Kidney Transplant Involving HIV Contraction

The Successful Defense of an Informed-Consent Case

By Matthew L. Johnson

A review of one verdict in an informed-consent case, noteworthy due to the nationally publicized circumstances surrounding the underlying event that led to the lawsuit.

On November 16, 2011, a 12-member Cook County, Illinois, jury found in favor of a major Chicago teaching hospital in an informed-consent medical malpractice case in which the plaintiff's attorney sought over $50 million dollars in compensatory damages. The case was tried by William V. Johnson, president of Chicago's Johnson & Bell, who represented the University of Chicago Medical Center (UCMC). He was assisted at trial by Johnson & Bell shareholder Matthew L. Johnson and associate Erin E. Blake.

The verdict is noteworthy due to the nationally publicized circumstances surrounding the underlying event that led to the lawsuit. In November 2007, almost four years to the day that the verdict came down, four Chicago-area organ recipients tested positive for human immunodeficiency virus (HIV) and hepatitis C. The diagnoses of these infections among the transplant recipients came within a year of their respective transplants. The organs for the transplants came from a deceased adult male who, unbeknownst to anyone involved, had contracted HIV and hepatitis C in the months before his fatal car accident. His relatives made the decision to donate his organs, and when the organs were harvested, they were tested for infectious diseases, including HIV and hepatitis C. Because the man contracted these infections during the "window" period between transmission and conversion to seropositive status, the organs tested negative at the time that they were harvested. Before these cases the last known transmission of HIV from an organ transplant had occurred in the late 1980s.

Illinois-based Gift of Hope, the organ procurement organization that contacted the various Chicago transplant centers about the availability of the organs, was the entity that tested the organs for infectious diseases, including HIV. When this happened, and even today, the standard test used in this scenario was the "ELISA" test. This test generally can detect antibodies to HIV within a window of about three months. Nucleic acid testing (NAAT), which tests for DNA or RNA of actual viruses, was not commonly available in 2007 in this setting and was not used in these cases. Nucleic acid testing can diagnose even infections obtained within 2–4 weeks of the test.

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The plaintiff's attorney's theory of liability in the Chicago trial did not have to do with the testing modalities used. Rather, central to the theory of liability was the social history of the deceased donor of the organs at issue. According to the social history that was provided by his relatives to the organ procurement organization, the deceased donor was a homosexual. The plaintiff's attorney predicated liability on the plaintiff's testimony that had the plaintiff known that the decedent was a homosexual, she would not have accepted the organ for transplant. In 2007, when the plaintiff received the organ, the informed-consent practices used by transplant centers varied widely throughout the United States.

A key trial issue was the relevance and application of certain guidelines issued by the Centers for Disease Control and Prevention (CDC) to the transplant surgery community, specifically, the "CDC Guidelines for High Risk Behavior," which outlined the CDC's definition of high risk for organ donors:

Donor Exclusion Criteria

Regardless of their HIV antibody test results, persons who meet any of the criteria listed below should be excluded from donation of organs or tissues unless the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease (*e.g.*, emergent, life-threatening illness requiring transplantation when no other organs/tissues are available and no other life-saving therapies exist). **In such a case, informed consent regarding the possibility of HIV transmission should be obtained from the recipient.**

Behavior/History Exclusionary Criteria

1. Men who have had sex with another man in the preceding five years.
2. Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding five years.
3. Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.
4. Men and women who have engaged in sex in exchange for money or drugs in the preceding five years.
5. Persons who have had sex in the preceding 12 months with any person described in items 1–4 above or with a person known or suspected to have HIV infection.
6. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane.
7. Inmates of correctional systems. (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population). (emphasis in original).

During the trial, the plaintiff's attorney argued that the CDC guidelines set the standard of care for the transplant surgeon at the UCMC who performed the kidney transplant. The plaintiff's transplant surgery expert, citing these guidelines, opined that the UCMC transplant surgeon was required to obtain the plaintiff's informed consent for the use of an organ designated by the CDC as high risk before performing the operation.

The defendant's attorney's response to this argument was, first and foremost, that the CDC did not set the standard of care for transplant surgeons. Rather, the standard of care on this issue was established in conjunction with the written policies of the Organ Procurement and Transplantation Network (OPTN). The U.S. Congress established the OPTN when it enacted the National Organ Transplant Act (NOTA) of 1984. The act called for a unified transplant network that a private, nonprofit organization would operate under a federal contract. Then, following further study and recommendations from a NOTA-commissioned task force, the U.S. Department of Health and Human Services (HHS) solicited proposals in 1986 for the operation of the OPTN. The United Network for Organ Sharing (UNOS) was awarded the initial OPTN contract in September 1986, and the UNOS has continued to administer the OPTN since that time. Effective March 2000, the HHS implemented a final rule establishing a regulatory framework for the structure and operations of the OPTN. Under the terms of the final rule, policies intended to be binding upon OPTN members are developed through the OPTN committees and board of directors and then submitted to the secretary of the HHS for final approval.

On the issue of communicating a donor's social history, the OPTN policies as they existed in January 2007 when the plaintiff's transplant occurred did *not* require that a hospital obtain informed consent from the recipient of a CDC-designated, high-risk donor before surgery. Rather, the OPTN guidelines, as revised on November 19, 2004, stated as follows:

4.0 Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases or Medical Conditions, Including Malignancies, of Donor Origin

4.1 Screening Potential Organs for HIV. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO [organ procurement organization]... must provide, to the recipient transplant center the screening results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

4.1.1 Donor History. The Host OPO [organ procurement organization] will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk"

group, as defined by the Centers for Disease Control. *The Host OPO [organ procurement organization] must communicate the donor history to all institutions receiving organs from the donor.* (emphasis added).

It was the last sentence of section 4.1.1 of the OPTN policies that was critical to the parties' respective theories in the case. The plaintiff's attorney took the position that 4.1.1 infers an informed consent process between the institution performing the organ transplant and the potential organ recipient; otherwise, the organ procurement organization would not have a reason to communicate the donor history to the institution performing the organ transplant. Meanwhile, the defendant's attorney argued that this sentence did not mean that informed consent was required; rather, the transplant surgeon needed to receive information that a donor belonged to the high-risk group as defined by the CDC and to weigh it in counseling a patient about the benefits of accepting a particular organ for a transplant. In other words, the transplant community had not yet adopted a specialized informed-consent process for using CDC-designated, high-risk organs. Therefore, it was incumbent on the individual transplant surgeon to weigh the risk of infection against the benefit of a transplant, and it was not necessary under the standard of care as it existed at the time to obtain a specialized informed consent to use a CDC-designated, high-risk organ.

The standard of care in the transplant community after the publication of the four Chicago cases was used to highlight the UCMC's transplant surgeon's compliance with the prevailing standard of care as it existed in January 2007.

The defense expert on this issue was Dr. Dorry L. Segev, a transplant surgeon and epidemiologist on the staff of The Johns Hopkins Hospital, Baltimore, Maryland. During the trial, Dr. Segev testified regarding the interplay between the CDC guidelines and the OPTN policies and the standard of care for transplant surgeons as it existed in January 2007 in this scenario. Dr. Segev testified,

> So in January, 2007, the standard consent process was the physician would distill down the important aspects of the donor to tell the recipient so they can make an educated decision about whether to accept the organ or not. The behavioral criteria that had been identified by the CDC in 1996 were nowhere on this radar because 20 years had gone by, not a single HIV infection had occurred. There are hundreds of other more important things we need to talk to the patient about, and so it was within the purview of the physician obtaining informed consent as to what aspects of the donor history should be discussed. And usually in those situations it was donor kidney function, the creatinine, the age, hypertension, the cause of death. So if it was stroke, it means there's more vascular disease than not. These things that will determine—will predict whether a kidney will last longer or less time, those were the things that were the standard of care. The standard of care was you as a physician, as part of the art of medicine, would tell the patient what you felt was important for them to know at the time.

See Trial Tr., *A.M. v. U.C.M.C.*, Nov. 9, 2011, at 112–13.

Dr. Segev noted that annually over 16,000 persons in the United States died while waiting on the transplant wait list for a suitable organ and that the list had over 92,000 persons on it. *See* Trial Tr., *A.M. v. U.C.M.C.*, Nov. 9, 2011, at 41. Meanwhile, over 425,000 transplants had occurred since the 1980s without transmitting HIV from a donor to a recipient. *See* Trial Tr., *A.M. v. U.C.M.C.*, Nov. 9, 2011, at 41. Therefore, Dr. Segev testified that "I and the general transplant community [feel] very strongly that these organs should be made available because the risk of transmission of HIV is incredibly small." *See* Trial Tr., *A.M. v. U.C.M.C.*, Nov. 9, 2011, at 111–12.

The jury weighed Dr. Segev's testimony in conjunction with evidence regarding the OPTN guidelines implemented after the transplanting occurred in this case. These guidelines read as follows:

> **4.1.1. Communication of Donor History.** The Host OPO [organ procurement organization] will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria..., the Host OPO [organ procurement organization] must communicate this information regarding donor history to all institutions receiving organs from the donor.
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> ...
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> If the transplant center receives information from the Host OPO [organ procurement organization] that the donor meets any of the above criteria, *the transplant center must inform the potential recipient prior to implantation.* The transplant center shall maintain documentation of the potential recipient's informed consent to receive an organ from the donor who meets any of the above criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter. (emphasis added).

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The second primary argument that the defense attorney raised was that although the standard of care did not require the UCMC transplant surgeon to obtain a specialized informed consent to implant a CDC-designated, high-risk organ, nevertheless a member of the transplant surgeon's team, a nurse coordinator, had informed the patient of the donor's homosexuality. The jury heard testimony from the coordinator, who testified that it was her custom and practice to provide such information. The jury also heard testimony from the plain-

tiff, who denied that she was told that the deceased donor was a homosexual. She and her family testified that the first time that plaintiff learned that the deceased donor was a homosexual was when she was diagnosed with HIV and hepatitis C in November 2007. Moreover, the plaintiff testified that she previously had rejected two previous kidney offers on the basis of the social history that the coordinator had provided to the plaintiff. Although the jury heard and considered this testimony regarding the two previous kidney offers, despite a defense objection and a pretrial motion in limine, the defendant's attorney used it to argue that the plaintiff knew about CDC-designated, high-risk organs due to her years on the transplant list and the education that she received during those years, and she decided to accept the kidney with knowledge of the donor's homosexuality.

In Illinois, it is rare for a medical malpractice case to proceed to a trial exclusively on an informed-consent theory. In these cases, a jury receives the following informed-consent instructions:

> In providing medical [services] [care] [treatment] to [patient's name], a [insert appropriate medical professional] must obtain [patient's name]'s informed consent.
>
> When I use the expression "informed consent" I mean a consent obtained from a patient by a [insert appropriate medical professional] after the disclosure by the [insert appropriate medical professional] of those [risks of] [and] [or] [alternatives to] the proposed treatment which a reasonably well-qualified [insert appropriate medical professional] would disclose under the same or similar circumstances. A failure to obtain informed consent is professional negligence.
>
> [The only way in which you may decide what (risks) (and) (or) (alternatives) the [insert appropriate medical professional] should have disclosed to [patient's name] is from expert testimony presented in the trial. You must not attempt to determine this from any personal knowledge you have.]

The instruction on burden of proof reads, in part, as follows:

> The plaintiff claims that defendant failed to inform the plaintiff of those [risks] [and] [or] [alternatives to] the [described the procedure performed] which a reasonably well-qualified [insert appropriate medical professional] would have disclosed under the same or similar circumstances; plaintiff further claims that if the defendant had disclosed those [risks] [and] [or] [alternative], a *reasonable person in the plaintiff's position* would not have submitted to the [describe the procedure performed]; and the plaintiff further claims that he was injured, and the defendant's failure to disclose [risk] [and] [or] [alternatives] was a proximate cause of that injury. The defendant [denies that he failed to inform the plaintiff of those [risks of] [and] [or] [alternatives to] the [describe the procedure performed] which a reasonably well-qualified [insert appropriate medical professional] would have disclosed under the same or similar circumstances; denies that a reasonable person in the plaintiff's position would not have submitted to the [describe the procedure performed] after being told of those [risks] [and] [or] [alternatives]; [denies that the plaintiff was injured or sustained damages] to the extent claimed; and denies that any failure to disclose those [risks] [and] [or] [alternatives] was a proximate cause of any injury].

See Illinois Pattern Jury Instructions 105.07.01 and 105.07.03 (2011).

With these instructions in mind, the defendant's attorney argued that a reasonable person would have submitted to the transplant under the circumstances in this case: the plaintiff had been on the transplant list for seven years and had recently converted to a dialysis method that required a port in her neck, and, statistically speaking, a patient faced an increased risk of a chance of death for each year that the patient was on dialysis, whereas, since the late 1980s, among over 425,000 transplants, no reported case of HIV transmission existed.

The court denied a directed verdict motion, grounded in the plaintiff's testimony that had she known of the risks of death versus contracting HIV and hepatitis C she would not have proceeded with the surgery, based on a ruling that the relevant testimony was equivocal. Nevertheless, the defendant's attorney used the testimony to highlight the apparent lack of meaningful risk in obtaining an organ from a CDC-designated, high-risk individual as of January 2007.

In closing argument, the plaintiff's attorney argued that the evidence was unequivocal that the UCMC negligently had practiced informed consent for the implantation of a CDC-designated, high-risk kidney to the plaintiff, and she would not have accepted the organ had she received a properly implemented informed consent. It followed that then she would not have had the surgery and she would not have contracted HIV and hepatitis C. Meanwhile, the defendant's attorney argued that while the standard of care did not require a specialized informed consent in this scenario, nonetheless the defendant had provided the plaintiff with the deceased donor's history of a homosexual lifestyle, and the fact of that history was at her disposal when she made the decision to proceed with the surgery.

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Respecting damages, the plaintiff's attorney argued that due to the medications necessary to treat the HIV, the plaintiff experienced kidney rejection, she had to go back on dialysis, and she could have a shortened life expectancy as a result. The plaintiff's attorney also argued that the plaintiff might experience liver failure as a consequence of her hepatitis C. Lastly, the plaintiff's attorney highlighted the emotional turmoil and life changes that accompanied these diagnoses.

The defendant's attorney, while acknowledging the poor outcome, argued that due to advances in medication the patient's HIV would very likely never convert to full-blown AIDS as long as the plaintiff continued her pill regimen, which at the time of the trial consisted of one pill per day. The testimony to support this argument came from Dr. Michael Wong, an infectious diseases specialist from Harvard University, Boston, Massachusetts. The defendant's attorney also argued that encouraging hepatitis C drug trials currently underway gave clinicians realistic hope that medicine could eradicate the disease within the plaintiff's lifetime. Lastly, the defendant's attorney highlighted the medical evidence from experts and treating physicians that supported the position that the plaintiff's kidney's rejection was unrelated to the HIV therapy.

The jury deliberated for shortly over two hours following a two-week trial. During the deliberations, the jury asked for the general informed-consent form for the surgery that the plaintiff had signed and for the medical center's booklet for transplant patients. Of the four medical malpractice cases that arose from the four infectious disease transmissions at the three Chicago transplant centers, three were resolved out of court. The case discussed here was mediated unsuccessfully during its four-year pendency as the parties held vastly disparate opinions on its value. Plaintiff's attorneys are currently seeking an appellate review by the First District Appellate Court of Illinois. **HD**