Health Care Law

Mid-Atlantic Ethics Committee Newsletter

University of Maryland Francis King Carey School of Law   Year 1994

Mid-Atlantic Ethics Committee Newsletter, Spring 1994

This paper is posted at DigitalCommons@UM Carey Law.
http://digitalcommons.law.umd.edu/maecnewsletter/24
PERSISTENT VEGETATIVE STATE, CPR, AND FUTILITY

The cases of Helga Wanglie1 and Baby K2 have brought ethical considerations of “futility cases” to the forefront of attention. Also, state statutes in Maryland and Virginia allow physicians not to provide “unethical” or “medically ineffective” care. There is, I believe, much confusion among health care providers, ethics committees, and the public about what futile or medically ineffective care is.

This article is an attempt to provide a typology of cases so that the discussion can proceed with some logical clarity. Some authors have made the error of confusing cases that involve treatment that is physiologically futile with cases where the treatment under consideration is of questionable, but possible benefit, i.e., marginal care. Conflicts arise in these cases when patients or family members request treatment(s) that physicians see as inappropriate.

I believe that there are four types of such cases: 1) when the treatment being considered has no possibility of benefit, (i.e., physiologically futile); 2) when the treatment has a very small chance of providing some benefit; 3) when the treatment being requested

Letter From the Editor

If there is a theme to this issue of the newsletter it is medical futility. Our feature article is on futility and we have two short pieces on the subject—one, a follow up on the Baby K case, and another on Washington Hospital Center’s efforts to reach a consensus among Washington D.C. health care providers on what constitutes medical futility. I suspect it is a topic that we will continue to report on and debate for some time to come. As always, we also have our Network News, Educating Ethics Committees, and Case and Case Comments sections. I hope you enjoy the issue and your comments and suggestions are welcome.

Diane E. Hoffmann

has a good chance of providing some benefit, but at great cost to society or to the patient; and 4) when the patient requests marginal treatment that is potentially harmful. The first type of case involves physiologically futile care, i.e., the intervention would not alter in any way the patients’ condition, course of illness, or outcome. The other types involve marginal or even inappropriate, but not futile care.

There has been a trend over the last 30 years toward patients participating

Cont. on page 8
The Mid-Atlantic Ethics Committee Newsletter is published quarterly by the Institutional Ethics Committee Resource Network.

Individual Subscriptions/$35 per year
Institutional Subscriptions/$90 per year (up to 30 copies)

Diane E. Hoffmann, J.D., M.S., Editor
Nancy Zibron, Layout Editor

Contributing Editors:
Louis Breschi, M.D., Member, Ethics Committee, Franklin Square Hospital
John Fletcher, Ph.D., Director, Center for Biomedical Ethics, University of Virginia
Sigrid Fry-Revere, J.D., Ph.D., Independent Bioethics Consultant
Jackie Glover, Ph.D., Bioethicist, George Washington University Medical Center and Children's National Medical Center
Edmund G. Howe, M.D., J.D., Director of Programs in Medical Ethics, Uniformed Services University of the Health Sciences
Sanford Leikin, M.D., Adjunct Medical Officer, Office of Protection of Human Subjects, National Institutes of Health
Joan Lewis, Coordinator, Washington Metropolitan Bioethics Network, D.C. Hospital Association
Steven Lipson, M.D., Medical Director, Hebrew Home
Franklin Miller, Ph.D., Bioethicist, Member, NIH Clinical Center Bioethics Committee
Jack Schwartz, J.D., Chief Counsel, Division of Advice & Opinions, Maryland Office of the Attorney General
Ian Shenk, M.D., Member, Fairfax Hospital and Reston Hospital Center Ethics Committees
Henry Silverman, M.D., Chair, Ethics Committee, University of Maryland Medical System
Peter Terry, M.D., Member, Johns Hopkins Hospital and Francis Scott Key Medical Center Ethics Committees
Jan Vinicky, Ph.D., Bioethicist, Washington Hospital Center
Margot White, J.D.

The Institutional Ethics Committee Resource Network
Law & Health Care Program
University of Maryland School of Law
500 West Baltimore Street
Baltimore, MD 21201
410/706-7191 or 410/706-7239

The information in this newsletter is not intended to provide legal advice or opinion and should not be acted upon without consulting an attorney.

University of Maryland at Baltimore

NETWORK NEWS

Baltimore Area Ethics Committee Network (BAECN)

The network met on March 24th at Harbor Hospital Center. Patricia Mazzarella, PhD, co-editor with Edmund Pelligrino of Transcultural Dimensions in Medical Ethics (University Publications of America, 1993) spoke on Ethical Issues in the Treatment of Patients from Different Cultures, and facilitated a lively discussion on the topic. A short business meeting was held after the presentation and suggestions for future activities of the Network were solicited. A suggestion was made that we expand the participants in the Network to include not only members of ethics committees but philosophers and theologians interested in bioethics. The next meeting of the Network will be held on May 26th at Good Samaritan Hospital. The topic will be: Where do we go from here? Different models of ethics committee networks will be discussed and an effort to decide where the Baltimore Network is going will be made.

Washington Metropolitan Bioethics Network (WMBN)

The next meeting of the Washington, D.C. Network will take place on May 24th from 4:00 - 6:00 p.m. at Children’s Hospital. Jacqueline Glover, PhD, is organizing the program on medical decisionmaking by minors. Since the last newsletter the Network has met three times. Topics for meetings have included “The Ethics of Health Care Reform” (Feb. 23rd); “Ethical Implications of Health Care Decisions Laws,” (March 22nd) and “A Catholic Hospital’s Perspective on Bioethical Decision-Making,” (April 26th). For more information about the Network contact Joan Lewis at the District of Columbia Hospital Association (202) 682-1581.

Virginia Bioethics Network (VBN)

The second organizational meeting of the Virginia Bioethics Network was held on February 26, 1994 in Charlottesville. Guest speaker, Dr. Paul Schyve, Senior Vice President, Joint Commission for Accreditation of Healthcare Organizations (JCAHO), gave a comprehensive analysis of the activities and expectations of JCAHO concerning the development of guidelines and standards for activities related to ethics in healthcare institutions. He suggested that in the development of these guidelines and standards attention must be given to the concept of healthcare “systems” and to the system-wide ethical issues which may occur; since ethics issues occur throughout the system, the function and role of an ethics committee will inevitably broaden. Dr. Schyve said he hoped the VBN would give serious consideration to this approach as the development of recommended guidelines for ethics committees proceeded.

West Virginia Network of Ethics Committees (WVNEC)

In January, the West Virginia Network of Ethics Committees held the first half of its two-part training course entitled “Developing Expertise in Ethics Consultation” at a conference center in Flatwoods, West Virginia.

More than 125 people from 41 different health care institutions in West Virginia and Pennsylvania participated in the course dealing with the “who, what, and why” of ethics consultation. Organizers introduced participants to a comprehensive process for ethical consultation in patient care, provided a workable model for ethics consultation in community hospitals and nursing homes that lack individuals with extensive ethical expertise, and

Cont. on page 11
WASHINGTON, D.C.  
Medical Futility: Is There Consensus?

In follow up to its Seventh Annual Bioethics Conference: Medical Futility: Is There A Consensus?, the Washington Hospital Center Bioethics staff has been working with health care providers in the District of Columbia to develop a consensus statement on futility. At the conference, held on October 20, 1993, representatives from a variety of local DC area health care and academic institutions, representing a number of different professions and disciplines, viewed a video tape which addressed the issue of medical futility, listened to presentations by nationally known experts on medical futility, broke into discussion groups in which specific questions regarding the notion of medical futility were addressed, and came together again at the end of the day to share the results of these discussions. While no specific consensus was reached at the end of the day, a number of well-thought out and insightful suggestions and comments resulted from the day’s discussions.

A preliminary summary of those results was developed based on reports from the discussion groups, and plans are being made to distribute those results to individuals who participated in the conference and to additional selected members of the community. These individuals will be asked to review the preliminary results and to complete a consensus development survey. This survey is a second, more concise iteration of the discussion group reports. Based upon the results of this survey, it is hoped that a “consensus statement” with respect to a community understanding of the notion of “medical futility,” a community process for addressing the problem, and some community “guidelines” regarding medical futility can be developed which would be applicable and available to all area health care institutions. A final consensus conference report will then be distributed on the basis of a synthesis of the comments received.

VIRGINIA
Baby K Decision Upheld by Fourth Circuit

As reported in the Winter 1994 issue of this Newsletter, the United States District Court for the Eastern District of Virginia, Alexandria Division, held that the denial of ventilator services to an anencephalic infant who presents with respiratory distress would violate the Emergency Medical Treatment and Active Labor Act (EMTALA), the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 (ADA).

On February 10, 1994, the decision of the district court was affirmed by the United States Court Of Appeals for the Fourth Circuit in a 2-1 decision. The Fourth Circuit’s decision relied solely on EMTALA in holding that Fairfax Hospital must provide ventilator services to Baby K when she presents with an emergency condition and the mother requests that treatment be provided.

The opinions of the appellate court to support its position that a declaratory judgment should issue stating that it was not required under EMTALA to provide treatment to Baby K other than what it would provide to other anencephalic infants— that is, warmth, nutrition and hydration. These were: (1) that the Fourth Circuit had previously interpreted EMTALA as only requiring uniform treatment of all patients exhibiting the same condition; (2) that Congress did not intend to require physicians to provide treatment outside the prevailing standard of medical care; (3) that requiring a physician to provide such treatment to an anencephalic infant fails to recognize a physician’s ability under Virginia law to refuse to provide medically or ethically inappropriate care; and, (4) that EMTALA only applies to patients who are transferred from a hospital in an unstable condition.

Relying on a plain language interpretation of EMTALA, the Fourth Circuit rejected these arguments. The Court was adamant that “it [was] not [their] role to rewrite legislation passed by Congress. When a statute is clear and unambiguous, we must apply its terms as written.” As written, EMTALA requires a hospital to provide stabilizing treatment for an emergency medical condition so as to prevent a material deterioration of a patient’s condition. In this case, what EMTALA requires is that the Hospital provide ventilator services to Baby K when she presents for respiratory distress so as to prevent a material deterioration of her condition.

Contrary to the argument of the Hospital, the emergency condition is the respiratory distress, not the underlying anencephalic condition. Such distress can only be stabilized by ventilator services. Further, there is no clear intent on the part of Congress that physicians can refuse to provide treatment they believe to be outside the prevailing standard of medical care under EMTALA. “In the absence of a ‘clearly expressed legislative intent to the contrary, unambiguous statutory language is ordinarily conclusive.” Thus, the appropriate branch to address such an argument is Congress, not the judiciary.

The Hospital’s third argument that Virginia law recognizes the right of a physician to refuse to provide medically or ethically inappropriate treatment was rejected because EMTALA
STATE NEWS
Cont. from page 3

does not provide for such an exception and it also "clearly provides that state
and local laws that directly conflict
with the requirements of EMTALA are
preempted." Finally, the appellate
court rejected the Hospital's fourth
argument that the use of the word
'transfer' in EMTALA limits the duty of
hospitals to provide stabilizing treatment
to situations where the patient will later
be transferred elsewhere.

Thus, while the appellate court
recognized the difficult moral and
ethical issues involved in this case, the
relevant factor for it was the language
of EMTALA which the court believed
was clear: "EMTALA does not carve
out an exception for anencephalic
infants in respiratory arrest any more
than it carves out an exception for
comatose patients, those with lung
cancer, or those with muscular dystro-
phy--all of whom may repeatedly seek
emergency stabilizing treatment for
respiratory arrest and also possess an
underlying medical condition that
seriously affects their quality of life and
ultimately may result in their death."

Finally, the dissenting opinion
argued that EMTALA is strictly an
anti-dumping statute which was not
intended to reach a case such as this.
The dissenting judge stated that
Congress, in enacting EMTALA, did
not mean "for the judiciary to superin-
tend the sensitive decisionmaking
process between family and physicians
at the bedside of a helpless and termin-
ally ill patient under the circum-
stances of this case." Therefore, since
this case does not fall within
EMTALA's scope, the decision should
be left to state malpractice law.

MARYLAND
Physician Assisted
Suicide Legislation and
Poll Results

The bill drafted by the Maryland
Office of the Attorney General that
would have criminalized physician
assisted suicide in the state (SB 343)
did not pass. The bill was reported out
unfavorably by the Senate Judicial
Proceedings Committee on March 25,
1994 (by a vote of 7-4). The commit-
tee may have been influenced by the
results of a public opinion poll con-
ducted in Maryland in the midst of the
legislative session. The Poll, conducted
by the marketing research firm of
Hollander, Cohen & McBride in
Baltimore, MD asked 500 Maryland
residents the following questions: 1) Do
you believe there are circumstances
when a patient has a right to take their
own life, or do you believe suicide is
never justifiable? 2) There is legisla-
tion currently being considered in Maryland
permitting physicians to assist people
in taking their own life when the
following conditions apply -- the
patient persistently requests it, and is
suffering from a painful or distressing
physical condition from which there is
little or no chance of recovery. Assuming
these conditions apply, would you
prefer (A) a law permitting physicians
to assist in a suicide if they believe it is
fully justified; or (B) a law with severe
penalties prohibiting physicians from
assisting in a suicide. There were no
real differences in responses to this
question with respect to the
respondent's age or level of education
but those who attended religious
services weekly or more often were
somewhat more likely to favor a law
with severe penalties than those who
attended less frequently. Thirty-seven
percent of weekly attendees favored
severe penalties, while responses for
others for this option ranged from 12 -
15%. In terms of religious denomina-
tion, those of the Jewish faith were
more likely to favor a law permitting
physicians to assist in a suicide (96%)
other religious groups (Catholics
(66%); Protestants (68%); others (67%)).

Governor's Executive
Order

On March 29, 1994, Maryland
Governor William Donald Schaefer,
signed Executive Order 01.01.1994.11.
The order creates a Health Care
Decisions Act Advisory Council. The
function of the Council will be to (1)
Monitor whether and in what manner
health care facilities are advising
patients about their health care deci-
sions pursuant to federal law and the
Health Care Decisions Act; (2) De-
velop a means to survey how the
Health Care Decisions Act is affecting
influencing health care decisions;
(3) Review and, if necessary, make
recommendations for changes to the
Health Care Decisions Act of 1993;
(4) Review and analyze important
etical issues that arise from the Health
Care Decisions Act, and make rec-
ommendations if appropriate; and (5)
Educate the public and health care
providers regarding the law. The
membership of the Council is to
include 19 individuals who are ap-
pointed by the Governor and who are
"representative of diverse and pertinent
ethical, provider- and public-interest
viewpoints for staggered terms of three
years." The appointment process to the
Council is just getting underway.
Although two states, New Jersey and
New York, have established bioethics
committees to address bioethical/
Case Presentation

One of the regular features of the Newsletter is the presentation of a case considered by an ethics committee in the region and how the committee resolved it. Individuals are both encouraged to comment on the case or analysis and to submit other cases that their ethics committee has dealt with. In all cases, identifying information of patients and others in the case should only be provided with the permission of the individual. Unless otherwise indicated, our policy is not to identify the submitter or institution. Cases and comments should be sent to: Editor, Mid-Atlantic Ethics Committee Newsletter, University of Maryland School of Law, 500 W. Baltimore St., Baltimore, MD 21201-1786.

Case Consultation in a Research Institution

PRESENTATION: THE CASE OF SALLY

Sally is a 64-year-old widow with Alzheimer’s disease. Her only living relatives are a 55-year-old brother, Bob, and a son, Sam, age 37. Bob holds Sally’s durable power of attorney (DPA) which was signed 10 years ago. Since that time Sally has had a falling-out with Bob, and the two have had limited contact. Sally’s symptoms include mild memory loss and severe visual/spatial difficulties. In particular, Sally has difficulty orienting herself in space, often cannot name the objects in her visual field, and occasionally is unable to locate medium-sized objects placed directly in front of her. Sally’s symptoms began four years ago and progressed to the point where it became impossible for her to live on her own. For this reason, Sally moved in with Sam, who is a bachelor living alone. During her stay with Sam, Sally’s difficulties increased to the point where she became unable to take care of herself while Sam was at work. At that point, Sam took Sally to University Hospital to be screened for a phase 1 study on the possible benefits of medication M for the visual/spatial difficulties associated with Alzheimer’s. Six months later, Sally was entered into the study.

Sally’s DPA is silent on the issue of research medicine. However, during a phone conversation at the time of Sally’s initial screening, Bob told Sam that, as a teenager, Sally often discussed a neighbor who was involved in a polio study. At that time, Sally said that she thought participating in medical research provided a wonderful opportunity for helping others. As Bob remembers it, Sally also said that she would want to participate in such a study if the opportunity ever presented itself. Sam does not recall his mother’s ever talking about research medicine in particular, but he notes that she is the kind of person who was always trying to help others.

Sally has been in the study now for three weeks and is scheduled to continue for another four months. Because she has a history of self-medicating contrary to her doctor’s orders, Sally will not be allowed any passes off the unit for the duration of the study. While on the unit, Sally is occasionally disoriented and sometimes cannot perform routine tasks on her own. Sally’s medication involves her taking one tablet of M twice a day. In addition, the study requires various noninvasive diagnostic tests that last a total of two hours per day.

During rounds at the end of the third week, Sally tells the medical team that she wishes to go home. She refuses to answer any of the attending physician’s questions. Instead, she simply repeats her desire to go home. The nurses are visibly upset. The attending physician, Mary, acknowledges that Sally has been expressing this same desire to leave intermittently throughout the study. However, while doing the diagnostic tests, Sally invariably expresses a willingness to continue in the study. The primary nurse feels that Sally’s requests to go home have increased, both in frequency and in level of insistence, over the past few days. On further questioning, Sally states that the reason she wants to go home is so that she can go back to her job as a taxi driver, a job she held for 30 years. Mary feels that Sally should remain in the study, particularly because Sally’s impairment makes it impossible for her to drive a taxi.

Sam says that Sally’s requests are not surprising. Wherever Sally is, she states a preference for being somewhere else. For instance, while at Sam’s, she often said that she would rather be visiting friends. When at her friend’s house, she continually asked to go back to work. Sally has expressed to Sam her desire to leave the study, but, given that these requests seem part of a general pattern on Sally’s part, Sam is not sure how seriously to take them. Sam also thinks that Sally does not really seem herself lately, although he does admit that she is fairly lucid much of the time. Sam worries that if his mother is taken out of the study he will not be able to care for her adequately, given the amount of time he must spend at work. Sam cannot afford to hire a caretaker. The nurses think that it would be unsafe for Sally to be left alone.

The family has had no contact with Bob since Sam’s single phone conversation at the time of Sally’s initial screening approximately 7 months ago. At that time, Bob was living in California. The health care team has made several unsuccessful attempts to contact him there. Their only information has come from Bob’s most recent employer, who believes that Bob is now working on a ranch somewhere in New Zealand.

Submitted by
David Wendler and
Fredrick O. Bonkovsky
The National Institutes of Health,
Dept. of Bioethics
Case Presentation
Cont. from page 5

Case Discussion:
Comments From a Lawyer/Ethicist

Sally falls into the area of special concern we reserve for research subjects who are particularly vulnerable as a result of cognitive impairment. Sally’s diagnosis as an Alzheimer’s patient alerts us to review her participation in any research with care; we should be similarly careful that we do not use a diagnostic label to automatically exclude her from the potential benefits that research may yield. Four questions we should ask about research subjects who are cognitively impaired are: 1) What is the nature and degree of the impairment? 2) How likely are the benefits and how serious are the risks of the proposed research? 3) Are any appropriate natural or legal surrogates available to consent to research? and 4) How is consent to research (or refusal to participate) different from consent to (or refusal of) medical treatment?

What kind of impairment does Sally have?

Whether a person is capable of giving informed consent is a critical inquiry that must precede enrollment in a research protocol. Although we are told that Sally has Alzheimer’s disease, that diagnosis can include a broad spectrum of conditions. It alone does not tell us if she is functionally capable of volunteering for research. The evidence of impairment is at best, equivocal. On one hand, she suffers from mild memory loss and problems in visual/spatial orientation. Yet her son Sam describes her as “fairly lucid much of the time.” She alternates between acquiescence and objection to the research procedures she must endure, but indecision is hardly a reason to override the usual presumption of competence.

According to NIH policy, even people with a diagnosed mental disorder may be capable of consenting to be a research subject. A functional assessment of Sally’s condition that focuses on her ability to understand the conditions of a research protocol and its possible impact on her should have occurred prior to her enrollment in the drug study. Since it is possible that mental status may change as a function of mental illness, mental health professionals should periodically reassess Sally’s capacity.

What risks does Sally face as a research subject?

Sally is enrolled in a Phase I drug study. Phase I studies typically involve a relatively small group of healthy subjects who are closely monitored to determine whether an investigational drug is effective as a treatment for certain disorders, and also to determine what dosage levels are safe. The only known risks of a drug at this stage of development must be extrapolated from the reactions of animals who have received it; the Phase I trial represents the first use by humans.

No hard rules exist concerning the level of research risk to which impaired subjects like Sally may be exposed. Some minor increase over risks generally characterized as minimal may be appropriate in this case. The research focuses on a treatment that, if found safe and effective, will be of direct benefit to Sally in alleviating her problems with spatial/visual orientation. If Sally was capable of consenting to the research, very careful attention should have been paid to the information communicated to her during the consent process. Any benefits of the drug are at best speculative; any risks that are likely, or that are suggested by previous animal studies, should have been disclosed in detail.

The greatest risk in situations such as this is that inflated promises of a therapeutic breakthrough will prove too powerful an incentive for a desperate person to refuse.

Can anyone decide for Sally?

We are told that Sally’s brother Bob holds a ten-year-old durable power of attorney that designates him as her proxy to make health care decisions. But the document does not address Sally’s wishes concerning participation in research, and her only comments on the issue were apparently made almost fifty years ago. Even if state law allowed a proxy to volunteer someone as a research subject, (not all states do, most do not address the issue) general comments about “wanting to help others” made by an adolescent would not, absent other more compelling evidence, provide an adequate basis to justify proxy consent to potentially risky research. Since Bob is unavailable, the decision to continue Sally’s enrollment in research will not be his to make.

What are we to make of Sam’s role as proxy? State law may empower him--as a blood relative who is available and willing--to decide on Sally’s medical care. Most states have not clarified whether this power extends to the decision to volunteer a subject for research. Even if the law would allow Sam the role he has assumed, the research team should have been wary of the motives he stated for wanting his mother in the drug study. Sam’s major reason for volunteering Sally seems to have been his need for day care. She was unable to care for herself while he was at work; he saw the study as an opportunity to provide caretakers that he could not otherwise afford. Sam’s benevolent motive—wanting adequate daytime supervision for his mother—is in conflict with the role he might play as a proxy for her. Sam is an inappropriate proxy because he must weigh the potential risks of this drug study against benefits which currently rise only to the level of hope. He seems to have considered potential risks, if at all, as features of the research that are trumped by Sally’s need for assistance with the tasks of everyday life. If Sally cannot decide for herself, someone other than Sam should be sought as a proxy.

Is Sally in the hospital for treatment, or research?

Not only is Sam confused about his role, Mary, the attending physician,
Case Discussion: Comments From an Ethicist/RN

The case of Sally, a 64-year-old widow with Alzheimer’s disease who is enrolled in a research study, poses some interesting questions. The first question that comes to mind is: How was consent obtained for Sally to be enrolled in the research study and is this consent valid? I believe that this question can be adequately addressed with additional information about the case and legal advice so I will not focus on it. Ethical questions about the case, however, seem to include the following:

- Will the results of the research study provide any direct benefits to Sally?

- Does participation in the research study pose any risks to Sally’s emotional and physical health?

- What kind of planning ought to be occurring with this family to adequately provide for Sally’s future needs as her disease progresses and her mental and physical functioning decreases?

Benefits and Risks to Sally

Sally clearly seems to fall into the “vulnerable” category of potential research subjects. She is mentally compromised by her disease process and cannot be considered a voluntary, consenting subject. While there are no federally mandated regulations for research involving mentally ill or disabled individuals, there are proposed guidelines that ought to be taken into consideration. Whether participation in research by such subjects is at issue. Generally, research on mental patients and other formerly competent individuals should be conducted with the same restrictions that govern research involving children and subject to whatever wishes were expressed by the individual while they were competent. Since her brother, Bob, remembers that Sally once said that she would participate in a study (“a wonderful opportunity to help others”), there is reason to believe that having voiced this interest in the past while she was clearly competent, it is likely that she would want to participate in this study. Even though Sally might be considered incompetent to make such a decision now, her previous wishes should be considered a reliable indication of what she would choose now, if she were able to do so.

The research to study the possible benefits of medication M for the visual/spatial difficulties associated with Alzheimer’s disease is considered therapeutic research because it provides a direct benefit to the research subject. Sally is experiencing “severe visual/spatial difficulties” and it is no longer possible for her to be at home (the nurses believe that it is “unsafe”). It is reasonable to believe that the visual/spatial impairments are a significant factor in providing a safe environment for Sally. The research promises to benefit Sally directly by reducing or perhaps even correcting the impairments.

Is this promised benefit to Sally sufficient to ethically justify her participation in the study by proxy consent? Not entirely. To be ethically justified, the research should not pose an unfavorable benefit/harm ratio. It is not clear from the case report whether there are any side effects of medication M that might be considered harmful or whether there is a potential for medication M to contribute to Sally’s growing disorientation and inability to perform routine tasks. While Sally seems to be experiencing these difficulties, it is not clear whether they are a result of her disease process or a retractable side effect of medication M.

Supposing, for the moment, that medication M is not considered harmful to Sally and the research study poses low or minimal risk, should Sally’s confinement to the study unit be considered harmful to her emotional

submitted by
Paul A. Lombardo, Ph.D., J.D.
Institute of Law, Psychiatry
and Public Policy
University of Virginia

Cont. on page 8
Case Presentation
Cont. from page 7

health? She makes repeated requests to go home and sometimes refuses to answer the physician’s questions. Yet she continues to “assent” to her participation in the study by expressing a willingness to continue while undergoing diagnostic tests. If the tests were painful or caused Sally discomfort, surely she would not indicate her “assent” to continue! It would seem, on balance, that Sally is not experiencing significant harm from her participation in the study and might, in fact, be benefited from receiving medication M.

To be sure of this favorable benefit/risk ratio, however, additional information about medication M and its potential side effects should be obtained and assessed. In addition, standard tests to assess cognitive and functional status levels should be done for all patients like Sally. Significant losses of cognitive and/or function status levels due to temporary hospitalization or medication would be considered “harmful” in the care of any Alzheimer’s patient because adequate levels are crucial to enjoy daily comfort and quality of life.

Planning for Sally’s Future Needs

The most pressing ethical question in Sally’s case concerns planning for her future needs, once the research study is over and she is released from the unit. University Hospital and its personnel have an obligation to help Sally and her family make adequate plans for her future and ought not take advantage of her compromised state by merely using her as an end to their own ends by enrolling her in their research study! Respect for Sally as a person who was once competent and now dependent on others means that a progressive plan of care should be explained to Sam and Bob with the goal of promoting her comfort and quality of life as her disease progresses. Sally’s significant others have the right to make informed choices about her care based on accurate information. Alzheimer’s disease is a terminal illness. Education and support of close family members begins at the time of diagnosis and should continue throughout the course of the illness. Bob and Sam need information to help them understand treatment strategies in the care of the Alzheimer’s patient and how to make choices that will provide respectful care for Sally and allow her a dignified death. As has been pointed out by others (Volger, 1986), shared decisionmaking between the interdisciplinary treatment team and the family members of the Alzheimer’s patient is the optimal way to lessen the burden of making these decisions and to avoid pointless and cruel prolongation of the dying act.

Having Bob continue as her proxy decision maker while he is not even living in the same country and not readily available for decision making will be a living nightmare for the health care team! Something will need to be done about this. Hopefully, Sam is listed an alternative decision maker on the DPA if Bob is not readily available. If he is not an alternative decision maker, then legal advice should be sought to adequately address this problem.

Reference


Submitted by Sara T. Fry, Ph.D., R.N., F.A.A.N.
Associate Professor, School of Nursing
Co-Director, Center for Biomedical Ethics
University of Maryland at Baltimore
Baltimore, Maryland

Persistent Vegetative State
Cont. from page 1

in decisions about their health care. However most authoritative reports such as that of the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research are aimed at protecting patients from a physician’s attempt to treat them against their wishes. This does not necessarily mean that patients can demand treatment that is of no possible benefit, or is potentially harmful. If a patient requests potentially harmful treatment that is of little or no benefit (type 4), then a physician is obligated not to provide it in order to avoid doing harm (the principle of non-maleficence). If the patient requests treatment that is physiologically futile, and is not expected to be harmful (type 1), then the physician may or may not provide it, and is not ethically or legally obligated to do either.

Decisions in the other two types of cases involving marginal but non-harmful care, are more difficult. Until (and if) controls on costs and medical decision making are imposed at a policy level in the future, decisions regarding marginal care are best made in the context of shared decision making.

A good example of a type 2 case (small chance of some benefit) is when a patient is first diagnosed as being in a persistent vegetative state. Initially there is a small potential for recovery, but this chance is small. There are various factors that can be evaluated to determine the likelihood of recovering from this condition. No one has recovered over the age of 40 and most of those that have recovered have had head trauma or sub-arachnoid hemorrhage as the inciting injury. Length of time in a PVS is inversely correlated with good outcome. More recent data on head trauma patients in PVS shows that 14% of head trauma victims were discharged with the diagnosis of PVS. Of these patients, 58% had improved to better than vegetative state within three years, however, most of them had improved by six months, and
very few improved after 1 year in PVS. There is no mention, in this study, as to what functional level these patients recovered to, but presumably they were left with a significant neurological deficit. Overall, PVS greater than six months, and coma secondary to hypoxic ischemic injury indicate poor probability of recovery.

The treatment of PVS patients involves around-the-clock nursing care, gastric tube feeding, urinary catheterization, but usually not a ventilator. A decision about the withdrawal and initiation of such treatment should be in the context of shared decision-making. A decision about the burdens and benefits of the treatment and outcome is value laden. The potential benefit is that the patient has a small probability of some recovery (although probably to a dependent state). A second benefit is continued life in PVS; however, some would not consider such an existence to be a benefit. The burden of the treatment itself is near zero since patients in a PVS experience no pain, so there is no direct harm to the patient from the treatment. However, a decision about the relative burden of a dependent outcome is a decision best made by those who know the patient’s wishes best.

Therefore, the recommendation is that if a patient is in a PVS, a full disclosure including prognosis and the physician’s recommendation should be made to the proxy decision maker. If the physician recommends it, often this may lead to withholding or withdrawing treatment. However, treatment should be continued if the proxy feels that the patient’s wishes would be that a very small chance of recovery is worth the risk of the possible poor outcome.

The case of Helga Wanglie is an extreme example of this type of case. She was diagnosed as being in a vegetative state, and had a very small chance of recovery because of age, prolonged time in PVS, and hypoxia as the cause of the condition. Even in this extreme case the hospital did not withdraw life sustaining treatment despite the opinion of the medical community that to continue was “futile.” Because of the very small, but finite chance of recovery, and the knowledge that the patient valued life of any nature over death, the hospital was obligated to continue treatment as long as Mrs. Wanglie’s husband agreed to it.

Type 3 cases involve a question not of the probability of success but of the quality of the patient’s life and cost of the treatment. I suggest that this is also a value judgement, and a decision regarding this type of treatment, since the outcome might be considered successful by the patient, is best made by the patient or a proxy. A common example occurs when a patient with metastatic cancer and multi-organ failure discusses CPR with his physician. The physician does not want to provide CPR because she thinks that it is “not medically indicated,” but the patient decides that everything should be done.

What are the possible benefits of CPR? There are several studies looking at the efficacy of CPR in the hospital and, most assess success as survival until discharge. It has been shown that in-hospital mortality is related to sepsis, cancer, advanced age, the number of medications used in the resuscitation, and whether or not the event was witnessed. However, a significant number of patients survived 24 hours or more. There was an average survival of 14-21 days. These studies are helpful in allowing patients and physicians to make an informed decision about accepting CPR or not. Ultimately, the decision rests on the value a patient has of living perhaps one day or more, versus certain death if CPR is not performed, a judgement that the physician cannot possibly make.

The cost of such treatment may be very high. The average cost (in 1984) of a 14-day stay in the ICU was greater than $30,000. Ongoing research is attempting to collect quantitative data that would predict the outcome of intensive treatment for various clinical situations. These data may be useful in setting limits (through legislation, or hospital policy) to ICU stays for patients with sepsis, multi-organ failure, etc. because society or the community determines that surviving 2-14 days in a ICU does not justify the expense. However, these decisions of macroallocation do not belong in bedside decision-making between physicians and patients. Such decisions are especially inappropriate in the situation of a critically ill hospitalized patient who cannot seek another physician to provide the treatment, such as CPR, which they request.

The case of Baby K is another extreme example of this type of case. Baby K is an anencephalic infant who has survived an uncharacteristically long time. She is able to live in a nursing home, but requires artificial means of feeding. She periodically develops respiratory distress, requiring a visit to the nearby hospital, intubation, and a short ICU stay until the distress is treated. The hospital does not want to continue providing such aggressive treatment because of the poor quality of life Baby K will always have. However, the baby’s mother wants to continue such treatment because it will save her life. The ventilatory support in this case is not futile in the physiologic sense, but the overall benefit is marginal, and expensive.

We have seen that there are four types of cases regarding patients’ demands for futile or marginal care. In the first two types the physician is not obligated to offer the treatment because the treatment is harmful or of no benefit. In the other two types the benefit may be small, or unlikely, but the decision to accept this is value laden and physicians should not unilaterally decide not to offer such treatment. In the majority of cases, experience shows that a thorough informed discussion of the outcomes of the treatment, or small likelihood of success probably will lead to agreement to forgo such treatment. Society may decide to limit access to some treatments in specific circumstances, because it is costly and of little benefit. But otherwise physicians should be...

Cont. on page 11
Network News
Cont. from page 2

outlined the qualities of an ethics consultant to enable participants to choose consultants for their institutions.

The second half of the course, called “The How of Ethics Consultation,” will be held September 23rd. The faculty will include Jacqueline Glover, Ph.D., who directs the bioethics program at George Washington University, and Michelle Carter, RN and Ph.D. from the University of Texas.

The West Virginia Network of Ethics Committees has developed a checklist for health care surrogate selection to help health care institutions comply with the state’s Health Care Surrogate Act of 1993.

The first part of the checklist assists in determining whether the Health Care Surrogate Act is applicable to the case in question. The second part walks the individual through the process of selecting the surrogate in accordance with the new state law.

In most instances, a social worker will gather the information about the patient’s family or close friends and give this data on the checklist to the attending physician, who is authorized under the law to appoint the surrogate.

Attorneys, physicians, and social workers from around the network provided input for the checklist.

EDUCATING ETHICS COMMITTEES

ANNOUNCING . . .

The Center for Biomedical Ethics at the University of Virginia’s Health Science Center is offering a course on Developing Nursing Home Ethics Programs (DNHEP) from July 21 - July 23. This three day session is designed exclusively for nursing homes and other long-term care facilities.

DNHEP grows out of the success of the Developing Hospital Ethics Programs (DHEP) project and is a response to nursing home and long-term care staff and administrators who have asked for appropriate educational resources. DNHEP has been developed with their help and we believe the program addresses the neglected areas in terms of needed education in practical clinical ethics for nursing homes and long-term care facilities.

Developing Hospital Ethics Programs

The Developing Hospital Ethics Programs course will be presented on August 15 - 20, 1994. This unique program is a six day course of residential study for health care professionals from hospitals, and other health care institutions. The DHEP course is designed to facilitate or strengthen the implementation of an ethics program within these facilities by discussions about the theoretical and practical aspects of a “working” ethics program.

DHEP draws participants nationwide; from large, medium, and small hospitals, and from hospitals with ethics committees in various stages of development. Evaluations indicate it has been of significant help in the formulation and achievement of individual goals.

For further information about either of the two programs, please call the Center for Biomedical Ethics at (804) 924-5974.

Conference to Address Issues in Emergency Medical Services

On June 18th George Washington University School of Medicine and Health Sciences will sponsor a conference on “Facing Ethical Issues in Emergency Medical Services.”

The multidisciplinary program is geared toward paramedics, nurses, physicians, and hospital administrators, and seeks to address the ethical considerations in managing terminally ill patients and the theoretical principles of ethical practice in the everyday application to emergency care delivery.

Organizers say this program is unique in that there have been few courses dealing with ethics directed at physicians, and especially out-of-hospital care providers.

Topics will include “Informed Consent and Capacity,” “Withholding and Withdrawing Treatment” and “Patient Confidentiality and Provider Safety.” Among the faculty will be Craig DeAtley, Director and Associate Professor at the Department of Emergency Medicine at George Washington University, Jacqueline Glover, Ph.D., Director of the Program of Bioethics at the Department of Health Care Science at George Washington University, and Suzanne Chevlin, Coordinator of the Department of Bioethics at the Washington Hospital Center.
Persistent Vegetative State
Cont. from page 9
willing to offer therapy that may be
difficult, painful, or costly, if an
informed, capable patient or proxy
decision maker, chooses to accept it.

1. Angell, M. The case of Helga Wangle: A
New kind of “Right to Die” case. NEJM.
2. In the Matter of Baby “K” United States
Court of Appeals for the Fourth Circuit, No.
93-1899.

3. Levin, H.S. et al. Vegetative State After
Closed Head Injury: A Traumatic Coma
Data Bank Report. Arch. Neurol. 48 580-
4. Becker, G.J.; Strachow, G.O.; and
Saranchak, H.J. Outcome and Cost of
Prolonged Stay in the SICU. Arch Surg. 119.

Submitted by
Jackie A. Syme, M.D.
Department of Neurology
St. Agnes Hospital

CALENDAR OF EVENTS

MAY

May 10th Washington Hospital Center’s Bioethics Appreciation Dinner and Educational Seminar. Eric Juengst, Ph.D. will speak on “Ethics and Genetics”

May 13th Medical Humanities Hour, University of Maryland Hospital. Speaker: Edmund Pellegrino, MD, Professor of Medicine and medical Ethics, Director of the Center of Clinical Bioethics, Georgetown University Medical Center. Topic: Assisted Suicide and Active Euthanasia. Time: 1:00 - 2:00, Shock Trauma Auditorium.

May 19th-21st "Ethics Committees and the Young: Families, Hospitals and the Courts Trying to Do the Right Thing." a conference sponsored by St. Louis University School of Law, Medicine and Nursing in conjunction with the American Society of Law, Medicine & Ethics. Adam’s Mark Hotel, St. Louis, Missouri. For information call 617-262-4990.

May 24th Washington Metropolitan Area Bioethics Network Meeting, 4:00 -6:00 p.m. Children’s Hospital. Topic: Medical Decision-making for Children.

May 26th Baltimore Area Ethics Committee Network, 4:30 - 6:30 p.m. Good Samaritan Hospital. Topic: Where do we go from Here?

JUNE

June 2nd - 3rd “The Spiritual Dimension of Illness, Suffering, and Dying,” A conference for clergy, Ethics Committees and consultants and health care professionals, sponsored by the West Virginia Network of Ethics Committees. Location: Robert C. Byrd Health Sciences Center, West Virginia University, Morgantown, West Virginia. For more information call 304-293-7618.

June 10th Medical Humanities Hour, University of Maryland Hospital. Speaker: Drew Leder, MD, PhD; Assistant Professor, Loyola Collage. Topic: “Losing Patients: Technology and the Transformation of the Clinical Encounter” Time: 1:00 - 2:00, Shock Trauma Auditorium

June 18th Conference on “Facing Ethical Issues in Emergency Medical Services.” Sponsored by GWU School of Medicine and Health Sciences. Call Deborah Moser at (202) 994-4372 by June 10th to preregister.
SUBSCRIPTION ORDER FORM
THE MID-ATLANTIC ETHICS COMMITTEE NEWSLETTER

NAME ____________________________________________________________

ORGANIZATION ____________________________________________________

ADDRESS _________________________________________________________

CITY, STATE, ZIP _________________________________________________

No. of Subscriptions Requested:
    _____ Individual Subscriptions @ $35/yr.
    _____ Institutional Subscriptions @ $90/yr. (up to 30 copies)

Please make checks payable to: The University of Maryland

and mail to: The University of Maryland School of Law
            Law & Health Care Program
            500 West Baltimore Street
            Baltimore, MD 21201

All correspondence including articles, cases, events, letters should be
sent to:
Diane E. Hoffmann,
Editor
The Mid-Atlantic Ethics
Committee Newsletter
University of
Maryland
School of Law
500 West Baltimore
Street
Baltimore, MD 21201

The Institutional Ethics
Committee Resource Network
Law & Health Care Program
University of Maryland School of Law
500 West Baltimore Street
Baltimore, MD 21201