The Role of Bioethics Research in Enhancing Patient Care

When Marion Danis, MD, spoke at the May 2010 Bioethics Research Day at Cleveland Clinic, she urged the clinicians and researchers in attendance to ask themselves: Where does bioethics really make a difference?

It’s clearly an important question to Dr. Danis, Chief of the Bioethics Consultation Service and Head of the Section on Ethics and Health Policy at the National Institutes of Health. And it’s at the heart of the research being done in the Department of Bioethics at Cleveland Clinic.

“All of the research we do here in the department is driven by our interest in improving patient care,” says Richard Sharp, PhD, Director of Bioethics Research. For Dr. Sharp and his colleagues, making a difference means helping patients now and in the future.

Whether the aim is improving communication with patients, making sure new technologies are handled in a responsible way or changing the way in which end-of-life options are presented, “The primacy of patient care is so, so fundamental to what we do,” he says. “It really is the focal point of our work.”

The department is unique in its emphasis on practical research. “I think Dr. Danis was pleased to see the work we are doing, and she would like to see [similar work] established more globally,” says Dr. Sharp. In the past five years, Cleveland Clinic’s bioethics researchers have received more than $10 million in grant funding, primarily from the NIH.

More than a dozen projects are under way, including one regarding the informed consent process used in enrolling pediatric cancer patients in Phase 1 clinical trials. The patients in this study have experienced a recurrence of cancer, leaving them with few or no medical options that would lead to cure. “A clinical trial offers very little chance of medical benefit for these patients, but it would advance medicine,” says Amy Yamokoski, MA, team leader for the project, which involves six children’s hospitals across the United States. (For more information on the project, see article on page 5.)

Some goals of this descriptive study are to record what actually transpires during conversations between clinicians and families and determine what parents and older child-patients understand about their options, including the Phase 1 clinical trial, says Ms. Yamokoski, Senior Research Coordinator in the department. “We want to use our findings to ensure that families and clinicians are getting the most out of their communication with one another so that parents and children can make good decisions for themselves and everyone can help to move medicine forward.”

Established 26 years ago, the Department of Bioethics is one of the older programs in the country. It was started early on partly because of the high-tech nature of Cleveland Clinic and “partly due to the hospital’s tradition of clinical innovation,” Dr. Sharp says. He notes that the department’s bioethicists were involved with the ethical issues surrounding the face transplant, which took place in December 2008, and are involved with research related to cancer, genetics, digestive diseases and neurology.

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Dear Colleague,

We are proud to announce the formation of the Center for Ethics, Humanities and Spiritual Care (CEHSC), which will bring four previously separated units — Bioethics, Spiritual Care, Medical Humanities and NeuroEthics — into one centrally structured collaborative organization. I am honored to be named the Director of this Center.

This innovative merger follows the success of the institute model of care that Cleveland Clinic adopted in 2007, emphasizing positive relationship building and best practices through thoughtful collaboration.

Martin Smith, STD, is serving as CEHSC’s Associate Director for Clinical Ethics and Spiritual Care; and Richard Sharp, PhD, is the Associate Director for Research and Education. Department leaders include Paul Ford, PhD (NeuroEthics), the Rev. Dennis Kenny, DMin (Spiritual Care), and Martin Kohn, PhD (Medical Humanities).

Aligning these departments will allow us to share our knowledge and resources more effectively. We see CEHSC as an extension of Cleveland Clinic’s central mission of collaboration, compassion and innovation in caring for patients.

You can delve deeper into this mission by reading the articles in this issue of Bioethics Reflections. In addition to the cover story, which explores the role of bioethics research in enhancing patient care, you will read about the informed consent process in pediatric cancer research; the issues surrounding geriatric cancer care; ethics consultations at our regional hospitals; and a new collaborative venture – the Center for Genetic Research Ethics and Law (CGREAL). CGREAL is one of six centers of excellence nationwide funded by the NIH’s National Human Genome Research Institute. In addition, there’s a profile on former fellow Karen Maschke, who is now a research scholar at The Hastings Center in Garrison, N.Y., and editor of IRB: Ethics & Human Research.

Thank you for your interest in Bioethics Reflections. We hope you enjoy this issue.

Sincerely,

Eric Kodish, MD
F.J. O’Neill Professor and Chairman,
Cleveland Clinic Bioethics Department
Geriatric Cancer Care: Researcher hopes to ascertain the role of age in cancer treatment decisions by older patients

As a society, we have yet to form a consensus on the value of cancer care – what chance of success and degree of benefit justify the expenditure of limited resources.

This ethical and philosophical debate plays out every day at Cleveland Clinic and other cancer centers around the country. Many cancer patients ask themselves whether they should choose a treatment that is costly but could prolong their lives for an undetermined amount of time. The trade-offs can be even more challenging for elderly patients diagnosed with cancer.

Even as the field of geriatric oncology grows, its goals are not uniformly stated. Some healthcare professionals assert that treatment of elderly cancer patients should aim to maintain or augment quality of life; others emphasize identifying effective treatments for the geriatric population as the goal, implying that any divergence from the approach taken with younger cancer patients reflects rationing or age-related bias.

Anne Lederman Flamm, JD, Associate Staff in Cleveland Clinic’s Department of Bioethics, hopes to shed new light on this ethical debate. She is proposing a research project that involves interviewing elderly cancer patients about whether and how their age and the cost of treatment influence their decision to pursue or reject chemotherapy.

Her aim is to increase the understanding of how elderly patients think about cost and age, allowing oncologists to feel more comfortable speaking with them about these issues. “Oncologists need to recognize the influence of cost on treatment decisions,” Ms. Flamm stresses.

Rising population, rising cancer rates
The influences of age and cost considerations have yet to be thoroughly investigated, but they are important because geriatric patients tend to be on fixed incomes, and they have comorbidities concurrently requiring medical treatment and other forms of supportive care.

Ms. Flamm says her urgency to research these issues is based on U.S. Census Bureau projections that the number of people age 65 and older will double from 35 million to 70 million by 2030, comprising about 20 percent of the population. More than 5 percent of the population will be age 80 and older.

The incidence of cancer diagnosed in the elderly is also rising, she says. The rising costs of cancer care further heighten the need to clarify what benefit and value mean to cancer patients.

She acknowledges there are empirical studies suggesting an age bias against treating geriatric cancer patients across treatment options – including surgery, chemotherapy and radiotherapy – despite evidence they tend to do as well as younger patients when stage-appropriate therapies are administered. “Age itself is not the kicker for whether a patient will or will not do well,” Ms. Flamm notes, adding that other issues, such as performance status, renal function or a combination of factors, might be better predictors of success. “Just knowing a patient is 75 is proving not to tell you much.”

Yet, there is uncertainty and a lack of best evidence as to how to treat geriatric cancer patients. Physicians often reduce the standard dosage of a cancer-fighting drug because they are worried about greater side effects or greater impact of known side effects.

Elderly patients are historically underrepresented in clinical trials compared with pediatric patients and younger adults. When they are offered participation, elderly patients don’t decline at any greater rates than other groups, but they are not offered the opportunity as much. Is that bias, uncertainty or is it legitimated in some way by outcomes? “We don’t have the empirical piece definitively answered yet,” Ms. Flamm says. “But depending on what you read, there are people who find it to be age bias.”

There is a growing movement among some geriatric oncologists to focus clinical studies directly on elderly cancer patients. Another push is for a more comprehensive geriatric assessment before designing and recommending treatment options, though Ms. Flamm points out the present state of healthcare does not lend itself to compensate in terms of time and money for an assessment that can take two hours or longer. (One of the initiatives of Cleveland Clinic’s Geriatric Oncology Group is to develop a screening assessment to indicate whether a patient needs a full, comprehensive assessment.)

Is it age bias?
Ms. Flamm hopes her research illuminates whether and how geriatric cancer patients factor their age into the decision-making process; for example, whether and how often patients conclude, “I would choose this treatment if I was 70, but not at 90,” and if so, what their reasoning is. Is it because they are satisfied with having lived a full life and they don’t want to experience treatment hardships for what they see is a limited payoff, or are there other considerations?

Is that attitude age bias? To the most objective and dispassionate person, the answer is yes. But is it age bias if the patient makes the decision for himself or herself?

These questions have implications not just for individual patient encounters but for societal policy as well. Few find age-based limitations a comfortable proposition to redress rising cancer care costs. “Should we weigh decisions in geriatric vs. non-geriatric settings differently?” Ms. Flamm asks. “I would say we could avoid it by being just as explicit and comprehensive in weighing the benefits and costs of cancer treatments at every stage of life.”
Jan Vinicky, PhD, persuaded Cleveland Clinic to hire her as a part-time consultant in 2006 to determine whether there was a need for someone to provide expert advice to Cleveland Clinic’s regional hospitals’ ethics committees. The need was there, so in 2007 she began coordinating clinical ethics services in the eastern regional hospitals under the direction of the Division of Medical Operations.

What she found during her needs assessment was that each hospital had developed its own way of conducting ethics consultations, according to the hospital’s available personnel and resources. For example, at some hospitals, ethics consultations were provided by physicians, while others used a team approach. Some hospitals had different ethics-related policies for different ethical issues, such as DNR Orders and Advanced Directives.

Dr. Vinicky also found that many of the regional hospitals’ ethics committees welcomed her expertise to rejuvenate their efforts. “Some committees were meeting regularly while some were not.”

She found strong support among the staff in the Department of Bioethics to continue to work with and support the regional ethics committees. As a formal recognition of her achievements and plans, she joined the Section of Regional Bioethics in the Department of Bioethics on June 15 and works closely with Martin L. Smith, STD, Director of Clinical Ethics. She is based at Cleveland Clinic Hillcrest Hospital but remains available to the ethics committees, healthcare professionals, patients and families of each regional hospital.

“Instead of each regional hospital taking on clinical ethics by itself, there is expert advice, education and policy direction available to the entire system,” she says.

Her challenge is to create an environment that takes into account the different cultures of the regional hospitals without compromising basic competencies essential to clinical ethics services. For example, the hospitals and their ethics committees will remain autonomous in how they carry out ethics consultation services.

She maintains that consistency in ethics-related policies for the regional hospitals is crucial, despite differences in institutional cultures and work environments. Many doctors see patients at more than one regional hospital; consistent ethics policies and procedures will contribute to good patient care, she points out.

Dr. Vinicky also wants to have a standardized ethics consult database for the regional hospitals. She envisions the collection of similar information for each ethics consultation at each hospital (e.g., What were the ethical issues in the case? What were the recommendations and ethical justifications?). “Collecting this kind of information should aid quality improvement efforts” throughout the Cleveland Clinic hospital system, she says.
By the time the family of a pediatric cancer patient considers whether the child should participate in a Phase 1 cancer trial, all available treatment options have been exhausted. The chance of medical benefit from the trial is only 5 to 10 percent, yet many families hope that the new therapy will cure the disease, provide better quality of life or serve as a bridge to another treatment that might become available. “Families confront incredibly difficult decisions – whether to enroll in a trial with limited chance of personal medical benefit that will advance scientific knowledge and may benefit other families, or to pursue other options, such as unconventional therapy or hospice care,” says Amy Yamokoski, MA, Senior Research Coordinator in the Department of Bioethics at Cleveland Clinic.

Uncovering the reasons why patients and parents decide to participate in Phase 1 childhood cancer trials and understanding their decision-making process are two of the goals of an ongoing multisite study, Phase 1 (One) Informed Consent (POIC), led by the Department of Bioethics with co-investigators at six children’s hospitals: Children’s National Medical Center, Washington, D.C.; National Cancer Institute-Pediatric Oncology Branch, Bethesda, Md.; Children’s Hospital of Philadelphia; Children’s Hospital Pittsburgh; St. Jude Children’s Research Hospital, Memphis; and Children’s Hospital and Regional Medical Center, Seattle. Begun in 2008, the study will continue until 2012 or 2013.

Study investigators aim to develop a fuller understanding of the Phase 1 consent communication process, the comprehension of parents and children, and the perspectives of clinician-investigators with the long-term goal of improving care for children with refractory cancer. “We want to learn what’s happening during Phase 1 consent conferences: how much parents understand and if there are fundamental misunderstandings so that we can improve the process for children and families,” says Eric Kodish, MD, holder of the F.J. O’Neill Endowed Chair in Bioethics and Chairman, Cleveland Clinic Bioethics Department, Professor of Pediatrics at the Lerner College of Medicine and principal investigator for POIC.

The Phase 1 study builds upon previous research on communication in Phase 3 childhood cancer trials, in which the situation is the opposite of that which is faced by parents in Phase 1 trials: the child has just been diagnosed and, in some cases, the family must decide quickly whether to participate in a Phase 3 trial. At this early stage, they have limited understanding of the disease and diagnosis. “We’re communicating very difficult concepts in a short period of time,” says Justin Baker, MD, co-investigator of the study. He is Director, Hematology/Oncology Fellowship Program, Attending Physician, Quality of Life Service, Division of Palliative and End of Life Care, St. Jude Children’s Research Hospital. “It’s hard for families to understand that they are participating in research while receiving the standard of care.”

Based on extensive parental input elicited from post-conference interviews, focus groups and a parent advisory group on informed consent, the research team developed specific guidelines for organizing the Phase 3 informed consent process, known as the PAGIC Model of Informed Consent (Pediatrics, April 2007). The PAGIC Model emphasizes allowing more time for family decision-making, providing more information about the trial and checking to make sure the information is understood. “The PAGIC Model may not be right for Phase 1 trials. We may adapt it or develop a new model,” says Dr. Kodish.

Yamokoski says the Phase 1 POIC methodology includes oncologist questionnaires along with the recording of consent conferences and interviewing of parents and patients who are 14 and older. “Families allow us to peek into their lives during a very difficult time so we can understand what is and isn’t going well,” she says. “These families are selfless in the midst of turmoil.”

The oncologist questionnaires already have been analyzed and the results published in the July 2010 issue of Cancer. The 103 completed surveys revealed that most physicians tended to present Phase 1 trials as an option rather than a strong recommendation and were reluctant to influence decisions of families. They contributed many suggestions for improving the informed consent process.

The central ethical issue in the IC process for Phase 1 conferences is “making sure informed consent does its job – helping parents and older kids to understand the contradiction between the scientific goal of the study and the unlikely, though possible, goal of experiencing medical benefit,” Dr. Kodish says. “These studies embody the hopes of parents, children and clinicians that these drugs will help kids.”

“There’s not a more ethically charged situation in pediatric oncology,” says Dr. Baker.

So far, 69 families have been interviewed, including 20 patients over age 14; the goal is to interview 125 families nationwide. All the families consented to participate in trials. “At the Phase 1 stage, families are so much better educated and engaged at a whole other level,” Dr. Baker says. “Most want open, transparent communication.”

The oncologist’s perspective is an important factor in the parents’ decision. “Parents are highly influenced by pediatric oncologists,” says Dr. Kodish. “Philosophically, some may be oriented toward Phase 1 studies and allowing parents to have hope; others toward hospice. If oncologists get signals from parents that they don’t want to give potentially toxic drugs to their child, they support that.”

“I haven’t noted coercion,” says Dr. Baker. “If anything, we are extra-protective of families and patients in Phase 1.”

Another important difference between Phase 1 and Phase 3 is the involvement of older patients. “At Phase 1, the child should be an active participant and know what it means to be enrolled,” Dr. Baker explains. “Parental autonomy can be honored while encouraging the child’s participation.”

“It’s critically important that adolescents be involved if they want to be involved,” says Dr. Kodish. “We can have high expectations of older kids, but they should be free to be kids.”

A software program, Encounter, will facilitate POIC data analysis by enabling researchers to code the digital recordings to pinpoint when a particular topic was discussed. Once the findings are presented, they may benefit not only families of pediatric cancer patients but also patients and families facing other difficult medical decisions.
A decade after completing a rough draft of the human genome, medical science is on the cusp of a revolution — more personalized care and treatment based on the unique genetic profile of each patient.

But this revolution in medicine brings with it a variety of implications for individuals and society to consider. For example, genetic technology may allow physicians to predict whether a 20-year-old is at risk of developing diseases such as Parkinson’s or Alzheimer’s decades in the future. Will patients want that information, or will it be seen as a burden?

Genetics is the future of medicine. As such, it is important that Cleveland Clinic stay on the leading edge of genetics research that’s now moving beyond the laboratory and into patient care, says Richard Sharp, PhD, Director of Bioethics Research in the Department of Bioethics. It is why Cleveland Clinic is partnering with Case Western Reserve University (CWRU) in a new venture, the Center for Genetic Research Ethics and Law (CGREAL).

CGREAL is one of six centers of excellence nationwide funded by the National Human Genome Research Institute, one of the National Institutes of Health. CGREAL faculty will address the most pressing ethical, legal and social questions raised by recent advances in genetic and genomic research. CWRU is the administrative home to the Cleveland center, and Dr. Sharp is its co-director.

“It is not by accident that we are partnering with CWRU in this regard,” he says. “We are at a key translational moment where many recent advances in genetics are actively being translated into clinical applications.”

She says that CGREAL will help answer the question of storing and releasing patient information in the context of rapid genomics advances.

The faculty at CGREAL is studying the contexts in which genetics is being introduced into patient care. Researchers go to patients who are likely to be users of genetic technologies, such as those undergoing routine genetic tests in cancer care, and ask them what they think about these new technologies.

This is a differentiating feature of the Cleveland center, compared with others nationally, Dr. Sharp says. “We are not asking abstract, hypothetical questions about genetics and its potential. We’re going directly to patients and asking them what they think about these technologies. We try to bring out those often unspoken beliefs that patients have about these technologies and identify challenges in their use.”

Dr. Sharp believes CGREAL has the ability to diffuse many misperceptions that individuals have about genetic research — misperceptions that reflect historical concerns and misunderstandings.

“There were a number of misuses of genetic information in the early 20th century, when many industrialized countries limited reproductive choices and pursued efforts to sterilize individuals,” Dr. Sharp says. “Many patients see new types of genetic testing through that lens.”

As for misunderstandings: “A patient who tests positive for a genetic risk isn’t guaranteed of actually contracting that disease,” he points out. “But that perception is out there in the mass media. A lot of what we do at CGREAL is to identify new ways to address these types of misunderstandings.”

Charis Eng, MD, PhD, FACP, Founding Chair of Cleveland Clinic’s Genomic Medicine Institute and Director of the Center for Personalized Genetic Healthcare, says Northeast Ohio is privileged to have CGREAL as one of the few centers of excellence in the country whose thrust is genetics research ethics and law.
As a teacher of constitutional law, Karen Maschke, PhD, was familiar with numerous health-law-related topics, particularly reproductive rights and cases challenging forced vaccinations and quarantines in the name of public health.

When she decided to make a career change in the 1990s, she knew she wanted to study in a health-related field. There were many options, but Dr. Maschke decided on the master's program in bioethics at Case Western Reserve University (CWRU). “Bioethics is interesting because it is interdisciplinary,” she says.

While at CWRU, Dr. Maschke applied for and was accepted into Cleveland Clinic’s Department of Bioethics Fellowship Program, where she was a fellow in 1999-2000.

Today, Dr. Maschke is a research scholar at The Hastings Center in Garrison, N.Y., and editor of IRB: Ethics & Human Research. She conducts research on a number of topics, teaches and guest lectures, and writes and publishes articles for academic and non-academic audiences. In addition, Dr. Maschke serves on several advisory committees for the National Institutes of Health, and is an IRB member at a community hospital in Poughkeepsie, N.Y., that conducts clinical trials.

She sees her primary responsibility as being an educator, trying to help policymakers – both governmental and institutional – think through the ethical issues as they develop and implement policies.

While finding common ground is important, Dr. Maschke knows it will shift over time, particularly as medical science develops new technologies, drugs and devices. “There will always be a necessity for constant re-evaluation of common ground,” she says.

As an example, Dr. Maschke cites hospital policy in community emergency preparedness plans, where a hospital not only would treat its own patients but also would partner with its fellow institutions in patient care. “During critical emergencies, there are scarce medical technologies,” Dr. Maschke notes. “The needs are constantly going to change, depending on the nature of the threat to the community, technology and resources.”

She says her political science background frames her perspective on bioethics issues. “Political scientists look at how decisions are made,” Dr. Maschke points out. They look at what values and interests are at play when those decisions are made, the dynamics that go into setting the agenda, issues of power, and how public funds are spent. “Philosophers are more likely to look at bioethics issues from the lens of concepts like justice, virtue, utilitarianism or pragmatism,” she says.

Her time as a Cleveland Clinic fellow gave Dr. Maschke the “eye-opening” experience of observing clinical ethics consultations, where physicians and patients had real-life discussions about the proper course of treatment and the decisions that had to be made. Cleveland Clinic also is where Dr. Maschke discovered her love of research ethics. She helped colleagues conduct a national survey about whether pediatric patients involved in clinical trials and their parents should be paid for participating in the studies.

Her Cleveland Clinic experience continues to pay dividends as Dr. Maschke’s career progresses at The Hastings Center. “I learned an enormous amount about clinical ethics on the front lines,” she says. “For someone who had never been in a clinical setting before, it was an unbelievable experience.”

Enhancing Patient Care

“Enhancing Patient Care” is a continuation of the story that started on page 6 of this issue. It highlights the ongoing work of Cleveland Clinic’s Department of Bioethics to improve patient care through research and education.

“A lot of our work is being done in collaboration with physicians,” he says. “We work with colleagues in all different parts of Cleveland Clinic. We want our work to impact patient care, and that’s only possible when you work closely with clinicians.”

Bioethics Research Day began in 2009 to spread the word locally about the work that Cleveland Clinic researchers are doing. “We go to national conferences and share our findings, of course, but sometimes our colleagues in the Cleveland area don’t hear about that work,” Dr. Sharp says.

Adds Ms. Yamokoski: “There’s a lot of great research going on in the department. Research Day brings it all together.”

The next one will be held in May 2011. Bioethics Research Day highlights the fact that “what we’re doing is performing research that translates to better patient care,” Ms. Yamokoski says. “It’s about the patient experience. We want to enhance the experience for patients everywhere.”
Open: Professional Staff Position in Regional Bioethics

The Center for Ethics, Humanities and Spiritual Care at Cleveland Clinic and its Department of Bioethics invite applications for a Professional Staff position in the Section of Regional Bioethics. The successful candidate will be appointed at the rank of Assistant, Associate or full Staff, depending on his/her qualifications, and will be eligible for academic appointment in the Cleveland Clinic Lerner College of Medicine at Case.

We are seeking an individual with demonstrated competencies for providing high-quality clinical ethics education and consultation, primarily in multiple community hospital environments, and for enhancing the proficiency and effectiveness of existing ethics committees. This individual should be able to work effectively and collegially with clinical professionals, leadership and other personnel.

Candidates for the position must have a doctorate/terminal degree in an area of study related to bioethics, such as medicine, nursing, philosophy, religious studies, law or one of the social sciences. Preference will be given to individuals with significant prior experience in providing ethics consultation and education, working with ethics committees, and developing ethics-related organizational policies and procedures.

Building on a 25-year history of excellence in clinical ethics, Cleveland Clinic is committed to developing a vibrant Section of Regional Bioethics within its system of 10 community hospitals. A hallmark of the clinical service provided by the Department of Bioethics is a focus on enhancing the care of patients and families, with attention to the ethics needs of healthcare professionals.

Cleveland Clinic is recognized internationally as one of the premier medical institutions in clinical education, research and patient care. Over the past several years, its Department of Bioethics has grown to include 11 professional staff members (faculty) and many affiliated clinicians. The Department is the administrative home of the Cleveland Fellowship in Advanced Bioethics (CFAB), a city-wide training program for the next generation of leaders in clinical ethics and bioethics research. Members of the department have numerous collaborations with other regional medical institutes.

The successful candidate for this position will be supervised by the Director of Clinical Ethics, and will work collaboratively with another in-place professional staff member in the Section of Regional Bioethics. The successful candidate also will have opportunities to pursue academic interests, including research and publication, and helping to teach and train CFAB Fellows as well as medical students in the Cleveland Clinic Lerner College of Medicine.

Applications will be considered as they are received, with preference given to candidates who can start by or prior to July 1, 2011. Interested individuals may apply by sending a cover letter, curriculum vitae and the names of three references to:

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