rare that (that possibility) does not interfere with a clinical diagnosis carefully established by experts" (2).

Even if the patient did retain a limited degree of awareness, a condition referred to as the "minimally conscious state" as asserted by two of the four expert witnesses, she had unequivocal evidence of a devastating neurological injury. Whatever the patient's neurological condition - whether a permanent vegetative state or severe dementia resulting from anoxic encephalopathy - there is no realistic hope for recovery of significant, independent neurological function. No treatment regimen thus far described has been shown to improve the quality of life (as defined in terms of degree of independent neurologic function) of people in this state.
2. Who is the appropriate decision maker?

The preferred decision maker is one appointed by a competent patient, ideally through a Durable Power of Attorney for Health Care (DPAHC). If there is no formal DPAHC, someone verbally identified by the patient to his or her physician, if documented in the medical record, would have some degree of both legal and moral authority to make decisions for the patient.

Several states have established medical surrogacy laws that provide a hierarchy of potential decision-makers for patients who have not completed a DPAHC or otherwise identified a surrogate (3). Although there is some variation from state to state, a typical surrogate hierarchy would proceed as follows: a legal guardian, the spouse, adult child or children, parents, siblings, other relatives, and finally, in many states, a close friend. According to such laws, the highest person on the list who agrees to act as a surrogate is authorized to make certain medical decisions for the patient, usually including decisions about discontinuing life prolonging treatment (LPT).

Surrogacy laws formalize the traditional approach, taken by physicians for centuries, of turning to the closest relative of an incompetent patient when important decisions must be made. Such laws, as well as many court decisions, support the continuation of that traditional practice, even in states without formal surrogacy laws.

It is important to realize that a surrogate, no matter how appointed, is required to make decisions according to particular guidelines. The preferred basis is to act according to specific instructions provided by the patient, e.g., according to a Living Will or the patient's prior verbal instructions, if the patient has left such a document or instructions and if they apply to the situation at hand. The next best basis for making decisions is "substituted judgment," wherein the surrogate attempts to make the decision that the patient would have made, on the basis of the values and beliefs of the patient. If the surrogate is unable to make a substituted judgment, he or she should make a decision based on his or her assessment of the patient's "best interests". It is the physician's responsibility to explain to the surrogate the appropriate basis for his or her decision. Furthermore, if the physician believes that the surrogate is not acting in good faith, the physician has the option of asking a court to appoint a different surrogate (4).

In this case, the patient had not appointed a surrogate, so her husband is the preferred surrogate; in addition to being her husband, he has the added authority of having been appointed her guardian - although not (apparently) for medical decision-making - and of a unanimity of opinion among her parents, family, and the guardian ad litem appointed by the supreme court. Although it is not required that the other family members agree with the decision of the patient's surrogate, such agreement is obviously preferable. Not only does such agreement reduce the potential for conflict, but it also tends to reinforce the appropriateness of the surrogate's decision.

3. What are the patient's preferences?

The physician should always inquire about the existence of a "Living Will" or other informal advance directives, such as specific serious and considered statements made by the patient while competent. One should be cautious about accepting less serious and considered statements as clear demonstrations of the patient's preferences, but such statements may nevertheless provide
some guidance, if they are consistent with what is known about the patient’s values and beliefs. In the absence of previously expressed preferences, decisions must be based on substituted judgment or best interests.

As is often the case when a young person suffers a sudden and unexpected catastrophic neurologic injury, the preferences of the patient in this case were not clarified in a manner that met the standard of “clear and convincing” which was required in her jurisdiction. However, the court endorsed the appropriateness of the husband and family's substituted judgment on behalf of the patient.

4. **What are the preferences of the patient’s family or surrogate decision makers?**

As stated, there was a unanimity of opinion among such persons in this instance. If this is not the case, the neurologist should seek - by repeated conversations, family meetings, and the like - to achieve consensus. If that is not possible, then the preferences of appropriate decision-makers should be honored.

5. **Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?**

Minor children may have an independent interest in the survival of a parent, especially if that parent retains the capacity to contribute to their care. However, in this case, we are not told of any minor children whose interests have not been articulated.

Financial pressures may affect the patient’s treatment. In capitated payment systems, hospitals have a financial incentive to minimize the costs of treatment. More traditional insurance plans have a financial incentive to find a way to limit the costs of treatment. Although it is easy to perceive such financial interests as “selfish”, the pressure to limit the costs of health care reflects a broad societal perception that much expensive medical treatment is inappropriate, especially for terminally ill patients or for those with severe neurological injuries.

The patient's family may have a financial interest in whether the patient lives or dies. For example, if the patient's family is responsible for a portion of the cost of the patient's treatment, the family members may have a financial interest in providing less prolonged and intensive treatment. However, in some cases, families benefit financially from prolonging the patient’s survival, in that they may depend on pensions or other income that will continue only as long as the patient survives. However, it is important to realize that, although either situation creates the possibility of a conflict of interest between the patient and the family, such conflicts may be more apparent than real. For example, many, probably most, families will disregard their own financial interests in favor of the patient’s medical interest, as long as there remains a reasonable possibility of meaningful recovery. Moreover, many patients would be concerned with the financial consequences of their illness for their families, especially if they were receiving expensive treatment that was unlikely to benefit them.

The physician should therefore try to be aware of financial pressures that may influence medical treatment decisions and should understand that such concerns may be legitimate. Financial issues become increasingly relevant as the chances for the patients recovery diminish.
6. Are there institutional, legal or other factors which need to be considered?
Hospital by-laws, particularly in institutions with a religious affiliation, may narrow the options for decision-making. However, as the legal history of this case documents, courts may override an institution's decision and require it either to carry out the decision of the surrogate or to transfer the patient to another institution that will honor that decision.

B. Identification of Ethical Problem(s)
7. List of ethical problems. In order of importance, the ethical problems raised by the case example include the following.

a. Surrogate decision-making. Since persons in a PVS by definition do not (at the time they are in that state) have the capacity to make or communicate decisions about their care, the neurologist must look to an advance directive or to a duly-identified surrogate before either implementing non-emergent medical treatment or withholding or withdrawing life-prolonging treatment. Since persons in a PVS by definition do not (at the time they are in that state) have the capacity to make or communicate decisions about their care, the neurologist must look to an advance directive, or a duly-identified surrogate before either implementing non-emergent medical treatment or withholding or withdrawing life-prolonging treatment.

b. Withholding or withdrawing treatment. Since there has yet to be demonstrated any treatment regimen that will "cure or substantially improve the fundamental neurologic deficits of patients in PVS, the treatments under consideration are basic nursing care, the management of intercurrent or underlying illnesses (e.g., infection, prevention of decubiti and contractures, gastrointestinal, renal, and cardiovascular dysfunction, etc.), and the artificial provision of hydration and nutrition. Over the past several years, there has developed a strong consensus that there is no ethical or legal difference between withholding and withdrawing a medical treatment. Indeed, there is generally a stronger ethical basis for withdrawing a treatment that has proved to be ineffective than for withholding a treatment when one is uncertain whether it will be effective. Nevertheless, for most people (including physicians) it is more psychologically distressing to withdraw than to withhold a treatment. This is true primarily because withdrawing a potentially life-prolonging treatment feels more "active," whereas withholding a treatment feels more "passive." Although either withholding or withdrawing a medical treatment may be the proximate cause of a patient's death, the ultimate cause of death is the underlying illness that has not responded to the treatment.

Generally, a benefit-burden analysis applies to most therapeutic decisions. There remains some controversy as to whether it is appropriate to consider patients in PVS, who are presumed to be completely unaware of anything, as capable of being benefited or burdened by medical treatment. However, even people who lack awareness may have interests that can be advanced or impeded, just as a dead person's interests may be advanced by carrying out the instructions of his or her "last will and testament." A similar line of reasoning supports the argument that we can reasonably analyze treatment decisions for patients in PVS on the basis of the benefit or burden of treatment for them. Nevertheless, for patients in PVS, it is difficult to exclude considerations of the interests of others (e.g., family and friends, other members of the patient's insurance plan, other patients in the same facility, society and its limited resources) from the benefit-burden analysis.
On the basis of this analytic approach to decision-making, there is a strong consensus that almost any medical treatment can be withheld or withdrawn from patients in PVS, especially once a firm prognosis has been established. However, respect for human dignity requires that routine nursing care always be provided to such patients. The one area of persistent controversy is the issue of discontinuing the artificial provision of hydration and nutrition to patients in PVS or with other severe or end-stage illnesses that prevent normal oral feeding. Some have argued that the withdrawal of artificial hydration and nutrition is fundamentally different from discontinuing any other medical therapy, since such withdrawal inevitably leads to death by dehydration within a relatively short time, whereas, when other therapies are withheld or withdrawn there is at least a theoretical possibility that the patient may survive without it.

Some have further argued that this certainty of outcome implies the intention that the patient die and therefore argue, through an analysis of intent, that it is unethical to take or authorize such an action, the necessary purpose of which is to cause the death by dehydration of the person in the PVS. (7) Furthermore, some would emphasize the symbolic nature of food and would consider it analogous to basic nursing care, which should never to be withheld or withdrawn. (8) However, others have argued that the certainty of outcome need not imply intent, i.e. if the patient could somehow recover the ability to take food and fluids orally, this would still be provided. Instead, it is argued, the emphasis must remain on the relative burdens of the treatment and the lack of any benefit to the patient from prolonging his or her life. Indeed, most ethicists and most courts have agreed with this court that the artificial provision of hydration and nutrition is a medical therapy, which may be withheld or withdrawn based on an assessment of the benefits and burdens of treatment, just as with any other medical therapy. (9) Those who regard such actions as licit emphasize the nature of the provision of nutrition and hydration to persons in a PVS - requiring a nasogastric or gastrostomy tube, usually with specially prepared feedings administered by electric pump.

A recent article stressed the differences between intending, foreseeing and desiring death, differences which appear to be key in this case. (22) Is there a difference between believing that a certain outcome will result from an action taken; desiring or even hoping that the outcome will happen; and intending that the action cause the outcome? These differences appear to be key.

c. Justice and Futility. Given a growing awareness and acceptance of the fact of limited resources, and in view of the potential costs of keeping people in the PVS alive, some believe that our society should provide only the most basic care to persons in PVS. (10) However, until society develops a more perfect process of deciding such limits and assures the reallocation of resources from one sector to another, most would regard the unilateral denial of specific medical treatments by individual physicians to individual patients as unjust.(11)

Some have raised the issue of futility to support a refusal to provide particular medical therapies, claiming that when the vegetative state becomes permanent, no substantial benefit can be derived from any treatment. However, unless one is invoking a justice argument that resources are being used wastefully and inappropriately, such an assertion hinges on the interpretation of the concept of “benefit”, which may be interpreted differently in this context by different people. In the few court cases on this issue, the courts have tended to support the family’s or surrogate’s
interpretation of the concept of “benefit.” Nevertheless, some would argue that those cases were flawed and therefore should be, and may be, overturned in future cases.

8. **What ethical considerations are most relevant?**

The consideration of balancing benefits and burdens has been discussed above. Disclosure, informed consent, and shared decision-making are important and became a source of conflict in this case, because the family, the physicians, and the institution could not agree on the best course of treatment.

The norms of family life are relevant, since the patient was a wife, daughter, and sibling, and all of these relationships were profoundly altered by her injury. Most families assume that their wishes will be of paramount importance in determining the course of treatment for a neurologically impaired loved one. The relationship between clinicians and the patient is important to the degree that the clinicians feel an obligation to the patient independent of the obligation to her family, which in this case was another source of conflict. The professional integrity of clinicians, as represented by the nursing home, was perhaps the paramount consideration in the nursing home’s refusal to discontinue the tube feedings as requested by the patient’s husband and family. Indeed, with the exception of family members, the impact of decisions to withhold or withdraw treatment from persons in PVS may fall most heavily upon people or institutions whose moral sense differs from that of the people making the decisions. In such instances, the people or institutions so affected should not be forced to carry out the decision, unless no other option exists. In this case, the patient was transferred out of the nursing home before tube feedings were discontinued.

Cost-effectiveness and allocation of resources were not a direct consideration in this case. Nevertheless, it may be legitimate for a person to consider the issue of protecting his or her family from excessive costs when completing a living will or DPAHC; it may even be appropriate for a person making a substituted judgment to consider how the patient might feel about the economic impact of his or her illness on the family. However, as discussed above, in our current system, it is difficult to justify refusing to provide requested treatment for patients in PVS on the basis of excessive cost.

Cultural and religious variations did not appear to play a role in this case. However, such issues should be recognized and given appropriate consideration when they are relevant. Considerations of power were not addressed in this case but may have been relevant in that the nursing home, which had “custody” of the patient, exercised de facto power over what happened to the patient. Of course, the patient had no power in this case. The husband and family may have considered themselves as trying to exercise a form of surrogate power on behalf of the patient, whereas the nursing home may have understood its role as protecting a vulnerable patient from the misguided decisions of her husband and family. Ultimate power in this case, as in most intractable medico legal disputes, resided in the courts.

9. **Are there analogous cases?**

There is a long line of cases dealing with medical decision-making for persons in PVS - starting with Quinlan (14) and moving forward through Brophy (15) and Jobes (11) to Cruzan (16) and others. Underlying all of these cases is the basic right first articulated in this country more than
80 years ago by Justice Benjamin Cardozo, when he wrote that "(e)very human being of adult years and sound mind has a right to determine what shall be done with his own body. (17) These cases, and others, affirmed that this right is not lost when one becomes competent and provided a legal framework through which a surrogate can exercise this right on behalf of the incompetent patient in PVS. The use of Advance Directives was initially supported in the Quinlan decision and was further endorsed in a concurring opinion in the Cruzan case. The only U.S. Supreme Court case that specifically addresses the situation of a patient in PVS, Cruzan, contained at least four important elements. First, it affirmed that a competent adult has a general right to refuse LPT. Second, it accepted that artificially provided hydration and nutrition are medical treatments that can be refused. Third, it affirmed that the right to refuse LPT is not lost when one becomes incompetent. Fourth, it empowered the individual states to establish the mechanism and criteria by which that right may be exercised by a surrogate.

Thus, although Missouri, the state in which Nancy Cruzan resided, was permitted by the court to require a clear and convincing evidence of her prior wishes, other states are free to establish different criteria. Indeed, for patients without formal advance directives, most states permit such decisions to be made according to the three standards discussed earlier: if possible, based on a "preponderance of the evidence" that such a decision is consistent with the prior wishes of the patient (e.g., an informal advance directive); if this is not possible, based on a substituted judgment; and finally, if neither of these is possible, based on a best interest standard.

These cases have also affirmed that, in the absence of either a specific directive to the contrary or evidence that the family is acting inappropriately, the patient's closest relative(s) is the appropriate surrogate decision-maker for patients in PVS.

10. What are the relevant guidelines for clinicians regarding the problems(s)?

Neurologists should be aware of the pronouncements of their societies on PVS, as well as of institutional policies relevant to management options in this condition. They should also be aware of any advance directive or health care surrogacy laws in their state.

C. Decision Making and Implementation

11. What are the ethically acceptable options?

In cases such as this one, the process of decision-making is ethically more important than the actual decisions made. Indeed, as long as the process is ethically sound, acceptable treatment options may range from discontinuing all medical treatment, including artificial nutrition and hydration, to providing very aggressive treatment. In the final analysis, there really is only one ethically acceptable option open to neurologists caring for patients in PVS - namely, the option chosen by the patient, as articulated in a Living Will or by their duly identified surrogate for health care decisions. However, if that option violates the conscience of the neurologist, he or she should make his or her concerns clear to the surrogate and, if they cannot be resolved, should then facilitate transfer of the patient to someone whose conscience is not so violated. Until that occurs, the treatment course desired by the patient or surrogate should be followed.

12. What justifications can be given for the ethically preferred resolution of the case?

The justification for following an advance directive or the decisions of an appropriate
surrogate is the principle of respect for patient autonomy and the judicial endorsement of that principle in dealing with similar cases. Having accepted the primacy of the patient - including a patient in a PVS - in making medical decisions, justification for the decision so made will vary, depending upon the particular circumstances of the case, as discussed above.

13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?

When caring for a patient with a severe neurological injury as exemplified by this case, the neurologist should begin by defining the diagnosis, treatment options, and prognosis with as much precision and clarity as possible. He or she should convey these findings and conclusions to relevant family members and surrogates as often and as compassionately as is necessary to assure understanding and acceptance. He or she must be cognizant of their own bias, in presenting the data upon which people make up their minds. The use of a conversation models in presenting those data may be the most helpful way of minimizing the influence of that bias. (21)

At the same time, the neurologist should begin to determine the most appropriate mechanism for making medical decisions for the patient. As a first step, it should be determined whether the patient had executed a Living Will or a DPAHC. If there is a valid DPAHC, the appointed surrogate should be provided with all of the same information that would normally be provided to a patient and his or her decisions should be honored. If there is a Living Will that applies to the situation at hand (usually if the patient is imminently terminally ill or permanently unconscious) then it should be invoked. If it does not apply to the current conditions, it may still provide some insight into what the patient would have wanted in the current situation, and may ultimately apply to the patient's condition evolves over time.

If there are no formal written advance directives, the neurologist should inquire about any serious verbal statements that the patient may have made which might provide guidance for the physician and family. Such statements are more significant if made more than once, in the presence of several different persons, and especially if made in circumstances where it is likely to have represented a seriously considered opinion, such as when involved in making decisions about the medical care of a loved one. If there is no formal DPAHC, and especially if there are no other written or verbal advance directives, the neurologist should determine who is the most appropriate surrogate decision-maker for the patient. In states that have a formal surrogacy law, the guidelines of the law should be followed. If there is no such law, the closest relative will usually be the most appropriate surrogate. When there is uncertainty as to which person is the most appropriate surrogate, consultation with an ethics committee or hospital attorney may be helpful.

The neurologist should assure that the surrogate understands the preferred basis for making decisions for the patient, i.e., on the basis of an advance directive if available, making a substituted judgment if there is no advance directive, or using best-interests standard if the surrogate cannot make a substituted judgment. Although a duly appointed surrogate may act independently of the other members of the patient's family, the physician should make a reasonable effort to assure that all concerned family members have the opportunity to understand the issues and options. It is ideal if all family members agree with any important decision, such as discontinuing LPT, although, if there is a duly appointed surrogate, this is usually not required as a matter of law or ethics.
Although physicians should always act as advocates for their patients, even in the face of economic pressures contrary to patient choice previously expressed or made known by surrogates, there may be times when their own best judgment differs from that expressed by the surrogate on behalf of the patient. At such times, they should be honest and open in discussing differences of opinion with decision-makers. If a meeting of the minds cannot be achieved, alternate arrangements for providing care should be made (rather than imposing the judgment of one upon the other).

As may be inferred from the case example, resolution of issues raised when a person is in PVS is never easy or simple. In most instances, PVS evolves inexorably after a sudden and usually unexpected disaster (an anoxic event, or craniocerebral trauma). Dealing with the shock of that disaster, and coming to grips with the inevitability of outcome while, at the same time, not giving up hope or giving in to a self-fulfilling prophecy, can strain the emotional, physical, and financial resources of the most stable and well-endowed person. In such an instance, ethics consultation can often provide a forum in which all sides of the case can be considered and all options explored by all those involved in the case. Ideally, this should be an ongoing process, reflective and open to change as circumstances require.

Judicial review, on the other hand - although an important part of the historical evolution of clarifying the options for decision-making for persons in a PVS - rarely confers any substantive benefit in a particular instance of the PVS today. Instead, such review is often demanded in a situation in which the affected parties are at opposite poles in their opinions. As the present case demonstrates, the process of judicial review may go on interminably.

IV. References


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CERTAIN ASPECTS OF THE CARE AND MANAGEMENT OF THE PERSISTENT VEGETATIVE STATE PATIENT

Report of the Ethics and Humanities Subcommittee

I. The persistent vegetative state is a form of eyes-open permanent unconsciousness in which the patient has periods of wakefulness and physiologic sleep/wake cycles, but at no time is the patient aware of himself or his environment. Neurologically, being awake, but unaware is the result of a functioning brainstem, and the total loss of cerebral cortical functioning.

A. No voluntary action or behavior of any kind is present. Primitive reflexes and vegetative functions which may be present are either controlled by the brain stem or are so elemental that they require no brain regulation at all.

Although the PVS patient generally is able to breathe spontaneously because of the intact brainstem, the capacity to chew and swallow in a normal manner is lost because these functions are voluntary, requiring intact cerebral hemispheres.

B. The primary basis for the diagnosis of PVS is the careful and extended clinical observation of the patient, supported by laboratory studies. PVS patients will show no behavioral response whatsoever over an extended period of time. The diagnosis of permanent unconsciousness can usually be made with a high degree of medical certainty in cases of hypoxic-ischemic encephalopathy after a period of one to three months.

C. Patients in a persistent vegetative state may continue to survive for a prolonged period of time ("prolonged survival"), as long as the artificial provision of nutrition and fluids is continued. These patients are not "terminally ill."

D. Persistent vegetative state patients do not have the capacity to experience pain or suffering. Pain and suffering are attributes of consciousness requiring cerebral cortical functioning, and patients who are permanently and completely unconscious cannot experience these symptoms.

There are several independent bases for the neurological conclusion that PVS patients do not experience pain or suffering.

First, direct clinical experience with these patients demonstrates that there is no behavioral indication of any awareness of pain or suffering.

Second, in all PVS patients studied to date, post-mortem examination reveals overwhelming bilateral damage to the cerebral hemispheres to a degree incompatible with consciousness or the capacity to experience pain or suffering.

Third, recent data utilizing position emission tomography (PET) indicates that the metabolic rate for glucose in the cerebral cortex is greatly reduced in PVS patients, to a degree incompatible with consciousness.
II. The artificial provision of nutrition and hydration is a form of medical treatment and may be discontinued in accordance with the principles and practices governing the withholding and withdrawal of other forms of medical treatment.

A. The Academy recognizes that the decision to discontinue the artificial provision of fluid and nutrition may have special symbolic and emotional significance for the parties involved and for society. Nevertheless, the decision to discontinue this type of treatment should be made in the same manner as other medical treatment decisions. i.e. based on a careful evaluation of the patient’s diagnosis and prognosis, the prospective benefits and burdens of the treatment, and the stated preferences of the patient and family.

B. The artificial provision of nutrition and hydration is analogous to other forms of life-sustaining treatment, such as the use of the respirator. When a patient is unconscious, both a respirator and an artificial feeding device serve to support or replace normal bodily functions which are compromised as a result of the patient’s illness.

C. The administration of fluids and nutrition by medical means, such as a G-tube, is a medical procedure, rather than a nursing procedure, for several reasons.

1. First, the choice of this method of providing fluid and nutrients requires a careful medical judgment as to the relative advantages and disadvantages of this treatment. Second, the use of a G-tube is only possible by the creation of a stoma in the abdominal wall, which is unquestionably a medical or surgical procedure. Third, once the G-tube is in place, it must be carefully monitored by physicians, or other health care personnel working under the direction of physicians, to insure that complications do not arise. Fourth, a physician’s judgment is necessary to monitor the patient’s tolerance of and response to the nutrients which are provided by means of the G-tube.

2. The fact that the placement of nutrients into the tube is itself a relatively simple process, and that the feeding does not require sophisticated mechanical equipment, does not mean that the provision of fluids and nutrition in this manner is a nursing, rather than a medical, procedure. Indeed, many forms of medical treatment, including, for example, chemotherapy or insulin treatments, involve a simple self-administration of prescription drugs by the patient. Yet such treatments are clearly medical and their initiation and monitoring require careful medical attention.

D. In caring for hopelessly ill and dying patients, physicians must often assess the level of medical treatment appropriate to the specific circumstances of each case.

1. The recognition of a patient’s right to self-determination is central to the medical, ethical and legal principles relevant to medical treatment decisions.

2. In conjunction with respecting a patient’s right to self-determination, a physician must also attempt to promote the patient’s well-being, either by relieving suffering or addressing or reversing a pathological process. Where medical treatment fails to promote a patient’s well-being, there is no longer an ethical obligation to provide it.

3. Treatments which provide no benefit to the patient or the family may be discontinued. Medical treatment which offers some hope for recovery should be distinguished from treatment which merely prolongs or suspends the dying process without providing any possible cure. Medical treatment, including the medical provision of artificial nutrition and hydration, provides no benefit to patients in a persistent vegetative state, once the diagnosis has been established to a high degree of medical certainty.
When a patient has been reliably diagnosed as being a persistent vegetative state, when it is clear that the patient would not want further medical treatment, and the family agrees with the patient, all further medical treatment, including the artificial provision of nutrition and hydration, may be forgone.

A. The Academy believes that this standard is consistent with prevailing medical, ethical, and legal principles, and more specifically with the formal resolution passed on 15 March 1986 by the Council on Ethical and Judicial Affairs of the American Medical Association, entitled "Withholding or Withdrawing Life-Prolonging Medical Treatment."

B. This position is consistent with the medical community's clear support for the principle that persistent vegetative state patients need not be sustained indefinitely by means of medical treatment.

While the moral and ethical views of health care providers deserve recognition, they are in general secondary to the patient's and family's continuing right to grant or to refuse consent for life-sustaining treatment.

C. When the attending physician disagrees with the decision to withhold all further medical treatment, such as artificial nutrition and hydration, and feels that such a course of action is morally objectionable, the physician, under normal circumstances, should not be forced to act against his or her conscience or perceived understanding of prevailing medical standards.

In such situations, every attempt to reconcile differences should be made, including adequate communication among all principal parties and referral to an ethics committee where applicable.

If no consensus can be reached, and there appear to be irreconcilable differences, the health care provider has an obligation to bring to the attention of the family the fact that the patient may be transferred to the care of another physician in the same facility or to a different facility where treatment may be discontinued.

D. The Academy encourages health care providers to establish internal consultative procedures, such as ethics committees or other means, to offer guidance in cases of apparent irreconcilable differences. In May 1985, the Academy formally endorsed the voluntary formation of multi-disciplinary institutional ethics committees to function as educational, policy-making, and advisory bodies to address ethical dilemmas arising within health care institutions.

It is good medical practice to initiate the artificial provision of fluids and nutrition when the patient's prognosis is uncertain, and to allow for the termination of treatment at a later date when the patient's condition becomes hopeless.

A. A certain amount of time is required before the diagnosis of PVS can be made with a high degree of medical certainty. It is not until the patient's complete unconsciousness has lasted a prolonged period—usually one to three months—that the condition can be reliably considered permanent. During the initial period of assessment and evaluation, it is usually appropriate to provide aggressive medical treatment to sustain the patient.

Even after it may be clear to the medical professionals that a patient will not regain consciousness, it may still take a period of time before the family is able to accept the patient's prognosis. Once the family has had sufficient time to accept the permanence of the patient's condition, the family may then be ready to terminate whatever life-sustaining treatments are being provided.
B. The view that there is a major medical or ethical distinction between the withholding and withdrawal of medical treatment belies common sense and good medical practice, and is inconsistent with prevailing medical, ethical, and legal principles.

C. Given the importance of an adequate trial period of observation and therapy for unconscious patients, a family member must retain the ability to withdraw consent for continued artificial feedings well after initial consent has been provided. Otherwise, consent will have been sought for a permanent course of treatment before the hopelessness of the patient’s condition has been determined by the attending physician and is fully appreciated by the family.

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurological problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

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This statement has been published in Neurology as shown below. Published version may include minor editorial changes.


Approved EB 04/21/88
Report of the Quality Standards Subcommittee

I. Overview: The Quality Standards Subcommittee (QSS) of the American Academy of Neurology develops practice parameters for neurologists to use in evaluating clinical disorders. This document is based on a report published in two parts, "Medical Aspects of the Persistent Vegetative State" written by The Multi-Society Task Force On PVS.  

II. Justification: Approximately 10,000 to 25,000 adults and 6,000 to 10,000 children in the United States are diagnosed as being in the persistent vegetative state (PVS). The Multi-Society Task Force on PVS recently reported on the medical facts of PVS in adults and children. The following summary provides a practice parameter that outlines diagnostic and management standards for adults and children in PVS.

III. Description of the Process: The Multi-Society Task Force on PVS, established in 1991, was charged with reviewing and analyzing all available data on PVS in adults and children and preparing a report that summarizes the medical facts of this condition. The Multi-Society Task Force, impaneled from representatives of the American Academy of Neurology, Child Neurology Society, American Association of Neurological Surgeons, American Neurological Association, and American Academy of Pediatrics, gathered and analyzed available information about PVS. An advisory panel of consultants from related medical and allied health fields with expertise on PVS, ethics, and law, reviewed and criticized the Task Force report and subsequently, this document was approved by the executive committee of each participating society. The Task Force adopted an explicit approach to the analysis of available data.

A comprehensive literature review from 1972 to 1993 of all MEDLINE references using the terms "vegetative state" and "persistent vegetative state" was undertaken. Additional case material was sought by publication of a "request for information" in the major neurological, neurosurgical, and pediatric medical journals. Data concerning outcome of PVS patients from the National Institute of Neurological Disorders and Stroke Traumatic Coma Data Bank were also reviewed. Media and lay press articles concerning unexpected recoveries from prolonged coma from available sources were reviewed and summarized as to their outcomes. These data were categorized into three classes: randomized controlled clinical trials (Class I), well-designed clinical studies (Class II), and evidence provided by non-randomized historical controls, case reports, or expert opinion and consensus (Class III).

Because of the nature of PVS, no Class I studies were found. All publications containing valid outcome data at three, six, and twelve months of adults and children in PVS one month after traumatic and non-traumatic brain injury were identified. These studies contained data on 754 patients and used the Glasgow Outcome Scale. Outcomes based on this scale include:

- **Good recovery:** these patients have the capacity to resume normal occupational and social activities, although there may be minor physical or mental deficits or complaints.

- **Moderate disability:** these patients are independent and can resume almost all activities of daily living. They are, however, disabled, as they no longer can participate in a variety of social and work activities.

- **Severe disability:** these patients are no longer capable of resuming the majority
of previous personal, social, and work activities. These patients have limited communication skills and abnormal behavioral and emotional responses. They are partially or totally dependent on others for their activities of daily living.

- **PVS**: See definition below.
- **Death**

These data were summarized in an evidence table (Table 1) and were used to calculate probabilities for predicting outcome (Table 2).

IV. **Definitions**: The vegetative state is a clinical condition of complete unawareness of the self and the environment accompanied by sleep-wake cycles with either complete or partial preservation of hypothalamic and brain stem autonomic functions.

**Criteria**

The *vegetative state* can be diagnosed using the following criteria. Patients in a *vegetative state* show:

- No evidence of awareness of self or environment and an inability to interact with others.
- No evidence of sustained, reproducible, purposeful, or voluntary behavioral responses to visual, auditory, tactile, or noxious stimuli.
- No evidence of language comprehension or expression.
- Intermittent wakefulness manifested by the presence of sleep-wake cycles.
- Sufficiently preserved hypothalamic and brain stem autonomic functions to permit survival with medical and nursing care.
- Bowel and bladder incontinence.
- Variably preserved cranial nerve (pupillary, oculocephalic, corneal, vestibulo-ocular, gag), and spinal reflexes.

The *persistent vegetative state* can be defined as a vegetative state present at one month after acute traumatic or non-traumatic brain injury, and present for at least one month in degenerative/metabolic disorders or developmental malformations.

**Permanent vegetative state** means an irreversible state, a definition, as with all clinical diagnoses in medicine, based on probabilities, not absolutes. A PVS patient becomes permanently vegetative when the diagnosis of irreversibility can be established with a high degree of clinical certainty, i.e., when the chance of regaining consciousness is exceedingly rare.

V. **Diagnosis of PVS**: PVS can be diagnosed on clinical grounds with a high degree of medical certainty in most adult and pediatric patients after careful, repeated neurologic examinations. The diagnosis of PVS should be established by a physician who, by reason of training and experience, is competent in neurological function assessment and diagnosis. Reliable criteria do not exist for making a diagnosis of PVS in infants under three months of age, except in patients with anencephaly. Other diagnostic studies may support the diagnosis of PVS, but none adds to diagnostic specificity with certainty.

VI. **Categories and clinical course of PVS**: There are three major categories of diseases in adults
and children that result in PVS. The clinical course and outcome of PVS patients depends upon the specific etiology:

a. Acute traumatic and non-traumatic brain injury
PVS usually evolves from a state of eyes-closed coma to a state of wakefulness without awareness with sleep-wake cycles and preserved brain stem functions within one month of injury.

b. Degenerative and metabolic disorders of the brain
Many degenerative and metabolic nervous system disorders in adults and children inevitably progress toward an irreversible vegetative state. Patients who are severely impaired but retain some degree of awareness may lapse briefly into a vegetative state from the effects of medication, infection, superimposed illnesses, or decreased fluid and nutritional intake. Such a temporary encephalopathy must be corrected before establishing that the patient is in PVS. If the vegetative state persists for several months, recovery of consciousness is unlikely.

c. Severe developmental malformations of the nervous system
The developmental vegetative state is a form of PVS that affects some infants and children with severe congenital malformations of the nervous system. These children do not acquire awareness of the self or the environment. This diagnosis can be made at birth only in infants with anencephaly.\(^1\) For children with other severe malformations who appear vegetative at birth, observation for three to six months is recommended to determine whether these infants acquire awareness. The majority of such infants who are vegetative at birth remain vegetative; those who acquire awareness usually recover only to a severe disability.

VII. Prognosis for recovery: Recovery from PVS can be defined in terms of recovery of consciousness and recovery of function. Recovery of consciousness can be verified when a patient shows reliable evidence of awareness of self and the environment, consistent appearance of voluntary behavioral responses to visual and auditory stimuli, and interaction with others. Recovery of function occurs when a patient becomes mobile, is able to communicate and learn, perform adaptive skills and self care, and participate in recreational or vocational activities. Using these parameters, recovery of function can be defined with the Glasgow Outcome Scale.

These parameters, as defined by the Glasgow Outcome Scale, were used as outcome measures to calculate the following probabilities for recovery in adults and children in PVS three months and six months after acute traumatic and non-traumatic injuries.
Table 1. Incidence of Recovery of Consciousness and Function in Adults and Children in a Persistent Vegetative State (PVS) after Traumatic or Nontraumatic Brain Injury.*

<table>
<thead>
<tr>
<th>Outcome and Functional Recovery</th>
<th>3 Months % of Patients</th>
<th>6 Months % of Patients</th>
<th>12 Months % of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adults</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traumatic injury (n = 434)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>15</td>
<td>24</td>
<td>33</td>
</tr>
<tr>
<td>PVS</td>
<td>52</td>
<td>30</td>
<td>15</td>
</tr>
<tr>
<td>Recovery of consciousness</td>
<td>33</td>
<td>46</td>
<td>52</td>
</tr>
<tr>
<td>Severe disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good Recovery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nontraumatic injury (n = 169)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>24</td>
<td>40</td>
<td>53</td>
</tr>
<tr>
<td>PVS</td>
<td>65</td>
<td>45</td>
<td>32</td>
</tr>
<tr>
<td>Recovery of consciousness</td>
<td>11</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Severe disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good recovery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Children</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traumatic injury (n = 106)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>4</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>PVS</td>
<td>72</td>
<td>40</td>
<td>29</td>
</tr>
<tr>
<td>Recovery of consciousness</td>
<td>24</td>
<td>51</td>
<td>62</td>
</tr>
<tr>
<td>Severe disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good recovery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nontraumatic injury (n = 45)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>20</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>PVS</td>
<td>69</td>
<td>67</td>
<td>65</td>
</tr>
<tr>
<td>Recovery of consciousness</td>
<td>11</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Severe disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good recovery</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Data were collected from series of patients in a PVS one month after injury and do not include individual case reports. Some patients who recovered consciousness died within 12 months after injury or were lost to follow-up. The data for nontraumatic injuries reflect all causes, not just postanoxic injury; for this category alone, the prognosis is poorer than that suggested by the data. Data on functional recovery are for patients who had recovered consciousness within 12 months after injury.
Table 2. Probability of Recovery of Consciousness and Function at 12 Months in Adults and Children in a Persistent Vegetative State (PVS) Three or Six Months after Traumatic or Nontraumatic Injury.∗

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>ADULT (N = 434)</th>
<th>CHILDREN (N = 106)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Traumatic Injury</td>
<td>Nontraumatic Injury</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients in PVS for 3 months+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>35 (27-45)</td>
<td>14 (12-27)</td>
</tr>
<tr>
<td>PVS</td>
<td>30 (22-38)</td>
<td>30 (13-47)</td>
</tr>
<tr>
<td>disability</td>
<td>19 (12-26)</td>
<td>24 (8-40)</td>
</tr>
<tr>
<td>Moderate disability</td>
<td>6 (0-13)</td>
<td>3 (0-11)</td>
</tr>
<tr>
<td>or good recovery</td>
<td>16 (10-22)</td>
<td>32 (15-49)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients in PVS for 6 months++</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>32 (21-43)</td>
<td>14 (0-31)</td>
</tr>
<tr>
<td>PVS</td>
<td>52 (40-64)</td>
<td>54 (31-78)</td>
</tr>
<tr>
<td>disability</td>
<td>12 (4-20)</td>
<td>21 (1-41)</td>
</tr>
<tr>
<td>Moderate disability</td>
<td>0</td>
<td>3 (0-11)</td>
</tr>
<tr>
<td>or good recovery</td>
<td>4 (0-9)</td>
<td>11 (0-26)</td>
</tr>
</tbody>
</table>

∗ Conditional probabilities were determined from data in Table 3. The numbers of patients given in parentheses refer to the numbers of patients who were in a vegetative state one month after the injury.

† A total of 218 adults with traumatic injuries, 77 adults with nontraumatic injuries, 50 children with traumatic injuries, and 31 children with nontraumatic injuries.

‡‡ A total of 123 adults with traumatic injuries, 50 adults with nontraumatic injuries, 28 children with traumatic injuries, and 30 children with nontraumatic injuries.
Additional data have been collected after 12 months in a PVS and these show almost no probability of recovery. The available data indicate that recovery of consciousness from post-traumatic PVS after 12 months in adults and children is unlikely. Recovery from non-traumatic PVS in both adults and children after three months is exceedingly rare. The above data are based on Class II studies. Several individual case reports (Class III) have described a few verified late recoveries of consciousness from traumatic (>12 months) or non-traumatic (>3 months) injury.1

VIII. Survival of patients in PVS: The life span of adults and children in a PVS is substantially reduced. For most PVS patients, life expectancy ranges from two to five years. Survival beyond 10 years is unusual. The chance for survival of greater than 15 years is approximately 1/15,000 to 1/75,000.1

IX. RECOMMENDATIONS

Diagnostic standard and management guidelines for adults and children in PVS include the following:

a. Diagnostic standard for establishing a persistent vegetative state

The vegetative state is diagnosable. It is defined to be persistent at one month. Based upon Class II evidence and consensus that reflects a high degree of clinical certainty, the following is a standard concerning PVS:

* PVS can be judged to be permanent 12 months after traumatic injury in adults and children. Special attention to signs of awareness should be devoted to children during the first year after traumatic injury.

* PVS can be judged to be permanent for non-traumatic injury in adults and children after three months.

* The chance for recovery after these time periods is exceedingly low and almost always to a severe disability.

b. Management guidelines:

* When a patient has been diagnosed as being in a PVS by a physician skilled in neurological assessment and diagnosis, physicians have the responsibility of discussing with the family or surrogates the probabilities of attaining the various stages of recovery or remaining in a PVS.

* Patients in PVS should receive appropriate medical, nursing, or home care to maintain their personal dignity and hygiene.

* Physicians and the family must determine appropriate levels of treatment relative to the administration or withdrawal of:

  1. Medications and other commonly ordered treatments
  2. Supplemental oxygen and use of antibiotics
  3. Complex organ sustaining treatments such as dialysis
  4. Administration of blood products
5. Artificial hydration and nutrition

Once PVS is considered to be permanent, a 'DO NOT RESUSCITATE' (DNR) order is appropriate. A DNR order includes no ventilatory or cardiopulmonary resuscitation. The decision to implement a DNR order, however, may be made earlier in the course of the patient's illness if there is an advance directive or agreement by the appropriate surrogate of the patient and the physician(s) responsible for the care of the patient.

DEFINITIONS

Class I: evidence provided by one or more well designed randomized controlled clinical trials.

Class II: evidence provided by one or more well designed clinical studies such as case control, cohort studies, etc.

Class III: evidence provided by expert opinion, non-randomized historical controls or case reports of one or more.

Standards: generally accepted principles for patient management which reflect a high degree of clinical certainty (i.e. based on Class I evidence, or, when circumstances preclude randomized clinical trials, overwhelming evidence from Class II studies that directly address the question at hand or from decision analysis that directly addresses all the issues).

Guidelines: recommendations for patient management that may identify a particular strategy or range of management strategies and which reflect moderate clinical certainty (i.e., based on Class II evidence that directly addresses the issue, decision analysis that directly addresses the issue, or strong consensus of Class III evidence).

Practice options/advisories: other strategies for patient management for which there is unclear clinical certainty (i.e., based on inconclusive or conflicting evidence or opinion).

Practice parameters: one or more specific practice management recommendations, from a scientifically based analysis of a specific clinical problem.

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QSS appreciates the reviews and comments on this practice parameter supplied by the following medical societies:

American Society of Internal Medicine
American College of Physicians
American Academy of Family Practice
American Association of Physical Medicine & Rehabilitation
Society of Critical Care Medicine
American Academy of Pediatrics
Child Neurology Society
PERSISTENT VEGETATIVE STATE

American Neurological Association
American Association of Neurological Surgeons

Quality Standards Subcommittee thanks all members of the American Academy of Neurology Member Reviewer Network for their review and comments.

The subcommittee wishes to express special thanks to Jay H. Rosenberg, MD, Chair of QSS, Stephen Ashwal, MD and Ronald E. Cranford, MD for their work in the preparation of this practice parameter and to The Multi-Society Task Force on PVS for producing the background paper.

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Approved by QSS 7/13/94
Approved by PC 7/28/94
Approved by EB 9/24/94

* Reprints of this practice parameter and the Multi-Society Task Force report, published in the New England Journal of Medicine, are available at the American Academy of Neurology office: 2221
University Avenue SE, Suite 335, Minneapolis, MN 55436. Phone: 612/623-2439.

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This statement was submitted to NEUROLOGY for publication. The published version may include minor editorial changes.

REFERENCES:


The following references consist of the major reported series of the patients with PVS in which there were sufficient data to construct the outcome and probability tables used for The Multi-Society Task Force report on PVS:


PERSISTENT VEGETATIVE STATE


Tillet JA. Unpublished data from the Traumatic Coma Data Bank, Department of Neurosurgery, Medical College of Virginia, 1992; personal communication.


I. Learning Objectives
By the end of these sessions, neurology residents will:
1. be able to define and explain the following words and concepts: competence, incompetence, surrogate decision maker, Durable Power of Attorney for Health Care, health care proxy, autonomy, self-determination, palliative care.
2. understand the importance of determining the prognosis for the patient with dementia.
3. understand the value of palliative care plans for patients with advanced dementia.
4. be able to identify the appropriate surrogate decision maker for an incompetent patient.
5. be able to discuss treatment options with the proxy decision maker.
6. be able to identify mechanisms to resolve disputes when members of the patient's family disagree about treatment.
7. understand that patients' legally authorized surrogate decision makers have the right and duty to determine what constitutes appropriate treatment for those patients.
8. understand that palliative care without feeding tubes may be appropriate treatment for many patients with advanced dementing illnesses, and integrate this understanding into their own practice patterns.
9. expect that all dying patients should receive proper palliative care and integrate this expectation into their own practice patterns.
II. Case

Because of progressive dysphagia and weight loss, neurological consultation was requested for Louise Donaldson, an 83 year old woman with Alzheimer's disease. Mrs. Donaldson had become demented seven years earlier and the disease had progressed steadily, requiring nursing home placement four years ago. She is a widow with two middle-aged, married, professional daughters. Before the onset of the illness, she had named the older daughter to be her Durable Power of Attorney for Health Care.

She was otherwise generally healthy except for mild, treated hypertension and degenerative joint disease of her hands and feet. Her daughters and their families visited her frequently, but for the past year she no longer seemed to recognize them, had stopped speaking, and had become incontinent. For the past several months, she developed difficulty eating. When she was fed, she didn't seem to know what to do with the food and often choked. Mealtimes became very lengthy, she consumed very little food, and she began to lose weight.

Neurological examination disclosed her to be severely demented with no speech, no ability to follow commands, and little attention paid to the examiner. She weighed 82 pounds, was diffusely wasted, and had begun to develop limb contractures. She moaned during testing of limb range of motion. She bit on a tongue depressor placed in her mouth and choked on a sip of water.

The neurologist explained to the daughters that she was dying from lack of nutrition and that unless a feeding gastrostomy tube was placed in the near future she would die. The daughters disagreed about the best course of action. The older daughter believed that a feeding tube should not be inserted and that her mother should be permitted to die "naturally." The older daughter reported that this course of action was consistent with what her mother's own wishes would be. The younger daughter believed that not feeding her mother was cruel and inhumane, and showed that they did not care about her. She strongly believed that a feeding tube should be inserted.
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). Introduction to Clinical Ethics, University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment
   1. What is the patient's medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient's preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments  
(by James Bernat, MD)

A. Assessment

1. What is the patient’s medical condition, and prognosis? What treatment options exist?

The patient has Alzheimer’s disease in an advanced stage. The prognosis is the certain continued progression of the dementia. No known treatment can improve her condition. The only treatment option at hand is whether to insert a feeding gastrostomy tube, without which she will die of inanition in the near future. She would be given proper palliative care to maintain her comfort in the absence of a feeding tube.

2. Who is the appropriate decision maker?

There are two general ways to execute proxy decision making for a patient lacking the capacity to make health care decisions: formally and informally. In the absence of a formal, legal appointment of a proxy decision maker, neurologists generally consult the family and ask them to function jointly as proxy decision makers. In the presence of family consensus, this informal mechanism works reasonably well. But in the face of family disagreement it fails, and the naming of a legally authorized proxy decision maker is required. Formal proxy arrangements include appointing a Durable Power of Attorney for Health Care, also known as the health care agent. Such an appointment is made by a patient before developing incompetence. Guardianship appointments are made by a court for an incompetent person in the absence of a legally authorized health care agent.

The preferred arrangement is for patients, while competent, to appoint another person to function as their health care agent or Durable Power of Attorney for Health Care in the event that they become incompetent to make health care decisions. (1) The appointment is activated only after the patient becomes unable to make health care decisions. The agent has the full legal authority of the patient to consent or refuse all therapeutic options ordinarily presented to the patient. It may sometimes be possible for demented patients in the earliest stages of dementia to execute advance directives such as the appointment of Durable Power of Attorney for Health Care. (2) In the present case, the patient had appointed her older daughter as Durable Power of Attorney for Health Care. Thus the older daughter is the appropriate and legally authorized proxy decision maker.

3. & 4. What are the preferences of the patient, family, or surrogate decision makers?

The precise preferences of the patient are unknown because she did not explicitly stipulate her wishes about life-prolonging artificial hydration and nutrition. These treatment preferences are highly relevant, however, because the older daughter, functioning in her capacity as the Durable Power of Attorney for Health Care, should base her decision on her best understanding of what her mother would wish to be done in this circumstance. This standard of decision making is known as the standard of substituted judgment. It should supersede the standard of best interests: that is, the daughter’s
attempting to decide on the basis of what she thinks represents her mother's best interest. When a standard of substituted judgment is followed, the patient's preferences are granted primacy. This process respects the patient's right of self-determination. The preference of the legally authorized proxy, the older daughter, not to insert a feeding tube is based on her understanding of her mother's wishes.

5. *Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?*

Other interests include the interest of the state to preserve life. The state maintains a valid interest, but state health care agent statutes and numerous rulings from high state courts consistently rank the abstract interest of the state below the more tangible interest of the individual not to receive unwanted treatment. Thus a patient or proxy's clear directive to refuse life-prolonging therapy trumps any interest of the state to provide it.

6. *Are there institutional, legal, or other factors which need to be considered?*

Some institutions have drafted policies pertaining to this circumstance, and those policies should be followed. States have laws requiring that decisions by agents who hold a valid Durable Power of Attorney for Health Care must be followed in this circumstance.

**B. Identification of the Ethical Problem(s)**

7. & 8. *What are the ethical problems in the case and what ethical considerations are most relevant?*

There are two ethical problems in this case. Is it ever right to allow a patient to die from lack of nutrition and hydration when a feeding tube could be easily inserted, thus preventing or at least postponing the patient's death prevented? How should the disagreement between the daughters regarding their mother's treatment be resolved?

The issue of withdrawal of artificial hydration and nutrition remains controversial when framed as a physician making the decision to withdraw, purportedly in the patient's best interest. However, when the issue is framed as a matter of a patient's right to be free of unwanted treatment, there is a clear consensus that patients may refuse all life-sustaining therapies, including artificial hydration and nutrition. The right of patients to refuse unwanted therapy, including artificial hydration and nutrition, may be exercised by a proxy decision maker when the patient is not competent to decide. The ethical concept here is the respect for a person's autonomy and self-determination.

The neurologist should attempt to resolve the disagreement between the daughters by holding a family meeting and explaining that the right decision is that which their mother would want made in this circumstance. Because the older daughter has decided not to consent to have a feeding tube inserted because she sincerely believes that her mother would not want to receive such life-prolonging treatment in her present state, this reason should be explained as the basis of her decision. When the younger daughter understands that the decision not to have a feeding tube is merely carrying out her
mother's wishes, some of her guilt in the decision making may be mitigated. The neurologist further can explain that death from inanition is the "natural" way to die for many patients with advanced Alzheimer's disease. This clarifies that the decision not to insert a feeding tube respects her mother's rights of autonomy and self-determination.

Telling the daughters that proper care, such as mouth care and offering water, should protect their mother from discomfort, and that persons able to express their feelings in similar situations (such as dying cancer patients) have not suffered discomfort (hunger and thirst) may reassure them.

9. Are there analogous cases?
State laws routinely give Durable Powers of Attorney for Health Care this degree of authority. Most states do not permit physicians to overrule such treatment refusals unless they are seriously irrational or violate the customary standards of medical care. Neither is the case here. Most of the prominent legal cases (e.g., Conroy, O'Connor, Cruzan) are not analogous because in these cases there had been no prior legally authorized proxy decision maker such as was available in the present case. (5)

10. What are the relevant guidelines for clinicians regarding the problem?
The American Academy of Neurology (AAN) has published a statement of ethical issues in the management of the demented patient that specifically considers the issue of the physician's duty to provide artificial hydration and nutrition for the patient with advanced dementia. (6) The AAN statement concludes as follows: "Oral hydration and nutrition are offered, assisted, and encouraged, but hydration and nutrition are not provided by artificial enteral or parenteral means unless they contribute to patient comfort or are chosen by the patient or proxy." (7) This statement makes it clear that it is acceptable medical practice for physicians not to insert a feeding tube in this case in the setting of a valid surrogate who has decided to refuse treatment on the basis of substituted judgment. There is a substantial body of scholarly literature supporting this position. (7-9)

11. What are the ethically acceptable options?
The treating physicians should not insert a feeding tube because the legally authorized surrogate decision maker has made a rational treatment refusal that is compatible with acceptable medical practices. The physicians caring for her have a duty to provide proper palliative care so that she does not suffer while dying. (10) If the physician caring for her cannot abide by this proxy treatment refusal, the physician should transfer her care to that of another physician who is willing to carry out the decision of the health care agent.

12 & 13 What justifications can be given for the preferred resolution of the case? How is a satisfactory resolution of this case to be accomplished?
This solution at once satisfies the three ethical duties of the neurologist in this case: 1) to respect the patient's autonomy and the resultant right to refuse life-prolonging therapy as exercised by a valid surrogate decision maker; 2) to provide palliative care to
minimize suffering during dying; and 3) to practice according to acceptable standards of medical care. Counseling of both daughters as to the correctness of their action is essential.

IV. References


Ethical issues in the management of the demented patient

The American Academy of Neurology Ethics and Humanities Subcommittee

The prevalence of dementia in the United States is increasing largely as a result of three factors: the number of elderly Americans is rising, the longevity of these elderly Americans is increasing, and the incidence of dementia increases with advancing age. Because the prevalence of dementia is increasing, the medical and ethical problems of our demented elderly will rank among the most common issues faced in the future by American neurologists.

Ethical questions arising in the management of the demented patient vary as a function of the stage of dementia. In the early stages, issues of decision-making capacity and the execution of advance directives are paramount. In the middle and later stages, issues involving the appropriate level of medical treatment, decisions to restrain patients, and caregiver issues are most relevant. End-of-life treatment issues become the major ethical issues in the final stages of dementia. Problems resulting from impairments in the professional relationship between the neurologist and the demented patient can occur in all stages.

The following statement summarizes the ethical issues arising in the management of the patient with dementia. It is intended to address how ethical considerations influence ideal patient management but is not intended to represent clinical practice guidelines.

Patient-physician relationship. The neurologist's relationship with the demented patient can become impaired and thereby jeopardize its therapeutic potential for three reasons. Neurologists may unintentionally de-personalize demented patients because subconsciously they may equate the loss of intellect with the loss of personhood. Neurologists further may fear the loss of their own intellect and, in an attempt to maintain denial, avoid the patient and neglect the patient's medical problems. Finally, neurologists may feel an overwhelming sense of failure and therapeutic nihilism because of their belief that no therapy possibly can benefit a demented patient. If unchecked, these impairments may create a self-fulfilling prophesy: nothing can help the demented patient and therefore nothing need be tried.

Neurologists should optimize the therapeutic benefit of the patient-physician relationship by striving to maintain respect for the patient and recognizing and avoiding de-personalization behavior. They should practice the principles of chronic and palliative medical care that emphasize the priority of care over cure by (1) paying careful attention to the seemingly minor but personally important details of the patient's daily life and attempting to maximize the patient's quality of life by such measures as optimizing nutrition, bowel function, and restful sleep, and improving safety, controlling agitation, and correcting urinary incontinence; (2) identifying and treating depression in the elderly, which may present as "pseudodementia" or may aggravate dementia; (3) carefully limiting the number and closely monitoring the dosages of medications to reduce the incidence of toxic encephalopathies that further can impair cognition; (4) carefully ensuring that coexisting medical illnesses are treated adequately, such as diabetes, hypertension, and chronic lung disease, because optimal treatment of these conditions may lead to improved cognition; (5) correcting sensory deficits by seeing to it that appropriate eyeglasses and hearing aids are prescribed because improved vision and hearing enhance the patient's ability to communicate; (6) encouraging patients to stop smoking tobacco and drinking alcohol, which could further impair their function and safety; (7) encouraging proper nutrition, with vitamin supplementation as necessary; and (8) providing continuity of care and availability in emergency situations.

Advance directives for medical care. Neurologists should urge all patients, including those with early stages of dementia, to complete advance directives for medical care and educate them about the potential adverse consequences of not doing so. These directives can provide information about the level of medical treatment that the patient wishes to receive in various stages of illness. Patients can complete written instructional directives ("living wills") and can execute directives appointing health care decision-makers whose decision-making authority is activated if the patient becomes incompetent later in the illness. Mildly demented patients should be en...
Patients should supplement their advance directives with detailed discussions with their physician and family about their preferences for medical care of varying intensities in different medical situations that are predictable because of their dementia and advanced age. These discussions are part of the ongoing process of informed consent and should be repeated periodically while the patient remains competent. As demented patients gradually lose decision-making capacity, proxy decision-makers must become involved to a greater extent. Completing and following advance directives is desirable ethically because it permits a type of patient self-determination even in states of incompetence.

The state of the demented patient's cognitive capacity should be reassessed whenever tests or treatment are ordered. Demented patients should be included in the consent process to the fullest extent consistent with their remaining cognitive capacity. In states of patient incompetence, the consent of an appropriate proxy decision-maker is necessary for all nonemergency tests and treatments.

**Proxy decision-making.** If the patient, when competent previously, had executed a written or proxy advance directive providing guidance for medical care, it should be followed as faithfully as possible and reasonable.

In the absence of clear advanced directives, an appropriate proxy decision-maker should be identified to make health care decisions for the patient. The neurologist has the duty to explain the patient's prognosis with and without treatment to permit the proxy to make an informed decision. The neurologist should make a treatment recommendation based on the neurologist's assessment of the benefits and risks of treatment, but the authority to consent to or refuse treatment rests with the proxy. The neurologist should follow the proxy's rational treatment refusal or consent.

Proxy decision-makers generally should try to use the standard of substituted judgment, to the extent permitted by law, and attempt to reproduce the decision that the patient would have made if he or she were competent. Accurate substituted judgment is difficult and requires both a knowledge of the patient's preferences and the courage to uphold them. In the absence of knowledge of the patient's treatment preferences, the proxy should use the standard of best interests. Using a best interests standard requires balancing the benefits against the burdens of medical treatment. If, in the judgment of the proxy, the perceived benefits of the proposed treatment exceed the burdens, usually the proxy should provide consent for the treatment. If the perceived burdens exceed the benefits, however, usually the proxy should refuse to provide consent.

**Family of the demented patient.** It is desirable for neurologists to maximize the success of the home caregiver of the demented patient, thereby permitting the demented patient more time to live at home before considering institutionalization, by (1) educating the caregiver about the ideal management of common outpatient problems of the demented patient through discussions, encouraging the caregiver to read available educational books, and arranging informal caregiver training; (2) identifying and attempting to minimize sources of caregiver stress, such as patient violence, accusatory behavior, incontinence, nighttime awakenings, and wandering; and (3) preventing caregiver "burnout" by arranging for assistance that might include caregiver training sessions, home-health aide visits, periodic respite admissions, adult day care, and caregiver participation in peer groups.

Neurologists should be careful to keep separate the legitimate interests of the caregiver from those of the patient. The neurologist should attempt to support the caregiver in his or her difficult task, but the interests of the caregiver should not be permitted unjustifiably to supersede those of the patient when the two conflict. Neurologists should try to support caregivers and encourage them to be strong and independent, thereby preventing them from assuming a dependency role that could diminish their confidence and effectiveness. The caregiver and the neurologist should work in a joint partnership to provide the patient with optimal medical and home care.

Encountering caregivers who appear preoccupied with their own welfare over that of the demented patient should alert neurologists to the potential of patient abuse.

When the caregiver wishes the neurologist to arrange nursing home placement, the neurologist should initiate a discussion with the caregiver. The neurologist should attempt to determine that the nursing home placement decision is appropriate for the patient and family and that reasonable alternatives have been excluded, such as periodic visits from home health aides, adult day care, caretaker training, and respite admissions. When appropriate to the circumstances, neurologists should try to place patients in specialized Alzheimer's disease care units where they are available and to encourage the development of specialized units in nursing homes because they contribute to the betterment of care of the demented patient.

**Restraining demented patients.** Mechanical and pharmacologic restraints commonly are ordered for and applied to demented patients to keep them from harming themselves and others. Institutional surveys of the prevalence of both types of restraints show that they are ordered with increasing frequency in increasingly severe states of dementia. Despite the putative benefits of improved patient safety and reduced institutional liability, restraints also pose potential risks to the patient, including
injury from improper application or prescription and impairment of physiologic functioning from bodily restriction and sedation.

The following ethical guidelines should be observed in the ordering of mechanical or pharmacologic restraints for demented patients: (1) restraints should be ordered when they contribute to the safety of the patient or others and are not simply a convenience for the staff; (2) restraints should not be routinely ordered or ordered as a substitute for careful evaluation and surveillance of the patient, as appropriate for good medical practice; (3) the perceived need for restraints should trigger a medical investigation of the precise reason for them intended to correct the underlying medical or psychological problem; (4) restraints should be ordered with informed consent by the patient or appropriate proxy decision-maker with full disclosure of risks and benefits; (5) when indicated, mechanical restraints should be applied carefully with the least restrictive device possible; (6) when indicated, pharmacologic restraints should be prescribed with the proper agent in the lowest dose possible; and (7) all orders for restraints should be reassessed frequently so that they may be in effect for the shortest duration necessary to achieve their goals.\(^\text{13,14}\)

Palliative care and withholding and withdrawing life-sustaining treatment. The most difficult ethical problem surrounds the decision to withhold or withdraw life-sustaining treatment and apply only palliative care measures. This decision often arises in the setting of an institutionalized patient with advanced dementia who develops an intercurrent illness or requires a feeding tube. The neurologist may believe that in the setting of advanced dementia it is most appropriate to write orders to maintain comfort care but not to provide life-sustaining medical treatment. Such orders may shorten the life of the demented patient.

There is a growing consensus among physicians and the public that the most appropriate form of medical treatment for many patients with advanced dementias is palliative care.\(^\text{15}\) Palliative care refers to a class of orders of medical and nursing treatment that is intended to maximize patient comfort but not necessarily to extend life. In general, palliative care provides symptomatic treatment for disorders that produce patient discomfort but omits curative treatment for those disorders that do not result in patient discomfort, even if the patient may die sooner as a result of the lack of curative treatment. The goal of palliative care is not to cause death but rather to permit it, in as gentle, as comfortable, and as painless a fashion as possible. Palliative care should be provided in advanced states of dementia based on the duties to respect persons and to prevent their suffering.\(^\text{16}\)

Palliative care plans often include supplemental oxygen; cleared airways; or morphine for dyspnea, atropine, or other therapies to reduce uncomfortable excess secretions; morphine for pain; antipyretics for fever; mouth care; hygienic measures such as bathing, grooming, skin care, bowel and bladder care; positioning; and passive range of motion exercises. Cardiopulmonary resuscitation attempts are not performed, and hospital admissions and surgeries are avoided unless it is likely that they will improve patient comfort. Oral hydration and nutrition are offered, assisted, and encouraged, but hydration and nutrition are not provided by artificial enteral or parenteral means unless they contribute to patient comfort or are chosen by the patient or proxy.\(^\text{17}\)

Palliative care plans have been administered successfully in dementia hospital and nursing home treatment units.\(^\text{18,19}\) Orders for palliative care should be written explicitly, clarifying which therapies will and which therapies will not be administered in various circumstances.\(^\text{20}\) Discussions with and explanations to the nursing staff are essential so they understand the ethical basis for the palliative care plan and concur that it is the correct course of treatment for the patient. In this way, demented patients can receive a treatment plan that is most appropriate for their degree of illness, follows their prior treatment wishes as expressed by their proxy, and remains consistent with the highest ethical standards of medical practice.

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This statement is provided as an educational service of the American Academy of Neurology. It is not intended to include all possible proper methods of care for a particular neurologic problem or to exclude any specific alternative therapies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

References


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OVERVIEW

The Quality Standards Subcommittee of the American Academy of Neurology is charged with developing practice parameters for neurologists for diagnostic procedures, treatment modalities, and clinical disorders. The Subcommittee defines practice parameters as results, in the form of one or more specific recommendations from scientifically based evidence of a specific clinical problem. The selection of topics for which practice parameters are developed is based on factors such as prevalence, frequency of use, economic impact, membership need, controversy, urgency, external constraints, and resources required. This document will outline what we believe to be the most useful components of the diagnostic evaluation of elderly patients with cognitive complaints suggesting dementia. Recommendations in this paper have been designated as standards, guidelines, and options based on the strength of available supporting evidence. See definitions.

JUSTIFICATION

Dementia is a major cause of disability and death in developed countries and accounts for a disproportionate share of medical resource utilization and health care expenditures. Accurate diagnosis of dementia syndromes is important to detect reversible or arrestable dementias. In addition, the impact of a demented individual on his or her family is substantial; accurate diagnosis enables the clinician to provide anticipatory guidance to the patient and family, to more accurately prognosticate, to facilitate legal and financial planning, and to assist with providing access to community resources.

PRACTICE PARAMETER DEVELOPMENT PROCESS

A Medline search from 1985 to 1993 was used to generate citations of the English-language literature using the keywords “dementia”, “senile dementia”, “Alzheimer’s disease”, and “vascular dementia” cross-referenced with “diagnosis”. Literature published before 1985 was sought by reviewing reference lists of the articles obtained in the literature search. Of 3096 citations identified, we reviewed 1843 abstracts or original articles, based on a preliminary screening of the article titles. Of these, we used 110 articles to prepare this document, those references having clearly described methods, uniformly applied diagnostic definitions, and sufficiently large samples of patients (usually > 25).

IDENTIFICATION OF DEMENTIA

Dementia is a clinical state characterized by a significant loss of function in multiple cognitive domains, that is not due to an impaired level of arousal. The presence of dementia does not necessarily imply irreversibility, a progressive course, or any specific cause.

Diagnosis of dementia requires either (1) assessing an individual’s current level of cognitive function and documenting a higher level of intellectual function in the past, or (2) documenting a decline in intellectual function by examination over time. Cognitive defects due to delirium, restricted brain lesions (e.g., aphasia), and psychiatric problems (e.g., depression) must be excluded. An initial diagnosis of dementia cannot be made when consciousness is impaired, or when conditions exist that prevent adequate evaluation of mental status. If dementia is identified, further evaluation is necessary to determine the etiology of the dementia and to stage its severity.
Individuals who should be evaluated for evidence of dementia include those with memory or other cognitive complaints with or without functional impairment, elderly patients in whom there is a question of competency, depressed or anxious patients with cognitive complaints, and patients who arouse physician suspicion of cognitive impairment during their interview despite the absence of complaints (GUIDELINE).

Some patients may not meet criteria for dementia, even though they or their families are concerned about changes in intellectual functioning. This group may include well-educated, high-functioning individuals, patients with psychiatric problems (e.g., depression or anxiety), and patients with early or very mild dementia who may be considered to be "at risk" for dementia. These patients should be encouraged to return for re-evaluation since observation over time, often 6-12 months, may help to document cognitive decline (OPTION). For these patients, neuropsychological testing is often valuable to detect subtle cognitive difficulties (OPTION).

Depending on the severity of the dementia, a skillfully taken history may reveal deficits in several areas of intellectual function. For most patients, this information should be obtained from, or at least substantiated by, an informant. In taking a history, certain functional items, such as difficulty recalling recent events, preparing a meal, playing games of skill, filling out business forms, handling financial records, and shopping alone, are helpful in confirming the presence of a significant intellectual impairment. It is also useful to inquire about a family history of Alzheimer's disease or other dementia.

Most neurologists gather information regarding cognitive decline, presence of depression, evidence of vascular disease, and social and occupational functioning by history. Many of these elements have been incorporated into instruments that, especially in research settings, may assist the clinician in diagnosis (OPTIONS).

Cognitive or mental status testing should include assessment of level of arousal, attention, orientation, recent and remote memory, language, praxis, visuospatial function, calculations, and judgement (GUIDELINE). The techniques used to assess these domains are at the discretion of individual physicians (OPTION). Various brief mental status screening instruments are useful adjuncts, which may improve recognition of deficits and enhance clinical judgment. However, test scores on such instruments do not, of themselves, establish a diagnosis of dementia, nor do they determine the etiology of the dementing illness if one is present. Scores on such screening tests may be abnormal when any form of cognitive impairment exists, and mildly demented patients may score in the "normal" range. In addition, age, education, ethnicity and language of the respondent have all been shown to influence responses to mental status test items and the clinician must make allowances for each of these in assessing patients with cognitive difficulties. Although cut-off points have been recommended for some of the standardized, well-known mental status tests, they are not definitive.

DIAGNOSTIC WORKUP

The neurological history and examination (including mental status examination) are essential components of the diagnostic workup of dementia (STANDARD) and may reveal important clues to the etiology of the patient's dementia. Careful attention should be paid to the existence of focal abnormalities, extrapyramidal signs, and gait disorders.

Diagnostic tests are also necessary in the differential diagnosis of dementia to rule out metabolic and structural causes (GUIDELINE). The detailed workup depends on the suspected diagnosis, but generally should include the following tests (GUIDELINE): complete blood count, serum electrolytes (including calcium), glucose, BUN/creatinine, liver function tests, thyroid function tests (free thyroid index and thyroid stimulating hormone), serum vitamin B12 level, syphilis serology. Other tests may be helpful in certain circumstances, but are not recommended as routine studies (OPTION): sedimentation rate, serum folate level, HIV testing (order according to Centers for Disease Control suggestions), chest x-ray, urinalysis, 24 hour urine collection for heavy metals, toxicology screen, neuroimaging study (CT or MRI),
neuropsychological testing, lumbar puncture, electroencephalography, positron emission tomography (PET), and single photon emission computed tomography (SPECT).

Neuroimaging should be considered in every patient with dementia based on the clinical representation and may facilitate identification of potentially treatable conditions which can otherwise be missed, such as tumors, subdural hematomas, hydrocephalus, and strokes. However, these conditions are uncommon when not anticipated clinically, particularly when clinical evaluations are performed by experienced examiners. In particular, there is no consensus on the need for such studies in the evaluation of patients with the insidious onset of dementia after age 60, without focal signs or symptoms, seizures, or gait disturbances.

While not generally necessary, neuropsychological testing may be helpful in (1) demonstrating cognitive impairment in individuals whose initial evaluation is borderline or suspicious; (2) distinguishing depression from dementia; (3) determining competency for legal purposes; and (4) assisting in the evaluation of early dementia, particularly when major decisions need to be made with regard to a patient's job (e.g., disability determination) or other personal affairs (OPTION). As indicated in the algorithm, neuropsychological testing is most valuable in making a longitudinal diagnosis of dementia when the presence of a significant cognitive decline is difficult to establish, as it often is in extremely high-functioning individuals, in individuals with mental retardation, or in individuals with very limited educational backgrounds.

Lumbar puncture is not recommended as a routine study in the evaluation of dementia (OPTION). However, assuming there are no contraindications, a lumbar puncture should be performed when any of the following are present (GUIDELINE): metastatic cancer, suspicion of CNS infection, reactive serum syphilis serology, hydrocephalus, dementia in a person under age 65, a rapidly progressive or unusual dementia, immunosuppression, and suspicion of CNS vasculitis (particularly in patients with connective tissue diseases).

EEG is not recommended as a routine study, but may assist in distinguishing depression or delirium from dementia (OPTION), and in evaluating for suspected encephalitis, Creutzfeldt-Jakob disease, metabolic encephalopathy, or seizures (OPTIONS).

DIFFERENTIAL DIAGNOSIS

In a small percentage of cases (less than 15% on average), a specific treatable or reversible etiology of the dementia syndrome will be identified, usually with the assistance of the diagnostic studies noted above. The most important examples are medication-induced encephalopathy, depression, thyroid disease, central nervous system infections (e.g., neurosyphilis or cryptococcal meningitis), vitamin deficiencies (especially vitamin B12 deficiency), and structural brain lesions (e.g., tumors, subdural hematomas, and hydrocephalus). When these conditions have been excluded, the remaining causes of dementia consist largely of AD and vascular dementia.

AD is the most frequent type of dementia in U.S. and most European elderly, comprising about 50-80% of subjects in various clinicopathological series. Difficulty with memory is the first and most notable complaint of either the patient or family. As the disease advances, problems with language, comprehension, arithmetic calculation, visuospatial orientation and praxis become increasingly apparent. Behavioral alterations such as depression, agitation, delusions, and hallucinations may become evident at any time during the course of the illness. The neurologic examination in AD (excluding mental status testing) is often normal. Associated features include primitive reflexes (snout, glabellar, grasp), and impaired graphesthesia. Late in the course, extrapyramidal signs (rigidity and bradykinesia), gait disturbances, and myoclonus can occur.
A diagnosis of AD is supported by the following: (1) the insidious onset and progressive worsening of dementia; (2) prominent difficulty with memory (especially retention and retrieval of new material) early in the course of the illness; (3) onset after age 60; (4) no focal signs or gait difficulties on neurologic examination, especially early in the course; (5) exclusion of other treatable conditions. The acute or subacute onset of disability, or the presence of focal signs, seizures, gait difficulty early in the course of the illness, or the presence of a significant behavioral alteration prior to a memory deficit suggest a dementia etiology other than AD.

A variety of useful and well-validated clinical criteria are available for diagnosis of AD (options). Using such criteria, with suitable laboratory and diagnostic studies, positive predictive values of 80-85% can be achieved, although lower rates are reported when patients with presenile-onset are included. However, the usefulness of such criteria is limited by (1) the difficulty of identifying individuals with mild dementia or atypical presentations; (2) exclusion of individuals with prevalent and potentially overlapping conditions (e.g., cerebrovascular disease); (3) difficulty of applying the extensive psychometric and laboratory evaluations to routine clinical practice; and (4) availability of considerable latitude for individual interpretation of the criteria, resulting in at best modest interrater reliability. Furthermore, it is not clear how much incremental gain in validity is achieved with these criteria over non-criterion based clinical diagnoses, particularly for experienced clinicians.

Vascular dementia, caused by one or more small or large brain infarcts, constitutes about 5-10% of patients with dementia. Symptoms appear when a certain volume of infarcted tissue is present, or if small strokes are strategically placed, but the size, number, and distribution of vascular lesions necessary to produce dementia remain uncertain.

A diagnosis of vascular dementia is supported by the following: (1) the sudden onset of dysfunction in one or more cognitive domains; (2) a stepwise deteriorating course; (3) focal neurologic signs, including weakness of an extremity, exaggeration of deep tendon reflexes, extensor plantar responses, and gait abnormalities; (4) history or neuroimaging evidence of previous strokes; (5) evidence of stroke risk factors and systemic vascular disease. These clinical features have been incorporated into a number of different clinical criteria or "ischemic" scores. Unfortunately, there are at present no widely accepted criteria for the diagnosis of vascular dementia. Differentiation of vascular dementia from either AD with superimposed cerebrovascular disease or mixed AD and vascular dementia is especially difficult.

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of the current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurological problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

DEFINITIONS:

Class I. Evidence provided by one or more well-designed randomized controlled clinical trials.

Class II. Evidence provided by one or more well-designed clinical studies such as case control, cohort studies, etc.

Class III. Evidence provided by expert opinion, non-randomized historical controls, or one or more case reports.
STRENGTH OF RECOMMENDATIONS

Standards. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on Class I evidence or, when circumstances preclude randomized clinical trials, overwhelming evidence from Class II studies that directly address the question at hand, or from decision analysis that directly addresses all the issues).

Guidelines. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on Class II evidence that directly addresses the issue, decision analysis that directly addresses the issue, or strong consensus of Class III evidence).

Practice options or advisories. Other strategies for patient management for which there is unclear clinical certainty (i.e., based on inconclusive or conflicting evidence or opinion).

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1. **Learning Objectives**
   At the conclusion of this case, neurology residents will:
   1. describe the formal clinical evaluation (history, physical examination) necessary for a diagnosis of brain death.
   2. know the institutional policy about diagnosis of brain death in the training institution.
   3. be able to incorporate local institutional policy in their diagnosis of brain death.
   4. understand the importance of sensitively informing lay persons about brain death, using terms understandable to them.
   5. be able to access institutional resources (e.g., chaplain, legal office) that may be helpful in resolving controversy about stopping treatment of a brain-dead person.
   6. be able to make an ethically defensible decision about the precise timing of stopping the treatment of a brain-dead person on the basis of all considerations in a given situation, including the patient’s history, family issues, availability of scarce resources, ethical obligations, legal rulings, and other contextual events.
II. Case

The patient (Mrs. M) was a newly married 23 year old woman who suffered a severe closed head injury when her motorcycle hit a car broadside. The medics arrived on the scene within minutes of the accident. They immediately administered cardiopulmonary resuscitation and took her to the nearest trauma hospital. When they arrived in the emergency room (within 20 minutes of the accident), her husband, who had been following behind her in a car, was angry and aggressive, stating that the medics' delay in getting to the scene demonstrated overt negligence. The admitting neurosurgeon explained to Mr. M. his plans for treatment and discussed the seriousness of Mrs. M's condition (the Glasgow Coma Scale score was 4 in the ER).

Her course in the ICU was stormy because of progressively more severe intracranial hypertension. Within a week of the accident, a formal clinical evaluation demonstrated no evidence of brain or brainstem functions, and a 4 vessel cerebral angiogram showed lack of blood flow to the cerebral hemispheres and brain stem. At a family meeting, which was attended by Mrs. M’s husband, her parents, and her 3 siblings, the neurologist and neurosurgeon explained the diagnosis of brain death and its ramifications. They discussed their medical decision to discontinue the ventilator and answered questions. Although the rest of the family was in agreement with the physicians and had asked them about the possibility of organ donation, Mr. M. said that he “refused to authorize removal” of the respirator and other treatments. He informed them that he had contacted his lawyer and that he was bringing suit of medical negligence against the ambulance service for their slow arrival at the scene of the accident.
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). Introduction to Clinical Ethics. University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment
   1. What is the patient's medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient's preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
   10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
   11. What are the ethically acceptable options?
   12. What justifications can be given for the ethically preferred resolution of the case?
   13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments
(by Alison Wichman, MD)

A. Assessment

1. What is the patient’s medical condition and prognosis? What treatment options exist?

   In all states, death is declared on the basis of cardiovascular or neurologic criteria. A person with irreversible cessation of circulatory and respiratory functions is dead. However, when a person’s respiration is maintained mechanically in the absence of respiratory drive, the determination of death is made according to neurologic criteria. The diagnosis of death by neurologic criteria (“brain death”) is based on well-delineated, reliable clinical criteria and confirmatory tests (1,2). Neurologists diagnosing death should be familiar with these guidelines, and with applicable state laws and relevant institutional policies. When death is confirmed by neurologic criteria, it is still possible for other organs (including heart and lungs) to be maintained by artificial means for some time. However, experience shows that cardiovascular collapse inevitably occurs within a variable period (hours, days, weeks, or, rarely, months), regardless of treatment.

   Because the determination of death by either set of criteria (cardiovascular or neurologic) confirms the patient’s biological and legal death, further treatment offers no medical benefits to the patient (3). The declaration of death by neurologic criteria is made when death is confirmed by clinical and confirmatory tests, not when the ventilator is discontinued. In Mrs. M’s case, death was confirmed when the four-vessel angiogram showed no blood flow to the cerebral hemispheres or brain stem. The attending physician entered a note in Mrs. M’s medical record documenting these results. Although a medical decision to discontinue all treatments is legally and ethically appropriate at this time, the attending physician is also responsible for assuring that the medical decision is carried out in a humane manner.

2. Who is the appropriate decision maker?

   Mrs. M had not implemented an advance directive such as a Living Will or a Durable Power of Attorney for health care which would take primacy in medical decision making. However, many states automatically provide in law a surrogate decision making hierarchy for health care decisions. In Maryland, where Mrs. M had her accident, the legal hierarchy is (1) spouse, (2) adult child (an adult must be 18 years of age or older), (3) parent, (4) adult sibling, (5) grandparent, (6) adult grandchild. Therefore Mrs. M’s legally authorized surrogate decision-maker was her husband.

3 & 4 What are the patient’s preferences? What are the preferences of the patient’s family or surrogate decision makers?

   The determination of Mrs. M’s death is a medical act, and Mr. M’s consent is not required for either the declaration of her death or for discontinuation of medical treatment, although his permission is necessary for organ donation. In any event, the physicians have an obligation to explain the medical facts to him and other family members in a clear and sensitive manner. It is not clear why Mr. M is refusing to agree to discontinuation of the ventilator. His stated reason — that he is bringing a legal suit against the ambulance service — does not explain his opposition to
discontinuation of treatment. Death, and communication about it, are difficult experiences for families and also for medical professionals. It may be that Mr. M is having a difficult time accepting the fact that his wife is dead when she exhibits obvious signs of life — a heart beat, warm skin, and the production of urine (4). A clear explanation that it were not for the ventilator Mrs. M would not have any heartbeat or respiration may help Mr. M understand the reality of his wife's death (see below for more suggestions on effective communication). Additional discussions with a social worker, church member, or pastor may help Mr. M understand the situation.

A few religious groups are opposed to the concept of brain death. Although this was not true in Mrs. M's case, physicians should be aware of this possibility. In 1991 New Jersey became the first state to enact a law providing an exemption to families who, because of religious or other strongly held beliefs, do not want a patient to be declared brain dead.

5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?

Generally, the primary responsibility of physicians and nurses is to promote the health and well-being of their patients. The diagnosis of Mrs. M's death is a strong justification for discontinuing medical treatments, none of which provides any benefits to Mrs. M. However, there are some circumstances in which physicians may justifiably continue medical treatments after death has been pronounced: to allow the family a reasonable length of time to decide whether transplantation is appropriate, and to allow adequate time to remove the organs when organ donation is approved. [Note: Continuation of treatment in a pregnant woman, when there is a possibility of delivering a viable fetus if treatment is continued, is ethically and legally controversial, as is the use of brain dead people for research and teaching purposes.]

The physicians and nurses should attempt to help the family understand the medical reality and, if possible, to help diminish their emotional pain and adjust to the situation.

The conflict between the ethical and legal responsibility to withdraw treatment and Mr. M's opposition presents a dilemma for the physicians and nurses. Mr. M's consent to discontinue the ventilator is not necessary, but the health care team would prefer to reach a consensus rather than withdraw treatment over his objection.

6. Are there institutional, legal or other factors which need to be considered?

Major medical centers and most hospitals in the U.S. have policies addressing the diagnosis of death. If you are unsure of your institution's policy or the state law, you should contact your hospital legal counsel or the Chairman of your Institutional Ethics Committee. Some insurance companies deny coverage of any subsequent medical costs after a patient has been declared brain dead.

B. Identification of the Ethical Problem(s)

7 & 8 What are the ethical problems in the case? (If appropriate, rank by magnitude.)
What ethical considerations are most relevant?

In this case there is a conflict between the physicians' obligation to promote the medical welfare of their patient and their responsibility to honor the preferences of her husband who would
usually be identified as her surrogate decision maker, in the absence of a durable power of attorney for health care. Also, the physicians and other health care workers must balance attempts to minimize the anxiety and emotional pain of the family with their responsibility to avoid providing treatments that offer no medical benefit to the patient.

A surrogate’s wishes are generally binding, but some medical situations do not require a surrogate’s authorization or may allow physicians to override surrogates’ decisions. The declaration of death, which is a medical determination, and the subsequent withdrawal of treatment do not require the consent of the surrogate. But, although it is not necessary, it is desirable, if possible, to reach a consensus with the family that termination of treatment is appropriate.

If consensus is not possible the physicians must whether it is ethically permissible to continue ventilating Mrs. M. mechanically. Stated another way, does Mr. M provide ethically justifiable reasons for maintaining the ventilator that override the physicians' ethical and legal obligations to discontinue the ventilator.

9. Are there analogous cases?
Communication with the family about death may be a difficult experience for health care workers and family members. Although family members will have several decisions to make including whether to donate organs, it is important that they understand that they are not being asked to decide to discontinue mechanical ventilation. The determination of death and the decision to discontinue ventilation are medical decisions and should not be left to the family. An Illinois case held that the physicians were permitted to ignore a family's desire to maintain their relative on a ventilator once brain death had been determined (2).

10. What are the relevant guidelines for clinicians regarding the problem(s)?
Guidelines for determining death are provided in the publications of many professional associations and most hospitals and health care institutions have relevant policies. Consultation with others - for example, the hospital legal counsel or the institutional ethics committee - may also be appropriate.

11 & 12 What are the ethically acceptable options? What justifications can be given for the ethically preferred resolution of the case?
The choices are to continue ventilating Mrs. M., which may appease her husband, or to discontinue it over his objections (but with the agreement of the rest of the family). Some might argue that, under the circumstances, continuing the ventilator may alleviate Mr. M’s distress while not significantly harming Mrs. M. They may argue that the needs of the husband should be put ahead of other considerations in the situation. They may point out that cardiovascular collapse usually follows determination of death by neurologic criteria within hours to days, regardless of treatment, and, therefore, the use of medical resources will be limited by the patient’s inevitable cardiac arrest. Another option is to continue mechanical ventilation but discontinue other treatments such as vasopressors.

However, this argument does not appear to outweigh the following strong incentives to discontinue the ventilator: the physicians’ and nurses’ responsibilities to avoid providing
nonbeneficial treatments and to conserve medical resources, and the rest of the family's agreement with their medical decision. Of the two choices in this situation, discontinuing treatment, even over the husband's objections, appears to be the most ethically and medically justifiable. However, identifying the ethically acceptable choices is only a first step; the attending physician must now decide on an appropriate method of implementing it.

A decision to maintain ventilation but to discontinue vasopressors and other medications is worthy of discussion because it reveals various attitudes of physicians about truth-telling and disclosure of information. For example, if a physician chooses this option, ought he or she inform the husband of the decision? If so, why? If not, why not?

13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?

A satisfactory outcome would be for the physicians, husband, and family to agree that discontinuing the ventilator is the best course of action. Can anything more be done to help Mr. M. understand the situation? For example, if not already in progress, consultation with a social worker, psychiatrist, ethics committee (or ethics consultant), or chaplain may be helpful. Has the hospital's legal counsel spoken with Mr. M's lawyer to understand better any legal basis for his opposition? If consensus cannot be reached, the attending physician will be called upon to make a decision taking into account all of the information available. Declaration of brain death is a medical action; however, consultation with the institutional ethics committee, legal counsel, or both may be helpful if there is conflict. In some settings, institutional policy mandates such consultation.

IV. References


Instructor Comments

Suggestions for Effective Communication About Death

1. Create an environment that promotes good communication and improves understanding. For example, avoid talking to members of the family at different times. It is best to have conversations
with the surrogate and other family members, along with the appropriate members of the health care team, at the same time and in a quiet room rather than at the bedside. Take time to explain the situation and arrange your schedule so that during your conversations you are not rushed and can be attentive (i.e., set meeting times if necessary rather than catching family "on the fly"). Talking to families successfully about death is a learned skill and if you are uncomfortable, or if you are not sure what to say, discuss the situation with a colleague or with your supervisor.

2. Talk about death clearly and in lay, not medical, terms. Explain what it is, how it is determined, what the legal implications are and what decisions the family will need to make (e.g., what are their attitudes about organ transplantation?). Discussions about death take place over several hours or days, so physicians should be available to carry on an ongoing dialogue. In Mrs. M's case, one time at which to begin a dialogue with Mr. M about death is during the informed consent process concerning the 4-vessel angiogram. For example, in getting approval to perform the angiogram, the neurologist has the opportunity to educate Mr. M about the meaning and implications of a possible finding of absent blood flow.

3. Avoid confusion:
   - The language you use is important. For example, do not call the respirator a "life-sustaining treatment" but rather a machine that is maintaining breathing temporarily and mechanically (explain that without the ventilator there would be no breathing or heart beat). The declaration of death is made when death is confirmed by appropriate neurological findings on exam and confirmatory tests: avoid implying that the patient dies when the ventilator is discontinued. In fact, the term "brain death" rather than "death" is confusing because it can be interpreted to mean that only the brain, not the patient, is dead.

   - Organize and discuss your approach with appropriate members of the health care team (physicians, nurses, social workers, chaplain, etc.). If necessary, assign an experienced physician to be responsible for talking with the surrogate or family on an ongoing basis. Conflicting information given by different physicians (and nurses), although well-intentioned, can cause serious but avoidable problems.

4. The determination of death and the subsequent decision to withdraw ventilation are medical decisions. It is important for the family to understand that they are not being asked to decide whether to discontinue ventilation, but rather to endorse the physicians' decision (or to understand the physician's legal and ethical obligation) to discontinue it. However, they will have other decisions to make (e.g., organ transplantation, autopsy) and they may require some time to make them.

   Serious disagreements between members of the health care team or with members of the family should prompt consideration of consultation with the institutional ethics committee (or ethicist).

   Do not hesitate to draw on the experience and help of others professionals. For example, it may be helpful to have a social worker, counselor, chaplain, or others participate in conversations with the surrogate or family.
PRACTICE PARAMETERS FOR DETERMINING BRAIN DEATH IN ADULTS

(Summary Statement)

Report of the Quality Standards Subcommittee of the American Academy of Neurology

Overview: Brain death is defined as the irreversible loss of the clinical function of the brain, including the brain stem. Brain death from primary neurologic disease usually is caused by severe head injury or aneurysmal subarachnoid hemorrhage. In medical and surgical intensive care units, however, hypoxic-ischemic brain insults and fulminant hepatic failure may result in irreversible loss of brain function. In large referral hospitals, neurologists make the diagnosis of brain death 25 to 30 times a year.

Justification: Brain death was selected as a topic for practice parameters because of the need for standardization of the neurologic examination and clinical examination criteria for the diagnosis of brain death. Currently, there are differences in clinical practices in performing the apnea test and controversies over appropriate confirmatory laboratory tests. This document outlines the clinical criteria for brain death and the procedures of testing in patients older than 18 years.

Description of the process: All literature pertaining to brain death identified by MEDLINE for the years 1976 to 1994 was reviewed. The key words "brain death" and "apnea test" (subheading, "adult") were used. Only peer-reviewed articles with original work were selected. Current textbooks of neurology, medicine, pulmonology, intensive care, and anesthesia were reviewed for opinion. On the basis of this review and expert opinion, recommendations are presented as standards, guidelines, or options. The recommendations in this document are guidelines unless otherwise specified (see Definitions).

I. Diagnostic Criteria for Clinical Diagnosis of Brain Death

A. Prerequisites; brain death is the absence of clinical brain function when the proximate cause is known and demonstrably irreversible

1. Clinical or neuroimaging evidence of an acute central nervous system catastrophe that is compatible with the clinical diagnosis of brain death
2. Exclusion of complicating medical conditions that may confound clinical assessment (no severe electrolyte, acid-base, or endocrine disturbance)
3. No drug intoxication or poisoning
4. Core temperature ≥ 32 °C (90°F)

B. The three cardinal findings in brain death: coma or unresponsiveness, absence of brain stem reflexes, and apnea

1. Coma or unresponsiveness: no cerebral motor response to pain in all extremities (nail-bed pressure and supraorbital pressure)
2. Absence of brain stem reflexes
   a. Pupils
      (1) No response to bright light
      (2) Size: midposition (4 mm) to dilated (9 mm)
   b. Ocular movement
      (1) No oculocephalic reflex (testing only when no fractures or instability of the cervical spine is apparent)
      (2) No deviation of the eyes to irrigation in each ear
with 50 mL of cold water (allow 1 minute after injection and at least 5 minutes between testing on each side)

c. Facial sensation and facial motor response
   (1) No corneal reflex to touch with a throat swab
   (2) No jaw reflex
   (3) No grimacing to deep pressure on nail bed, supraorbital ridge, or temporomandibular joint

d. Pharyngeal and tracheal reflexes
   (1) No response after stimulation of the posterior pharynx with tongue blade
   (2) No cough response or bradycardia to bronchial suctioning

Apnea: Apnea testing performed as follows:

a. Prerequisites
   (1) Core temperature ≥ 36.5°C or 97°F
   (2) Systolic blood pressure ≥ 90 mm Hg
   (3) Corrected diabetes insipidus Option: positive fluid balance in the past 6 hours
   (4) Normal PCO₂ Option: arterial PCO₂ ≥ 40 mm Hg
   (5) Normal PO₂ Option: Preoxygenation to obtain arterial PO₂ ≥ 200 mm Hg

b. Connect a pulse oximeter and disconnect the ventilator

c. Option: Place a cannula at the level of the carina and deliver 100% O₂, 8 L per minute

d. Look closely for respiratory movements (abdominal or chest excursions that produce adequate tidal volumes)

e. Measure PO₂, PCO₂, and pH after approximately 8 minutes and reconnect the ventilator.

f. If respiratory movements are absent and arterial PCO₂ is ≥ 60 mm Hg (Option: 20 mm Hg increase in PCO₂ over a baseline normal PCO₂), the apnea test result is positive (supports the diagnosis of brain death)

g. If respiratory movements are observed, the apnea test result is negative (does not support the clinical diagnosis of brain death)

h. Connect the ventilator if during testing the systolic blood pressure becomes ≤ 90 mm Hg or the pulse oximeter indicates significant oxygen desaturation and cardiac arrhythmias are present; immediately draw an arterial blood sample and analyze arterial blood gas (if PCO₂ is ≥ 60 mm Hg or PCO₂ increase is ≥ 20 mm Hg over baseline normal PCO₂, the apnea test result is positive [supports the clinical diagnosis of brain death]; if PCO₂ is < 60 mm Hg or PCO₂ increase is < 20 mm Hg over baseline normal PCO₂, the result is indeterminate and an additional confirmatory test can be considered)
II. Pitfalls in the Diagnosis of Brain Death

The following conditions may interfere with the clinical diagnosis of brain death, so that the diagnosis cannot be made with certainty on clinical grounds alone. Confirmatory tests are recommended.

A. Severe facial trauma
B. Preexisting pupillary abnormalities
C. Toxic levels of any sedative drugs, aminoglycosides, tricyclic antidepressants, anticholinergics, antiepileptic drugs, chemotherapeutic agents, or neuromuscular blocking agents
D. Sleep apnea or severe pulmonary disease resulting in chronic retention of CO₂

III. Clinical Observations Compatible With the Diagnosis of Brain Death

These manifestations are occasionally seen and should not be misinterpreted as evidence for brain stem function.

A. Spontaneous "spinal" movements of limbs (not to be confused with pathologic flexion or extension response)
B. Respiratory-like movements (shoulder elevation and adduction, back arching, intercostal expansion without significant tidal volumes)
C. Sweating, blushing, tachycardia
D. Normal blood pressure without pharmacologic support
E. Absence of diabetes insipidus (normal osmolar control mechanism)
F. Deep tendon reflexes; triple flexion response
G. Babinski's reflex

IV. Confirmatory Laboratory Tests (Option)

Brain death is a clinical diagnosis. A repeat clinical evaluation 6 hours later is recommended, but this interval is arbitrary. A confirmatory test is not mandatory but is desirable in patients in whom specific components of clinical testing cannot be reliably performed or evaluated. It should be emphasized that any of the suggested confirmatory tests may produce similar results in patients with catastrophic brain damage who do not (yet) fulfill the clinical criteria of brain death. The following confirmatory test findings are listed in the order of the most sensitive test first. Consensus criteria are identified by individual tests.

A. Conventional angiography: No intracerebral filling at the level of the carotid bifurcation or circle of Willis. The external carotid circulation is patent, and filling of the superior longitudinal sinus may be delayed.

B. Electroencephalography: No electrical activity during at least 30 minutes of recording that adheres to the minimal technical criteria for electroencephalographic recording in suspected brain death as adopted by the American Electroencephalographic Society, including 16-channel electroencephalographic instruments.

C. Transcranial Doppler ultrasonography:
   1. Ten per cent of patients may not have temporal insonation windows. Therefore, the initial absence of Doppler signals cannot be interpreted as consistent with brain death.
   2. Small systolic peaks in early systole without diastolic flow or reverberating flow, indicating very high vascular resistance associated with greatly increased intracranial pressure.

D. Technetium 99m hexamethylpropyleneamineoxime brain scan: No uptake of isotope in brain parenchyma ("hollow skull phenomenon")
E. Somatosensory evoked potentials: Bilateral absence of N20-P22 response with median nerve stimulation. The recordings should adhere to the minimal technical criteria for somatosensory evoked potentials recording in suspected brain death as adopted by the American Electroencephalographic Society.

V. Medical Record Documentation (Standard)
A. Etiology and irreversibility of condition
B. Absence of brain stem reflexes
C. Absence of motor response to pain
D. Absence of respiration with $\text{PCO}_2 \geq 60 \text{ mm Hg}$
E. Justification for confirmatory test and result of confirmatory test
F. Repeat neurologic examination (Option): The interval is arbitrary, but a 6-hour period is reasonable

Definitions

Class I: Evidence provided by one or more well-designed, randomized, controlled clinical trials.

Class II: Evidence provided by one or more well-designed clinical studies, such as case control and cohort studies.

Class III: Evidence provided by expert opinion, nonrandomized historical controls, or case reports of one or more.

Standards: Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on class I evidence or, when circumstances preclude randomized clinical trials, overwhelming evidence from class II studies that directly address the question at hand or from decision analysis that directly addresses all the issues).

Guidelines: Recommendations for patient management that may identify a particular strategy or range of management strategies and that reflect moderate clinical certainty (i.e., based on class II evidence that directly addresses the issue, decision analysis that directly addresses the issue, or strong consensus of class III evidence).

Practice options or advisories: Strategies for patient management for which clinical certainty is lacking (i.e., based on inconclusive or conflicting evidence or opinion).

Practice parameters: Results, in the form of one or more specific recommendations, from a scientifically based analysis of a specific clinical problem.

This statement is provided as an educational service of the AAN. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Nor is it intended to exclude any reasonable alternative methods. The AAN recognizes that specific decisions on patient care are the prerogative of the patient and the physician caring for the patient and are based on all the circumstances involved. Regardless of the conclusion of this statement, the Quality Standards Committee of the AAN recognizes the need to comply with state law.
Medical societies invited to comment on this practice parameter (* indicates those who provided comment):

American Academy of Family Physicians*
American Association of Neurological Surgeons
American Academy of Pediatrics

Quality Standards Subcommittee thanks Ethics and Humanities Subcommittee and the fifteen members of the AAN Member Reviewer Network who reviewed and returned comments on this practice parameter. The Subcommittee appreciates the reviews of several other critical care specialists.

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* The background paper by Eelco F. M. Wijdicks, MD is available upon request at the American Academy of Neurology office (612/623-2439).

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11/94
1. **Learning Objectives**

At the conclusion of these sessions, neurology residents will be able to:

1. define and explain the following terms and concepts: suicide, physician-assisted suicide, voluntary euthanasia, terminal illness, end-stage disease, and [the doctrine or principle of] double effect.
2. formulate a personal position about assisting in the death of a patient under their care.
3. identify the resources available to deal with an implied or overt request from a patient to assist in that person’s suicide.
II. Case

Robert Smith, Jr. -- Bob, as he prefers to be called -- is a 23 year old single man with end-stage Duchenne muscular dystrophy (DMD). He is of normal intelligence and has a high school education, but he has never held a job. He is assisted with respiration by a positive-pressure mechanical ventilator (Bi-PAP). He alternately uses nasal prongs and a face mask. He needs the ventilator at night and intermittently during the day. His dependence on it is increasing, and he has been advised to have a tracheostomy, something he says he does not want. Bob experiences respiratory distress when he breathes on his own for more than a couple of hours, and he becomes panicky if he cannot be helped promptly when it is time to restart the ventilator, a task he cannot perform independently.

Bob's caregiver during the day is his paternal grandmother, who is infirm and increasingly forgetful. His parents are divorced; his father lives in another city and does not maintain contact with him or his mother. For the past 3 years his mother has held the same full-time job, which she says she cannot afford to give up to stay home with Bob. Bob's younger brother died of DMD 4 years ago, at the age of 16.

Bob is on Medicaid, but after a series of bad experiences with home health aides, he refuses help from anyone except family members. He spent several months in a nursing home, has been hospitalized repeatedly for pneumonia, and is adamant that he will never return to institutional care. He wishes to die at home. For some time, he has been especially interested in TV programs dealing with end-of-life issues. He tries to tell his mother about Jack Kevorkian and Derek Humphry when she comes home from work, but she begs off, saying that it is hard enough to spend 8 hours at a stressful job without having to be further depressed in the evening.

For the past 3 months, Bob has repeatedly called to request a prescription for a sleeping pill from his neurologist, Dr. Elizabeth Dann, who is the principal provider of his medical care. (Bob does not have cardiac failure or other significant health problems.) Dr. Dann has seen Bob twice a year for the past 4 years. She was first consulted after the death of Bob's brother, because Bob's mother did not want her older son to continue with the neurologist who had followed both her sons until that time. She wanted a younger doctor, who might be more up-to-date on treatment. To date, Bob has not been eligible for any clinical trials.

Dr. Dann has questioned Bob about depression and has specifically asked him whether he wants to use the sleeping pills to bring about his death. Bob reports that he is aware that he has a limited life expectancy; he denies being suicidal. Bob and Dr. Dann both know that he would be able to tolerate discontinuing ventilatory support only if he were heavily sedated or unconscious, and that he would not survive long without the machine. Dr. Dann has referred Bob to a psychiatrist, but he has refused to go through with the consultation. He claims that the only thing that puts him in a negative frame of mind is daytime fatigue brought on by nighttime insomnia. In his most recent telephone conversation with the neurologist (which he can conduct via speaker phone without assistance), he reports he has been worrying about his future and about his grandmother's physical and mental decline, can't fall asleep, and would like the help of a sedative. He has the conversation out of his mother's and grandmother's presence.
The neurologist writes the prescription for a sedative, specifies an easy-open cap, mails it to the pharmacy, arranges for delivery of the pills, and telephones Bob. She tells him she has given him a 30-day supply, but that he must be careful not to take too many pills at one time. The pharmacy delivers the medication while Bob’s mother is at work and he is alone with his grandmother. He asks her to open the container for him and bring him water. She does this unquestioningly.

A short time later, the grandmother leaves the house to have a long lunch with an elderly neighbor whom she likes to visit. She often does this although her daughter-in-law has told her she must never leave Bob alone. Usually, as Bob’s mother leaves, she says, “He’s all I’ve got. I can’t lose him!” But by the time Bob’s mother arrives home from work, his grandmother always seems to have forgotten that she received such instructions, or that she has violated them. Bob has stopped telling on her, because it just causes an argument.
When the grandmother returns, she finds Bob dead in bed. Seeing the bottle of pills with some pills still in it, she flushes the pills down the toilet and discards the container. She then telephones Bob's mother. When Bob's mother arrives home, the grandmother tells her nothing about the pills. An investigator from the Medical Examiner’s office comes to the home. When he questions the women about the circumstances leading to Bob's death, the grandmother says she was with Bob all day and gave him aspirin for a headache. She gives no indication that she has anything to hide.

The investigator notifies the neurologist, who tells him she has recently been in contact with Bob and that his death was expected. She does not ask the mother to grant an autopsy: she knows from conversations with Bob and his mother in the past that he had asked his mother a year ago not to permit an autopsy and to have his body cremated when he died. His mother assured him that she would respect his wishes. The neurologist completes the death certificate, giving the cause of death as Duchenne muscular dystrophy. The Medical Examiner releases the body to the funeral director for cremation.

At the funeral, the grandmother's remarks force Bob's mother to conclude that her mother-in-law is confused enough to believe the service is being held for her own son, Bob's father. Bob’s mother is overwhelmed by emotion and barely able to remain through the service.
When the grandmother returns, she finds Bob dead in bed and telephones his mother. When Bob’s mother arrives home, she finds the container by Bob’s bed, with some pills still in it. Bob’s grandmother says she does not recall anything about the pills. The investigator comes to the house, and Bob’s mother gives him the container, with Dr. Dann’s name on the label. Autopsy and toxicologic study reveal that Bob’s body had high blood and tissue levels of drug, although not high enough to be considered lethal to an otherwise-healthy person. Bob’s mother is angry. She speaks with the District Attorney, expressing the belief that Dr. Dann helped her son kill himself. The District Attorney presents the case to a grand jury, seeking to indict the neurologist on the criminal charge of assisting suicide.

In addition, the state medical licensing board convenes to consider disciplinary action, against Dr. Dann, which could include censure and suspension or revocation of her license to practice medicine.

Bob’s mother brings a wrongful-death suit against Dr. Dann in civil court.
Continuation Version Three

When the grandmother returns, she finds Bob unconscious in bed. She calls 911. Bob is admitted to the ICU, unconscious. His mother signs a consent for tracheostomy. After regaining consciousness, he remains ventilator-dependent and is later transferred to a long-term care facility in another city because there is no such facility for mechanically ventilated patients in his home town.

Bob is uninterested in TV, reading, or the few activities offered him. His mother visits when she can, but he rarely says much to her. He often tells the physician who has assumed his care that he wants to die, but his mother tells the doctor not to take her son seriously, and the doctor does not.
Continuation Version Four

The pills are delivered while Bob's mother is still at home. Their arrival triggers an extensive and long-overdue discussion of his situation, in which Bob convinces his mother that he has the right to stop using the ventilator, even though he cannot live without it. Not wanting to lose her son, but realizing that he is determined to give up mechanical ventilation and will no doubt accomplish that at some time when she is away from the home, she accepts his decision. A month later, after several visits to talk with Bob and his family and be sure of the constancy of his decision, Dr. Dann comes to Bob's home and administers morphine intravenously, in a dose that is sufficient to make Bob lose consciousness. As soon as Bob becomes unconscious, Dr. Dann stops the ventilator (on which he has by now become completely dependent). Bob dies in the presence of his mother and grandmother. Dr. Dann later completes the death certificate, listing the cause of death as Duchenne muscular dystrophy. The Medical Examiner releases the body for cremation. No autopsy is performed.
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). Introduction to Clinical Ethics, University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment
   1. What is the patient's medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient's preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments
(by David Goldblatt, MD, in collaboration with Jane Greenlaw JD, RN and Jeffrey Spike, PhD.)

A. Assessment

1. What is the patient’s medical condition and prognosis? What treatment options exist?

Although the primary diagnosis of DMD is firmly established, and lengthy additional survival is quite unlikely, the patient, as described, is not “terminally” ill: survival for another year or more seems achievable. He does, however, have end-stage disease: his condition is life-shortening and is expected to worsen, to be unresponsive to available treatment, and to result in his death at a time unlikely to exceed a couple of years, although supported ventilation is capable of extending his survival time.

A secondary diagnosis of depression is less firmly established. If an antidepressant proves to be indicated, it should be tried. (Perhaps the neurologist will have to develop a contract with her patient: she may promise a bedtime sedative at a later date, if the patient agrees to psychiatric consultation, trial of antidepressant, or both. At this time, she should not provide him with potentially lethal medication.)

Depression may prove to be both present and untreatable by usual means; nevertheless, attention to the details of the patient’s daily life may prove rewarding: chronic hypoventilation at night can lead to daytime fatigue and a discouraged mood, which may improve dramatically when adequate ventilation has been achieved. It should also be determined that the patient uses nothing, such as alcohol, that may have a depressant effect. Depression can, in some situations, lead to altered decisional capacity, and may even render a patient clinically incompetent for medical decision making. However, a diagnosis of depression does not automatically deprive the patient of the right to accept or refuse treatment (such as mechanical ventilation). When a diagnosis of depression is made, it is appropriate to assess the patient’s capacity to make medical decisions in his or her own behalf. The attending physician should record the result of the assessment, with a statement of opinion as to whether the patient has or lacks such capacity.

The caregivers must be informed if the patient is considered to be a danger to himself. (Query: How can this best be accomplished in order to protect the patient without destroying the patient-doctor relationship?) The caregivers should be interviewed. If the neurologist is aware of the family dynamics, she may be able to readdress Bob’s resistance to outside help and achieve more reliable care for him without overriding his autonomy. He might well be less anxious if he did not have to rely on an unreliable person for care in potentially life-threatening circumstances.

With regard to his choices, it must be remembered that there is a presumption of competence, and any patient who has not been shown to lack the capacity to make medical decisions on his or her own behalf has the right to refuse any medical treatment, even if such refusal will result in death. Furthermore, Bob must be given humane medical care, so that he will not suffer if he does choose to discontinue use of the ventilator and its use is stopped. Physicians experienced in the procedure often advocate managing the patient as Bob was managed in the fourth version of the case (once it is established that the patient is indeed
dependent on the ventilator and that, although rendered unconscious by the drug, the patient will actually die of respiratory failure). The principle of double effect holds that the death of the patient must be unintended, although it can be foreseen. The principle is sometimes invoked in the debate about ‘killing vs. letting die’ and has been cited in support of palliative care that may prove to be life-shortening. For those who subscribe to the principle of double effect, if an intervention is expected to shorten a patient’s life, the death of the patient must be an unintended effect, although it can be foreseen.

Bob’s behavior in obtaining the pills suggests that he believed that his mother would not go along with the course of action described in the fourth version of the case, in which the physician is present to assist in stopping the ventilator.

2. **Who is the appropriate decision maker?**

Bob is an adult and of normal intelligence. As such, he has the right to make decisions in his own behalf. This is especially important to remember when caregivers, such as his mother, try to preempt the decision-making role. (This often happens when children who have had a disabling condition since childhood grow up but continue to be treated like children. For instance, in this case, the mother chose a neurologist for Bob when he was 19 years old; she didn’t ask him to choose his own doctor or give him an opportunity to do so.) Should Bob’s capacity to make decisions be challenged because of the possibility that he is depressed? If so, what should be done to ascertain his capacity with greater certainty?

3. **What are the patient’s preferences?**

The patient is suspected of not being forthright about his preference for living or dying. Family, clergy, and friends may be helpful in informing the physician about the patient’s real agenda. The confidential nature of the patient-doctor relationship can make gathering information difficult, but if Bob is judged to be a danger to himself, it may be necessary to reveal that fact to those involved in his care.

4. **What are the preferences of family or other surrogate decision makers?**

No surrogate decision maker has been formally identified by the patient. (He has not appointed a health care agent.) A surrogate decision maker is not required except during his unconsciousness in the third version of the case (if he could not be maintained on intubation and really did require tracheostomy before he regained consciousness). But it is helpful to the treating physician to understand the feelings of the family: chronic, progressive illness is stressful on all family members and may lead to inappropriate attitudes and behavior. Moreover, recognizing the fact that the grandmother’s judgment is seriously impaired might have led to a more successful treatment plan if her impairment had been taken seriously.

5. **Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?**

The mother’s need or desire to work away from the house may well be reasonable and even lifesaving for her, because nobody can successfully be the sole 24-hour-a-day caregiver for someone who is chronically ill; but her absence, and her attitude when she comes home from work, may well have contributed to the diminished quality of the patient’s life. Bob’s mother
might have benefitted from professional help, which Dr. Dann might have helped her find.

6. Are there are institutional, legal, or other factors which need to be considered?

Legal issues in this case devolve from the interpretation placed on Dr. Dann's act: prescribing medicine that actually contributed to Bob's death (in the first and second versions) was not, in and of itself, an illegal act; and charges of felonious activity or professional misconduct may or may not be justified; but those are labels that someone could potentially place on what she did. It is hard to imagine that those charges could be brought against the neurologist even if there was no physical evidence that the patient took an overdose of pills (the first version); in the second version, however, the presence of the evidence makes the charge of assisting in suicide seem more plausible. The doctor's documentation of her dealings with Bob, and her recollections, would probably satisfy an investigator that she had not acted deliberately to bring about his death.

In the different versions of the case, the neurologist experiences legal, professional, and financial consequences as a result of prescribing a sedative for her patient -- or no such consequences at all. That these greatly different outcomes could hinge on the unpredictable actions of an "innocent third party," the demented grandmother, makes it clear that those consequences do not provide a suitable means of getting at the ethical issues in the case.

B. Identification of the Ethical Problem

7. What are the ethical problems in the case?

If this is a case of physician-assisted suicide, and if you wish to judge it (rather than just analyze it), it is necessary, first, to confront your own position on the question of suicide. If you consider suicide to be an immoral act, it follows that assisting in the suicide of another person is also immoral. If that is not your fixed position, it is still important to acknowledge your view on the subject before proceeding to analyze and advise in the case.

But is this such a case? Is it fair to conclude that, because Bob is not terminally ill, in the sense that he is not imminently dying of muscular dystrophy, Bob is actually taking his own life, or killing himself, when he takes the pills? Or is he simply making his discontinuance of a burdensome, unwanted treatment tolerable? And if he is either withdrawing from (stopping) or withholding (not starting) any unwanted treatment, is he doing something that mainstream medical thinking accepts as a decision that a patient is entitled to make, no matter what the consequences may be (and even if the consequence is the death of the patient)?

Has there been any violation of trust in the relationship between doctor and patient in this case? Has the patient deceived his doctor? If so, does that alter the doctor's obligation to do what is best for her patient? Does it change her own obligation to tell the truth? It can be argued that she should have said to Bob, "I don't believe what you are telling me," or even, "I sympathize with the idea that you don't want to live a life of diminishing security, increasing anxiety, and increasing burdensomeness to people you care about. I'll help you to end your life" (if that was truly what motivated her to write the prescription as she did). It is important for doctors to be true to themselves, and to look into their own conscience. They can then act in the
way that is best for their patient and can accept the consequences, rather than pretending that they
don't know what the patient will do, hoping in that way to avoid responsibility.

Does an obligation to truth-telling extend beyond an obligation to the patient? If sworn to
tell the truth in a court of law, the doctor would be expected to disclose her motives -- or at least
the prosecution would try to get her to do so. If, as in the first, third, and fourth versions of the
case, no such legal scene was likely ever to be played out, should the doctor nonetheless make a
public "confession" (or "disclosure," if she believed that she had violated no moral code) and,
following the lead of Dr. Timothy Quill, describe to the world her "individualized decision
making" --- perhaps not in an article in the New England Journal of Medicine, but at least in a
conversation with the patient's mother?

More broadly, can this case be analyzed in terms of motives? Does it depend upon a
universal principle: that we must tell the truth? Can it be unraveled in a utilitarian approach,
looking at the consequence of Bob's death for him, for his family, for his doctor, and for society?
Can consequences matter, even if, as stated earlier, consequences for the doctor that are
dramatically different may depend on an unpredictable and, in that sense, chance occurrence?

8. **What ethical considerations are most relevant?**

From a practical point of view, the most important ethical problem is whether doctor and
patient must tell each other the truth: if the patient tells the doctor that he is contemplating
suicide, the doctor's view of the morality of suicide is not immediately relevant, in the sense that
it is an obligation of the doctor to attempt to preserve her patient's life, with the hope that the
patient will come to value life once more, whereas there is no corresponding obligation to assist
the patient in committing suicide. Moreover, the physician has an obligation to obey the law, in
order to be able to continue to practice medicine and serve the sick, including other patients,
present and future, besides the one who is contemplating taking his own life. (Of course,
doctors, like anyone else, can choose to violate the law as a matter of conscience, but that is not
the expectation we have of most physicians.)

Respect for the patient's autonomy may, however, require the physician to withdraw
unwanted treatment. Whether permitting death to occur in that way constitutes voluntary
euthanasia, rather than a "natural death" from the underlying disease or condition, is a question
that still deserves discussion, although the latter interpretation is generally accepted today.

9. **Are there analogous cases?**

The case of "Diane" is one in which the physician, Dr. Timothy Quill, provided his
patient with a prescription and made sure that she knew how much she would have to take to
bring about her own death. By so doing, he made it clear to her that he understood her intent and
did not actively oppose it. Although a grand jury decided not to indict him on a charge of
assisting suicide, we do not know whether another grand jury would make the same decision.

10. **What are the relevant guidelines for clinicians regarding the problem(s)?**

The American Academy of Neurology and the American Medical Association, as well as
many other professional organizations, have guidelines stating that physicians should refrain
from engaging in any act that directly or indirectly abets the suicide of a patient. On the other hand, physicians are obligated to withdraw burdensome treatment from patients who are capable of making a valid decision about their own care and who consistently demand that such treatment be withdrawn, even if the result (anticipated but not directly intended) is the death of the patient. Such a death is not generally held to be a suicide, and the physician is therefore not implicated in assisting suicide.

11 &12. What are the ethically acceptable options? What justifications can be given for the ethically preferred resolution of the case?

Given the uncertainties of clinical medicine, the neurologist should not be required to extract some sort of confession from Bob: her suspicion that he intends to end his life is enough for her to refuse to prescribe sleeping pills. The proper use of sedatives is limited; they are not for long-term use, and there are better ways to solve his sleeplessness. She should delve more deeply into the family situation (perhaps by involving a Social Worker in the case) and try to work out the problems imposed by an incompetent caregiver and an ostensibly neglectful mother (who may in reality prove to be distancing herself from her son because she is still suffering from the loss of his brother, her only other child, and is unable to face a repetition of that loss). The neurologist should see him in her office or his home and not just talk to him on the telephone.

Enlisting the help of other professionals will, we hope, relieve the neurologist of the sense that she is not responding to the perceived need of her patient when she does not do what he asked her to do. His obdurate refusals may prove to be cries for help, but he must not feel that he is being rendered powerless. The disabled need to exert control over their environment, human and physical, and Bob must be empowered to obtain what is his due: respect, dignity, good care, and a sense that his life is valued and valuable. Only if all efforts fail to make Bob’s life seem to him to be preferable to death should the neurologist proceed as in the fourth version.

IV. References


V. Instructor Comments

The case is best discussed in two sessions, the first session devoted to the first and second versions, and the second session to the third and fourth versions.
I. **Learning Objectives**

At the conclusion of this case, neurology residents will be able to:

1. define and explain the following terms and concepts and their application in a situation involving a newborn child: futility, autonomy, nonmaleficence, beneficence.
2. formulate a plan regarding the management of small newborns with low potential for meaningful recovery.
3. understand the particular difficulties inherent in decision making when the patient has never been competent, and when the patient is a newborn child.
II. Case

Neurologic consultation was requested for advice regarding prognosis and treatment of a three day old infant. The pregnancy was complicated by vaginal bleeding at three months gestation. Intermittent abdominal cramps occurred thereafter. Onset of labor was spontaneous at 24 weeks and vaginal delivery was accomplished 4 hours later. The neonate, a male, weighed 590 gm, was floppy and pale, had minimal spontaneous movement of the extremities, and had a heart rate of 40. The newborn exhibited no spontaneous respirations.

Intubation was accomplished after 10 minutes of bagging. Umbilical cord pH was 6.95. Heart rate rose to 90. BP was 48/30. Temperature was 36.8 degrees C. Occasional small spontaneous, symmetrical movements of the extremities continued. Serum sodium was 128 meq/l and serum calcium 7.4 mg/100ml. Chest x-ray showed a homogeneous, miliary granularity. The infant was anuric. Ventilator dependency continued. Total bilirubin was 8.6 meq/dl on day 2. On day 2 bowel sounds were absent and the abdomen was slightly distended. Brain ultrasound that day revealed blood in the body of the left ventricle and a question of subependymal blood on the same side. A 2 x 2 cm cystic cavity was present in the right parietal area without mass effect.

By day 3 the fontanel was full. Hemoglobin was 9 gm. Ultrasound now showed germinal matrix hemorrhage and blood in the ventricles. The parents were advised of the hopelessness of the situation and the unlikely possibility of a meaningful neurologic outcome. Even though the parents expressed understanding of the situation, they insisted that all measures be undertaken to preserve the neonate's life. They felt that the caregivers were mistaken and that a favorable outcome would occur. The parents said repeatedly, "We believe in miracles."
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). Introduction to Clinical Ethics, University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment
   1. What is the patient’s medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient’s preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
A. Assessment

1. What is the patient’s medical condition and prognosis? What treatment options exist?

This newborn patient has multiple medical problems including prematurity, intraventricular hemorrhage, developmental or acquired brain anomaly, and probable hypoxic damage to the brain, liver, bowel, and kidneys. Only 50 percent of neonates survive with this degree of prematurity. The almost certain hypoxic-ischemic injury, multisystem disease, and demonstrated brain pathology increase the risk of death and make full neurologic recovery most unlikely. Should this infant survive, the infant will almost certainly have major deficits (6). Prognostication always involves a degree of uncertainty. Treatment options include discontinuation of ventilator support with certain death; continuation of ventilator support but no fluids, antibiotics, or vasopressors; fluids only; or use of all treatments available.

2. Who is the appropriate decision-maker?

When the patient is a neonate, the parents are the surrogates and the legal decision-makers. A conflict arises when the parents’ decisions are not consistent with the decisions of the care givers. The best interests of the neonate should be foremost but are difficult to determine.

3. What are the patient’s preferences?

A neonate cannot formulate or express preferences. Surrogates must be relied upon.

4. What are the preferences of the patient’s family or other surrogate decision makers?

The parents have expressed their preference that all therapies be provided.

5. Are there interests other than, and potentially conflicting with, those of the patient that need to be considered?

There are interests potentially in conflict with those of the patient. The caregivers realize that the neonate has only the slightest chance for a full neurologic recovery. Some of the caregivers believe that treatment may be harmful, painful, and experimental, and may serve only to prolong suffering. The parents’ interests conflict with those of the care givers. The parents are interested in relief of suffering, and survival of the child, and they believe that a miracle may occur. The care givers are interested in relief of suffering and prevention of a life with severe neurologic handicap and limited life expectancy; the caregivers do not believe that a miracle will occur. The caregivers are under no obligation to support the parents expressed belief in miracles, whether or not their own belief systems allow for such a possibility.

6. Are there institutional, legal, or other factors that need to be considered?

The fact that the patient is a minor introduces legal restrictions. Government administrative regulations in the United States, known as the "Baby Doe Rules," were superseded by the Child Abuse Amendment Act of 1984 (Public Law 98457). Discontinuation of treatment was prohibited unless the infant was chronically and permanently comatose, the treatment would merely prolong dying, or the treatment was virtually futile for survival and would be inhumane.
Neonatal intensive care units approach these regulations variously. The spectrum of care can run from full maintenance with attention directed at all treatable problems to withdrawal or withholding of ventilator support, vasopressors, antibiotics, and nutrition.

B. Identification of the Ethical Problem(s)

7. What are the ethical problems in the case?
   A. Surrogate decision makers. Should the physician accede to the parents’ wishes? Vigorous treatment seems medically inappropriate to the caregivers and may be a cause of suffering or even harm. Treatment could be considered futile in that it only prolongs suffering and provides no physiologic benefit.

   B. Physician’s responsibility. If the clinical situation is hopeless, the treatment offers little or no physiological benefit and may be harmful, and suffering is being prolonged, does the physician’s responsibility to provide treatment end? Death or disability is likely to occur even if treatment is maximum (56% survival in one series with only 21% of the survivors escaping severe intracranial abnormality, (6)) There remains a statistical chance of a meaningful survival, although that chance is small. Is the real cost of a day in intensive care the same as the hospital charges?

   C. Is this a futility issue? Does treatment have any physiologic benefit? Treatment that permits life to continue may be considered of physiologic benefit.

   D. Responsibility to neonate. The responsibility is to prevent suffering (can a 590 gm neonate suffer?), prevent harm, provide comfort, limit injury, and prevent inappropriate experimentation.

   E. Conflict resolution. The ethical problem requires conflict resolution, which has not yet been successfully achieved.

8. What ethical considerations are most relevant?
   Things to consider include the following. Could this become a case of inappropriate withholding and withdrawal of treatment? Are the surrogates’ wishes paramount? Does futility become an important issue if death is imminent? Are there additional medical investigations which would help determine prognosis? Is there a risk of abandonment? Does nonmaleficence (duty not to inflict harm) relate to the care of this neonate? Does distributive justice (duty to allocate resources equitably) play a role in decision making? Failing to treat the patient vigorously could violate the principle of patient-centered beneficence (the necessity to do everything possible to benefit the patient). How valid are prognostications contained in the medical literature and based on the experience of other groups in other institutions?

9. Are there analogous cases?

10. What are the relevant guidelines for clinicians regarding the problem(s)?
C. Decision Making and Implementation

1. What are the ethically acceptable options?

A variety of options may be ethically acceptable. The best interest of the neonate is the primary consideration. Quality of life considerations are from the neonate's perspective. Absolute prognostic certainty is not necessary and is not available. Considerations include the following.

A. A bioethics committee may provide help in this situation. Some institutions have special bioethics committees for the neonatal intensive care unit. These special committees are constituted because of the unusual nature of the issues surrounding the neonate and because of the need for experience in dealing with these problems. Such a committee could help deal with the questions of surrogate autonomy and appropriate treatment decisions.

B. If the parents maintain their position, Child Protective Services or other legal options can be invoked if survival appears to be prolonged without a favorable ultimate prognosis or if therapies become indicated that are unusual, painful, or expensive. Involvement of legal options would be only a last resort if conflict cannot be resolved by other means. Legal involvement may increase rather than decrease conflict.

C. The question concerns maintenance of ventilator support, intervention for increased intracranial pressure, treatment of hypotension and bradycardia, and other therapies which may become indicated while waiting for the outcome. Can the physician ethically refuse to mention these options to the parents if their continuation or introduction becomes clinically indicated? Is there a duty to tell the truth regarding management?

12. What justifications can be given for the ethically preferred resolution of the case?

The preferred resolution is the application of the best interest of the neonate. However, the surrogates have rights that must be respected.

13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?

Conversations with the surrogates and compassionate explanations may be all that is necessary. Allowing time for the parents to accept the loss may be useful. Involve other caregivers such as the ICU nurses. If resolution still does not occur, involvement of a bioethics committee may be essential.

IV. References

1. Luce, JM. Physicians do not have a responsibility to provide futile or unreasonable care if a patient or family insists. Crit Care Med 1995;23:760-6.


Instructor Comments:
This case study is best used to consider the limitations of futility, the problems which can occur in dealing with surrogates and the implications of surrogate decisions, and the difficulty in determining the best interests of the patient, in the context of child neurology.
UNCOOPERATIVE PARENTS

I. Learning Objectives
   At the conclusion of this session, neurology residents will be able to:
   1. define and explain the following terms and concepts: surrogate decision maker, abandonment, abuse, neglect, mature minor.
   2. articulate helpful skills in working with uncooperative families.
II. Case

Joe Smith is a 14 year old boy who has had modest developmental problems and "spells" since contracting bacterial meningitis at 6 months of age. The meningitis was complicated by seizures, and spells have persisted. Walking began at age 14 to 15 months, and the child first began to put words together at the age of 3 years. CT scan of the brain at that time showed mild atrophy. When Joe entered school, he was placed in special education. Balance and coordination were below normal. He fell frequently, failed to cooperate, and was hyperactive.

Neurologic evaluation at age 7 revealed a head circumference of 50 cm (30th percentile), normal strength and tone, ataxia on finger-to-nose test, choreiform movements of the outstretched hands, short stride with toeing in, ankle clonus, and flexor toe signs. EEG had generalized atypical polyspike and wave as well as generalized 3 Hz spike and wave. The results of the MRI were normal. Urine organic and amino acids were normal as were blood lysosomal enzymes, carnitine, and ammonia.

Joe's spells include brief episodes of staring and also brief episodes of eyes rolling up and fluttering as often as 200 times a day. He also has 3 or 4 generalized tonic-clonic seizures each year. At various times he has been on phenobarbital, primidone, valproate, ethosuximide, felbamate, clonazepam, lorazepam, and clorazepate. Dexedrine was begun for hyperactivity with improvement in the problem. On prolonged video EEG his staring spells did not have EEG correlates.

Recently, Joe's physicians noted that the mother showed concern over the possibility that the dexedrine prescription would lapse and appeared defensive and difficult. Since video EEG did not show abnormality, the possibility of pseudoseizures was considered. The suggestion was made that anticonvulsant drugs be discontinued.

Joe's mother does not wish to discontinue anticonvulsant medication and wishes to explore epilepsy surgery. Psychiatry evaluation raised a possibility of physical and sexual abuse of the child. Further psychiatric intervention was refused.

Joe's parents are unhappy with the care they have been receiving. They have been given the names of three alternate physicians from whom they can seek care. However, they threaten legal action if continued care is not provided.
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I. Assessment
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   3. What are the patient’s preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
A. Assessment

1. What is the patient's medical condition and prognosis? What treatment options exist?

Developmental delay and hyperactivity are present. Joe probably had epileptic seizures at one time and may be having pseudoseizures or epileptic seizures now. Treatment options depend upon whether this is a case for pharmacologic intervention, behavioral intervention, or both. Should anticonvulsant drugs be discontinued even though the parents want them continued? Should dexedrine be discontinued? Is epilepsy surgery a reasonable consideration? Is a referral to Protective Services appropriate? What is the role of behavioral or social medicine?

2. Who is the appropriate decision maker?

For a minor child, the parents are the legal decision makers. An ethical and legal problem arises when the parents' decisions may not appear to be consistently in the best interest of the child in the view of the caregivers.

3. What are the patient's preferences?

It is difficult to determine the preferences of children who may be unreasonable and easily swayed by others. Is there a difference between age of legal competency and age of understanding? Courts have increasingly recognized the opinions of mature minors.

4. What are the preferences of the patient's family or other surrogate decision makers?

The parents prefer to continue pharmacologic care and pursue consideration of epilepsy surgery. They are opposed to psychologic intervention.

5. Are there interests other than, and potentially conflicting with, those of the patient that need to be considered?

The parents' interests appear to conflict with those of the caregivers, and in the caregivers' opinion, with those of the patient. Are the caregivers correct? Is the patient at risk either mentally or physically? Does the family have any reason to perpetuate a conflict? Has physician behavior produced the conflict?

6. Are there institutional, legal, or other factors that need to be considered?

The fact that the patient is a minor introduces particular legal issues. Child Protection and Advocacy statutes are available if legal intervention for protection of the child seems appropriate. Must a physician provide care to a family which the physician feels is unreasonable, uncooperative, and not benefiting from the physician's services? The parents have threatened to sue, although the basis for a suit is unclear.

B. Identification of the Ethical Problem(s)

7. What are the ethical problems in the case?

A. Surrogate decision makers. Should the physician yield to family's perceived needs
even though these needs appear to the physician as medically inappropriate? When is involvement of Child Protective Services appropriate, necessary, or a legal obligation?

B. Physician's responsibility. Have the caregivers displayed appropriate objectivity? Is the problem one of personalities and not of appropriate medical care? If the physician believes that the medical care being provided is not improving the clinical situation, should the physician withdraw? What is the mechanism by which a physician can withdraw? Should the physician, in order to reduce conflict, provide medical therapy which is not dangerous but does not appear appropriate? What are the goals in the management of this case? What is the physician's responsibility if the child is harmed by the parents or by medication?

C. Responsibility to next care giver. Physicians are usually reluctant to pass "troublesome" patients to their colleagues. The parents are dissatisfied with present care but reject alternate care.

D. Responsibility to child. Assure best medical management and prevent harm.

8. What ethical considerations are most relevant?
A. Can this case be considered abandonment by the physician? What is meant by abandonment in the legal sense? Can and should physicians extricate themselves from a case?

B. Is this a case of inappropriate withholding and withdrawal of treatment?

C. Is this a case of child abuse and neglect? What is the caregivers' responsibility when abuse or neglect is suspected? What are the available resources?

D. Is there additional medical investigation which would help in resolution?

9. Are there analogous cases?

10. What are the relevant guidelines for clinicians regarding the problem(s)?
A surrogate decision maker must be respected. Preservation of autonomy should be maintained. Beneficence and nonmaleficence for the child are uppermost considerations. Could refusal of further care be considered abandonment or abuse and neglect?

C. Decision Making and Implementation

11. What are the ethically acceptable options?
All of the following options may be appropriate, and combinations of the following options may provide the best approach.
   a. Attempt to reestablish rapport.
   b. Transfer care to other caregivers at the same or another facility.
   c. Make continued care contingent upon psychiatric involvement.
   d. Refuse to prescribe anticonvulsants or dexamphetamine with complete explanation of reasons.
   e. Repeat video EEG.
Refer to state Child Protective Services. Reporting suspected child abuse is ethically appropriate. Suspected child abuse reporting is governed by state statutes and is legally mandatory in most states.

12. What justifications can be given for the ethically preferred resolution of the case?
Continued care in the current setting is the preferred resolution. This provides continuity of care by someone familiar with the issues of the case.

13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
Attempt to reestablish rapport with the family, perhaps by bringing in a third party such as a psychiatrist, social worker, epilepsy nurse, or counselor. Recommend alternatives for source of care if the parents wish to make a change. If alternative care is sought, consider communication with the alternative care source concerning existing problems. A meeting with the Bioethics Committee would be a consideration.

IV. References


Instructor Comments:
The purpose of this case study is to demonstrate an unsuccessful physician-parent interaction which may be interfering with the health of a child, and to explore ways that it may be improved upon.
I. Learning Objectives

At the conclusion of this case, neurology residents will:

1. be able to define and explain the following terms and concepts: phase I drug trial, phase II drug trial, phase III drug trial, altruism, decision-making capacity.
2. Be able to discuss mechanisms for determining decision-making capacity in a patient.
II. Case

Sue Morris is a sixty-five-year-old woman who has shown increasing signs of dementia over the past two or three years. She lives with her 72-year-old husband in the home they built when their first child was born, forty-one years ago. Mr. and Mrs. Morris have three children, all daughters, all of whom are married and have families of their own. They all live close enough to each other that they enjoy a close, lively, and interactive extended family life. Mrs. Morris' progressing dementia has been worrisome to her family; they have expressed concern about her safety in the home because of her forgetfulness and disorganization while performing simple household tasks. At first, they noticed that she did things like forgetting to turn the stove off after cooking a meal. More recently, she got lost while driving home from the grocery store where she has shopped for thirty years. The family has developed an informal system of accompanying and supervising Mrs. Morris, so that there is usually a grandchild or other family member in the home and available to run errands with her.

During Mrs. Morris' most recent routine physical exam, her primary care provider referred her to a neurologist for a complete evaluation of her symptoms. The neurologist diagnosed Alzheimer's Disease (AD) and offered her an opportunity to participate in a Phase 11 trial of a drug to determine its effectiveness in slowing the progressive dementia associated with AD. Randomization will be equal between placebo-treated and drug-treated subjects.

The members of Mrs. Morris' family are divided as to whether she should be a subject in the study and as to whether she should be able to make her own decision about this. One daughter strongly asserts that Mrs. Morris should receive State-of-the-art treatment for her AD, while another argues that since the drug is unproven she should not be exposed to the possible side effects. Mrs. Morris likes the idea of "helping medical science" and wants to sign up to be in the study, and Mr. Morris will support whatever his wife wants.
III. Case Comments
(by David Goldblatt, MD)

A. Assessment

1. What is the patient's medical condition and prognosis? What treatment options exist?

This patient's primary diagnosis is dementia of the Alzheimer type. At this point there is no known successful treatment for the disease itself. Close follow-up investigation of the patient's environment and safety is the primary indication. Clearly, her condition is not terminal, but it is potentially life-shortening.

2. Who is the appropriate decision maker?

A central issue in this case is the patient's capacity to make her own decision to become a subject in a clinical trial. The observations of her family about her deficiencies in carrying out her daily activities do not necessarily dictate a finding that she lacks capacity to decide about medical treatment. It needs to be determined whether these deficiencies represent a cognitive limitation, and if so whether it is of such significance that she is unable to assess the information provided about the clinical trial and its relevance to her situation.

3. What are the patient's preferences?

The patient has expressed her preference clearly and unambiguously. She wishes to participate in the trial.

4. What are the preferences of the patient's family or other surrogate decision makers?

The family are divided in their opinions. Whether any family member should be recognized as her surrogate depends on the determination of the patient's capacity. The opinions of her family about her capacity are relevant. If she has capacity, then no surrogate is needed; if she lacks capacity, then she may previously have named a surrogate to make decisions on her behalf. Further, if she has not named a surrogate, she may have capacity to name one now, even if she lacks capacity to make the more complex decision about treatment. If she has not chosen and cannot choose a surrogate herself, then identifying a surrogate involves determining who can best make decisions consistent with the patient's values and preferences. Consensus among family members is not necessary, but the importance of family harmony cannot be ignored.

5. Are there interests other than, and potentially conflicting with, those of the patient that need to be considered?

Others may have interests that are different from or contrary to those of the patient. Investigators have an interest in gathering data and in enrolling patients in trials. In this situation the patient may have diminished capacity to understand the potential benefits and risks to her.

Family members may have reasons for preferring one choice over another that are not directly related to the patient's interests and well-being. Sometimes caregivers are concerned
that family members have financial interests that motivate decisions about continuing or discontinuing treatment.

6. Are there institutional, legal, or other factors that need to be considered?
Federal and state regulations apply to the selection of human subjects in research studies and to the process of informed consent.

B. Identification of the Ethical Problem(s)

7. What are the ethical problems in this case?
Ethical problems in the case include: 1) Is this type of research ethical? Should a patient with dementia be enrolled in a research study that has the potential to harm her?

2) Should a patient with dementia be considered capable of giving valid consent? Is there a difference between capacity to give consent for treatment and capacity to give consent to research?

3) What is the effect of disagreement among family members? When there is disagreement among family members, is it necessary to obtain consensus? Should one dissenting voice be allowed to override?

8. What ethical considerations are most relevant?
The most relevant question is that of the patient's capacity to give consent. The others are important and must also be addressed.

9. What are the analogous cases?
One potentially useful analogy to the gradual loss of understanding in progressive dementia is the gradual improvement in understanding during childhood development. Different stages of development of children have dictated different degrees of involving them in decision making about medical treatment: some children are considered mature enough to give consent; some are too immature to give consent but capable of giving assent. Parents decide for very young children.

10. What are the relevant guidelines for clinicians regarding the problem?
Practice parameters for determining capacity have been developed by some organizations, such as AAN and APA.

The widely accepted standard for decision-making capacity is that the patient understands her condition and the information about treatment options, and that she understands and appreciates the consequences of her decision. Abnormal or significant findings on a traditional mental status examination do not necessarily signify a lack of capacity to make decisions about treatment.

C. Decision Making and Implementation

11. What are the ethically acceptable options?
One option is to recognize that the patient has capacity to make the decision and to allow
her to enroll in the study. Another option is to find the patient lacking in capacity, to identify a surrogate decision maker, and to identify the appropriate standard that the surrogate should use.

12. **What justifications can be given for the ethically preferred resolution of the case?**

The patient’s capacity, although tenuous, is supported by her husband’s affirmation of it. The fact that he believes she is capable of deciding, and that he believes her decision is consistent with her lifelong values, is justification for accepting her decision.

13. **How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?**

An important strength in this case is the unified, loving family of the patient. This can be very useful in the resolution of the case, if the clinician takes the time to meet with the family and help them understand that their role is to identity and support the wishes of the patient. Whether the decision to allow the patient to enroll in the study is made by the patient herself or by her husband as a substituted judgment, the standard respects the patient’s autonomy (self-determination).

IV. **References**


I. Learning Objectives
At the conclusion of this session, neurology residents will be able to:
1. define and explain the following terms and concepts: deontological, consequentialist, mistake. [A mistake, in the sense used in this case, is a commission or omission in the care of a patient which has potentially negative consequences for the patient. This act or failure to act would be considered wrong by skilled and knowledgeable peers at the time it occurred. (Modified from Wu, 1997)]
2. formulate a position regarding management of physician's mistakes.
3. identify personal resources to deal with the inevitability of mistakes.
4. identify institutional resources for dealing with mistakes.
II. Case

A 46-year-old white male stock broker had been under psychiatric care for three years for depression. Antidepressants had been tried. He had received recent criticism from his colleagues regarding his lack of participation in the activities of the business and forgetfulness.

Fluoxetine had never previously been used in the patient's treatment. Seven months ago, therapy with fluoxetine was begun. After three weeks of being on fluoxetine as his only antidepressant, he suddenly developed a state of fluctuating consciousness with brief periods of alertness and normal cognition interspersed with periods of confusion and perseveration lasting several hours. His psychiatrist stopped the fluoxetine, hospitalized the patient, and obtained an immediate neurology consultation.

Neurology consultation had never been performed previously. No focal deficits were noted by the neurologist. MRI was recommended, and the results were normal. No pharmacologic intervention was begun, and he was treated with supportive therapy.

Two days later, the behavioral episodes were still occurring. No improvement was noted. Repeat neurology consultation recommended an EEG. After an additional two days, when there was finally an opening in the schedule, the EEG was performed and showed continuous repetitive focal spike and sharp waves with variable spread. Lorazepam was immediately given intravenously and produced an immediate improvement in level of responsiveness, although there was persistent lethargy and poverty of movement for an additional 4 days. Continuous anticonvulsant therapy was instituted.

Past history revealed that a similar episode may have occurred approximately 5 years ago when the patient was on no medication. This episode lasted only for several hours, resolved spontaneously, and was not brought to the attention of any care givers.

In the clinic today (six months after hospitalization), you noted that the patient has been unable to return to work as a stock broker because of difficulty in concentration and memory. His handwriting is now illegible. He has not been able to return to his previous avocation of tennis. A repeat EEG showed only background slowing and rare frontal spikes. He remains on anticonvulsants.

As the office visit concludes, the patient asks you to explain what has happened to him.
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). Introduction to Clinical Ethics, University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment

1. What is the patient's medical condition and prognosis? What treatment options exist?

2. Who is the appropriate decision maker?

3. What are the patient's preferences?

4. What are the preferences of her family or surrogate decision makers?

5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?

6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)

7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)

8. What ethical considerations are most relevant?

9. Are there analogous cases?

10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation

11. What are the ethically acceptable options?

12. What justifications can be given for the ethically preferred resolution of the case?

13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments  
(by Russell Snyder, MD)

A. Assessment

1. What is the patient's medical condition and prognosis? What treatment options exist?

The illness for which the patient was admitted, although not initially recognized, was nonconvulsive status epilepticus. When nonconvulsive status epilepticus is left untreated, as in this case for several days, an unfavorable outcome may occur with subsequent permanent deficits. Whether or not a particular outcome is related to a mistake may be an important part of the analysis of professional mistakes.

Mistakes made in this case included the late diagnosis of nonconvulsive status epilepticus, resulting from the failure to consider the diagnosis early on, and delay in obtaining the EEG.

2. Who is the appropriate decision maker?

In this case, the individual who will identify that a mistake was made, and who will decide to disclose the mistake or not, will be the physician. There is no evidence that anyone else has identified the physician's mistake to the patient or to other parties.

3. What are the patient's preferences?

In general, patients wish truthful answers to questions. If the patient has asked the reason for the deficits, it is reasonable to presume that he would wish to be fully informed regarding responsibility for his seemingly permanent deficits. A more difficult analysis applies to whether or not a patient prefers full disclosure of information that may be beyond the scope of his questions.

4. What are the preferences of the patient's family or other surrogate decision makers?

This does not appear applicable to this case. In most situations the family would wish to be fully informed.

5. Are there interests other than, and potentially conflicting with, those of the patient that need to be considered?

Conflicting interests include the continued career of the physician, the need for the physician to establish trust, the medicolegal system, hospital privileges, quality assurance issues, licensure, the National Practitioner Data Bank, and malpractice insurance coverage.

6. Are there institutional, legal, or other factors that need to be considered?

The institution's interests may be contrary to truth-telling because of publicity, insurance, legal issues, and staff privileges.
B. Identification of the Ethical Problem(s)

7. What are the ethical problems in the case?

A mistake was made that was largely, if not entirely, a mistake by the neurologist in not recognizing the clinical presentation of nonconvulsive status epilepticus. This mistake probably led to neurologic deficits that are probably permanent and that will prevent the patient from pursuing his current employment and other activities. The ethical issues are truth-telling, disclosure of unasked for information, and the patient's right to know. Should the patient be informed when the doctor errs?

A "consequentialist" ethical theory holds that one ought to do that act that will realize the best overall consequences. A "deontological" theory maintains that one ought to do that act by which one fulfills one's duties or obligations.

The fiduciary relationship to the patient invokes the principles of nonmaleficence, beneficence, respect for patient autonomy, and justice. These relationships argue for disclosure.

Other problems may include the following: What if the mistake is a witnessed mistake made by another physician? Is a mistake without negative consequences for the patient different in approach from a mistake with negative consequences? Is there an ethical difference between non-disclosure of a known mistake that is not asked about, and lying in response to a specific question about the mistake?

8. What ethical considerations are most relevant?

9. Are there analogous cases?
Mistakes in medical practice are common. Many of these mistakes are not, however, widely discussed.

10. What are the relevant guidelines for clinicians regarding the problem(s)?

C. Decision Making and Implementation

11. What are the ethically acceptable options?
Ethically acceptable options include disclosing the error and seeking forgiveness from the patient; seeking advice from the Bioethics Service; attempting to ameliorate the harm (e.g. voiding all medical expenses related to the mistake). It may be important to consider institutional policy.

Additional considerations include the following. Consider whether or not the common statements which follow are true, and whether or not they are relevant to decision-making in this case, and if so, how. [It may be particularly useful for the facilitator to elicit residents' perceptions about errors, and how they are handled in the training environment.]

1. Ethical rules are not immutable.
2. We should learn from our mistakes but not be crucified for them.
3. The climate of blame in this country makes it difficult to acknowledge mistakes.
4. The medical community needs to change so that mistakes can be allowed.
5. Cover-ups antagonize juries.
6. Is giving the patient something less than full disclosure ever acceptable?
7. Confessing a mistake is to commit professional suicide.
8. An unfavorable outcome is not necessarily an error.
9. The patient may be too depressed to learn about the mistake.
10. Insurers and those granting hospital privileges look unfavorably upon physicians
    who confess mistakes.
11. Every word in a "confession" can be used against the physician.
12. What justifications can be given for the ethically preferred resolution of the case?
    Truth-telling with full disclosure as soon after the event as possible is the preferred
    resolution. It is difficult to enter into such a situation without considering the impact of truth-
    telling upon the patient-doctor relationship and upon the physician's career and status.
13. How is a satisfactory resolution to the case to be accomplished? Is ethics
    consultation necessary or desirable? Is judicial review necessary or desirable?
    An easy resolution is not readily apparent in many situations such as this. Hilfiker
    has observed that medicine simply has no place for its mistakes. A satisfactory resolution
    could be achieved if a process existed whereby a mistake could be acknowledged without
    sanctions. Truth-telling could then easily become the norm in medical practice. But what about
    egregious mistakes? Is this case an egregious mistake? Is this a case of malpractice?

IV. References
   1993;34(S1):S21-S28.
5. Lantos JD. On mistakes and truth telling. Chapter 7 in: Do We Still Need Doctors?
6. Witman AB, Park DM, Hardin SB: How do patients want physicians to handle mistakes?
7. Wu AW, Folkman S. McPhee SJ, Lo B: Do house officers learn from their mistakes?


**Instructor Comments:**
The overall purpose of this case study is to demonstrate an unfavorable outcome secondary to a mistake, the ethical issues which are raised by the mistake, and the courses of action which are available. It may also provide a valuable time to discuss the training environment and how mistakes are handled in your particular environment.
I. **Learning Objectives**

By the end of this case, neurology residents will:

1. be able to articulate the AMA’s ethical position determining which gifts from industry are and are not acceptable;
2. be able to explain the conflict of interest that gifts from industry may create for the physician, and the implications of this conflict for the patient-physician relationship;
3. be able to identify whether the AMA and the AAN have ethical positions on certain topics, and obtain access to these statements when formulated;
4. have additional skill in communicating a decision about funding to a pharmaceutical representative;
5. ascribe to the principle that the patient’s interest must remain paramount to any interest in or loyalty toward a pharmaceutical firm or equipment manufacturer.
The following format is advised for the systematic analysis of the cases presented. This outline can be used whether an individual case is used over one or more sessions. This outline is taken from JC Fletcher, CA Hite, PA Lombardo, MF Marshall (eds.). *Introduction to Clinical Ethics*, University Publishing Group Inc., Frederick, Md. 1995.

I. Assessment
   1. What is the patient’s medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient’s preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
II. Case

Dr. Daniel Barker was recently named chief resident for the Neurology Service for the upcoming academic year. Among his many responsibilities in this role will be organizing the weekly grand rounds (a weekly conference with CME credit open to all members of the hospital community) and the weekly residents’ neuroscience course (a weekly basic science education conference for the residents). Typically, lunch has been provided at both of these conferences by various pharmaceutical and equipment manufacturers. Dan schedules meetings with the various company representatives to confirm that this will be the ongoing practice. The last thing that Dan wants to deal with during his first month on the job is NOT having lunch available at these conferences; he is concerned that the faculty members and residents will not come to the conferences or will be angry with him.

Dan meets with Mr. Pibbs, a representative of Pharmaceutical Firm A. Mr. Pibbs informs Dan that his company is cutting back on the money available for supporting educational activities. However, he believes that he can probably buy lunch once a month for each conference. In exchange, Mr. Pibbs would like to be able to attend the conference, have his company mentioned as the sponsor of the conference at the meeting and on any flyers produced, and have the opportunity to talk informally with the participants before and after the meeting.

Mr. Pibbs would also like to provide funding for two grand rounds speakers over the course of the year. These speakers would be nationally recognized experts chosen from a panel maintained by Firm A. The firm would pay the entire honorarium and costs for the speaker. Mr. Pibbs would like to suggest the speakers, but Dan will have final approval.

Mr. Pibbs also suggests to Dan that he would like to arrange for Dan to be invited to participate in an invitadonal epilepsy conference to be held later in the year. Dan has heard about this conference; others who have gone to it have returned with rave reviews about the educational experience, the networking with experts in epilepsy, the quality of the food, and the amenities of the resort setting. Mr. Pibbs explains that Firm A will cover all costs of Dan’s participation and will include a small honorarium ($500) as well. If Dan chooses, he can waive the honorarium and instead identify a guest whose costs will be borne by the Firm.

Dan wants to talk with the other pharmaceutical firms before making a decision about how to handle the conferences. As part of another conversation, the departmental administrator for Neurology tells him to remember the AMA Guidelines on gifts when he’s setting up grand rounds. Dan is not sure what these guidelines are, and he begins to wonder what ethical issues might be relevant.

Before he leaves for the day, Dan stops by the sample closet in the office. Dan’s wife has a sero-negative polyarthritis, and Dan uses samples to keep the cost of her expensive anti-inflammatories down. There is one box of her current medication available. He takes that box, and when doing so notes that the drug is made by Mr. Pibbs’ firm.
III. Case Comments
(by Lois Margaret Nora, MD, JD)

A. Assessment
1. What is the patient's medical condition and prognosis? What treatment options exist?

The concern about gifts from industry relates to the potential for the gift to negatively interfere with the patient-physician relationship and the physician's responsibility to the patient by interposing a real, perceived, or potential coercion to the physician about prescribing practices.

Dr. Barker's wife, and her illness, may be relevant in the discussion of his taking drug samples, as well as in the potential conflict it creates for Dr. Barker if he wishes to obtain samples or low-cost drugs for his wife from Mr. Hall's company.

2. Who is the appropriate decision-maker?

Again, a question more related to ethical decisions in practice rather than in the physician's personal behavior. But emphasize that Dan, the resident, will be the decision-maker here. He is the one who will have to make the decisions for himself.

3 & 4 What are the preferences of the patient's family, or surrogate decision-makers?

Not obviously related to this issue. But this can provide an opportunity to have the residents look at the case from the perspective of themselves as patients, and from the perspective of their patients. What are the possibilities of a real conflict? Perceived conflict?

5. Are there interests other than, and potentially conflicting, with those of the patient which need to be considered?

Interests in this case that are potentially, although not absolutely, in conflict include those of the physician and those of the pharmaceutical firm and its representative. The pharmaceutical firm has a significant interest in motivating physician behavior toward prescription of their products. The physician, Dan, may also have competing interests. He is interested in caring for his patients. However, other interests include caring for his own wife, limiting his out-of-pocket expenses for medical care, the opportunity for a vacation with his wife, and the opportunity to network and experience an excellent educational program at no cost. Also to be considered is the resident's interest in not having people mad at him or being perceived as incompetent (e.g., if food is not available at conferences). Although the latter factor may seem funny or trivial, avoiding problems is an important modifier of resident behavior, and this should be discussed.

6. Are there institutional, legal, or other factors which need to be considered?

Guidelines regarding gifts from industry and support of continuing medical education activities have been promulgated by many professional associations and the AMA. These are discussed below.
B. Identification of the Ethical Problem(s)

7 & 8 What are the ethical problems in the case and what ethical considerations are most relevant?

Gifts from industry have the potential to provide great benefit to patients and physicians, and also the potential to create real or perceived conflicts of interest for the physician. The ethical problems that arise in this case include the relationship, if any, that Dan Barker should have with the pharmaceutical firms; the criteria that must be met for ethically appropriate support by industry of educational activities; whether the conference meets those criteria; and Dan’s use of medication samples for his family. The case provides opportunities to gain an appreciation for the perspective of business via the pharmaceutical firm, the practitioner, and the patient. The relationship of drug company give-aways and the cost of drugs lends itself to a discussion of the ethical principle of justice.

The most ethically relevant considerations are the importance of the patient-physician relationship and the physician’s role as patient advocate. The primary concern with gifts to physicians by industry is the potential for the gifts to influence the physician’s best judgment about a particular therapy for a patient. The larger the gift, the greater the potential for the gift to influence the practitioner’s judgement. The guidelines that have been promulgated by various specialty organizations and the Council for Continuing Medical Education of the American Medical Association suggest that no physician is immune from the explicit or implicit pressure that significant gifts can play in modifying physician behavior. Also of concern is the fact that patients might reasonably perceive a conflict in physician’s interest and be concerned about physician behavior if gifts are significant enough, even if that physician in reality had no change in behavior related to the gift.

Specific standards, included in the reference list, have been established regulating the involvement of industry in formal continuing medical education (in this case, most clearly the grand rounds sessions; the resident training sessions are not subject to the same regulations, but they form a good basis for handling the content). These guidelines include rules about choice of speakers, honorarium, and other aspects of the conference. It seems likely that Dan can work out the grand rounds arrangement with Mr. Pibbs in an ethically appropriate fashion. He will have to make sure that the speakers do not endorse products, that potential conflicts of interest (like the speaker being supported in the visit by the pharmaceutical firm) are announced to the audience, and that Mr. Pibbs has no formal time to meet with physicians during the session. Dan has a responsibility to make sure that a balanced approach is used in all of the grand rounds, with all speakers identifying conflicts, using generic names for drugs, etc.

AMA guidelines on gifts to physicians provide background that is useful in the discussion of the potential educational conference. It is valuable to stress that the rules are different for residents and attending physicians, and to explore why there might be these differences. The conference is described in a way that should allow discussion and disagreement. Certain aspects of it seem very useful and educationally beneficial. However, certain things are very problematic. These include the free travel, lavish amenities, and honorarium for learners. Overall, participation in the conference as described is ethically problematic.
The ethical issue of using free samples is also presented. The guidelines allow physicians to use free samples for themselves and their families as long as the use of the samples does not interfere with patient access. Areas for discussion here include whether or not anti-inflammatories are routinely prescribed in this clinic (if not, why in the sample cabinet?) and Dan taking the last box of samples. The case is also written to allow discussion of whether or not Dan can speak to Mr. Pibbs about getting samples. Note that contrary to usual practice, this is not considered ethically appropriate for physicians. The AMA guidelines note that it is inappropriate for physicians who have not retired to request free drugs for themselves or their families.

9. Are there analogous cases?
Reference can be made to ethical guidelines as well as state and federal laws that govern the referral of patients to testing facilities in which the referring physician has a significant ownership interest. Physicians are precluded from such referrals, except in very limited situations, because of the conflict that is created. The conflict in these cases is much more obvious and direct than in the case of gifts from industry, but is of a related nature.

C. Decision Making and Implementation

10. What are the relevant guidelines for clinicians regarding these problems?
AMA guidelines provide fairly clear limits on the permissible gifts to physicians from industry. The Association of American Medical Colleges has guidelines that are applicable to the training setting. Although the Academy has no published guidelines on this issue related to neurology, other specialties (cardiology, pediatrics) have developed guidelines that may be useful.

These guidelines permit gifts to physicians that primarily entail a benefit to patients and are of substantial value and serve a genuine educational function. Individual gifts to a physician are acceptable if of minimal value and related to the physician's work (e.g., pen, notepad, reflex hammer). Cash gifts are not acceptable.

Monies to support continuing medical education programs are permissible. The conference organizers must maintain complete control of the content, faculty, educational materials and methods for the conference. Any monies should be given to the conference sponsor to help reduce registration fee. Physicians should not receive monetary payments directly. Industry subsidies should not be accepted directly or indirectly to pay for costs of travel, hotel rooms, or personal expenses of physicians attending meetings. Consultants and faculty who provide genuine services may be reimbursed for travel, lodging and meals, and receive reasonable honoraria.

Special guidelines related to trainees (medical students and residents) allow scholarship funds to be available so the trainees can attend "carefully selected" educational conferences. The trainees must be selected by the training program, and appropriate conferences are meant to include the major educational, scientific and policy making conferences of national, regional or
specialty medical associations. Under no circumstances can a gift be accepted if there are strings attached.

11. What are the ethically acceptable options?

Gifts from industry, as noted above, are not absolutely prohibited. Support for the educational conferences may be welcome and valuable, as long as guidelines are met. Similarly, the use of free drug samples by Dr. Barker and his family is acceptable within certain parameters. Even attendance at educational conferences is possible within guidelines.

Conference organizers should be aware of the published rules, and utilize their institutional CME offices to help insure that they are in compliance. These offices may also provide help in determining the appropriateness of a conference opportunity sponsored by industry. If in doubt, discussion with faculty or with personnel at the AMA Section on Ethics may be useful. Physicians should not request specific drug samples for themselves. They may use samples otherwise available, but must make sure that this use does not interfere with patients having access to the medication samples.

12. What justifications can be given for the ethically preferred resolution of the case?

Note that the ethically optimal resolution may not be the one preferred by the residents. For example, not using drug samples will avoid any real or perceived conflict of interest, and insures that no patient will not have drug available because of physician behavior. However, physicians are not precluded from using the samples.

13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?

IV. References


PROFESSIONAL MISCONDUCT OF A SEXUAL NATURE

I. Learning Objectives
By the end of this case, neurology residents will:
1. be able to define and explain the following terms and concepts: professional conduct and misconduct, sexual misconduct, boundary issues, consensual and nonconsensual romantic and sexual relationships, AAN Code of Professional Conduct.
2. understand that what appears at the time to be a consensual romantic relationship may later be construed by the patient as the professional taking advantage of the patient's vulnerability.
3. understand that physicians may lose their licenses they engage in a consensual sexual relationship with a patient.
4. understand that the expense of litigation surrounding claims of sexual misconduct is not covered under malpractice insurance and that the physician must bear the full expense of legal defense.
5. be able to articulate the requirements of the AAN Code of Professional Conduct and integrate the requirements into their practices.
6. be able to recognize signs suggesting that a professional relationship is becoming a romantic relationship.
7. understand the professional standards that sexual or romantic relationships with current patients are expressly forbidden, and that sexual or romantic relationships with past patients are discouraged, and follow these standards in their own practice.
8. understand that sexual misconduct is only one form of professional misconduct addressed by the AAN Code of Professional Conduct.
II. Case

A middle-aged, divorced male neurologist had been treating a 35 year-old woman with common migraine for two years. She was a high school counselor, divorced, and the mother of two small children. She confided in him the emotional stress she suffered over her recent divorce, and he provided her with psychological support and neurological care. She responded well to the amitriptyline and naproxen he prescribed.

The neurologist looked forward to her office visits because he sensed a mutual physical attraction, and he believed that she behaved seductively in his office. He spent extra time talking with her and believed that this was therapeutically useful. Eventually, he began to date her and a romantic relationship developed into a sexual affair. He saw her rarely for appointments during their affair but continued to refill her prescriptions.

After two years, the neurologist discontinued the affair and began to date another woman. The patient became angry and contacted the state medical licensing board, accusing him of sexual misconduct with a patient. The neurologist admitted to the affair with her but claimed that he did nothing unethical because the sexual relationship was consensual. The state board acknowledged that the affair was consensual but nevertheless censured the physician claiming that any physician's sexual affair with a patient constituted professional misconduct.
PROPOSED OUTLINE FOR ETHICAL ANALYSIS

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I. Assessment
   1. What is the patient’s medical condition and prognosis? What treatment options exist?
   2. Who is the appropriate decision maker?
   3. What are the patient’s preferences?
   4. What are the preferences of her family or surrogate decision makers?
   5. Are there interests other than, and potentially conflicting with, those of the patient which need to be considered?
   6. Are there institutional, legal or other factors which need to be considered?

II. Identification of the Ethical Problem(s)
   7. What are the ethical problems in the case? (If appropriate, rank by magnitude.)
   8. What ethical considerations are most relevant?
   9. Are there analogous cases?
  10. What are the relevant guidelines for clinicians regarding the problem(s)?

III. Decision Making and Implementation
  11. What are the ethically acceptable options?
  12. What justifications can be given for the ethically preferred resolution of the case?
  13. How is a satisfactory resolution to the case to be accomplished? Is ethics consultation necessary or desirable? Is judicial review necessary or desirable?
III. Case Comments  
(by James Bernat, MD)

This discussion most appropriately begins with Question 7 in the Ethical Analysis.

B. Identification of the Ethical Problem(s)  
7 & 8 What are the ethical problem(s) in the case? What ethical considerations are most relevant?

There is a strong tradition in medicine that it is unethical for physicians to have sexual relationships with patients. In his Oath, Hippocrates made this specific prohibition very clear: "... I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons." (1) More recently, the American Medical Association Council on Ethical and Judicial Affairs reaffirmed its bright-line standard that all sexual contact between physicians and their patients counts as sexual misconduct. (2)

Sexual contact with a patient counts as professional misconduct because the physician is abusing or can be seen to be abusing the trust intrinsic to the patient-physician relationship. Patients consult physicians when they are ill and vulnerable. They communicate intimate information, surrender their privacy, and place the complete trust for their welfare in the hands of physicians. For physicians to take advantage of vulnerable patients for their own gratification is exploitative and counts as professional misconduct.

The degrees of sexual misconduct vary based on the consensuality of the relationship. Sexually assaulting a patient is the worst offense and, as is true of any sexual assault, is a serious violation of criminal law. Construing sexual activity with the physician as a form of therapy is next worst offense because of its clear exploitative and nonconsensual elements. Using the vulnerability of a patient to initiate a sexual relationship is next on the unethical scale because doing so psychologically manipulates and thereby exploits the patient. A consensual sexual relationship with a current patient generally is more unethical than such a relationship with a former patient. But even fully consensual relationships are unethical because physicians may use knowledge of the patient’s vulnerability or other protected information and emotions for exploitative purposes and because the romantic relationship probably will obscure rational medical judgment about the patient.

10. What are the relevant guidelines for clinicians regarding the problem?

In its Code of Professional Conduct, The American Academy of Neurology states that "The neurologist must not abuse or exploit the patient psychologically, sexually, physically, or financially" (3). The Council on Ethical and Judicial Affairs of the American Medical Association provides more specific guidelines. Nonsexual touching of patients is not forbidden, but physicians should take care that patients understand the nature of required touching during examinations.
One class of nonsexual touching is that which is required to perform an adequate physical examination. When the female breast or genital or anal area of a patient of either gender must be examined, the physician should explain the reason that an intimate part of the patient's body must be examined. Many physicians request that an office nurse or other third party be present during such examinations for their protection in the event that the patient later alleges professional impropriety. Such allegations may be more likely if there is an adversarial relationship between the patient and the physician; such as in the case of the physician who performs independent medical examinations.

Another class of nonsexual touching is the offering of affectionate and reassuring gestures to patients. Gestures such as pats or hugs, may be reassuring and comforting to patients in certain cases but physicians should approach this practice with caution and prudence to avoid misunderstanding.

All nonconsensual sexual contact with patients is expressly forbidden. Consensual sexual contact with current patients is unethical when the physician takes advantage or risks taking advantage of the patient's emotional or psychological vulnerability. Because these risks are inevitable in any ongoing patient-physician relationship, physicians are cautioned to immediately terminate any professional relationship when a romantic relationship with a patient begins.

The question of having a sexual relationship with a former patient is complex. Such relationships are unethical to the extent that the physician "uses or exploits the trust, knowledge, influence, or emotions derived from the former professional relationship."(2) In the case of an emergency room physician who saw a patient for a sore throat two years earlier, then began to date the patient after meeting at a party, it is unlikely that there is anything unethical in the romantic relationship because the previous professional relationship was so transient and limited. In the case of a psychiatrist, however, the intensity of the emotional professional relationship may have created such a prolonged effect that it is likely to endure for years and to influence the current romantic relationship. The American Psychiatric Association has warned that: "sexual involvement with one's former patients generally exploits emotions deriving from treatment and is therefore almost always unethical."(4).

C. Decision Making and Implementation
11. What are the ethically acceptable options?

Physicians should be alert to the developing signs of a romantic relationship, such as a physician devoting extra attention to the patient or scheduling appointments with the patient outside of regular office hours or in private, nonprofessional locations. Physicians should try to avoid developing romantic relationships with patients and should immediately terminate the professional relationship if a romantic relationship develops. Physicians should not have romantic relationships with former patients if they "use or exploit trust, knowledge, emotions, or influence derived from the previous professional relationship"(2). If physicians are not sure whether a romantic relationship with a former patient is unethical, they should discuss it with a few colleagues to get a more objective opinion.
What justifications can be given for the preferred resolution of the case? How is a satisfactory resolution to this case to be accomplished?

Unpleasant legal repercussions may follow unadvised sexual or romantic relationships between physicians and patients. Criminal law codes govern sexual assaults and other nonconsensual sexual contacts. A patient's formal complaint of sexual misconduct may be sustained, as in this case, even when the relationship clearly was consensual.

State medical boards and other disciplinary bodies are becoming more aware of and more active in their enforcement of rules governing sexual misconduct in the practice of medicine. Most state boards would revoke the medical license of, or provide other punitive actions against, a physician against whom a claim of sexual misconduct by a patient or former patient was sustained. Several states have enacted legislation punishing physicians for any physician-patient sexual contact. Physicians considering sexual relationships with patients, or even with former patients, would be well-advised to acquaint themselves with these statutes.

Physicians should also be aware that personal and institutional medical malpractice insurance does not cover sexual misconduct allegations, whether or not they are of a criminal nature. The full expense of defending these allegations must be borne by the physician involved.

IV. References


