HIV Screening Practices for Living Organ Donors, New York State, 2010: Need for Standard Policies

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Our survey of kidney and liver transplant centers in New York State found a wide variation among transplant centers in evaluation and screening for HIV risk and infection among prospective living donors. Survey results underscore the need to standardize practices.

A recent transmission of human immunodeficiency virus (HIV) from a living donor to a kidney recipient revealed a possible limitation in existing screening protocols for HIV infection in living donors. We surveyed kidney and liver transplant centers (N = 18) in New York State to assess HIV screening protocols for living donors. Although most transplant centers evaluated HIV risk behaviors in living donors, evaluation practices varied widely, as did the extent of HIV testing and prevention counseling. All centers screened living donors for serologic evidence of HIV infection, either during initial evaluation or ≥1 month before surgery; however, only 50% of transplant centers repeated HIV testing within 14 days before surgery for all donors or donors with specific risk behaviors. Forty-four percent of transplant centers used HIV nucleic acid testing (NAT) to screen either all donors or donors with recognized risk behaviors, and 55% never performed HIV NAT. Results suggest the need to standardize evaluation of HIV risk behaviors and prevention counseling in New York State to prevent acquisition of HIV by prospective living organ donors, and to conduct HIV antibody testing and NAT as close to the time of donation as possible to prevent HIV transmission to recipients.

The first successful living kidney donation was performed between identical twins in 1954 in Boston, Massachusetts. Since then, the number and percentage of living organ donors have increased in the United States [1, 2]. In 2010, 6564 (45%) of a total 14 507 US organ donors were living donors, compared with 1829 (31%) of a total 5909 US organ donors in 1988 [2]. In 2010, US transplant centers performed 16 900 kidney transplants (ie, multiple kidney transplants may originate from single deceased donors), of which 6278 (37%) used kidneys from living donors, and 6291 liver transplants, of which 282 (4%) used livers from living donors [2]. Screening deceased organ donors for human immunodeficiency virus (HIV) infection has been required since 1985, and, in 2009, the Organ Procurement and Transplantation Network (OPTN), which establishes the national standards for organ procurement, issued a guidance document on the medical evaluation of prospective living organ donors, including HIV screening [3].

Transmission of HIV from a living organ donor through solid organ transplantation is very rare but has been recognized [4, 5]. A recent investigation of a case of HIV transmitted from a living organ donor in New York City suggested that existing screening...
protocols for HIV infection in prospective living donors may be inadequate and highlighted a need to assess current practices of transplant centers [4]. We surveyed New York State transplant centers to assess their HIV infection screening protocols for prospective living donors, including the extent of HIV behavioral risk assessment, HIV prevention counseling, and the type and timing of HIV testing.

MATERIALS AND METHODS

We used the OPTN online database (http://optn.transplant.hrsa.gov/data/) to identify solid-organ transplant centers that performed living donor kidney and liver transplants in New York State in 2009. For each kidney or liver transplant center identified, we sent email invitations to at least one transplant coordinator and one transplant physician director in January 2011 to request their participation in an online survey regarding screening protocols for HIV infection.

Respondents were asked to submit responses on the basis of their transplant center’s HIV screening practices as of 1 January 2011. The survey queried respondents on number and type of transplants performed, current institutional practices for behavioral risk assessment, HIV serologic testing (enzyme immunoassay [EIA] and confirmatory Western blot or other supplemental test), nucleic acid testing (NAT), and time intervals between testing and organ recovery. Behavioral risks, as defined by the 1994 Centers for Disease Control and Prevention (CDC) Guidelines for Preventing Transmission of HIV through Transplantation, include history of injection drug use, history of hemophilia or related-clotting disorder, history of engaging in sex in exchange for money or drugs, and if male, history of having sex with another man [6].

We sent follow-up reminders by email and by telephone to nonresponders. No incentives were provided for completing the survey. Survey responses were collected via Survey Monkey (Palo Alto, California) prior to the publication of our investigation of HIV transmission from a living organ donor [4].

Because of the small number of the transplant staff and the frequent communication between transplant coordinators and physician directors at each transplant center, respondents were allowed to submit one joint response for each kidney or liver transplant center. Alternatively, multiple responses from the same transplant center were collapsed into a single response, with reconciliation of discordant responses by either averaging ordinal or interval responses, or using the response that was most internally consistent with screening practices described by respondents from the same transplant center.

De-identified data were analyzed using SPSS (version 18; IBM Corporation) using standard frequency distributions. No bivariate analyses or significance tests were performed because of the limited sample size of transplant centers in New York State.

RESULTS

Characteristics of Respondent Transplant Centers

In 2009, 14 kidney transplant centers and 4 liver transplant centers performed a total of 567 living-donor kidney transplantations (median, 23.5; interquartile range [IQR], 14–35.3; range, 7–138) and 23 living-donor liver transplantations (median, 2.5; IQR, 2–3; range, 1–17) in New York State. Nine of the 14 kidney transplant centers were located in New York City, Westchester, or Long Island, and accounted for 83% of all living-donor kidney transplantations in New York State in 2009. All 4 liver transplant centers that performed living-donor liver transplantations were located in New York City, Westchester, or Long Island. We received 15 completed surveys representing all 14 kidney transplant centers, with 2 surveys from respondents from the same kidney transplant center, and 4 completed surveys representing all 4 liver transplant centers. Of the 15 respondents who completed the kidney transplant survey, 8 were transplant coordinators, 1 was a transplant administrator, and 6 were transplant medical or surgical directors; 14 respondents were directly involved in providing care to living kidney donors. Of the 4 respondents who completed the liver transplant survey, 2 were transplant coordinators and 2 were transplant medical or surgical directors; all 4 respondents were directly involved in providing care to living liver donors.

Evaluation of HIV Risk Behaviors Among Prospective Living Donors

Thirteen (93%) kidney transplant centers and all 4 (100%) liver transplant centers evaluated prospective living organ donors for HIV risk behaviors, but their evaluation practices varied widely (Table 1). The majority of transplant centers did not use standardized written questionnaires to assess CDC-defined risk behaviors, and the specific types of risk behaviors evaluated varied by center. Most transplant centers (13/14 [93%] kidney; 4/4 [100%] liver) questioned donors regarding any history of injection drug use, whereas fewer centers (9/14 [64%] kidney; 1/4 [25%] liver) questioned male living donors regarding any history of sex with another man. Transplant centers differed on whether prospective living donors with any history of risk behavior and negative HIV test results were allowed to donate (Table 1). Although 2 (14%) kidney centers did not accept prospective living donors with a history of any type of risk behavior, 9 (64%) kidney centers allowed former injection drug users with negative HIV test results to donate, and 12 (86%) kidney centers allowed men with a history of sex with another man to donate if HIV test results were negative.
### Assessment of HIV Behavioral Risks in Prospective Living Organ Donors

<table>
<thead>
<tr>
<th>Data</th>
<th>Kidney Transplant Centers, N = 14</th>
<th>Liver Transplant Centers, N = 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment of HIV risk behaviors in living donors</td>
<td>Yes, using standardized written questionnaire</td>
<td>3 (21)</td>
</tr>
<tr>
<td></td>
<td>Yes, but do not use standardized written questionnaire</td>
<td>10 (71)</td>
</tr>
<tr>
<td></td>
<td>No, do not routinely assess for risk behaviors</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>

Types of risk behaviors assessed in living donors

| History of injection drug use | 13 (93) | 4 (100) |
| History of hemophilia or related clotting disorder | 11 (79) | 3 (75) |
| History of transactional sex | 7 (50) | 2 (50) |
| If man, history of sex with another man, ever | 9 (64) | 1 (25) |
| If man, history of sex with another man, past 12 months | 8 (57) | 1 (25) |
| History of injection drug use | 9 (64) | n/a |
| History of hemophilia or related clotting disorder | 5 (36) |  | 
| History of transactional sex | 8 (57) |  | 
| If man, history of sex with another man, ever | 12 (86) |  | 
| If man, history of sex with another man, past 12 months | 10 (71) |  | 

Provide posttest counseling on the following topics

| Negative test does not guarantee HIV infection-free status | 7 (50) | 0 (0) |
| HIV tests have “window periods” | 9 (64) | 1 (25) |
| Modes of HIV transmission | 9 (64) | 1 (25) |
| HIV can be transmitted via transplanted organs | 10 (71) | 3 (75) |

Provide HIV prevention counseling that HIV can be acquired

| Through transfusion of blood or blood products | 7 (50) | 2 (50) |
| By sharing needles or syringes used in injecting illicit drugs | 5 (36) | 0 (0) |
| By engaging in unprotected sex with any person with high risk behaviors | 5 (36) | 1 (25) |
| In men, by engaging in unprotected sex with other men | 6 (43) | 1 (25) |

Data are No. (%) of participants unless otherwise indicated. Abbreviation: HIV, human immunodeficiency virus.

* Questions not asked for liver transplant services.

### HIV Prevention Counseling for Prospective Living Donors

Posttest counseling practices and discussion of HIV prevention topics with prospective living donors varied (Table 1). Although most transplant centers discussed modes of HIV transmission with prospective living donors (9/14 [64%] kidney; 1/4 [25%] liver), few transplant centers provided specific instructions to prospective donors on reducing the risk of HIV acquisition following initial screening. Fewer than half of kidney and no liver transplant centers reported counseling living donors that HIV can be acquired by sharing needles or syringes (5/14 [36%] kidney; 0/4 [0%] liver), through unprotected sex with a person with high risk behaviors (5/14 [36%] kidney; 1/4 [25%] liver) or in men by engaging in unprotected sex with other men (6/14 [43%] kidney; 1/4 [25%] liver). Most centers (10/14 [71%] kidney; 3/4 [75%] liver) did inform living donors that transplanted organs can potentially transmit HIV.

### HIV Testing of Prospective Living Donors

All centers reported screening all prospective living organ donors for HIV infection using EIA, either ≥1 month before transplant surgery or during initial evaluation with an unspecified time interval before transplant surgery (Table 2). Regarding the time limit permitted between a negative HIV EIA result and transplant surgery, most centers (8/14 [57%] kidney; 3/4 [75%] liver) reported that there was no maximal time limit or that negative HIV EIA results dating from >3 months prior were accepted as sufficient evidence of the absence of HIV infection for preoperative donor clearance at the time of transplant surgery. Three (21%) kidney transplant centers performed repeat HIV testing for all prospective living organ donors, whereas 6 (43%) performed repeat testing for some donors with a history of specific HIV risk behaviors, and 5 (36%) never performed repeat testing. No liver transplant centers performed repeat HIV testing before transplant surgery. Most centers reported that the average turnaround time from ordering an EIA to receipt of results was ≤2 days (8/14 [57%] kidney; 3/4 [75%] liver), of which some centers had same day HIV EIA results (2/14 [14%] kidney; 1/4 [25%] liver).

Eight (57%) kidney centers and 2 (50%) liver centers did not perform HIV NAT (Table 2). Although 1 (7%) kidney center performed HIV NAT for all living kidney donors, 5 (36%) kidney centers and 2 (50%) liver center performed HIV NAT only for donors with a history of specific HIV risk behaviors. Among centers that performed NAT, most centers obtained results within 1 week of ordering NAT (4/6 kidney; 1/2 liver). Although 1 kidney center and 1 liver center reported having NAT testing capacity within their institution, most centers that performed HIV NAT reported sending the test to an outside laboratory (4/6 kidney).
To our knowledge, this is the first survey to assess current HIV infection screening protocols for prospective living organ donors among transplant centers performing solid-organ transplants. Although HIV antibody screening is universally practiced and HIV transmission from a living organ donor is rare [4, 5], screening protocols for living organ donors should recognize that living donors can acquire HIV and other blood-borne viral infections, such as hepatitis B or C, between initial evaluation and transplant surgery, as occurred in our recent case. Our survey found that there is no standard approach to evaluating for this possibility among transplant centers in New York State.

The degree to which prospective donors were evaluated for established risk factors for HIV infection varied widely. Most centers did not use a standardized written questionnaire to assess for behaviors associated with a higher risk of HIV infection, although many centers collected such data in a less formalized manner, such as through confidential directed history taking. Moreover, only 36% of kidney transplant centers and none of the liver transplant centers counseled HIV-negative prospective living donors regarding approaches to reduce their risk of acquiring HIV, such as by avoiding specific behaviors. Challenges in evaluating and counseling donors for HIV risk factors may include lack of a standardized questionnaire to assess behavioral risks, providers’ difficulty in recalling a lengthy list of behaviors defined as “high risk” during the clinical encounter, providers’ difficulty addressing topics related to drug use and sexuality, and lack of standardized training on risk reduction counseling [7, 8]. Furthermore, because most donors have a familial or social connection to the recipient, eliciting an accurate risk history from prospective living donors can be a sensitive and intricate undertaking.

Given the challenges and variations in the risk assessment and prevention counseling process for prospective living donors, HIV screening using a sensitive test near the time of surgery is an important safety measure for preventing unrecognized transmission. However, most transplant centers...
reported that the time interval permitted between a negative HIV EIA result and time of transplant surgery could be ≥3 months, an interval during which living donors have the opportunity to acquire new infections after initial screening. Sixty-four percent of kidney transplant centers repeated HIV testing at the time of transplant surgery for either all living donors or for some donors with a history of risk behaviors. In contrast, none of the liver transplant centers repeated HIV testing for living donors, which may reflect the increased urgency for transplantation in end-stage liver disease. Challenges to repeat testing may include access to the prospective donor in the days before transplant surgery and concern with the consequences of delaying transplant surgery for the recipient. Our results indicate that 8 (57%) kidney centers and 3 (75%) liver centers received HIV EIA results within 2 days, and that the majority of transplant centers received HIV EIA results within 7 days. These results suggest that repeat testing with EIA within 1 week of transplant surgery is feasible. HIV NAT, which detects HIV nucleic acid material, permits detection of HIV infection prior to the development of serologic response, that is, during the 3-8 weeks "window period" of HIV infection when serologic results are negative and when the donor may be asymptomatic [9]. Although NAT allows for earlier detection of HIV infection, it is not 100% sensitive, as the period (termed eclipse period) from time of infection to detection of virus in blood is estimated to be 9 ± 0.6 days [9]. At the time of the survey, OPTN policies did not specify the use of NAT in screening for HIV infection. However, an advisory group to the New York State Department of Health, the New York State Transplant Council, had issued a Workgroup Report in 2008 that recommended HIV NAT in addition to HIV EIA for all organ donors that met the 1994 CDC guidelines for high-risk behavior, although those recommendations were targeted toward deceased donors (personal communication 2010). Our results revealed that use of HIV NAT among transplant centers evaluating prospective living donors was lower than that reported for testing of deceased donors through organ procurement organizations (OPO) in the United States [10]. Only 1 kidney transplant center reported using HIV NAT to test all prospective living donors, whereas more than half of kidney and liver transplant centers never used HIV NAT. In contrast, among organ procurement organizations (OPO) in the United States, 52% always perform HIV NAT whereas 24% never perform NAT for deceased organ donors [10].

In addition to previously mentioned challenges for repeat testing of living donors, transplant providers may have concerns about NAT screening related to cost, timeliness, and false positive results [11]. However, most centers in our survey that used NAT obtained results within a week of ordering the test, despite the fact that most centers had to send the test to an outside laboratory. These results suggest that testing with HIV NAT near the time of surgery is feasible. Although NAT may be the most sensitive screening test for early HIV infection, the future advantages of HIV NAT in screening living organ donors may warrant reexamination as Food and Drug Administration (FDA) approval for donor screening is granted to more fourth-generation EIAs that can detect early HIV infection during the window period prior to serologic conversion. Most multiplatform analyzers for fourth-generation EIAs, which detect both p24 antigen and HIV antibody, offer a 1-hour turnaround and have the potential to expedite repeat testing prior to surgery [12].

Although kidney and liver transplantation in carefully selected, chronically HIV-infected patients on combination antiretroviral therapy who have relatively intact immune function and virologic suppression is feasible and safe with high patient- and graft-survival rates, the outcomes in people who acquire HIV infection during transplantation are not well understood [13, 14]. There is very little literature on the course of HIV disease when acquired through organ transplantation. Two published case reports describe 2 kidney transplant recipients who acquired HIV infection through the transplant, were diagnosed <2 months after transplantation and were in good clinical condition 1.5 years after transplant surgery [5, 15]. However, other case reports suggest that HIV acquisition during transplantation combined with delayed diagnosis of infection may compromise patient and graft outcomes, with morbidity and mortality amplified by hepatitis C virus coinfection [16].

Given the significant costs and resources needed for organ transplantation, screening living donors for HIV infection according to the 2011 CDC guidance would help reduce the risk of unrecognized transmission [4, 17]. The draft Public Health Service guidelines [15] recommend the following: evaluate all prospective living donors with a standardized set of questions in a confidential, nonbiased context; inform all prospective living donors about modes of transmission and risk factors for HIV infection; counsel living donors to avoid behaviors that would place them at risk for acquiring HIV infection before transplant surgery; and supplement serologic screening tests for HIV conducted on prospective living organ donors during their initial evaluation with repeat testing using an HIV serologic test and HIV NAT as close to the time of surgery as possible [4, 17].

This survey provides a comprehensive assessment of transplant center practices related to HIV screening of living organ donors in New York State; however, results may not be generalizable to transplant centers elsewhere in the nation. Moreover, although respondents were asked to describe HIV screening practices for their transplant center, individual transplant providers may deviate from institutional protocols, and we were unable to corroborate responses by examination.
of written protocols. Although the reported maximum interval between HIV screening and transplantation at most transplant centers could be ≥3 months, it may not be that long in routine practice. Finally, our data were collected before the Morbidity and Mortality Weekly Report publication of our investigation of HIV transmitted from a living organ donor in New York City and 2011 CDC guidance on screening for HIV infection in living organ donors [1]. Our findings may not reflect current practice if transplant centers have updated their HIV screening protocols in response to the case report and the guidance.

In conclusion, our results showed a wide variation among transplant centers in evaluating risk behaviors, counseling prospective donors, and, and timing and type of HIV testing performed on living organ donors. Our results underscore the need to standardize evaluation and screening for HIV risk and infection among prospective living donors. Repeat HIV testing with NAT and serologic testing for all living donors as close to the time of donation as possible would help prevent the transmission of HIV to organ recipients.

Notes

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Disclaimer. The findings and conclusions of this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Potential conflicts of interest. All authors: No reported conflicts.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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