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Organs for change

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In the annual Ryerson lecture, a pioneering medical ethicist traces Chicago scientists' contributions to organ transplantation—and the questions those advances continue to raise.

In organ transplantation we encounter every important ethical issue in medicine. I sometimes use the image of the Rosetta Stone to suggest that just as it helped us to understand and translate the mysteries of hieroglyphics, so organ transplantation can help us understand the complexities of medical ethics. Essentially, if you can grasp the ethical issues in transplantation, you grasp the major ethical issues in medicine.

The idea of transplanting organs and limbs is not new. Throughout medical history, physicians and patients have sought ways to extend life or to improve the quality of life by transferring an organ or a limb from one person to another. In 300 AD Cosmas and Damian performed innovative surgery, transplanting a leg from a recently deceased person to a patient whose own leg was removed because of cancer. This extraordinary scene was recorded in many Renaissance paintings—as was Cosmas and Damian's later beheading. Some might regard their fate as worse than a malpractice suit.

From the time of Cosmas and Damian, there was little progress on the transplantation scene for about 1,600 years, when the following statement was made: "The problem of organ transplantation in man has been solved." This optimistic declaration was published [in the *Journal of the American Medical Association (JAMA)*] in 1905 by Alexis Carrel, then an assistant to Professor G. N. Stewart at the Hull Biological Laboratory at the University of Chicago. How should I say it? Carrel's statement is *so* Chicago.

In the 21 months—from November 1904 to August 1906—that Carrel was at the University, his research achievements were astounding. He published 33 papers describing breakthroughs that remain the basis of modern transplantation surgery: the ability to sew blood vessels together, to reattach severed limbs, and to transplant organs including kidneys and hearts into dogs and cats. Carrel's earliest description of his work appeared in "The Transplantation of Organs: A Preliminary Communication" (*JAMA*, July–December 1905), where he included the prophetic statement: "From a clinical standpoint, the transplantation of organs may become important...and may open new fields in therapy and biology."

For his research at Chicago, Carrel received the 1912 Nobel Prize in medicine "in recognition of his work on vascular suture and the transplantation of organs." He was the only physician or surgeon between 1901, when the Nobel Prize was first awarded, and 1933 to receive the prize in medicine for work done in the United States. Carrel also was only the second U of C person to win the prize, after A. A. Michelson's 1907 physics award.

We can now ask whether Carrel's 1905 statement—that "the problem of organ transplantation in man has been solved"—was true. It was not. Despite Carrel's technical achievements, scientists did not understand immunology. After several weeks or months, most of his animals died from immune rejection of the transplanted organs. In fact, more than 40 years passed before a partially successful organ transplantation was performed on a human. And when it was done, it was by a Chicago medical-school graduate, David Hume, MD'43.

The story of the first transplant goes like this: While working as a surgical resident in Boston in 1947, Hume was caring for a 29-year-old woman dying from acute renal failure. He decided to try to save her life by performing a kidney transplant. One evening Hume obtained a kidney from an elderly patient who had just died during surgery. He and another resident wheeled the woman to the treatment room at the end of the hall, and, using two gooseneck lamps for light, they attached the donor kidney to the

woman's forearm so that it rested outside the skin. They then covered the kidney with a plastic bag and watched as the patient's urine drained into a jar. This primitive transplant lasted only four days, but that was long enough to allow the woman's own kidneys to recover, and she survived to be discharged. It was the first successful kidney transplant. Seven years later doctors performed the first long-term kidney transplant, which succeeded for eight years, and since then more than 1 million organ transplants have occurred.

Following Hume's 1947 case, he conducted the first series of more traditional kidney transplants, inside the body, and performed nine transplants using cadaver kidneys. Unfortunately, immune-suppression drugs did not become available until the early 1960s, and the longest survival among the cases was 175 days. For his pioneering work, Hume—who died in a 1973 plane crash—is regarded today as the Father of Renal Transplantation.

Carrel and Hume were two in a long line of great clinicians and scholars from the University of Chicago. The advancement of knowledge and intellectual innovation have been at the core of the University's mission since its founding. In an 1897 convocation speech, President William Rainey Harper expressed his hope that when the University finally opened a medical school, it would be one committed to research and innovation: "I do not have in mind...an institution which shall devote itself merely to the education of a man who shall be an ordinary physician," he said, "but rather an institution...whose aim it shall be to push forward the boundaries of medical science,...one from which announcements may be sent from time to time so potent in their meaning as to stir the whole civilized world."

I reflect back on my own Chicago medical-school experience and on my teachers who contributed to the growth of knowledge and made amazing scientific discoveries. Leon Jacobson, MD'39, was the first physician to use chemotherapy. Charles Huggins won the 1966 Nobel Prize for establishing the relationship between hormones and cancer. Don Steiner, MD'56, SM'56, discovered pro-insulin and revolutionized the fields of diabetes and endocrinology. In 1977 Gene Goldwasser, SB'43, PhD'50, my biochemistry teacher, isolated erythropoietin, a substance now used to treat anemia in more than 3 million people each year. And Janet Rowley, PhB'45, SB'46, MD'48, my teacher and colleague, established the link between cancer and genetics. I also think of my clinical mentors, who taught me to be a doctor and to care for patients: the incomparable Joe Kirsner, PhD'42; Lou Cohen, SB'48, MD'53; Joe Baron, SB'58, MD'62, SM'62; Al Tarlov, MD'56; Arthur Rubenstein; and the late John Ultmann and George Block.

I was honored to be invited to join the faculty in 1972, when my very first assignment changed my career path permanently. Chair of Medicine Al Tarlov asked me to establish and then direct the first medical intensive-care unit in our hospital and one of the first such ICUs in the city. At that time we didn't have good ways to monitor patients, we didn't have effective breathing machines to treat patients, and we didn't have doctors who specialized in intensive care. Instead we had enthusiastic amateurs, physicians like me, who suddenly found ourselves in the ICU facing clinical and ethical issues for which we were neither trained nor prepared.

I remember my residents and students asking questions about whether we could ever stop a breathing machine after we had started using it, about how truthful we should be when we told families the prognosis of their loved ones, or how we decided who got admitted to the ICU and whether we could move people out if sicker patients came along. These three issues—end-of-life concerns, truth-telling, and rationing of beds—were tough problems for which I could find no answers in medical journals or texts. My residents and I started to call this kind of practical, patient-centered work *clinical medical ethics*. That is how the field got started.

Meanwhile the developing transplant field made it imperative that we begin to address in a systematic way the clinical ethical issues associated with organ transplantation: in 1963 Thomas Starzl had performed the first liver transplant at the University of Colorado; in 1967 Christian Barnard had performed the first heart transplant in South Africa; and in 1969 the first brain-death standards were developed.

We realized that clinical ethics was an important area for doctors, nurses, and patients, and I have spent my entire career working to develop this new field, by teaching students and residents, training fellows, consulting for patients and hospital staff, and doing research and writing. In 1984 we started the MacLean Center for Clinical Medical Ethics, named for its benefactors and visionary advisers Mary Ann and Barry MacLean, at the University of Chicago, and this work has been the center's mission. In fact, the MacLean Center is the first and leading ethics program in the world that is primarily devoted to research and training in clinical medical ethics.

In our search for answers to the ethical problems in patient care, I discovered that many intellectual leaders of the new American bioethics movement were on the U of C faculty in the early 1970s. These

ethics scholars were willing to help me learn on the job—a kind of apprentice system. My main teacher was James Gustafson, DB'51, University professor in the Divinity School, with whom I met weekly to discuss cases I had seen in the ICU that raised ethical questions. Jim introduced me to Father Richard McCormick, one of the foremost Catholic moral theologians of the 20th century, who was then at the Jesuit School of Theology in Hyde Park, and to Stephen Toulmin, a philosopher who joined the Committee on Social Thought in 1973. Several years later Leon Kass, SB'58, MD'62, another distinguished bioethicist and recently the chair of the President's Council on Bioethics, joined the faculty. These mentoring relationships continued for the next ten years. Jim Gustafson also introduced me to Ann Dudley Gold-blatt, LLM'78, a brilliant teacher and legal analyst, who has been a valued colleague and friend for more than 30 years.

Together we began the new field. Clinical medical ethics aims to improve patient care and health outcomes. It does so by helping patients and families as well as doctors and nurses reach good clinical decisions—decisions based on both the medical facts of the situation and the patient's personal preferences and values.

Nothing I do gives me as much joy and satisfaction as providing good and conscientious care to my patients. I also have spent a great deal of time thinking and writing about the doctor-patient relationship. To my surprise, a paper I had published in 1981, in the *Bulletin of the New York Academy of Medicine,* was discovered a year later by the President's Commission for the Study of Ethical Problems in Medicine, which was rethinking the doctor-patient relationship in the United States. That paper, "Searching for Moral Certainty in Medicine: A Proposal for a New Model of the Doctor-Patient Encounter," rejected the extreme versions of physician paternalism and patient autonomy and instead proposed a new model of shared decision-making. The commission agreed and came to the conclusion: "In this report, the commission encourages a relationship between patients and professionals characterized by mutual participation and by shared decision-making." Since then, shared decision-making has become the nation's prevailing model.

While I would like to claim credit for proposing this new model, I was in fact scooped, beaten to the punch, by Plato about 2,400 years ago. In *The Laws*, Plato contrasts bad and good doctor-patient relationships. In the bad relationship, according to Plato: "The physician never asks the patient for an account of his complaints. The physician prescribes treatments in the brusque fashion of a dictator, and then rushes off in haste to the next patient." Sounds like managed care to me. In contrast, Plato wrote of the good doctor-patient relationship: "The physician treats the patient by going into things thoroughly from the beginning in a scientific way and takes the patient and family into confidence. The physician never treats until he has won the patient's trust and then aims to produce a complete restoration to health." This sounds very much like shared decision-making, stressing the importance of communication, trust, and agreement between patient and doctor.

For more than 20 years physician-ethicists at the Mac-Lean Center have worked closely with transplant surgeons to help solve the transplant field's two central ethical challenges: first, how to increase the supply of organs, and then how to distribute available organs in a fair and equitable way. Two stories, one on livers for children and the other on kidneys for adults, point to solutions for increasing the organ supply.

In the 1980s liver transplantation had become effective at saving lives. Unfortunately, because there were not enough pediatric livers, 30 percent of infants and children with congenital liver disease died before they received a transplant. In 1985 Christoph Broelsch and his U of C medical center team solved this problem by developing a new operation that allowed living donors, usually parents of the child, to donate segments of their own liver to their child.

The living-donor liver operation was challenged on ethical grounds because the procedure was new and the risks to living donors were unknown. Would it be safe to remove a portion of a healthy person's liver? What would be the short- and long-term consequences? One commentator asked, "Will this be the first operation with a 200-percent mortality?"

The general issue Broelsch's critics raised involved the ethics of surgical innovation. Unlike procedures used for testing new drugs, surgical innovation is not controlled by a regulatory process. As an observer put it, "There is no FDA for surgeons." Instead most surgical innovation is managed through professional and peer oversight. Working with Broelsch and his team, MacLean Center ethicists developed a new approach to the ethical problems in innovative surgery. The Chicago model emphasized four key elements: establishing the clinical need for the innovation; assuring adequate scientific and clinical strength of the team; meticulously protecting human subjects; and announcing the plans for surgery publicly before performing the first operation.

On the matter of public disclosure, we did something that had never been done before. Four months

before the first operation, we published a paper in the *New England Journal of Medicine* ("Ethics of Liver Transplantation with Living Donors," 1989) to alert the public and the transplantation community and to invite responses and criticisms of the Chicago model for ethical surgical innovation. The model has improved the process of professional self-regulation and has helped advance scientific knowledge while protecting patient rights and patient safety. Our clinical-ethics work enabled Broelsch's program to go forward, initially in Chicago and later worldwide.

The first living-donor liver recipient, in 1990, was Alyssa Smith, whose mom, Teri, was her donor. Alyssa graduated from high school in May 2006—a healthy and happy teenager. Her success prompted a series of pediatric living-donor transplants at Chicago, and surgical programs in the United States, Europe, and Asia began to perform the operation. Since 1989 living-liver pediatric transplantation has been performed successfully in more than 30 countries and has saved the lives of more than 10,000 infants and children. In the U.S. and Europe, mortality for children born with congenital biliary atresia—still the most common reason for pediatric liver transplants—has decreased from 30 percent in the 1980s to less than 5 percent today.

Today we face an inadequate supply of kidneys for adults. In 2006 there were more than 100,000 people on the transplant waiting list, with fewer than 30,000 transplants performed. Even with dialysis, many potential recipients suffer and die while awaiting a kidney transplant.

In 1997 a MacLean Center team proposed a new model to increase the supply of adult kidneys. The group, headed by Lainie Ross and Dick Thistlethwaite, suggested a paired-kidney exchange model: Let's say Donor One wants to give a kidney to a relative, Recipient One, but biological barriers—such as the wrong blood type—do not allow for such a donation. Meanwhile a similar problem exists for another pair of relatives, Donor Two and Recipient Two. But what if Donor One were a good donor for Recipient Two and Donor Two for Recipient One? Please note that Donor One and Recipient Two, and Donor Two and Recipient One, don't know each other. You could do a swap, a paired exchange of kidneys. Paired exchanges like these could greatly increase the supply of kidneys by opening the possibility of a national or even an international registry of unrelated donors.

Unfortunately, a major ethical obstacle has delayed the implementation of this novel idea. Currently in the United States, only altruistic donations are permitted. A 1984 federal law prohibits the exchange of organs for "valuable consideration." So the question arose: does paired-kidney exchange violate federal law? Ross and Thistlethwaite considered this issue in their 1997 *New England Journal of Medicine* article and stated: "In our view, the transplantation law was not designed to prohibit altruistic donations of organs by family members or close friends." Rather, the law was intended to prevent the buying and selling of organs, and paired exchange involves no financial transaction.

Still, for the past ten years legal and ethical uncertainty has limited the widespread application of paired-kidney exchanges; about 150 were done throughout the world, 30 to 50 of those in the United States. I am delighted to say that in March 2007 the U.S. House passed the Norwood Living Organ Donation Act, which amends the 1984 National Organ Transplant Act specifically to allow paired exchange without risk of criminal or civil penalties. The Norwood Act, slated for the Senate's summer schedule as of May, is expected to be signed by the president.

Because the paired-exchange program encourages the use of living donors unrelated to the recipient, many think the Norwood bill opens the door to a broader consideration of using market solutions to address the organ-shortage problem. Graduate School of Business professor Gary Becker, AM'53, PhD'55, and Law School professor Richard Epstein have written powerful and controversial papers proposing that the buying and selling of organs be legalized. Janet Rowley, a member of the President's Council on Bioethics, says such market proposals are attracting a lot of discussion in Washington.

Chicago faculty have also worked to improve the fair distribution of organs. The United States had been divided into 63 organ-procurement areas, generally representing states or large metropolitan areas. Under this system, donated organs were kept within the same area in which they were donated. From one area to another, however, there were often great disparities in the waiting time to receive a liver transplant. Sometimes the areas with the shortest and longest waiting times were adjacent states. In Kansas, for instance, a recipient could wait 0–131 days, while in Colorado the wait was at least 180 days.

The ethical problem was whether allocating organs based primarily on geographic area resulted in the fairest distribution. My colleague David Meltzer, U-High'82, AM'87, PhD'92, MD'93, conducted research for the Institute of Medicine that showed that in transplant areas with larger populations, donated livers were more likely to go to the sickest patients, those who really needed a liver to survive. By contrast, in less populous transplant areas livers often went to people who could have waited two or three more years for a transplant. Based on this research, in 1999 the Institute of Medicine committee

recommended, to the full institute and to the United Network of Organ Sharing, sharing livers across geographic regions and allocating them based on clinical need. The official name for this recommendation, which was implemented, is the MELD system, which stands for Model for End-Stage Liver Disease. I prefer to call it Meltzer's Equitable Liver Distribution. Several years of data now suggest that the MELD system is more equitable and effective than the previous geographic system and is saving an additional 300 to 500 lives per year.

My concluding example of the U of C at the crossroads of organ transplantation and clinical ethics brings us to the present—and to China. China estimates that up to 1.5 million of its people need an organ transplant, usually a liver because hepatitis B is endemic there. China now performs only 10,000 transplants a year, and those operations pose a major ethical problem because 95 percent of donor organs come from executed prisoners. This practice raises several questions: whether prisoners are being executed to get organs; whether condemned prisoners can really give voluntary informed consent the night before their execution (although the law requires that prisoners or their family provide informed consent, the practice is not well-documented); and whether organs should, as they are now, be sold to non-Chinese visitors—so-called transplant tourism.

As you might suspect, the Chinese organ-transplant system is under attack. Nationally, the Falun Gong accuses China of killing dissidents to use their organs. Globally, China is reviled for human-rights violations, especially using executed prisoners' organs.

Three key players are working to improve the organ-transplantation system in China. Huang Jiefu is the Chinese vice minister of health and a distinguished liver-transplant surgeon. In November 2006, at a national transplantation meeting in Guangzhou, China's president, Hu Jintao, appointed Huang to chair a new national committee charged with changing China's transplantation policies.

Roy Schwarz, a physician, medical educator, and former dean at the University of Colorado Medical School, chairs the University of Chicago's Biological Sciences Division Visiting Committee. Schwarz is also the former president of the China Medical Board, a philanthropic foundation in New York that in November 2006 awarded a $1 million grant to Chicago and to China, with Huang and U of C surgery professor Mike Millis as the co-principal investigators. Millis, Chicago's chief of transplantation, has been doing a Henry Kissinger imitation—shuttle diplomacy—traveling to Beijing twice in April. In March a Chinese delegation spent a week visiting at the University of Chicago.

Through this partnership with Chicago, China hopes to achieve four clinical outcomes: improve the training of its transplant surgeons; decrease the number of approved transplant programs; establish a national registry, which no country currently has; and develop a national system of organ sharing across regions.

China also hopes to achieve several ethical outcomes. First, to join the world transplantation community by adhering to global ethics standards, the nation plans to stop using executed prisoners as an organ source. In April China's Supreme Court announced it would review every death sentence before an execution is carried out. Most observers believe this decision is meant to discourage the use of executed prisoners to obtain organs. Second, China hopes to join most other advanced technological countries by establishing brain-death standards, which would greatly increase the country's supply of cadaveric organs. Third, China plans to greatly expand its use of living donors. Finally, the country intends to prohibit the buying and selling of organs and to criminalize transplant tourism.

Huang Jiefu authored an extraordinary paper published in the April *Liver Transplantation*, the field's leading journal, announcing China's goals over the next three years for achieving these clinical and ethical changes. In fact, in April the first changes were instituted when the Chinese government decreased the number of approved transplant programs from 600 to approximately 100 and established the national-transplant registry.

So the University of Chicago and its clinical-ethics group are working not only to improve transplantation practices worldwide but also to improve global human rights. Those of us working on the Chicago side of the China grant are not naive. It is not a done deal that the changes promised will happen or that they will happen in the short time frame we would like. But our collaboration with the leaders of Chinese medicine is a milestone. Vice Minister Huang's *Liver Transplantation* paper was a public declaration of China's intent, and we at the MacLean Center and at the University are cautiously hopeful that good things will come from this partnership.

After a century of Chicago's clinical and ethical contributions to organ transplantation, we know that we will see many more medical and surgical innovations in the next 100 years as today's incurable diseases yield their secrets. Isn't such innovation the meaning of the University of Chicago motto, *Crescat scientia: vita excolatur*? Professor Paul Shorey, who created this motto in 1910, translated it as follows: "Let knowledge grow from more to more; and so be human life enriched." As a

physician-ethicist, I am proud that our group will continue working with basic and translational scientists to assure that we develop and apply new cures quickly and that we do so while adhering to the highest ethical standards of medicine.

Should organ donors be paid?

With 96,000 Americans on the organ wait list and only 29,000 transplants performed last year, the transplant community constantly tries to encourage more people to donate. Yet some observers believe the volunteer system will never meet the need. Market proposals to increase the organ supply, MacLean Center for Medical Ethics Director Mark Siegler, MD'67, noted in his Ryerson lecture, "are attracting a lot of discussion in Washington." The currently illegal practice of paying donors is also a hot topic within the University, where medical, business, and law faculty have taken part in the national debate.

Proposals range from a free-market system, in which individuals pay for organs, to a regulated system where the government (Medicare or Medicaid) or private insurance pays donors, at suggested rates from a few hundred to tens of thousands of dollars. The idea isn't new: in a 1997 *Business Week* column GSB professor Gary Becker, AM'53, PhD'55, asserted that "the federal government might be designated as the only authority with the power to buy organs for transplants and would allocate them to hospitals with patients that need transplants." In a working paper Becker and Julio Jorge Elías, AM'01, PhD'05, argue that monetary incentives could increase the organ supply, eliminating the long waiting list "without increasing the total cost of transplant surgery by a large percent." They estimate the value of a kidney at around $15,000 and a liver around $35,000.

Yet cash might not be the preferred incentive, notes law professor Richard Epstein, who organized a July 6–7 Law School conference on transplant policy and in April 2006 argued for a market system before the President's Council on Bioethics. A "package of benefits to cover illness or death," he says, might serve a donor better. He's not sure which forms the transactions would take "because no one's allowed to try them." Several hospitals, including Johns Hopkins, have begun successful paired-kidney exchange programs, showing, Epstein says, "that markets run better than you think."

Market incentives, however, raise concerns. Moral objections include the arguments that buying and selling organs demeans human beings, commodifies the body, and changes the relationship between doctors and patients into a commercial exchange. The practice also could exploit the poor, who would be more likely to accept money for organs. Yet patients already pay for services and medications, Siegler says, and the poor, unfortunately, get exploited in many areas of life. He's more concerned "about the utilitarian aspects of shifting from a voluntary, altruistic system to a commercial system." Until the 1970s the United States used commercial blood banks, he notes, and studies showed the paid-for blood was more likely to carry hepatitis than volunteer blood; paid organ donors likewise may prove riskier. Siegler also worries that paid donors would replace, rather than supplement, volunteers. "If you do the experiment of a market system and end up with fewer organs," he says, "you not only spend a lot of money but you also cost a lot of lives."

For Chicago transplant surgeon Richard Thistlethwaite, the moral concerns are convincing. Thistlethwaite, president of the International Pediatric Transplantation Association, spoke against financial incentives at the group's March meeting. Although increasing the supply is a dire need, he says, market proposals are "not about the recipient but the donor." Asking for organs in exchange for money, he says, violates "human dignity," changing donors "from an end in themselves to a means for someone else." In Iran, which has a highly regulated paid system, "the majority of donors are worse off afterward," he says, because they don't seek follow-up care. The $1,300 government fee doesn't improve their lives. India, which banned paid transplants in 1994 but where the practice continues illegally, faces a similar situation. The poor who donate don't have sick leave and often lose their jobs during recovery. Yet in the United States, Epstein argues, donors would continue to be physically and psychologically screened, and they would receive much more money and possibly health care.

While proponents contend that individuals should have the autonomy to decide whether to donate an organ, for Thistlethwaite absolute autonomy is "an extremist view that could justify anything." In the United States "you can't sell yourself into slavery" and "people have to wear seat belts. Autonomy doesn't trump everything else." In the free market a woman can sell her egg for about $10,000. "But if it's the right race and athletic ability, it could get $100,000." To him such pricing, and college-newspaper ads soliciting egg donations, are "an atrocity." And if the government set the price like many proposals suggest, he says, the autonomy argument becomes moot.

Then there's the exploitation issue. No matter how much you pay donors, Thistlethwaite says, it's "the upper class preying on the lower class." It may work in an economic model, he says, but not in a "justice model." And even with their health costs covered, poor people may not seek out postsurgical

care. Although anecdotal evidence shows health risks to donors are rare, long-term studies haven't been done on a large enough population. In the end, he says, "the ethical justification for doing this to people doesn't exist."

For Epstein, on the other hand, ethics demands the United States try a market system. In a May 2006 *Wall Street Journal* column decrying the Institute of Medicine's recommendation against financial incentives, he argues that potential lives saved outweigh other concerns. "Only a bioethicist could prefer a world in which we have 1,000 altruists per annum and over 6,500 excess deaths over one in which we have no altruists and no excess deaths." And with the money saved from reducing "the horrifically expensive dialysis program," the country could provide organ donors with social services.

Epstein isn't holding his breath. Though the President's Council on Bioethics plans to issue a report on the topic in coming months, council member and Chicago professor of medicine Janet Rowley, PhB'45, SB'46, MD'48, notes that a market system is "highly unlikely to happen"—at least until "the list gets so big that it's politically effective, or if someone who's a big name dies" waiting for a transplant.