

Ethical Issues in Near-Total Face Transplantation

In December 2008, Cleveland Clinic surgeons performed the first near-total face transplant in the United States. The 22-hour procedure involved a team of eight surgeons who replaced 80 percent of a trauma patient's face – essentially transplanting the full face except her upper eyelids, forehead, lower lip and chin.

This is the largest and most complex face transplant in the world to date. And, of course, because of the nature of the procedure and its risks, it raises some important ethical concerns.

Eric Kodish, MD, Chairman of the Cleveland Clinic Bioethics Department, answers questions about the issues the procedure raised.

Q. The purpose of the face transplant surgery was to correct facial disfigurement – a non-life-threatening condition. As a bioethicist, how do you justify such a serious risk for this type of issue?

Dr. Kodish: There's been a radical change over the last several decades in how we think about risk-benefit assessment. Thirty or 40 years ago, decisions were made based on mortality risks and quality of life was not really emphasized. Chances are, based on that type of thinking, this procedure would have been considered unacceptable 30 to 40 years ago.

In the past few decades, however, quality of life has come to be considered as important, if not maybe more important, as quantity of life. This patient had profound damage to her face, which interfered tremendously with her quality of life, and even with some of her functioning. This is what justified the risky undertaking.

Q. This type of transplant is still considered experimental. What protocols were followed to ensure the patient's safety?

Dr. Kodish: The face transplant team prepared a research protocol about five years ago, which was discussed at great length by the Institutional Review Board (IRB). The patient underwent a complete psychiatric evaluation, and consultations with the Bioethics Department and social workers.

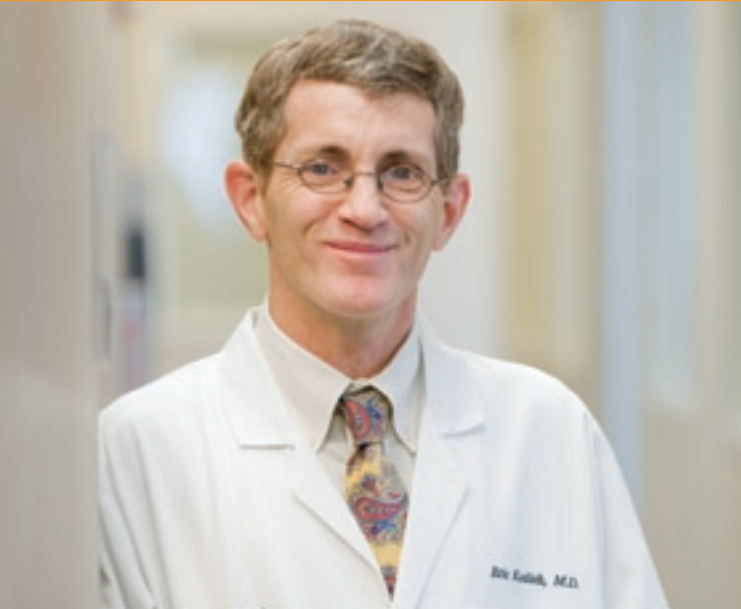
The risks were also very carefully articulated to the patient. Those risks involved rejection, infection and malignancy, and potentially, a risk of the patient losing her privacy. She was also made aware that there was no guarantee that the transplant would, in fact, help with her functioning and appearance.

Q. Are there any concerns that this procedure could potentially be used under less grave circumstances, such as for cosmetic enhancements or even identity change?

(Continued on page 5)



From the Chairman



Dear Colleague,

Welcome to the first issue of *Bioethics Reflections*. We are proud to present this newsletter to update you on the activities of the Cleveland Clinic Bioethics Department.

The timing of this first newsletter coincides with the recent celebration of the 25th anniversary of the department. Included is a recap of our history. Our cover story highlights the ethical issues surrounding the groundbreaking near-total face transplant Cleveland Clinic surgeons performed in December.

Also included in this issue are stories about the latest research projects we are working on, along with an interview with Anthony Thomas, MD, a member of our department, regarding bioethics and the Cleveland Clinic Patient Experience initiative.

We include, as well, a profile on Joal Hill, a former fellow in the Cleveland Clinic Bioethics Department. Joal is an example of the success of our fellowship program, which was just reestablished in 2007. The Cleveland Fellowship in Advanced Bioethics (CFAB) is a two-year program and educational partnership we have with Case Western Reserve University, MetroHealth Medical Center, University Hospitals Case Medical Center and the Louis Stokes Cleveland VA Medical Center. We will bring you more news about the CFAB program in future editions.

Thank you for your interest in this first issue of *Bioethics Reflections*. We hope you enjoy reading it.

Sincerely,
Eric Kodish, MD
*F.J. O'Neill Professor and Chairman,
Cleveland Clinic Bioethics Department*

Bioethics Reflections provides news and information from the Cleveland Clinic Bioethics Department for our colleagues across the country.

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The Intersection of Bioethics and Patient Experience



We asked Anthony Thomas, Jr., MD, to talk about how morality affects patient care. Dr. Thomas is a staff member in the Bioethics Department, and is the Institute Experience Officer for the Glickman Urological & Kidney Institute at Cleveland Clinic.

Bioethics Reflections:
How does bioethics influence patient experience?

Dr. Thomas: The practice of medicine is a quiet practice.

That's why we call it a private practice – people deserve their privacy. Bioethics involves respecting a patient's privacy and their right to choose what they believe is in their best interest. A good patient experience means treating our patients and their families respectfully and in the same way we would want to be treated if we were the patient. The two complement one another.

BR: Must doctors always obey a patient's choice? Is the physician ever obligated to say "No"?

Dr. Thomas: A physician has the ethical and moral responsibility to always try to do the right thing. One of the first mottos we learn is *primum non nocere* – "First, do no harm." Adult patients who have the mental capacity to decide their fate have a right to refuse treatments if they so choose. And while they can refuse, they do not have a right to demand a treatment that the physician feels is not appropriate. Physicians may say "no" if the act asked for goes against their own moral code or would not offer any benefit to, or could possibly harm, a patient.

BR: If a patient wants to die, does he have the right to refuse life-saving treatment?

Dr. Thomas: If a patient has the mental capacity to make such a decision, then he has the right to be not interfered with, even if it could mean his death. For example, if a very ill patient requires dialysis in order to live, he or she may refuse this life-sustaining therapy. This happens on occasion for reasons we, as physicians and ethicists, cannot understand, and at other times when it is felt by the patient that the burdens of dialysis far outweigh its benefit in their particular situation and circumstance.

But with children as patients, it is different because a parent may not refuse a life-saving treatment solely because their own personal belief system does not allow them to accept certain forms of medical or surgical treatment. On the other hand, there are instances, particularly with a gravely ill child, when parents may decide that the benefit of any treatment is so small and the burdens so great that it would not be in their child's best interest to suffer further with little or no hope of improvement.

BR: Are religion and bioethics at odds with each other?

Dr. Thomas: No. Having a spiritual (not necessarily religious) sense of oneself is an important aspect of life for many men and women. Ethics often involves an element of moral decision-making and, for those who have thought about their lives and their relationships within a spiritual or religious sense, having a spiritual sense may actually make it easier for them to understand some of the ethical principles that guide our actions, as well as the advice we may offer them.



Cleveland Clinic's Bioethics Department Celebrates 25 Years

Since its founding in 1984, the Department of Bioethics has remained unique in the United States. Cleveland Clinic was the first non-university-affiliated hospital that had an active institutionally supported office of bioethics. From the beginning, faculty members in the department were members of the full professional staff in Cleveland Clinic's group practice. This ranks the bioethics consultation service with that of any other subspecialty in the hospital for the care of patients.

The History

Clinical bioethics began informally at Cleveland Clinic in 1980 when George Kanoti, STD, was hired as a consultant to provide bioethical consultation on the ethical aspects of healthcare. In August 1984, the Board of Governors created the Office of Bioethics and asked Dr. Kanoti to join the professional staff and direct the efforts of the office.

Under the leadership of Dr. Kanoti and Dr. Shad Hartwell an ethics committee was established in 1984. The committee serves in policy-forming, advisory and educational capacities for ethical issues and needs that arise in the care of patients. It also serves in a consultative role when ethical dilemmas are not resolved at other levels. Dr. Dale Gullledge, a staff psychiatrist, served as first chair of the ethics committee. Since its founding, the ethics committee has had six chairs, among them urologist Anthony Thomas, MD, (2000-2006) and the current chair, cardiac intensivist Allen C. Bashour, MD.

Within the first year of its establishment, the department's staff was expanded with another full-time ethicist, Janicemarie Vinicky, MA. Martin L. Smith, STD joined the office in 1987, expanding the faculty to three. Dr. Kanoti retired in 1997 and Dr. George Agich served as department chair from 1997-2004.

The Bioethics Department has added five new faculty members in the past three years and is now one of the strongest and most diverse academic and clinical ethics units found in any hospital, university or academic health center. Current Chairman Eric Kodish, MD, leads a group of nine faculty members and approximately 20 administrative, research and support staff members within the department.

Fellowship Program Established

In 1984, Dr. Kanoti, Jan Vinicky, and Dr. Smith developed the first Bioethics Fellowship Program at Cleveland Clinic. Initially there were two fellows.

Today, under the leadership of Program Director Kathryn Weise, MD, the department is the physical and administrative home of the Cleveland Fellowship in Advanced Bioethics (CFAB). This fellowship represents an educational partnership across Cleveland medical institutions including Case Western Reserve University, MetroHealth Systems, University Hospitals and the Louis Stokes Cleveland VA Medical Center. In 2007, with generous support from the Cleveland Foundation, CFAB welcomed its three inaugural first-year fellows. A variety of types of fellows with doctoral degrees in philosophy, theology, law, social/behavioral sciences, economics or medicine are chosen to participate in the program, reflecting the multidisciplinary nature of bioethics. This heterogeneity of fellows also provides the program with rich teaching/learning experiences among the fellows themselves.

Clinical Activities

The Bioethics Department supports a robust clinical ethics consultation service and provides clinical ethics continuing education for professional staff, residents, nurses and allied health professionals. Members of the faculty and fellows routinely present at international, national and regional conferences. In the 2008-09 reporting year, the Bioethics Department provided 267 ethics consultations at Cleveland Clinic.

2009

“The Bioethics Department has averaged more than 200 consults per year for the past five years making it likely to be the busiest service in the country.”

Martin Smith, STD, one of the first staff members of the Bioethics Department. (Opposite page left)

A group including Dr. Smith and George Kanoti, STD, discuss a bioethics case. (Opposite page right)



Eric Kodish, MD, discusses ethical issues surrounding the recent near-total face transplant performed at Cleveland Clinic.

Face Transplant

Cover story continued

Dr. Kodish: Although that is not a huge concern because there are safeguards in place, we need to be really vigilant to prevent that from happening. As a society, we can prevent the misuse of face transplant and ensure it is utilized only for those who are severely injured and have suffered loss of function.

Also, we need to keep in mind that the surgeon himself or herself has moral and ethical obligations in his or her work. We will need to count on the integrity of surgeons to prevent this from happening as well.

Q. What are some other potential ethical issues the patient or her physicians may be faced with in the future regarding her case?

Dr. Kodish: If and when she decides to disclose her identity there will be lots of media attention. The media so far has been remarkably responsible and has handled this very sensitively.

Q. Can you comment on any previous medical cases that raised similar ethical issues?

Dr. Kodish: This case is pretty unique.

When Food Becomes Medicine

How do you feel about ingesting bacteria? Would you be willing to place bioengineered microorganisms into your body, even if your physician said they were good for you?



The issue behind these questions is at the heart of a three-year, \$1.1 million study now under way in the Cleveland Clinic Bioethics Department. Richard Sharp, PhD, Director of Bioethics Research, and Ruth Farrell, MD, are co-directing the study; Mary Beth Mercer is the Project Coordinator. Collaborators in the study, which is funded by the National Institutes of Health, are Mayo Clinic and Johns Hopkins Hospital and Health System.

The study, entitled “Patient Understandings of Bioengineered Probiotics and Clinical Metagenomics,” seeks to evaluate how patients see bioengineered probiotics as a therapy to combat digestive diseases like Crohn’s Disease or ulcerative colitis, says Dr. Sharp. Probiotics are bacteria that are found in the intestinal tract, and are also a food supplement in products like yogurt and orange juice.

“These are living microorganisms, and it’s hard to predict what might happen when these organisms are introduced to the body,” Dr. Sharp says. “What will patients make of this uncertainty? We might encounter the ‘yuk factor’ – people saying ‘I don’t want them, I find them repugnant.’”

Even though many health experts believe probiotics are helpful, Dr. Sharp cautions that “to patients in an immunocompromised state, the addition of a high level of bacteria could be life-threatening.”

Still, Dr. Sharp is intrigued with the study – the first of its kind to investigate patients’ attitudes toward bioengineered food as medicine. He says, “How do patients see the medicalization of food? That interests me.”

The researchers are currently implementing the protocol and beginning patient recruitment to get the study running. Their goal is to enroll 200 patients in the study, which will be conducted mainly through focus groups.

Ms. Mercer speculated on the type of questions that will be put to the focus groups.

“We want to get their reactions to the fact that probiotic products contain millions of live microorganisms, and will this affect their willingness to try a genetically modified probiotic product,” she says. “We want their reactions to both nonengineered probiotics, in terms of those products containing millions of live microorganisms, as well as to bioengineered probiotics, where the genetic material of those microorganisms has been altered for a specific purpose. One line of questioning we may use is, ‘What would you want to know about a specific probiotic before deciding if it was right for you? Where would you go for this information? What sources would you trust the most and why?’”

Results from the study will help health professionals identify patients’ expectations and their concerns about probiotics. That information will enable physicians to help their patients make informed choices. They also will learn ways to promote the responsible introduction of bioengineered probiotics into the care of patients with chronic gastrointestinal illnesses.

“I’m particularly interested in learning how patients think of probiotics in terms of potential benefits and risks compared to pharmaceutical drugs,” Ms. Mercer adds.

As a precursor to the study, Drs. Sharp, Farrell and others will publish a paper in the *American Journal of Gastroenterology*: “Helping Patients Make Informed Choices About Probiotics: A Need For Research.”

Joal Hill, JD, MPH, PhD



What do plumbers have that bioethicists don't? Authority, according to Joal Hill, JD, MPH, PhD, a 1992-93 fellow of the Cleveland Clinic Bioethics Department. Just like lawyers, doctors and many other professionals, plumbers have expertise in their subject matter that makes them authorities on their subject matter.

But a bioethicist? Rather than being looked at as authorities on ethics, Joal sees professionals in her field as consultants with training and expertise in moral analysis who offer a "framework for decision making." Bioethicists can help people make decisions they can live with for the rest of their lives.

While studying political science and law in Tennessee, Joal became very interested in medical ethics. For a short time she practiced law and worked as an office manager for a friend who was a surgeon. Because of her interest, he encouraged her to work in healthcare, and she went on to get a master's degree in Public Health at Columbia University. During her fellowship training at Cleveland Clinic she received clinical ethics training and got practical field experience by observing protocols, informed consent interviews and investigational procedures.

"When you hear people's stories, you see the human face of not only the patients, but the people who take care of them too," Joal says. "This fellowship, especially for someone like me without a healthcare background, was key in showing me that I could be comfortable and effective in this field."

Joal went on to earn a doctorate in Medical Humanities from the University of Texas Medical Center in Galveston. In 1999 she moved to Chicago and is currently Chair of the Institutional Review Board and Director of Research Ethics for Advocate Health Care. Advocate is a large integrated health system with five community hospitals, three teaching hospitals and two children's hospitals. The health system has four bioethicists on staff, including Joal.

Joal says she finds her profession very interesting. She enjoys looking at old questions in new ways and looking at what was resolved in previous cases and applying that learning to new cases.

"One thing about the field I really love is always working on the edge of your knowledge," she says. "You acquire a depth of knowledge, but always in a shadow. You must keep reading the literature and keep talking with your colleagues."

Welcome New Fellows

We are pleased to announce the following fellows joining us for The Cleveland Fellowship in Advanced Bioethics program beginning in July.

Charlisse Caga-anan, JD

University of Minnesota Law School – June 2008

Certificate in Health Law and Bioethics

Founder of law school's Health Law and Bioethics Association

Interests: Research ethics, boundary between research and clinical practice, rights of research subjects, international bioethics, public bioethics

Laura Buccini, PhD, candidate in Public Health

University of Wollongong, Australia – July 2009

Graduate Certificate in Bioethics from Cleveland State University

Interests: Developing effective approaches to managing competing interests between biomedical research and clinical care

Valarie Blake, JD

University of Pittsburgh School of Law – April 2009

Albert Schweitzer Fellow 2007-2008

Interests: Teaching; bioethics and global health law

The Cleveland Fellowship in Advanced Bioethics (CFAB) is a two-year, full-time program designed to train the next generation of leaders in the field of bioethics. Applications will be considered from professionals with terminal post-graduate degrees in medicine, philosophy, nursing, social work, religious studies, law, and other fields related to the practice of clinical and academic bioethics.

For the 2010 academic year, completed applications must be submitted by December 15, 2009. For more information about the CFAB and the application process, visit clevelandclinic.org/bioethics.



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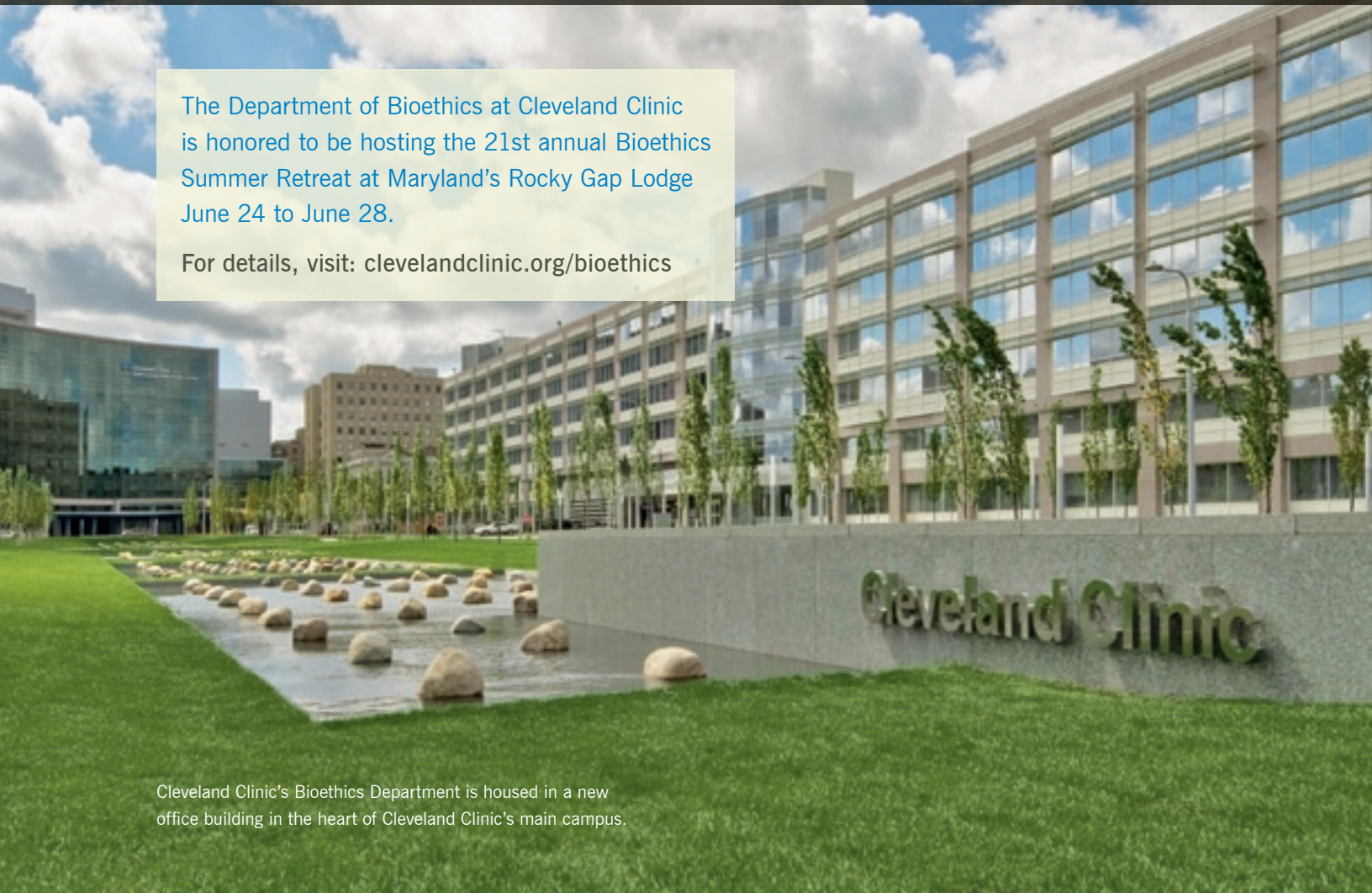
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Bio|ethics Reflections

The Department of Bioethics at Cleveland Clinic is honored to be hosting the 21st annual Bioethics Summer Retreat at Maryland's Rocky Gap Lodge June 24 to June 28.

For details, visit: clevelandclinic.org/bioethics



Cleveland Clinic

Cleveland Clinic's Bioethics Department is housed in a new office building in the heart of Cleveland Clinic's main campus.