

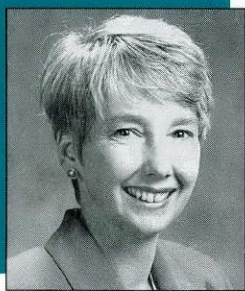
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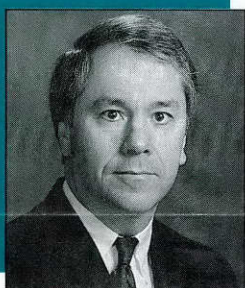
MD Anderson Oncolog

Handling medically inappropriate care requests: helping patients and physicians reach consensus

Ethics



Rebecca Pentz is M. D. Anderson's clinical ethicist



David Gershenson is a professor in the Department of Gynecologic Oncology

In the face of a grim prognosis, patients with late-stage cancers, as well as their families, may feel difficult emotions—denial, grief, and even guilt. Often these emotions cloud their ability to make choices about treatment. Further, with the medical advances of recent years, many patients and families have come to expect the miraculous. Refusing to give up hope for a cure, they may have trouble accepting that their physician has described all appropriate treatment options. They may ask their physician for treatments that they have heard have been successful for other patients, high-profile treatments that have made news headlines, or even treatments from protocols that they have found on the Internet, not understanding that their circumstances are different or that their disease is too far advanced.

In fact, from the physician's point of view, the requested intervention may be medically inappropriate. He or she may believe that the treatment will not help the patient get well enough to be discharged or improve the patient's quality of life. The physician may hesitate because the requested intervention would likely incur increased morbidity and higher health care bills without any benefit.

This conflict between hope and reality can add to the stress a patient and family are experiencing. It also presents an ethical dilemma for the physician, who is practicing medicine amidst pressures from the legal system, the government, and insurance companies. To help resolve such patient-physician conflicts, physicians and faculty at The University of Texas M. D. Anderson Cancer Center and other institutions of the Texas Medical Center have defined a policy outlining a step-by-step approach for handling requests for medically inappropriate interventions.

Rebecca D. Pentz, Ph.D., clinical ethicist at M. D. Anderson Cancer Center, described a 1993

case that helped spark the organized effort to establish an official policy. It was the first consult presented to M. D. Anderson's newly reconstituted ethics committee. "We had a patient who had terminal lung cancer and was intubated in the intensive care unit," Pentz said. "Her family insisted that she have very aggressive care, probably medically inappropriate care. When the ethics committee was consulted, we recommended that she not be resuscitated if she suffered cardiac arrest. The physician wasn't sure he could count on this brand new ethics committee and kept her on full support. She died four weeks later after some pretty aggressive, probably inappropriate, interventions."

What happened after this case was the formation of a city-wide task force in Houston, led by Baylor College of Medicine's Baruch Brody, Ph.D., director of the Center for Medical Ethics and Health Policy, and Amir Halevy, M.D., assistant professor of medicine and medical ethics. Physicians, patients, and patients' families were experiencing similar dilemmas at other hospitals in the Texas Medical Center, none of which had a formal policy or mechanism to deal with requests for inappropriate interventions. By early 1995, the task force, which included Pentz, had developed a prototype policy. "Three institutions have adopted it," Pentz said, "M. D. Anderson included. The rest have supported it in principle until we can get legislative support."

Policy outlines steps for resolving conflicts

M. D. Anderson's ethics committee has had 113 consults in the past three years, Pentz said. About 20 percent of those dealt specifically with requests for medically inappropriate interventions. And there have been many more instances in which the issue has come up but been resolved informally.

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To help patients and physicians develop a treatment plan they are both comfortable with, the policy lays out a formal process for attending physicians to follow when facing requests for treatments they think are futile. First, the physician carefully outlines to the patient or surrogate decision-maker the nature of the illness, the prognosis, alternatives such as palliative or hospice care, and the reasons why he or she believes the requested intervention is medically inappropriate. Next, the physician provides the options of transferring the patient to another physician or institution and obtaining an independent opinion on the appropriateness of the intervention in question. The third step entails offering the patient or surrogate decision-maker the assistance of other resources within M. D. Anderson, ranging from chaplaincy and social services to patient care representatives and the clinical ethics committee.

During the fourth step, the policy truly goes into effect. The attending physician obtains an opinion from a second physician who has examined the patient and then prepares to present the case, with clinical and scientific evidence that the intervention is inappropriate, for review by an institutional interdisciplinary body. In the fifth step, the physician informs the patient or decision-maker of the time and site of the review and the possible outcomes of the review; the patient can still choose to be transferred during this process. The institutional review is the sixth step. The physician and patient or surrogate decision-maker must be present at the review to voice their views about the intervention in question and possible alternatives.

In the seventh step, the review committee arrives at a finding. Decisions made by the review committee are binding, which Pentz said sets the policy apart from other ethics guidelines. "Almost all ethics committees are advisory only," Pentz said. "But if the medical institutional review committee decides that a patient should not receive further curative treatment, then the patient will not receive further curative treatment. Of course, such a decision will only be made after due process, and we will always offer palliative care and psychological support."

The task force did not specifically define medically inappropriate interventions because all of the existing definitions were inadequate, Pentz said, and attempts to come up with a new definition were fruitless. Instead, a case-by-case approach is taken, in which the evidence for and against each intervention is weighed.

"What we try to do in this policy is provide a fair review when the patient or surrogate feels

that they need an intervention and the physician feels that it is medically inappropriate," Pentz said. "Our approach provides both due process and a resolution to the dispute."

Physicians receive support from policy in making difficult decisions

The first to adopt the prototype policy was M. D. Anderson, an institution that deals regularly with life-or-death situations. According to David Gershenson, M.D., chairman of the M. D. Anderson case management executive committee, the development of a formal policy was welcomed by M. D. Anderson physicians and faculty. "In general, the reaction has been very positive," Gershenson said. "The physicians fully understand that these are difficult situations and that there are medical, ethical, and legal issues surrounding inappropriate care. Most of the physicians and faculty welcome any support they can receive from Dr. Pentz and others.

"There has been a tremendous change in philosophy in delivering medical care just over the last 5 years or so. It has, in general, been a difficult transition; I think we're all becoming more comfortable with it. There are still a few who might view these sorts of support systems as potential interferences in the doctor-patient relationship. But I think the policy simply facilitates and enhances that relationship in difficult circumstances."

The first three steps in the policy have so far proved adequate, and no cases have advanced to the review board, showing that physicians can come to a point of agreement with patients and their families. "A lot of it is educating the patient and the family and counseling them about what the options for medical care are, what the pros and cons are," said Gershenson, who is a professor and deputy chairman of the Department of Gynecologic Oncology. "We hope that early discussions will prevent any severe, significant problems down the road."

Gershenson and Pentz hope that the futile care policy will be adopted by other institutions. "I would like to see it be an industry standard," Gershenson said. "I think it helps the physician, patient, and patient's family to all feel comfortable with the level of care."

—DONALD R. NORWOOD

Clinicians who have questions or wish to request a copy of the futile care policy may call Dr. Rebecca D. Pentz, clinical ethicist, at (713) 792-3204 or write to her at Box 43, The University of Texas M. D. Anderson Cancer Center, 1515 Holcombe Blvd., Houston, TX 77030. ■

A step-by-step look at the policy

The following fictional account of one cancer patient and her family demonstrates step by step how the policy on requests for medically inappropriate interventions works.

An 11-year-old girl is admitted to The University of Texas M. D. Anderson Cancer Center for treatment of acute lymphoblastic leukemia. The patient is experiencing great bone pain and discomfort.

The girl's attending physician prescribes an intensive chemotherapy regimen, which the girl undergoes for 4 weeks. The attending physician prescribes continuation therapy during the fifth week and finds that her disease has gone into remission.

After about 13 months, the girl's disease relapses. The attending physician then suggests a bone marrow transplant. The girl's 16-year-old brother donates the bone marrow.

The girl survives the transplant although there are serious complications. She does well for about 5 months after receiving the transplant; then the disease recurs again. The physician prescribes an intensive chemotherapy regimen to try to induce a third remission.

The girl undergoes the chemotherapy regimen, but her disease does not go into remission. Feeling that another bone marrow transplant would be counterproductive, the physician has no choice but to prescribe palliative care.

The girl's parents become desperate upon hearing the physician's outlook on her condition. The girl's mother tells the physician that she has heard of a few leukemia patients surviving after receiving a second bone marrow transplant. Having found a suitable marrow donor in the girl's older brother, the mother requests a second transplant.

At this point, the attending physician again explains the nature of their daughter's disease and her prognosis. He also reassures the parents that abandoning curative therapy for the girl's leukemia does not mean that the institution is abandoning appropriate medical care.

The attending physician then gives the parents the option of transferring their daughter to another physician at M. D. Anderson or to another institution to obtain a second opinion. The parents turn down the offer.

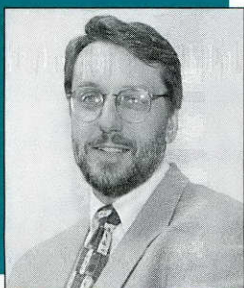
The services of several institutional resources within M. D. Anderson, including chaplaincy and social services, are offered to the family. The parents persist in their desire for the second marrow transplant, however, even after the attending physician tells them that the procedure would only add unnecessary suffering for the girl and medical costs for the parents. The physician obtains his own second opinion from another leukemia specialist at M. D. Anderson, who reaffirms his prognosis. The physician then has no choice but to present the case for review by an interdisciplinary body within the institution.

The physician informs the parents of the review, telling them that they can still transfer to another institution on their own; the parents decline. During the review, the physician and the girl's parents both express their views on the care the girl should receive, presenting information to back up their requests. The review board agrees with the physician's prognosis, assigning a plan of palliative care that ensures the girl's comfort until her death. The parents accept the decision and ask to meet with a counselor and support group.

—DONALD R. NORWOOD

Central Texas home to M. D. Anderson Environmental Health Science Center

Research



John DiGiovanni is associate director of Science Park—Research Division

Located in Smithville, Texas, between Buescher and Bastrop state parks is the M. D. Anderson Science Park—Research Division. In this tranquil setting in central Texas, more than 50 researchers are conducting laboratory and animal studies on the causes and prevention of cancer. Their findings have contributed to our growing understanding that many cancers are induced or accelerated by environmental factors, such as smoking, asbestos exposure, and dietary elements.

Last July, Science Park created a new program for continuing and expanding these studies, the Center for Research on Environmental Disease. The center, which is funded by a five-year, \$4.2 million grant from the National Institute for Environmental Health Sciences (NIEHS), a branch of the National Institutes of Health (NIH), is one of 17 NIEHS Environmental Health Sciences Centers, whose purpose is to study how our environment affects disease processes. The first of these centers was established more than 30 years ago, when the NIEHS decided that the most effective way to address this complex research prob-

lem was to promote cooperation between researchers working in different but complementary fields. The center in central Texas is a hub of collaboration, with members in Smithville, Houston, and Austin from the fields of epidemiology, pharmacology, and biostatistics as well as carcinogenesis.

Center's structure is multidisciplinary, dynamic

In creating the M. D. Anderson center, its director, John DiGiovanni, Ph.D., professor of carcinogenesis and associate director of Science Park—Research Division, has kept in mind the division's three goals—research, training, and public education.

To promote the first goal, research, the center formally brings together researchers from three different components of The University of Texas: Science Park—Research Division, the main M. D. Anderson Cancer Center campus in Houston, and The University of Texas in Austin. The 47 faculty members in the Center are organized by research interest into five research cores: Mechanisms of Chemical Disposition and Toxicity, Mechanisms of DNA Damage and Mutagenesis, Environmental Influences on Cell Growth and Differentiation, Environmental Epidemiology and Ecogenetics, and Nutrition and Disease Prevention.

"To qualify as a center, you have to already have a million and a half dollars in annual direct costs from peer-reviewed grants," explained DiGiovanni. "The idea is that the bulk of the money in the center grant is to provide support for already existing, funded research programs and for training people to work together." About 60% of the center's funds support six service core laboratories—Molecular Biology, Transgenic Animals, Histology and Tissue Processing, Flow Cytometry/Cell Elutriation, Analytical Instrumentation, and Biostatistics and Data Processing. These core labs perform assays that the individual scientists do not have the equipment or expertise to do.

DiGiovanni continued, "To be a full member in the center, you have to already have at least one peer-reviewed grant. There are also associate members, good people who don't have



Irma Gimenez-Conti of the Histology and Tissue Processing core lab cuts a tissue sample.

funding for a short time and junior faculty who could benefit from interacting with center members. Associate members have access to center resources through collaborations with full members. Everything is designed to try to get people to work together.”

Project draws together epidemiology and molecular biology

One of the projects that has flourished as a result of such interactions is a study of smoking and lung cancer. With her colleagues in the Department of Epidemiology, Margaret R. Spitz, M.D., M.P.H., professor and chair, Department of Epidemiology, and head of the Environmental Epidemiology and Ecogenetics research core, is conducting a study of susceptibility markers in lung cancer. Spitz’s coworkers have developed an assay to measure individual sensitivity to smoking-related carcinogens by using white blood cells, which are easy and inexpensive to obtain from large numbers of people. A pilot study showed that smokers with lung cancer were more likely than smokers without lung cancer to be mutagen sensitive. By working with DiGiovanni and other members of the Mechanisms of DNA Damage and Mutagenesis research core and the Molecular Biology service core, Spitz and colleagues were able to extend their work by showing that there was a consistent relationship between mutagen sensitivity and the level of DNA adducts, which are the actual physical changes mutagens make in DNA.

Center recruits new members

While the research cores are organized to encourage collaboration, their composition is not static. “That’s one of the great things about the center grant,” said DiGiovanni. “The makeup of the center is now what we thought was important at the time we submitted the grant proposal, but the center is dynamic, and as needs and research areas change, we are entitled to make changes and allocate our resources differently. Out of necessity, we must. What we think is important now might not be in five years. Already I see some new research directions.”

NIEHS centers are organized to respond to those changes in research direction by adding new researchers. The Science Park center can fund five or six pilot projects a year. “The idea is to fund somebody who’s got a great idea but needs to generate some preliminary data to get



Michael LaBate of the Molecular Biology core lab analyzes samples by gel electrophoresis.

an NIH grant, and also to bring new people into the center from the three component campuses,” DiGiovanni explained. The success of the pilot projects and whether they eventually are funded by the NIH will be one of the criteria by which the achievements of the center are measured when its grant is up for renewal in five years.

Training new scientists a priority

Training young scientists is the center’s second aim. Science Park—Research Division already awards M.S. and Ph.D. degrees through The University of Texas Graduate School of Biomedical Sciences in Houston and a variety of departments at The University of Texas in Austin. The center grant will allow Science Park—Research Division to fund undergraduate and high-school students in its summer scholars program.

A seminar series, which will feature seven to ten internationally known environmental-health scientists each year, is part of the center’s commitment to educating both its faculty and its trainees. The seminars, which are held at all three campuses, are transmitted to all center members using teleconferencing technology.

Speakers bureaus will educate public

The third goal of the center is educating the public through a public outreach program

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The Environmental Health Sciences Center comprises research, training, and public education programs

Environmental disease research

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headed by Robert M. Chamberlain, Ph.D., associate professor of epidemiology, M. D. Anderson Cancer Center. Science Park—Research Division has always had a speakers' bureau that provided interested public groups with expert lecturers, and through the center the bureau is being expanded. "We are extending the CancerWise Community Speakers' Bureau [an M. D. Anderson program based in Houston] into the central Texas community. We are also going to develop an environmental health community speakers' bureau to talk about general environmental health issues. Probably the first thing we will develop is a module on risk of other diseases from environmental exposures."

The center also takes calls for general information on cancer and other environmentally related diseases. Calls about cancer are referred

to the Cancer Information Service ((800) 4CANCER).

"Science Park's recent designation as an Environmental Health Sciences Center recognizes our key role in advancing the nation's health," DiGiovanni said. The three goals of the center—research, training, and public education—make it a unique resource for Texas and the country.

—MAUREEN E. GOODE

Physicians who desire additional information may write Dr. DiGiovanni, Center for Research on Environmental Disease, The University of Texas M. D. Anderson Cancer Center, Science Park—Research Division, P.O. Box 389, Smithville, TX 78957, or call (512) 237-2403. For information on speakers, call Don Cook, coordinator of community outreach and education, at (512) 237-9404. ■

Neuropathology second opinions

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Study shows second opinions to have significant clinical impact

The M. D. Anderson Cancer Center study evaluated the number and types of diagnosis errors detected by the Section of Neuropathology and the types of changes in diagnosis that were suggested. The study showed that a significant number of diagnosis errors had been detected before irreversible treatment damage or neglect had occurred.

Of 500 second-opinion reviews, 214 (43%) showed some degree of error. Forty-four of the 214 discrepancies (21%) were considered to be errors that would result in serious complications for the patient, that is, an immediate or delayed consequence affecting survival or quality of life.

Ninety-six of the 214 discrepancies (45%) were less serious but substantial in nature. These errors were deemed less likely to affect long-term survival but were likely to affect the patient's immediate treatment plan. Fifty of the 214 discrepancies (23%) were considered to be minor errors for which the originally prescribed treatment would not be changed.

The study findings emphasized the role of radiologic studies and clinical information in the accurate interpretation of brain and spinal cord biopsies. In addition, in some cases, results of immunohistochemistry, *in situ* hybridization, and electron microscopy confirmed a change in diagnosis.

“We regard ourselves as partners with the community-based physicians and pathologists”

Brain and spinal cord tumors pose particular challenges

Second-opinion diagnoses are considered particularly prudent for brain and spinal cord tumors. These tumors are uncommon in a general pathology practice; yet they are often life threatening. For this reason, before making critical care decisions, community clinicians and pathologists may feel more comfortable consulting with a specialist who deals more frequently with these diseases and their radiologic and biologic characteristics. “On average, M. D. Anderson’s neuropathology service reviews about 1500 cases of brain and spinal cord tumors annually, whereas fewer than 100 such cases are typically diagnosed at a general acute care community hospital with an active neurosurgery practice,” Bruner said. In addition, M. D. Anderson’s multidisciplinary approach means that other specialists, such as neurosurgeons, neuro-oncologists, and neuroradiologists, are available for diagnostic and therapeutic consultations.

Another reason second-opinion diagnoses may be helpful when brain and spinal cord neoplasms are indicated is that these tumors can mimic other disorders. “Stroke, infection, and even multiple sclerosis have been mistaken for brain or spinal cord tumors,” Bruner explained. “Likewise, benign diseases sometimes appear malignant on the original pathologic analysis. Such misdiagnoses could lead to serious, costly treatment errors and unnecessary suffering for patients.”

Bruner described a case in which a patient was referred to M. D. Anderson for treatment of a benign meningioma. When the patient’s biopsy slides were reviewed by neuropathologists at M. D. Anderson, a routine process before a patient is treated, the diagnosis was changed to oligodendroglioma, a malignant primary brain tumor. The treatment plan had to be completely revised. In another case, a patient was sent to M. D. Anderson for radiotherapy after being diagnosed with a malignant brain tumor. Neuropathology review at M. D. Anderson revealed evidence of multiple sclerosis rather than a tumor; radiotherapy would have been inappropriate.

Some patients have come to M. D. Anderson on physician or self-referral for treatment of post-radiotherapy discomforts they attribute to tumor recurrence. “In some cases, we have found that the patient never had a tumor, underwent radiotherapy unnecessarily, and is experiencing side effects caused by the radiotherapy,” Bruner said. “In one case we reviewed, a patient had been diagnosed with glioblastoma, a highly malignant brain tumor, and had received radiotherapy to the brain. When the case was re-diagnosed, we discovered that the patient actually had benign central neurocytoma, a tumor that can be cured with surgery.”

The goal of the referral and, likewise, the second-opinion review is to optimize patient care. “This is not a finger-pointing process,” Bruner said. “We’re teaming up with the community-based clinicians and using our expertise to deliver the most accurate diagnosis. In many cases, we end up confirming the initial diagnosis, but it is always good news for everyone involved when we can reverse a dreadful diagnosis.”

Second-opinion diagnoses can be cost effective

The cost of a second-opinion diagnosis at M. D. Anderson is usually less than \$200; but, as the study shows, this fee is well justified when compared with a loss of tens of thousands of dollars for a treatment based on a misdiagnosis, the potential harm (or even death) of the patient, and physician liability for an incorrect treatment.

“The study confirms that second-opinion diagnoses optimize patient outcome while cutting total medical costs,” commented Bruner. “Our findings also should help third-party insurance companies and managed care organizations justify the cost of second opinions.”

—VICKIE J. WILLIAMS

Physicians who desire additional information may write Dr. Bruner at the Department of Pathology, Box 85, The University of Texas M. D. Anderson Cancer Center, Houston, TX 77030; call (713) 792-7935; or send e-mail to janet_bruner@path.mdacc.tmc.edu. To refer a case for diagnosis, call the New Patient Referral Office at (800) 392-1611 (in Houston, (713) 792-6161).■

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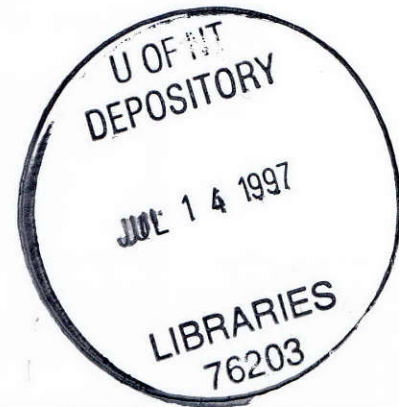
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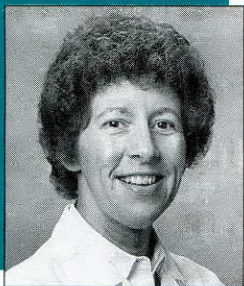
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Second-opinion consultations assist community physicians in diagnosing brain and spinal cord biopsies

Diagnosis



Janet Bruner is chief of the Section of Neuropathology

Reliance on second opinions is common practice when making many kinds of decisions. Few people, for example, accept the first estimate they receive for a major automobile or home repair; most typically "shop around." Even when the second estimate is the same as the first, the second opinion gives consumers the confidence they need to make their decision.

With the increase in the incidence of cancer, a peer structure has emerged in which community physicians and diagnosticians often consult with oncology and pathology specialists regarding cancer diagnoses and treatment planning. Such consultations are gaining acceptance as an important aspect of the health care continuum, says Janet Bruner, M.D., neuropathologist and chief of The University of Texas M. D. Anderson Cancer Center's Section of Neuropathology, who, along with her colleagues, regularly provides second-

opinion diagnoses. "We regard ourselves as partners with the community-based physicians and pathologists," Bruner said. "They refer cases to us for review because we have the latest available technology and up-to-date information as well as greater experience in cancer diagnosis. Both the physician and the patient can be assured of an expert diagnosis while still opting for local care. It is a team approach that benefits everyone."

Some insurance companies argue that second opinions are unwarranted, that the cost is not justified. However, the results of a study conducted by the Section of Neuropathology suggest that second-opinion diagnoses are prudent and cost-effective and have important implications as a strategy for optimizing patient care and ensuring medical and legal integrity. The study was published in the February 15, 1997, issue of the journal *Cancer*.

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