As Transplant Medicine Evolves, Innovative Fellowship Focuses on Critical Ethics Issues

The rapid growth of medical technology is making organ transplantation more viable — and raising more ethical questions — than ever before.

“Organ shortages, allocation issues and informed consent policies for living donors are among the many ethical issues that confront the transplant field on a daily basis,” says Eric D. Kodish, MD, Director of the Center for Ethics, Humanities and Spiritual Care.

Cleveland Clinic is one of the busiest transplant centers in the country, and about 50 of the 400 ethics consults performed each year involve transplantation. The Cleveland Clinic Fellowship in Transplant Ethics was established in June 2013 to address this growing need.

“It’s critical that we develop experts in an area of medicine that will only become more complex in terms of ethics,” says Dr. Kodish.

The one- to two-year fellowship, now the nation’s only transplant ethics-focused program, may serve as a model for other centers.

Fellows help transplant teams explore issues

Charles Miller, MD, Program and Surgical Director of Liver Transplantation and a member of the Transplant Ethics Fellowship Steering Committee, adds that “transplantation is a complex field that has the potential to save many lives. But as you push the limits to save those lives, more and more ethical issues emerge. That is why it is so wonderful to have these young fellows to investigate these issues and help us think them through.”

Ethical issues in transplant medicine are often multilayered. They may affect practice or policy, and involve decisions by clinical teams, patients, families and donors.

Organ scarcity is key

“The organ shortage is at the heart of many ethical issues in transplantation,” says medical ethicist Kathryn Weise, MD, MA, the fellowship’s program director. “For example, many family members only consider making a live liver donation because of the dearth of available organs.”

Each year in the United States, about 120,000 people await organ transplants, yet in 2012, only 28,051 received them.1

The program’s first fellow, David Shafran, MD, MA, a fellow in pediatric nephrology with a master’s degree in biomedical ethics, says that perspective is important.

“In everyday medicine, patients who are in dire straits tend to be the first priority. In transplant medicine, you have to step back and consider the broader good of the transplant community and how to use a scarce resource to its maximum potential,” he says.

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Dear Colleague,

Welcome to the 2014 issue of Bioethics Reflections. Our bioethicists are privileged to work at one of the nation’s leading academic medical centers, where continuous quality improvement and “Patients First” are overarching goals. Last year, the Department of Bioethics provided consultations in more than 360 cases in support of Cleveland Clinic’s mission.

In this issue of Reflections, we feature two unique programs, our Transplant Ethics Fellowship and our Neuroethics Program. We share staff highlights from a Cleveland Clinic continuing education course focusing on the key area of reproductive ethics. We introduce you to our newest staff member, regional ethicist Cristie Cole, JD. We also welcome new bioethics fellows Bryan Kibbe, PhD, and Bryn Esplin, JD, and new transplant ethics fellows Jed Gross, JD, MA, and Jonathan Wiesen, MD.

Finally, we’d like to give a special shoutout to our colleague, Paul Ford, who was invited to present on Aug. 20, 2014, to the Presidential Commission for the Study of Bioethical Issues about ethical issues raised by the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.

We hope you enjoy this issue of Bioethics Reflections. Stay well, and keep in touch!

Eric Kodish, MD
F.J. O’Neill Professor and Chairman, Cleveland Clinic Bioethics Department
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Bioethics Reflections provides news and information from the Cleveland Clinic Bioethics Department for our colleagues across the country.

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Transplant Ethics, continued

“Medical urgency and the patient’s prospect for success are considered in tandem, representing the tension between justice and utility.”

**Informed consent key for donors**

“Ethicists of course don’t make any final decisions about who gets to donate,” says Dr. Weise. “But we can help the potential donor and the transplant team — physicians, surgeons and social workers — evaluate whether it’s a good donation process.”

In live organ donation, donors must fully understand their own procedure has no prospect of medical benefit. “We need to make sure that the donor is a willing volunteer who has not been unduly pressured by others and is not being compensated in any way,” says Dr. Shafran.

Higher-risk live donations, such as liver, automatically flag an ethics consult. Kidney donation does not trigger a consult unless donors are younger than normal, do not seem to grasp informed consent information, or participate in “nondirected” donations through an organ donation website, community, church or other source.

“We want to better understand donor motivation in these cases and ensure that they understand the risks,” Dr. Shafran explains.

**Setting the stage for success**

During the first year of his fellowship, Dr. Shafran conducted and published a review on the issue of organ shortage and observed multidisciplinary transplant meetings. He worked with Dr. Weise to build the fellowship’s curriculum based on emerging clinical developments and related ethical issues. During the second year, he will provide consults on ethical issues in transplantation.

Former U.S. Treasury Secretary Robert E. Rubin and his wife, Judith, provided startup funding for Cleveland Clinic’s program. The goal is to sustain the transplant fellowship with philanthropic funding and with endowments.

This year, two new transplant fellows join Dr. Shafran. Jed Gross, JD, MA, earned his JD and an MPhil in history at Yale. Jonathan Wiesen, MD, a Cleveland Clinic Pulmonary, Allergy and Critical Care fellow, earned his MD from Albert Einstein College of Medicine and has been a resident/fellow representative on Cleveland Clinic’s Ethics Committee.


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**NEW STAFF**

We welcome Cristie M. Cole, JD

We are pleased to announce the appointment of Cristie M. Cole, JD, to the Department of Bioethics in the Center for Ethics, Humanities and Spiritual Care. She is Regional Ethicist (East) for Cleveland Clinic health system hospitals.

Cole graduated from the University of Arizona, James E. Rogers College of Law. There she earned the CALI Excellence for the Future Award in Bioethics and Law, and the Student Health Law Award from the American Society of Law, Medicine, and Ethics.

Tracing her interest in bioethics back to childhood, Ms. Cole was captivated by childhood books describing the dilemmas facing a child living with cancer and her caregivers. “It wasn’t until college that I would learn that the field of bioethics existed,” she says. “When I took a Health Care Ethics class sophomore year, I immediately changed majors.”

While in law school, a personal experience during her father’s hospitalization shifted her interest in bioethics from academic to clinical. “I learned the impact an ethicist can have on a patient’s and family’s life,” she says.

Ms. Cole is gratified by the momentum building in the ethics programs at Euclid, Hillcrest, Marymount and South Pointe hospitals. “There is a strong desire to create robust ethics programs within each hospital,” she says. “I am excited to capitalize on that energy and to respond to caregivers’ ethics-related needs.”
Neurologists, neurosurgeons and behavioral health specialists practice in an increasingly complex ethical landscape. Brain surgery for epilepsy, deep brain stimulation (DBS) for movement disorders and preclinical diagnostic tests for Alzheimer disease pose ethical challenges for patients, families and clinicians.

“As we better understand brain mechanisms, clinicians and researchers will continue to propose new scans and interventions that challenge our core senses of identity, privacy and the mind,” says Director Paul J. Ford, PhD.

The Department of Bioethics and the Neurological Institute established Cleveland Clinic’s NeuroEthics Program in 2009. NeuroEthics faculty help clinicians and researchers explore ethical issues, offer guidance to patients and families struggling with decisions on diagnosis and care, conduct innovative research, sponsor continuing education, and aid policy development.

NeuroEthics Program: Matters of the Mind

Embedded in clinical operations
Cleveland Clinic’s NeuroEthics Program, one of the few in existence, has a unique focus on clinical practice and clinical research dilemmas. “We participate in weekly meetings during which clinical teams evaluate individuals’ cases and think through the best treatment,” says Associate Director Jalayne J. Arias, JD, MA.

On the epilepsy surgery evaluation committee, Dr. Ford helps assess ethical challenges in decision-making and informed consent. “We offer pragmatic support; emotional and value elements are important and should be considered,” he says.

Innovative clinical research
The faculty’s neuroscience research is unique. Ms. Arias is Principal Investigator for a study on the legal and ethical ramifications of new diagnostics for Alzheimer disease, which include biomarkers that predict the disease years ahead of symptoms.
Other research focuses on the use of evolving technology such as DBS for a growing range of brain conditions; on addiction challenges; on dementias as contraindications for care; and on approaches to psychogenic nonepileptic seizures.

The NeuroEthics faculty helps researchers build additional safeguards into studies where patient-subject vulnerability risks are high. They review grants for the National Institutes of Health, U.S. Department of Defense, Health Research Board (Ireland), Netherlands Organization for Health Research and Development, and other institutions.

Sharing knowledge and expertise
NeuroEthics faculty are in demand nationally and internationally. For five years, faculty member Cynthia Kubu, PhD, has been a key part of a German-based internal consortium on ethical issues in deep brain stimulation. Faculty members have presented in Canada, England, Germany, France, Sweden and Switzerland; at major U.S. neurosurgery, neurology, epilepsy and neuropsychology conferences; and at the Board on Health Sciences Policy for the Institute of Medicine.

"Neurotechnology is increasingly a societal issue, and our program offers a practical model of ethics applied in clinical settings," says Dr. Ford. "While factors such as universal healthcare in Canada play differently, the debate about quality of life and neurological disorders remains markedly similar in clinical settings around the world."

Staff Congratulations

Ruth Farrell, MD, was invited to join the American College of Obstetricians and Gynecologists - Society for Maternal/ Fetal Medicine Periviability Birth Writing Committee.

Paul J. Ford, PhD, was invited to speak at the Cambridge-ICM Brain and Spine Institute Neuroethics Network conference in Paris, France, on June 19, 2014.

He also co-edited an issue of the American Journal of Bioethics: Neuroscience, based on submissions from our 2012 conference, “Brain Matters 3: Values at the Crossroads of Neurology, Psychiatry, and Psychology.”

Erik Kodish, MD, and Paul J. Ford, PhD, were named associate editors for the Journal of Clinical Ethics.

Kathryn Weise, MD, MA, co-chaired the planning committee for the May 21, 2014, CME course “Pediatric Ethics: Hot Topics and Enduring Challenges,” sponsored by the Northeast Ohio Regional Pediatric Ethics Consortium (NOPEC).

Dr. Weise is Coordinator for NOPEC, which includes Akron Children’s Hospital, Cleveland Clinic Children’s, Hospice of the Western Reserve, MetroHealth Medical Center, and Rainbow Babies and Children’s Hospital. Her committee co-chair was Ann Kessler, LISW, of the Rainbow Center for Pediatric Ethics.

The faculty offers continuing medical education for trainees, clinicians and ethicists, including the international “Brain Matters” conference and Distinguished Neuroethics Lecture Series. Last year, Paul Appelbaum, MD, Director of Law, Ethics and Psychiatry at Columbia University, spoke on gun policy and mental illness. On Nov. 12, 2014, Kristine Yaffe, MD, of the University of California, San Francisco, will address ethics in dementia and women’s health disparities research.

The faculty continually seek new opportunities to collaborate with professionals and patients. For more information on the NeuroEthics Program, visit clevelandclinic.org/neuroethics.
Reproductive Ethics CME

As physicians grow increasingly adept at assisted reproduction, perinatal care and prenatal genetic screening, the inherent ethical issues grow increasingly complex. Bioethics Department staff helped address these issues at Cleveland Clinic’s continuing medical education course “Ethical Dilemmas in the Practice of Obstetrics, Gynecology & Reproductive Medicine” on April 23, 2014.

Perivable births
Deliveries at the threshold of viability are ethically complex, noted Ruth Farrell, MD (pictured), the course director and an ob/gyn specialist and bioethicist. Survival rates and neurodevelopmental disability for newborns of 20 to 25 6/7 weeks’ gestation are highly variable, and outcomes are vastly uncertain. The short time frame for key obstetric management and delivery decisions and the need for multidisciplinary care discussions further complicate matters.

“If intensive treatment uniformly led to survival and an acceptable quality of life, that would be the obvious choice,” said maternal-fetal medicine specialist Amanda Kalan, MD. Yet intensive treatment may cause pain and prolong time until death, and withholding treatment may increase newborn morbidity and mortality.

Paul J. Ford, PhD, Director of the NeuroEthics Program, noted that when pregnant women with a perivable fetus ask caregivers to “do everything” at delivery, the phrase is ambiguous. “We’re going to do everything to reach the goal we jointly agree to,” he said. “That may mean doing everything to preserve life or doing everything to provide comfort care after birth.”

Communication must be clear and direct among providers, pregnant women and family, and consider values, needs, gestational changes, laws and regulations, and caregivers’ ethical obligations.

Prenatal genetic screening
New advances in prenatal genetic screening and testing increase the type and amount of information available to pregnant women, yet they raise important clinical and ethical concerns. One example is noninvasive prenatal testing, which screens for fetal aneuploidy risk more accurately than conventional screening does.

Another example, chromosomal microarray analysis (CMA), is a prenatal genetic test so sensitive and specific that it reveals submicroscopic chromosomal abnormalities. Yet some genetic variants may cause no disease and others may cause adult-onset diseases of unknown severity, noted Marissa Smith, CGC. CMA may also reveal unexpected or new information, including consanguinity and nonpaternity. These significant clinical and ethical implications call for clear, thorough counseling and informed consent for invasive and noninvasive tests that reveal fetal genetic information.

“We are ethically obliged to discuss available prenatal screening and diagnostic options so that patients can make the best choices — including potential decisions to continue or end the pregnancy,” said Dr. Farrell. “Regardless of how accurate and noninvasive new prenatal genetic tests may be or may become, we will continue to help pregnant women navigate the uncertainty that can come with such decisions.”

Conscientious objection
Conscientious objection holds special relevance in reproductive medicine. Hospitals must balance respecting caregiver objections with patient-care obligations, said bioethicist Cristie Cole, JD.

Key issues include the scope of the objections, the practical impact accommodations have on scheduling and staffing decisions (including the increased burden on other caregivers), and the hospital’s responsibilities to meet treatment expectations and provide access to care.

Collective wisdom
Ethics consults do not render decisions in these cases. Yet when conducted with appropriate goals by the right parties, they can resolve uncertainty and clarify ethically supportable actions.

“There is a collective wisdom that emerges from a variety of voices and perspectives,” said Martin Smith, STD (pictured), Director of Clinical Ethics and Vice Chair of Cleveland Clinic’s Ethics Committee.
Recognized for Exceptional Care
In 2014, Cleveland Clinic was ranked one of America’s top four hospitals in the U.S. News & World Report “Best Hospitals” survey. The survey ranked Cleveland Clinic among the nation’s top 10 hospitals in 13 specialty areas, and the top hospital in heart care (for the 20th consecutive year) and in urologic care.

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The Cleveland Clinic Way
by Toby Cosgrove, MD, CEO and President of Cleveland Clinic

Great things happen when a medical center puts patients first. Visit clevelandclinic.org/ClevelandClinicWay for details or to order a copy.

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Bioethics Department Welcomes New Fellows

Bryan Kibbe, PhD, earned his undergraduate degree from Calvin College in Grand Rapids, Michigan, with a double major in media production and philosophy. He received his PhD in philosophy in May 2014 from Loyola University in Chicago with a dissertation titled “Mindful Mending: The Repair of Thought and Action Amidst Technologies.” Dr. Kibbe served as coach of both the Ethics and Bioethics Bowl teams at Loyola, advancing to national competition. He has presented twice at the American Society for Bioethics and Humanities (ASBH) annual meeting and was awarded the ASBH Student Essay Prize. His primary interests are the ethics of new technologies, telehealth and telemedicine advances.

Bryn Esplin, JD, received her JD with an emphasis in neuroethics and health law policy from the William S. Boyd School of Law in Las Vegas, Nevada, in May 2014. She earned her BA in rhetoric and philosophy of mind from UC Berkeley. Ms. Esplin served as a neuroethics student intern at Cleveland Clinic’s Lou Ruvo Center for Brain Health in Las Vegas in 2013 and 2014. Her current interests are neuroethics and mental illness. She has presented papers at several national conferences.