ORIGINAL ARTICLE

Provider Response to a Rare but Highly Publicized Transmission of HIV Through Solid Organ Transplantation

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Objective: On November 13, 2007, the first reported case in 20 years of HIV (human immunodeficiency virus) transmission from a Centers for Disease Control and Prevention high-risk donor (HRD) made national headlines. We sought to characterize change in the practice of transplant surgeons resulting from this rare event.

Design: We performed a survey between January 17, 2008, and April 15, 2008, assessing attitudes and practices of transplant surgeons regarding HRDs. Descriptions of changes in practice after the event were categorized, and associations between responses and regional-, center-, and physician-level factors were studied.

Setting: Transplant centers in the United States.

Participants: Four hundred twenty-two transplant surgeons in current practice.

Main Outcome Measure: Changing practice following the 2007 HIV transmission event.

Results: Among surgeons who responded to the survey, 31.6% changed their practice following the event. Also, 41.7% decreased use of HRDs, 34.5% increased emphasis on informed consent, 16.7% increased use of nucleic acid testing, and 6.0% implemented a formal policy. Ranking fear of being sued or hospital pressure as important disincentives to HRD use was associated with more than 2-fold higher odds of changing practice. Ranking medical risks of HIV as an important disincentive was associated with 8.29-fold higher odds of decreasing HRD use.

Conclusion: The most common responses to this rare event were avoidance (decreased HRD use) and assurance (increased emphasis on informed consent) behaviors rather than patient safety measures (increased use of nucleic acid testing and implementation of formal policies), suggesting that fear of legal or regulatory consequences was the biggest driver of physician decision making and that the current litigious environment is failing to protect patient interests.

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In November 2007, four transplant recipients contracted human immunodeficiency virus (HIV) and hepatitis C virus (HCV) from a deceased donor, an event that made national headlines[1] and sparked intense debate about informed consent and serologic testing practices in the transplant community.[2] The case generated particular interest because the donor had been classified as a high-risk donor (HRD) according to guidelines established by the Centers for Disease Control and Prevention and the Public Health Service.[3,4] Despite this designation, the result of antibody testing of donor serum was negative for both diseases, yet the result of retrospective nucleic acid testing (NAT) was positive, suggesting that the infections likely occurred in the weeks before death, termed the *window period* between seroconversion and detectability. Although tragic, this type of transmission is presumed to be extremely rare, supported by the fact that this event was the first case of HIV transmission through solid organ transplantation reported in the literature in more than 20 years.[5]

A central problem in transplantation is balancing the risk incurred from receiving a less-than-ideal organ with other risks, such as those from not receiving an organ.[6] High-risk donors, who account for 8.6% of donors from whom at least 1 organ is recovered, attenuate the organ crisis because they expand the organ supply, decrease wait times, and have organs that are typically of higher quality compared with their non-HRD counterparts.[7] Furthermore, the slightly increased risk of infectious transmission from an HRD is likely far outweighed by the benefits of receiving a transplant; in fact, the risk of acquiring HIV or HCV from an HRD organ

transplant is not much higher than the risk of acquiring either disease while awaiting an organ transplant.[8]

However, the burden of HIV/HCV transmission resulting from transplantation falls much heavier on the transplant surgeon than does the burden of transmission resulting from nontransplant care (eg, hemodialysis) or the burden of death while on the waiting list. In addition to the obvious legal risks, the transplant community is also particularly vulnerable to regulatory pressures, as center-specific outcomes are tracked and (1) listed on a public Web site, (2) commonly cited in newspapers, (3) used by the United Network for Organ Sharing to investigate centers, and (4) used by the Centers for Medicare & Medicaid Services to reconsider Medicare contracts for centers with questionable outcomes.

In a recent survey,[9] a total of 93% of physician specialists in Pennsylvania reported practicing *defensive medicine*, defined as care or recommendations provided not for the benefit of the patient but to reduce the likelihood of legal or regulatory repercussions. The 2 most common types of defensive medicine were *assurance behavior*, defined as providing additional services for the purpose of legal coverage but with little to no medical benefit, and *avoidance behavior*, defined as avoiding certain practices or procedures primarily owing to their potential legal risk. In this framework, a potential response to the highly publicized HIV/HCV transmission case discussed herein could have been decreased use of organs from HRDs (avoidance behavior), which was seen in Canada,[10] where restrictions on organ donation were tightened after this event. Another potential response could have been an increased focus on informed consent (assurance behavior)[2]; this was recently implemented in the United States, with a new requirement for special informed consent when organs from HRDs are used, but the timing and amount of information disclosed are left to the individual surgeon.[11] However, several potential responses focused on patient safety could also have occurred, including increased use of NAT,[12] which shortens the window period from 22 to 9 days for HIV and from 59 to 7 days for HCV,[13] or implementation of other formal policies to select, monitor, and potentially treat appropriate recipients.[12]

We hypothesized that the litigious and highly regulatory nature of the solid organ transplant system in the United States would result in an increased risk of defensive medicine responses to rare but highly publicized complications despite the severity of the organ shortage and proven benefits of transplantation in these circumstances. The goals of our study were to (1) characterize changes in clinical practice in response to the highly publicized 2007 transmission event and (2) identify factors associated with different types of responses.

METHODS

SURVEY ADMINISTRATION

We performed a national survey of transplant surgeon use of and attitudes toward organs from HRDs between January 17, 2008, and April 15, 2008.[14,15] This survey was reviewed and approved by the Johns Hopkins Medicine Institutional Review Board (protocol NA_00015153). We sent surveys to any publically available e-mail addresses potentially belonging to transplant surgeons. When we were unable to locate e-mail addresses for a transplant center, we called and requested them directly. Of physicians who were sent the survey, 422 responded and were eligible, 123 were ineligible, 5 were eligible but chose not to participate, and 348 did not respond. Because of the possibility that surveys could be blocked by e-mail filters, we could not know the eligibility of those who did not respond or whether they even received the e-mail message.

STUDY POPULATION

We evaluated the responses from 422 transplant surgeons from adult transplant centers in the United States, representing 66.7% of transplant centers in the United States and 89.1% of the country's transplant volume from 2007. Respondents had been practicing for an average of 13.3 years. Of the respondents, 47.6% were kidney, pancreas, and liver transplant surgeons; 32.4% were kidney and/or pancreas transplant surgeons; 10.7% were liver-only transplant surgeons; and 8.3% were heart and lung transplant surgeons.

SURVEY QUESTIONS

After initial formative work including in-depth interviews and pilot testing, a national cohort of transplant surgeons was asked the following questions regarding HRDs:

1. How important is each of the following as a disincentive to your use of CDC [Centers for Disease Control and Prevention] high-risk donors (1, not important; 5, very important):

   A. Stigma of HIV
   B. Stigma of HCV
   C. Medical risks of HIV
   D. Medical risks of HCV
   E. Getting sued by your patient
   F. Pressure from your hospital
   G. Worries that organ quality is poor

2. Has your practice changed, or will your practice change, in light of the recent highly publicized report of HIV transmission to 4 solid organ transplant recipients? If yes, how? (open-ended response)

Responses to question 1A through G were dichotomized as important (responses of 4-5 vs 1-3). Open-ended responses to question 2 were abstracted independently by 3 reviewers (L.M.K., R.L.R., and D.L.S.) and placed into the following categories: (1) decreased use of HRDs, (2) increased emphasis on informed consent, (3) increased use of NAT, and (4) implementation of a formal policy or recipient profile. Data regarding NAT performance by the Organ Procurement Organization (OPO) where the surgeons practiced had been previously collected[7] and were linked to the survey.

ASSOCIATIONS BETWEEN PHYSICIAN-, CENTER-, AND OPO-LEVEL FACTORS AND CHANGES IN PRACTICE

Using logistic regression models, we examined associations between a change in practice and physician factors (surgeon type, number of years in practice, and rating any of survey questions 1A-G as important disincentives to HRD use), center factors (number of transplants performed, proportion of volume composed of HRDs, and mean center waiting time), and OPO factors (number of donors, proportion of donor volume composed of HRDs, and HIV and HCV NAT performance). All analy-

Table 1. Comparison of Transplant Surgeons Whose Practice Changed in Response to the Event and Those Whose Practice Did Not Change[a]

Variable	No Change in Practice (n=203 [68.3%])	Change in Practice (n=94 [31.6%])	*P* Value
Years in practice	13.9	10.7	.002
Surgeon type, %			.39
K/P only	31.0	28.0	. . .
K/P/Li	48.3	49.5	. . .
Li only	13.3	9.7	. . .
H/Lu	7.4	12.9	. . .
Importance of disincentives[b]			
Medical risks			
HIV	4.3	4.4	.42
HCV	4.1	4.3	.05
Fear of being sued	3.1	3.6	<.001
Hospital pressure	2.1	2.7	.001
Poor organ quality	3.1	3.3	.29
Total center volume, %ile	52nd	49th	.45
Total volume from HRDs, %	8.0	9.3	.20
Mean center wait time, d	758	789	.38
Quintile of OPO donor volume			.08
1	7.1	2.2	. . .
2	13.1	7.5	. . .
3	18.2	16.1	. . .
4	21.2	18.3	. . .
5	40.4	55.9	. . .
OPO never uses NAT, %			
HIV	22.7	31.2	.12
HCV	30.3	36.6	.29

Abbreviations: ellipses, not applicable; H/Lu, heart/lung; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HRD, high-risk donor; K/P, kidney/pancreas; K/P/Li, kidney/pancreas/liver; NAT, nucleic acid testing; OPO, Organ Procurement Organization.

[a] Excludes transplant surgeons who never used HRDs.

[b] Average ranking of importance of disincentive: 1 (not important) through 5 (very important).

ses were performed using multiprocessor Stata 10.0/MP for Linux (StataCorp LP, College Station, Texas).

RESULTS

Of the 297 surgeons who used HRDs, 31.6% changed their practice in response to the 2007 HIV/HCV transmission event (**Table 1**). Surgeons who made changes had been in practice for an average of 10.7 years, as compared with an average of 13.9 years for surgeons who did not institute changes ($P=.002$). Those who changed their practice ranked fear of being sued ($P<.001$) and hospital pressure ($P=.001$) as more important disincentives to HRD use compared with those who made no changes. There were no statistically significant differences in surgeon type, center transplant volume, center proportion of transplant volume from HRDs, OPO volume, or proportion of OPO volume from HRDs between physicians who changed practice and those who did not.

Of the 94 transplant surgeons who made changes in their practice following the event (**Table 2**), the most common change (41.7%) was decreased use of HRDs (avoidance behavior). These responses ranged from overall decreases in use to decreases in use of specific donor types. In addition, 34.5% of transplant surgeons who changed practice following the event did so by increasing their emphasis on informed consent (assurance behavior) through the development of specific forms or the placement of greater emphasis on risks during counseling sessions. Fewer than 25% of the respondents instituted a practice aimed at improving the safety of recipients, with 16.7% increasing their use of NAT and only 6.0% implementing a formal policy or identifying a target recipient profile.

Table 2. Types of Practice Changes Reported

Type of Change	%[a]	Examples of Statements Falling Into This Category
Decreased use of CDC-HRDs	41.7	"We are using fewer high-risk donors."
		"We are less willing to accept organs from inmates of correctional facilities."
		"I would be wary of using any high-risk donors."
Increased emphasis on informed consent	34.5	"We are developing a specific consent form for high-risk donors."
		"[We] highlight [the] limitation[s] of current serologic testing during [the] informed-consent process."
		"[We] made a video explaining the informed consent [process] for recipient candidates to watch before signing the consent [form] indicating what type of organ they would be willing to accept."
Increased use of NAT	16.7	"We insist on NAT testing."
		"We make every effort to obtain NAT on all donors."
Implementation of a formal policy or recipient profile	6.0	"[We are] only using them in select patients who are sensitized or very sick with informed consent."
		"[We] no longer consider [HRDs] for kidney or kidney/pancreas."
		"[We are] developing a written policy and procedure as to which patient might be considered for CDC-HRD [organs], ie, [those having] FHF with [imminent] death."

Abbreviations: CDC-HRD, Centers for Disease Control and Prevention high-risk donor; FHF, fulminant hepatic failure; NAT, nucleic acid testing.

[a] Numbers do not total 100% because some transplant surgeons reported multiple types of changes.

The odds of changing practice in response to the event decreased with the number of years a surgeon was in practice (odds ratio, 0.77 for every 5 years in practice; 95% confidence interval [CI], 0.65-0.91) (**Table 3**, column 1). Indicating that fear of being sued was an important disincentive to HRD use was associated with 2.26-fold higher odds of changing practice (95% CI, 1.37-3.73), and indicating that hospital pressure was an important disincentive was associated with 2.52-fold higher odds of changing practice (1.39-4.56). Ranking medical risks of HIV, medical risks of HCV, or fears of poor organ quality as important disincentives to HRD use was not associated with statistically significant differences in changing practice. Surgeon type, center volume, proportion of center volume from HRDs, center waiting time, and use of OPO HIV or HCV NAT were not associated with significantly increased odds of

Table 3. Associations Between Physician-, Center-, and OPO-Level Factors and the Following Responses to the Event

Variable	Odds Ratio (95% Confidence Interval)		
	Change in Practice	Less CDC-HRD Use, Avoidance Behavior	More Informed Consent, Assurance Behavior
Physician level			
Surgeon type			
K/P only	1 [Reference]	1 [Reference]	1 [Reference]
K/P/Li	1.14 (0.64-2.02)	0.86 (0.39-1.90)	0.59 (0.23-1.55)
Li only	0.80 (0.33-1.95)	NA	1.78 (0.58-5.42)
H/Lu	1.94 (0.80-4.70)	1.83 (0.61-5.47)	2.02 (0.61-6.65)
Per 5-year periods in practice	0.77 (0.65-0.91)[a]	0.85 (0.67-1.07)	0.86 (0.66-1.10)
Importance of disincentives			
Medical risks of HIV	1.28 (0.65-2.51)	8.29 (1.11-62.05)[a]	0.43 (0.18-1.00)
Medical risks of HCV	1.67 (0.89-3.12)	5.70 (1.33-24.41)[a]	0.43 (0.19-0.96)[a]
Fear of being sued	2.26 (1.37-3.73)[a]	1.79 (0.88-3.66)	1.39 (0.64-2.99)
Hospital pressure	2.52 (1.39-4.56)[a]	1.84 (0.82-4.10)	1.98 (0.85-4.61)
Fear of poor organ quality	1.50 (0.91-2.47)	1.39 (0.69-2.83)	0.68 (0.30-1.52)
Center level[b]			
Total center volume	0.91 (0.76-1.10)	0.97 (0.74-1.26)	0.86 (0.65-1.16)
% Total volume from CDC-HRD	1.10 (0.92-1.30)	1.19 (0.91-1.57)	1.04 (0.82-1.34)
Mean center waiting time	1.11 (0.93-1.32)	1.09 (0.85-1.41)	1.35 (1.01-1.80)[a]
OPO level[c]			
OPO donor volume[b]	1.38 (1.06-1.80)[a]	1.06 (0.79-1.43)	1.48 (0.97-2.26)
% OPO volume from CDC-HRDs	1.28 (1.02-1.61)[a]	1.13 (0.87-1.46)	1.57 (1.13-2.18)[a]
OPO never uses HIV NAT	1.42 (0.68-2.97)	1.06 (0.47-2.40)	2.23 (0.90-5.55)
OPO never uses HCV NAT	1.16 (0.57-2.35)	1.00 (0.47-2.15)	2.44 (1.05-5.66)[a]

Abbreviations: CDC-HRD, Centers for Disease Control and Prevention high-risk donor; HCV, hepatitis C virus; HIV, human immunodeficiency virus; H/Lu, heart/lung; K/P, kidney/pancreas; K/P/Li, kidney/pancreas/liver; Li, liver; NA, not applicable; NAT, nucleic acid testing; OPO, Organ Procurement Organization.
[a] $P<.05$ by logistic regression.
[b] All odds ratios for volume, proportion of volume, or waiting time are per quintile.
[c] Odds ratios of OPO-level factors adjusted for OPO-level random effects.

changing practice. With each increasing quintile of OPO donor volume, surgeons had 1.38-fold higher odds of changing practice (95% CI, 1.06-1.80). Similarly, each increasing quintile of proportion of OPO donor volume from HRDs was associated with 1.28-fold higher odds of changing practice (95% CI, 1.02-1.61).

When we repeated the analysis using the 2 most common subcategories of changes as the outcomes (increased informed consent and decreased HRD use), we found that different factors predicted different types of changes. Ranking medical risk of HIV and HCV as important disincentives to HRD use was associated with 8.29-fold higher odds (95% CI, 1.11-62.05) and 5.70-fold higher odds (1.33-24.41) of decreasing HRD use following the 2007 transmission event, respectively. No other physician-, center-, or OPO-level factors were associated with decreasing HRD use. Practicing at a center with longer waiting times was associated with 1.35-fold higher odds of increasing special informed consent use (per quintile of center waiting time; 95% CI, 1.01-1.80). Practicing in an OPO that never used HIV NAT or HCV NAT was associated with 2.23-fold higher odds (95% CI, 0.90-5.55) and 2.44-fold higher odds (1.05-5.66) of increasing special informed consent use, respectively. Furthermore, each increasing quintile of proportion of OPO donor volume from HRDs was associated with 1.57-fold higher odds of increased emphasis on special informed consent use (95% CI, 1.13-2.18). Increasing emphasis on informed consent was also associated with 0.43-fold lower odds of ranking medical risk of HIV as an important disincentive to HRD use (95% CI, 0.18-1.00) and 0.43-fold lower odds for ranking medical risk of HCV as an important disincentive (0.19-0.96).

COMMENT

A significant proportion of transplant surgeons reported changing their practice in response to an extremely rare but highly publicized transmission of HIV and HCV in 2007, and most (76.2%) of the reported changes could be described as defensive medicine. The most common response was avoidance behavior (ie, decreasing use of HRDs). This is particularly worrisome, because HRDs constitute 8.6% of recovered donor volume and have been shown to provide significant survival benefit to transplant recipients despite the very small risk of infectious disease transmission.[6,8] The second most common response was increasing emphasis on special informed consent, a type of assurance behavior. Notably, fear of being sued and fear of hospital pressure were strongly associated with changing practice, suggesting that formal policies are needed to guide transplant surgeons' practices regarding HRDs.

Only 23.8% of changes reported by transplant surgeons in response to the event could be described as patient safety measures. For example, only 16.7% indicated they would increase use of NAT. Negative results of NAT reduce the risk associated with transplant of an HRD organ, as NAT can detect HIV and HCV infections

occurring months to weeks earlier than can standard antibody testing. In the 2007 transmission event, the antibody-negative donor was retested after the transplants using NAT, and the results were positive for HIV and HCV, suggesting that NAT would have prevented this catastrophic event.[5] Given that NAT mitigates the infectious disease risk associated with HRDs and seems to be associated with increased comfort for physicians regarding use of HRD organs, it might be reasonable to recommend that NAT testing of all donors be performed. However, the potentially increased risks of false-positive results of NAT complicate such a resolution.

Our study is limited in that all data were self-reported; as such, it is possible that surgeons systematically overreported or underreported changes to their practice following the event. Furthermore, generalizability may be limited because those who responded to the survey may differ from those who did not respond. However, we believe that this is unlikely to affect our inferences, given that survey respondents represented 89.1% of the transplant volume in the United States. Our survey was performed only after the transmission event, so our inferences might be limited by recall bias.

CONCLUSIONS

The transplant surgeons' responses to this rare event were widely varied, and previous studies have shown similar incongruity in their attitudes and practices regarding HRDs.[14,15] Given the severity of the organ shortage and high incidence of waiting-list mortality, centers should strive for appropriate rather than decreased use of HRDs. We recommend that centers develop formal policies that address NAT, the informed consent process, and the identification of recipients who would benefit from transplantation of organs from HRDs.

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