Ethics and the Vaccine Controversy

Vaccination is one of medicine’s greatest accomplishments, reducing and in some cases eradicating once life-threatening diseases such as smallpox and polio. Yet in recent years, opposition to vaccines has grown, fueled by the suggested link between autism and the MMR (measles, mumps, rubella) vaccine, the rise in the number of recommended vaccinations (which has doubled in the past 25 years) and unfamiliarity with the diseases vaccines protect against.

Most parents have never seen a child seriously ill with measles or whooping cough but they can easily read stories on the Internet about children who have been harmed by vaccines. “It’s ironic that misleading information about vaccines is spread “virally” on the Internet when we are trying to prevent children from contracting viral diseases that can kill them,” says Eric Kodish, MD, F.J. O’Neill Professor and Chairman, Cleveland Clinic Bioethics Department and Professor of Pediatrics at the Cleveland Clinic Lerner College of Medicine.

When parents express concerns about vaccinations to pediatricians, “pediatricians should explore parents’ reasons for refusal and educate them. An ethical framework allows both parents and physicians to advocate for the best interests of the child. In some cases, parents may decide that vaccinations are not in their child’s best interest,” says Kathryn L. Weise, MD, MA, Staff Physician, Department of Bioethics and Program Director of the Cleveland Fellowship in Advanced Bioethics.

Most pediatricians “believe that the benefits of vaccination outweigh the risks to the individual child,” says Dr. Weise. Some decide that they can’t care for patients whose parents refuse vaccination. “I think it’s a mistake for physicians to drop patients and their families because of vaccination refusal. Pediatricians need to respect a parent’s concerns and be patient and persistent,” says Dr. Kodish.

“Most codes of medical ethics require physicians to follow a practice of nonabandonment,” says Dr. Weise. “However, if the therapeutic alliance is irretrievably damaged, then the child may be better served by someone else.”

The vaccine controversy presents a typical ethical dilemma of autonomy versus beneficence, Dr. Kodish explains. Some vaccine opponents object to state laws requiring children to be vaccinated before entering public school. But these laws are a major factor in the high (80 percent) vaccination rates in the United States that keep infectious diseases under control and help protect unvaccinated children and people vulnerable to disease, such as the elderly.

Vaccine exemptions are granted by nearly all states for medical and religious reasons and an increasing number of states allow philosophical reasons. While only an estimated 3 percent of schoolchildren have been granted exemptions, the number is rising, worrying public health officials that “herd immunity” will be

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Dear Colleague,

We hope you enjoy reading the spring 2010 edition of *Bioethics Reflections*. We chose to focus on ethics and pediatric immunization for our cover story because of the concerns in recent years over a possible link between vaccination and autism. Although the vaccine controversy is not likely to end in the near future, as bioethicists we can assist parents and physicians by providing an ethical framework for discussion and analysis.

Also in this issue, we share with you a story about a fabulous program second-year fellow Monica Gerrek, PhD, started here to introduce high school students to the world of bioethics and critical thinking. The program has been successful and will be passed on next year to another second-year fellow. Dena Davis, a former Cleveland Clinic bioethics fellow is interviewed regarding her current work on page 7.

Finally, we talk with Martin Kohn, PhD, about his newly appointed role as Director of Medical Humanities; we explore the Research Ethics Consultation Program run by Carmen Paradis, MD; and on page 5 we pay tribute to our longtime friend and co-founder of the Bioethics Department here at Cleveland Clinic, the late Shattuck Hartwell, MD.

We appreciate your interest in *Bioethics Reflections*. We hope you enjoy reading it and feel free to contact us with your comments and suggestions.

Sincerely,

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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**Eric Kodish, MD**
*Chairman, Department of Bioethics*

**Barbara Goulden**
*Administrator, Department of Bioethics*

**Bioethics Staff:**
Ruth Farrell, MD
Anne Lederman Flamm, JD
Paul Ford, PhD
Martin Kohn, PhD
Carmen Paradis, MD
Richard Sharp, PhD
Martin Smith, STD
Anthony Thomas, MD
Kathryn Weise, MD, MA

**Christine Harrell**
*Managing Editor*
harrelc1@ccf.org

**Irwin Krieger**
*Art Director*

**Lesley Richard**
*Marketing*
Ethics Consultation Program Bridges Scientific Knowledge, Human Dimension of Research

There inevitably comes a time when researchers need to consider the ethical implications of their work. "Researchers want certain kinds of information," says Carmen Paradis, MD, a Staff Physician in the Department of Bioethics. "But in trying to get at the science, they might put a research participant at risk or, by not appropriately informing them, infringe upon their right to make decisions based upon an accurate understanding of what the research involves."

When concerns of this type occur, an ethicist can provide guidance to a researcher on how best to proceed. It's for this reason that the Cleveland Clinic Department of Bioethics created the Research Ethics Consultation Program. The program, which began in 2009, is voluntary. Its goal isn't to infringe, but to help researchers consider the human dimension in developing scientific knowledge.

Ethical concerns can arise at any point in research, from protocol development to data analysis. Because research can take place over a long period of time — perhaps years — new ethical concerns may develop as knowledge expands. This can happen, for instance, when a provision to store redundant specimens for further research is added to a protocol, Dr. Paradis says. "If such storage is not integral to the main objective of the research, the participant needs to be able to opt in or out of future research, both at the time of the original consenting and in the future," she points out. "The researcher needs to develop a mechanism to manage that, as well as to possibly inform the participant of new clinically relevant findings."

Education is an important element of the program. In her consults, Dr. Paradis tries to give researchers the knowledge they need to make their own decisions the next time they're confronted with similar ethical questions.

She does not have the authority to stop a research project. Only the Institutional Review Board can do that. Though she might ask a researcher to voluntarily suspend his or her research until an ethical question is resolved, she has not yet seen a case where that was necessary. She believes most researchers, while committed foremost to science, are not unmindful of the ethical and human dimensions of the equation.

According to Dr. Paradis, Cleveland Clinic is one of the few organizations in the country to have a research ethics program. "Though the program has been in existence for less than a year, we are already doing as much work as anybody else in this area," she says.

Researchers deal with many questions that were unheard of three decades ago. The breadth of these questions will continue to accelerate in the future as technological capacity increases and an appreciation for the importance of a respectful relationship with research participants evolves.

"Research ethics is the interface between a sophisticated scientific world and personal and societal values," Dr. Paradis says. "As such, it will impact how research develops."
Is it possible to discuss and debate controversial issues in a thoughtful and considerate manner in which opinions on both sides are respected? If you watch the adults on nightly cable political talk shows, you might think the answer is no.

But students from a number of high schools are proving that it is possible to have a calm, rational debate — even on some of the most controversial ethical issues of our day.

These students participate in a distant learning video course created by Cleveland Clinic’s Fellowship in Advanced Bioethics (CFAB), Department of Bioethics and Office of Civic Education Initiatives. Students study bioethical issues, learn how to argue and defend their positions, and experience what amounts to a college preparatory course.

The program is the brainchild of Monica Gerrek, PhD, a CFAB second-year fellow, who developed the course as a way to fulfill the requirement that fellows give back to the community.

“It allows high school students to read bioethics articles and discuss them at a higher level,” Dr. Gerrek says. “These articles are written by PhDs, JDs and MDs. We’re giving the students something similar to a college freshman- or sophomore-level intro to bioethics course. They could not get this in a regular high school class.”

For the course, Dr. Gerrek chose six topics that she believed were particularly relevant to today’s students. The topics include animal ethics, world hunger and poverty, cloning, stem cell research, reproductive ethics and euthanasia.

Each topic includes two articles — one defending the moral rightness and one defending the moral wrongness of an action, procedure or policy. CFAB fellows conduct a short lecture covering the important aspects and moral issues of the topics, followed by an interactive discussion. Each article is presented in an unbiased manner.

Students are required to read the assigned articles, which are posted online, before each session, and they are encouraged to think through each issue. “We all have intuitions about what’s right and wrong,” Dr. Gerrek says. “But [the students] have to figure out how to explain and defend their intuition.”

She emphasizes that the articles are not “dumbed-down.” Each has been published in a professional journal and debated by philosophers. “It is difficult material presented by doctoral-level professionals,” she maintains.

Dr. Gerrek is impressed with the students, both from an intellectual standpoint and by how they handle themselves in class. “A lot of students are open to considering the implications of their views,” she points out. “But they are also very respectful of each other and they respectfully disagree.”

She says it is hard to determine whether any student participating in the class will consider a career in bioethics. But she believes the experience will benefit the students once they reach college and in their everyday lives. “I hope there is a life lesson here, as well as an educational lesson,” Dr. Gerrek says.

Dr. Gerrek concludes her fellowship in June, but the course will return next academic year facilitated by a new second-year fellow. One of Dr. Gerrek’s goals was to create a program that will continue long after her fellowship ends.
In Memoriam
Shattuck Wellman Hartwell, MD, FACS
1928-2009

Created Cleveland Clinic Department of Bioethics

Former Cleveland Clinic Chief of Staff, Director of Professional Staff Affairs and Vice Chairman of the Board of Governors, Shattuck Wellman Hartwell, MD, FACS, died October 8, 2009, from complications of lymphoma and Parkinson’s disease. He was 80.

Dr. Hartwell received his bachelor’s degree from Amherst College and his medical degree from the University of Michigan. He took additional training in Health Services Management at Harvard University’s Schools of Public Health and Business Administration. From 1955 to 1957, he served as a lieutenant in the United States Navy.

Dr. Hartwell joined Cleveland Clinic’s Plastic Surgery Department in 1963 and was Acting Chairman from 1983 to 1985. He created the Department of Bioethics and chaired the Aesthetics Committee. He also was the author of the second edition of “To Act as a Unit,” a book on Cleveland Clinic’s history. As Director of Professional Staff Affairs between 1974 and 1986, Dr. Hartwell spearheaded the development of the Annual Professional Review and the Staff Compensation Program, which equalized compensation differentials between male and female staff members.

Dr. Hartwell was widely known in Cleveland for his extensive service to a number of nonprofit organizations including Musart Society of the Cleveland Museum of Art, the Cleveland Institute of Music, the Cleveland Museum of Natural History, WVIZ-TV, the Cleveland Medical Library Association and the Ohio Humanities Council, and served as a campaign leader for United Way Services of Cleveland. Dr. Hartwell is survived by his wife of 56 years, Mary Jane Davis Hartwell; three children, Davis Hartwell (Jane), Emily Taylor (John Maxwell Taylor) and Samuel Hartwell (Kimberly); two sisters; and eight grandchildren.

“Dr. Hartwell will always be remembered by me as a role model for how physicians should act toward others. He was ever the gentleman, his demeanor professional, his handshake and smile warm and compassionate. When I met him in 1982 in his role as Director of Professional Staff Affairs, it was abundantly clear that he felt that to practice medicine at Cleveland Clinic was not just a “staff position” but a privileged position that we earned every day. I came to understand this and agree with him in very short order.” – Anthony Thomas, MD

“Shad Hartwell was both a gentle and erudite man; a man of vision and determination. I was privileged to get to know him in recent years and will always appreciate his friendship and generosity.” – Eric Kodish, MD, Chairman, Cleveland Clinic Bioethics Department

Welcome New Fellows

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

Joshua Crites, PhD
Philosophy, Vanderbilt University
Interests: Ethics in clinical research development, ethics of public health resource allocation

Thomas Harter, PhD
Philosophy and Applied Ethics, University of Tennessee
Interests: Ethical limits of healthcare markets, healthcare systems and ethics

Olubukunola Mary Tawose, JD
St. Louis University School of Law
Interests: Health law, clinical ethics

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 July 2011 class, completed applications must be submitted by December 15, 2010. For more information about the CFAB and the application process, visit clevelandclinic.org/bioethics.
We discussed how medical humanities contributes to bioethics study and practice with Martin Kohn, PhD, the newly appointed Director of Medical Humanities in the Bioethics Department.

Q: How would you define medical humanities?

Dr. Kohn: Medical humanities uses the disciplines traditionally associated with the humanities—literature, history, philosophy, religion, art history—to integrate the human dimension into health care, medical education and research. The humanities and arts offer insights about the human condition and help medical professionals and students understand that medical treatment resides within a larger human story. By studying the humanities, practitioners can integrate the technical aspects of healthcare with a deeper meaning in caring for others.

Q: What is the relationship of medical humanities to bioethics?

Dr. Kohn: Medical humanities and bioethics deal with human values. Historically, both fields emerged from the human values movement in healthcare and later came together with the formation of the American Society of Bioethics and Humanities.

Bioethics identifies important ethical issues and explores them through moral principles; medical humanities complements that study with examples from history and literature. The humanities bring a real-world context and perspective to abstract discussion.

I sometimes describe we who work in the medical humanities as the wayward cousins of the bioethicist. While bioethics is focused on finding solutions, medical humanities is interested in asking questions that have only provisional answers. We revel in the struggle to live with uncertainty, ambiguity, and multiple perspectives that are characteristics of the human condition.

Q: Can you give a specific example of applying the humanities to bioethics?

Dr. Kohn: Many medical ethics classes study the U.S Public Health Service Tuskegee syphilis experiment (the infamous study in which researchers denied treatment to impoverished African-American subjects with untreated syphilis because it would interfere with their study). Students can read a report about the study, which engages them in an intellectual way. Seeing the film based on the experiment, “Miss Evers’ Boys,” engages students on an emotional level by helping them to identify with the subjects. We can discuss the principle of protecting human subjects in medical research but the film allows us to experience it by creating a world we can enter.

Q: As the first Director of Medical Humanities, what will be your role in the Bioethics Department?

Dr. Kohn: I’ll bring a medical humanities and narrative perspective to the study of bioethics and the department’s clinical ethics practice. I’m working closely with Bioethics Department faculty to revamp the bioethics curriculum at the Cleveland Clinic Lerner College of Medicine and am co-directing the Foundations of Clinical Medicine seminar, which will focus on the art of doctoring and the human experience of health and illness.

Q: What do you hope to accomplish in this position?

Dr. Kohn: I want to build on the culture of innovation at Cleveland Clinic and incorporate the creative and performing arts into medical humanities and bioethics education. They enliven learning and provide a shared common experience for healthcare professionals and the people they serve. For example, educators in medical humanities are using the study of jazz to teach students how to communicate more effectively with patients. Jazz has a structure but it also allows for improvisation.

In similar ways, the course proposal that Martin Smith, STD, Director of Clinical Ethics, and I have developed for the Cleveland Clinic Academy that looks at humanistic care through poetry and performance, will be calling upon actors to bring literary work (poetry) to life through their embodied interpretation of words.
Interpreting regulations is a central component of many lawyers’ careers. “It’s something you learn to do in law school,” says Dena Davis, JD, PhD, professor of law in Cleveland State University’s Cleveland-Marshall College of Law and adjunct professor in Case Western Reserve University’s Department of Biomedical Ethics.

For the foreseeable future, Dena, a 1989 fellow of Cleveland Clinic’s Department of Bioethics, will combine her experience in interpreting regulations and her expertise as an ethicist to analyze some of today’s most sensitive issues. She has been appointed to the working group for human embryonic stem cell eligibility review established by the National Institutes of Health (NIH).

Dena has spent her career looking at bioethical issues. She grew up in Westchester County, N.Y., near the Hastings Center, a bioethics research institute. She says the proximity helped spur her interest in the subject. “Once I got interested, it was easy for me to meet people,” she notes.

She has written extensively on issues such as reproductive technology, stem cells and cloning. Her work focuses on the social and ethical consequences of advances in genetics and reproductive technology.

One way to resolve the issue is to extend minor treatment statutes, which currently allow adolescents to get contraception and STI treatment without parental permission, to include the HPV vaccine. “It’s important for healthcare policy to be consistent. The HPV vaccine, contraception and STI treatment are all essential to good reproductive healthcare,” says Ruth Farrell, MD, Assistant Professor of Surgery at the Cleveland Clinic Lerner College of Medicine, and staff member in the Department of Bioethics and the Department of Obstetrics and Gynecology. Dr. Farrell co-authored an article in Pediatrics about the issue.

“As children get older, they can participate in a meaningful way in decisions concerning their health. From an ethical standpoint, we should be thinking about allowing informed consent for older teenagers,” says Dr. Kodish.

Dena believes the group will contemplate questions focused more on ethics and less on science. As the only nonmedical, nonscientific member, she feels she brings a unique perspective to the group. “It’s a question of reading the regulations on treating human subjects and trying to figure out how they fit a particular situation,” she points out. “It’s very much a question of ethics and interpreting regulations. That’s the role I think I will play.”

This isn’t the first time that Dena has looked at ethical issues related to stem cell research. In the late 1990s, she was a member of a working group at the American Association for the Advancement of Science looking at such questions, and she has written on informed consent issues in embryo donation.

“I’ve been interested in the subjects of genetics and stem cells for quite a while,” she says. “So, I was extremely pleased to be asked by the NIH to be on its working group.”
Open:
Assistant/Associate Professional Staff Position in Bioethics

The Bioethics Department is accepting applications for a professional staff position (associate or assistant level depending on qualifications) who will be eligible for academic appointment at the rank of assistant/associate professor of medicine at Cleveland Clinic Lerner College of Medicine.

Candidates for the position must have a PhD or equivalent terminal degree in an area of study related to bioethics, such as medicine, philosophy, law, sociology, health services research, or medical anthropology. Preference will be given to individuals with significant prior research achievements or strong potential for building a nationally recognized research program in bioethics.

For a full description of the position, visit clevelandclinic.org/bioethics/research or contact Richard Sharp, PhD, Chair, Search Committee, at sharpr3@ccf.org or 216.445.2739.