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Early Experiences of Independent Advocates for Potential HIV+ Recipients of HIV+ Donor Organ Transplants

Juli Bollinger, MS*,

Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD.

Ann Eno, BS

Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD.

Shanti Seaman, BA, Diane Brown, RN, MS

Department of Medicine, Johns Hopkins School of Medicine, Baltimore, MD.

Sarah E. Van Pilsum Rasmussen, BA,

Department of Surgery, Johns Hopkins University School Medicine, Baltimore, MD.

Aaron A.R. Tobin, MD, PhD,

Department of Medicine, Johns Hopkins School of Medicine, Baltimore, MD; Department of Epidemiology, Johns Hopkins University School of Public Health, Baltimore, MD; Department of Pathology, The Johns Hopkins Hospital, Baltimore, MD.

Dorry L. Segev, MD, PhD,

Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD; Department of Medicine, Johns Hopkins School of Medicine, Baltimore, MD; School of Nursing, Johns Hopkins University, Baltimore, MD.

Christine Durand, MD,

Department of Medicine, Johns Hopkins School of Medicine, Baltimore, MD.

Jeremy Sugarman, MD, MPH, MA

Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD; Department of Medicine, Johns Hopkins School of Medicine, Baltimore, MD.

Abstract

Background—HIV+ to HIV+ solid organ transplants in the United States are now legally permitted. Currently, these transplants must adhere to the HIV Organ Policy Equity (HOPE) Act Safeguards and Research Criteria that require the provision of an independent recipient advocate. Having a designated advocate for recipients is a novel requirement for solid-organ transplant programs. The objective of this study was to understand the experiences of the first advocates serving this role.

Methods—We conducted 15 semi-structured interviews with HOPE Independent Recipient Advocates (HIRAs).

*CORRESPONDING AUTHOR: Juli Bollinger, MS, Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD, USA. jmurph46@jhu.edu.

Results.—All HIRAs had a professional degree in nursing/allied health, social work, or medicine as well as experience in transplantation or infectious diseases. HIRAs encounters with potential recipients varied in length, modality (phone or in-person), and timing. The newness of the role and the lack of guidance regarding it was associated with unease among some HIRAs. Some HIRAs questioned whether their role was redundant to others involved in transplantation and research, since some potential recipients experienced informational fatigue.

Conclusions: HIRAs are providing a check on the voluntariness of potential participants' decision to be willing to accept an HIV-infected organ. Many interviewees suggested that having guidance regarding qualifications, training, and practice would be helpful and alleviate unease related to their role. However, HIRAs' concerns about informational fatigue and potential role redundancy raises the question of whether the HIRA requirement may inadvertently be increasing burden for potential recipients. Future work that captures the experiences of potential recipients.

Introduction

HIV-infected donor (HIV D+) to HIV-infected recipient (HIV R+) solid organ transplants are now being performed as research under the provisions of the HIV Organ Policy Equity (HOPE) Act in the United States.^{1,2,3} Currently, these transplants must adhere to the HOPE Act Safeguards and Research Criteria⁴, which are aimed at protecting patients' welfare and rights.

While HIV D+ to HIV R+ transplants are hypothesized to be safe and effective, this novel practice may pose physical and psychosocial risks to recipients. Physical risks include increased risk of graft dysfunction and HIV superinfection with a drug-resistant strain of HIV.^{5,6,7,8} Psychosocial risks center on deciding between choosing to accept an investigational HIV D+ organ or remaining on an organ waitlist for an HIV-uninfected donor organ.⁹ These factors pose challenges to obtaining informed consent.¹⁰

The HOPE Act Safeguards and Research Criteria require, among other things, that transplant hospitals develop policies and procedures for securing consent that involve an independent advocate for potential HIV-infected organ recipients. The policy specifies that the HOPE independent recipient advocate (HIRA) must: “i) promote and protect the interests of the HIV-positive recipient (including with respect to having access to a suitable HIV-negative organ if it becomes available) and take steps to ensure that the HIV-positive recipient's decision is informed and free from coercion; ii) review whether the potential HIV-positive recipient has received information regarding the results of SOT [Solid Organ Transplantation] in general and transplantation in HIV-positive recipients in particular and the unknown risks associated with HIV-positive transplant; and iii) demonstrate knowledge of HIV infection and transplantation.” Furthermore, the HIRA, “must be independent of the research team and must have knowledge and experience with both HIV infection and organ transplantation.”⁴

Although these criteria seem sensible, independent advocates are not typically required for solid organ transplant recipients. Nonetheless, while independent *living donor* advocates (ILDAs), who are charged with ensuring the “protection of living donors and prospective donors”¹¹ are commonplace this is qualitatively different for several reasons. For instance,

the risks of living donation are better known, the donation process is not typically being done as research, and donation is arguably far more optional than deciding to receive an infected organ.

In addition, the HOPE Safeguards do not articulate comprehensive details about what HIRA's roles and responsibilities. As a result, there is some concern that there would be a range of practices that might be associated with enrollment bias.¹²

Accordingly, the objective of our study was to understand the specific roles, responsibilities and experiences of the first HIRAs by conducting semi-structured interviews with them in order to: 1) determine their backgrounds, qualifications, and training; 2) understand their experiences; and 3) assess any need for further guidance and training.

Materials and Methods

Between June 2017 and September 2018, we conducted 15 semi-structured interviews with HIRAs regarding their experiences in serving in this role. This research was reviewed and deemed exempt by the Johns Hopkins Medicine Institutional Review Board.

Sample

Twenty-five transplant centers with an IRB-approved HOPE protocol and United Network for Organ Sharing variance to perform HOPE transplants were identified. [Supplement A]. A member of the ethics study team (JB) contacted HOPE study coordinators at each of the transplant centers by email and/or phone to obtain the name and contact information of the site's HIRA(s). HIRAs were contacted by email with a letter from the Principal Investigator (JS) of the interview study inviting them to participate. Up to two email reminders were sent to non-respondents. HIRAs had to have served as an advocate for at least one potential HOPE recipient in order to participate. Individuals who were interviewed received a \$25 gift card as a token of appreciation.

Data Collection

We developed an interview guide that included a range of topics including professional background and training, preparation for the advocate role (e.g., training provided and resources used), relationship to the transplant team, encounters with potential recipients, and challenges/needs facing HIRAs.

To protect confidentiality and consistency, all interviews were conducted by a single member of the team (JB) who was not otherwise affiliated with ongoing HOPE multicenter trials at Johns Hopkins University. [and]

Individuals gave oral consent to participate in an audio-recorded telephone interview. To foster an open discussion, interviewees were assured that (1) their name and the name of the institution they represented would remain confidential; (2) the interviewer was independent of the HOPE clinical trial research team; and (3) data collected from the interviews would only be presented in aggregate. Interviews took 30–48 minutes. The audio recordings were

professionally transcribed. The interviewer reviewed the transcripts for accuracy, removed personal identifiers and assigned each transcript a unique code.

Data analysis

Using an integrated approach,¹³ two members of the research team developed thematic codes based on the interview guide and initial interview transcripts. The codebook was iteratively revised by the coding pair over the course of coding the initial interviews. Each transcript was assigned a primary and secondary coder who subsequently discussed and resolved any coding discrepancies. Coded transcripts were entered into NVivo 11 (QSR International Pty Ltd, MA). Text was organized and analyzed for recurring themes.

Results

After explaining the process of identifying HIRAs and the characteristics of the interviewees, we describe the major themes that emerged in the interviewees along with representative quotes: 1) being selected as a HIRA; 2) preparing to be a HIRA; 3) perceived roles and responsibilities; 4) encounters with potential recipients; 5) impressions of potential recipients; and 6) challenges.

Identifying HOPE Independent Recipient Advocates

As of September 2018, 20 of the 25 institutions that have IRB-approved protocols for HIV D +/- R+ organ transplants [HOPE web page] had enrolled participants for HOPE clinical trials and were invited to participate in this study. Invitations were extended to 27 HIRAs at 17 distinct institutions. Five institutions reported having more than one HIRA. We interviewed 15 independent recipient advocates representing 12 institutions [Table 1 – Recruitment]

Characteristics of HIRAs

All of the advocates interviewed had a professional degree in one of three disciplines: nursing/allied health (6), social work (6), or medicine (3). They all had professional experience in transplantation (8) or infectious diseases (7) and all reported that their HIRA role was added to their full-time job responsibilities. [Table 2 - Characteristics of HIRAs and Encounters]. Only two interviewees had previous experience serving as an ILDA.

Becoming an “Independent” Advocate

Most HIRAs were chosen to serve in this role based on their professional experience with transplantation or HIV as well as their independence from the HOPE Transplant Research Team.

“I’m a clinician and manage patients with HIV and that I also understand and work within the research side of things [so] that I might be one of the better people at the institution to maybe take on this role since I can kind of speak to all the different aspects and kind of understand where these participants are coming from and kind of bridge that gap and serve in the advocate role”.

[Interviewee 3]

Given the potential overlap of HIRAs' primary professional/clinical responsibilities and their role as independent advocates, interviewees described deliberate measures taken to ensure their independence. These included not being an employee of the transplant team/department, not being a member of the HOPE transplant research team, and not providing care to a patient for whom they served as an advocate.

“I'm a social worker in the HIV clinic here [REDACTED] and so they had approached me and asked me if I would be willing to fill this role for the purposes of the whole study because of my... independence from the team.”

[Interviewee 5]

Interviewer: “So you are the advocate for recipients who could potentially receive an HIV-positive [organ].”

Interviewee: “Correct, but I don't take care of the recipients who are waiting for a [organ].”
[Interviewee 6]

Preparing to be a HIRA

When asked how they prepared for their role as a HIRA, most interviewees described meeting with members of the HOPE transplant research team (most commonly the transplant center HOPE study principal investigator or coordinator) and reading the study protocol and consent form. Several other resources were also frequently mentioned: the HOPE Act Final Rule, the HOPE Act Safeguards and Research Criteria, and the Johns Hopkins HOPE Independent Advocate encounter template form. [Appendix B]

A few interviewees described other preparation that included conducting a literature review, attending a conference or Webinar on HOPE transplants, and speaking with someone with experience as an ILDA. Only one interviewee reported being trained by another HIRA. All of the interviewees recounted feeling adequately prepared to serve as a HIRA.

Perceived Scope of Responsibility

When describing their HIRA role and responsibilities, interviewees consistently articulated two main duties: to ensure potential participants understand the risks and benefits of receiving an HIV-infected organ and to confirm that their decision to participate in the HOPE transplant research study was voluntary.

“So, my understanding is I just need to make sure that the patient understands what they're consenting to, that... this is something optional, they're not-- they don't have to and they can withdraw at any time that they want. ...and kind of be independent third party so that just to make sure that the patient is going into this with open eyes and of their free will.”

[Interviewee 9]

“I think the concern with clinical trials and studies is that people who are actually involved in the research and may be potentially biased because they are involved in research and just to be able to provide an outside perspective with regards to the

risks and benefits of the study to the participant that is essentially as I said unbiased.”

[Interviewee 12]

Most HIRAs informed potential recipients of their independence from the clinical and research teams. All described discussing risks, benefits, and voluntariness of participation with potential recipients, yet some HIRAs described doing this in a narrow sense while others held a broader view of their role, as depicted in these quotations.

Narrow view:

“Well, they have one-on-one with all their doctors, but I think it’s a very overwhelming issue, and I have to keep coming back to “My job is to tell you about the risk of the HIV -positive organ,” but it’s also written into the consent form that I will talk to them about any risks post-transplant.”

[Interviewee 6]

Broad view:

“The biggest thing is really we have to make sure that the patients understand what they’re getting involved into. They understand the risks of taking on an HIV organ, that they have a choice, that they don’t have to do it. That’s the biggest thing. One of the things that we took on ourselves is we want to make sure that the support person that they have is also aware of their HIV status, because if they’re going to be a support person and they’re going to be taking on an HIV organ that takes on their own inherent risk, we want to make sure that their support person is aware that this is something additional to it...It’s mostly to make sure that the patients are not being coerced into this role at all, that they have clear understanding and that they understand that they can get either an HIV organ or a non-HIV organ and it’s their choice.”

[Interviewee 13]

Encounters with Potential Recipients

There was wide variability among HIRAs with respect to the number of potential recipients with whom they have met, as well as the timing, format, content, and duration of those encounters. Approximately half of those interviewed had met with less than five potential recipients and the majority of those encounters occurred in-person. A few advocates reported that all of their encounters occur by phone, while others spoke by phone only when an in-person visit was not possible (e.g., the potential recipient resides out-of-town).

Timing of Encounters

The majority of HIRAs met with potential recipients *after* the individual had given consent to enroll in the HOPE transplant research study (that is a pre-requisite to being placed on the waitlist to receive an HIV-infected organ if an organ becomes available). Four advocates met with potential recipients *before* they signed the study consent form. The other three advocates were not sure of the exact timing in relation to signing the consent form. The

timing of the advocate-potential recipient encounter appeared to reflect differing beliefs about how best to ensure informed, voluntary consent. Some expressed the view that the only way to evaluate whether or not informed consent was obtained without ‘coercion’ was to meet with participants *after* they have provided consent. Others believed that it was their responsibility to ensure that the potential recipient adequately understood the risks and benefits of accepting an HIV-infected organ *before* they gave consent. For a few, the timing of the HIRAs discussions appear to have been driven solely by logistical factors (e.g., the meeting occurs when the advocate is available or when the potential participant is otherwise in clinic).

Meeting after consent had been obtained

Interviewer: “Was there a preference for when you would want to get to these people, before or after consent?”

Interviewee: “I would rather after, because part of the question is, ‘Were you coerced?’”
[Interviewee 1]

Meeting prior to obtaining consent

“I think they bring the patient back for a second appointment to have them come in and discuss the trial with them. And I think at that time they meet with the research team. So they’ll meet with an infectious disease doctor. She goes over all the complications and the limitations of the trial, and then I think, and the research person meets with them, and then I meet with them last... to see how they feel about the trial, are they willing to do this? And then after I meet with them, I go back to the infectious disease doctor and the research team to say the patient’s willing to consent, or the patient’s not willing to consent. And then they meet with the patient last to do consent forms.”

[Interviewee 14]

Meeting based on logistics

“We usually kind of come in around the end of the interviews after they’ve met with the team members... they can just pull us out, it’s in that same clinic. Usually I keep it pretty light. In general, ask them how their experience was, ask them what they’ve learned, ask them about the HIV to HIV listing; if they felt like there was any, you know, incentives or, you know, what they felt about it. Sometimes I don’t use the word pressure and coercion because I’m not sure if they completely understand what that means...But keep it general and open-ended and see. And then, again, ask if that’s something they’re interested in doing and make sure that they know that they do not have to do it, that it’s up to them. And if anything else comes up I’ll try to address that with them, as well”.

[Interviewee 8]

Duration of Encounters with Potential Participants

The reported length of a typical HIRA encounters with patients varied, ranging from 10 minutes to one lasting two hours. Two-thirds of interviewees reported that their typical encounter lasted less than 30 minutes, with half of these averaging less than 15 minutes.

None of the advocates interviewed met with a potential recipient more than once. Despite providing potential recipients with their contact information and encouraging them to follow-up with questions, advocates did not recall anyone ever doing so. Most of the interviewees did not know whether one of the potential recipients with whom they met was offered an HIV-infected organ. In this regard, a few stated that the mechanisms in place to preserve their independence for the study team and lack of follow-up interactions with potential recipients precluded them from readily learning this information.

Materials Used During Encounters

Several advocates reported using the research study consent form or HOPE Independent Advocate encounter template form to guide their discussion with potential recipients. A few advocates created or added their own notes or checklists while others didn't use any prepared materials.

"I do have a standard blurb. I just keep a little sticky with a couple of things that-- I can add or paste. It's not cut and paste necessarily....we talked about HIV to HIV, ask about pressure and coercion. It's maybe five sentences".

[Interviewee 8]

Documentation of Encounters

At the conclusion of the encounter, all of the advocates reported documenting their meeting with the potential recipient by adding a brief note to, or completing a short checklist, in the potential recipient's electronic health record. A few directly notified a member of the study/transplant team, particularly if the encounter occurred during a clinic/study visit.

"I put a note in [the electronic medical record] that the patient came in, was consented for the program and by which doctor, because we have a few that do consents, by what doctor. And then I say, you know, I met with this patient in the role of, you know, the advocate."

[Interviewee 4]

Impressions of Potential Recipients

When describing their encounters, advocates repeatedly described potential recipients as "savvy", "well-informed", and "enthusiastic" about the HOPE transplant research study.

"They are very gung-ho about being involved in this and being listed on the HIV positive list."

[Interviewee 10]

However, one advocate was cautious to manage potential recipients' expectations.

“Yeah. They’re pretty enthusiastic. Some of them might be not-- you know, they were expecting the organ years ahead of another, so sometimes there’s a little bit of a realism and we have to talk about not really always knowing. But otherwise, yeah, they’re enthusiastic.”

[Interviewee 13]

A few advocates described encounters during which potential recipients expressed informational fatigue. Interviewees attributed this fatigue to the fact that potential recipients have already met with, and received information, from multiple sources (e.g., transplant surgeons, infectious disease physicians, nurses, transplant social workers, etc.) prior to their encounter with the independent advocate. One advocate struggled with finding a balance between ensuring the risks, benefits, and voluntariness of an individual’s decision was understood and annoying them.

“I have the consent, that’s what I use but I think a lot of it is also the very first time I got in touch with this person and in my mind, I was kind of like, okay, basically sort of a quick whirlwind of the consent essentially but ...he was like, “Look, I spent like an hour with the research, I’ve spoken about this with my primary care physician, I’ve spoken with the transplant team, I’m honestly not sure what you’re going to say that I haven’t already been told and I feel like I have a great understanding of this, of the risks and benefits and I’m fully ready to jump into this thing...I’m not exactly sure why you’re calling me but thank you anyways and the team has been just absolutely fantastic and I feel like all my questions are answered”... And at least this particular person struck me as someone who is very, very motivated and kind of dealing with it and so he was just-- I don’t think there was really much there, I didn’t want to annoy either, but I don’t think we were going there but I did get the sense that he felt very comfortable for entering and consenting for this study.”

[Interviewee 12]

Concern about informational redundancy was not limited to the potential recipients. One advocate questioned the utility of their role:

“So I’m not familiar with an independent advocate for other research studies, so I’m not sure if this is an HIV-specific thing or not. Because we are going through informed consent, right. So I don’t know how necessary it is; if we’ve truly done informed consent, then there should be no coercion and patients should understand the risks and benefits. So if we did our job right the first time around, this shouldn’t be necessary, right?”

[Interviewee 9]

None of the advocates reported having a potential recipient change their mind after meeting with them (i.e., no one withdrew their consent from the HOPE transplant research study). However, one advocate, who also served as a transplant coordinator, spoke of an individual who decided to wait for an HIV- organ, but it was unclear as to whether that decision was the result of the advocate encounter.

Challenges

All interviewees were asked to share any challenges that they have encountered serving as a HIRA. None reported encountering any experiences that made them uncomfortable. Nevertheless, they described a number of issues and concerns that stemmed from the lack of clear guidance regarding qualifications, training, and practice related to the HIRA role. Several interviewees expressed uncertainty regarding who was qualified to serve as an advocate and the challenge of finding someone familiar with both HIV and transplantation who was *not* a member of the research team.

“What does that mean, like, when you say that you want the advocate to know about HIV, know about transplant, what does that mean?”

[Interviewee 9]

Others struggled with how much detail to provide and whether or not they should answer specific questions.

“So that’s where that --this difficult song and dance where I kind of have to take a step back and be like, ‘Okay, is it appropriate for me to answer this question?’”

[Interviewee 3]

Several interviewees, all of whom functioned as the sole HIRA at their institution, expressed an interest in speaking with others serving in this role. The desire of some to speak with others and “compare notes” highlights a sense of unease that emerged in several interviews. Interviewees both directly and indirectly cited the lack of guidance regarding their role and responsibilities as the source of their unease.

“What I’m curious is who are advocates and what they talk about when they meet. Like ... what level of detail, because again, informed consent has been done. So, that would be my question if I meet other advocates would be, like, what do you actually talk about? Like, how fast is this visit, you know, how much detail do you go into? And, like, again, identifying who’s an appropriate advocate, like, how much HIV or transplant experience they need”.

[Interviewee 9]

“I felt prepared with the training, just if there was some formalized thing. Again, maybe some formalized checklist of sorts... just kind of like when I do studies now when the sponsor provides kind of checklists and documents to use, you feel a little more comfortable if, okay, well they’ve provided me these documents so I think I’m covering anything and if I don’t then it’s their fault because they forgot. And when we have to make our own things it’s like, ‘Okay, well did I miss something?’ There’s that tiny level of uneasiness of, ‘I’m not knowingly forgetting to do this, it’s just an oversight.’ So again, I feel comfortable with what I’m doing but maybe having something a little more formalized for people to use as a tool of some sort”.

[Interviewee 3]

“So, I think the newness of the role was the biggest challenge”.

[Interviewee 4]

Others believed that speaking with other advocates would be helpful in preparing for situations and addressing issues that they might not have otherwise anticipated.

“You know, I think in a way especially with that question that you asked me, what is the challenges, sometimes asking what the other independent advocates, their experiences, kind of challenging questions or scenarios that have arisen but it may be good to-- this is probably one extreme in terms of being completely simple but I'm sure there have been the opposite extremes as well where it was very challenging to ask very good questions that we don't have the answer to, it would be interesting to know that.”

[Interviewee 12]

Discussion

HIV D+/R+ transplantation is now underway in the United States being allowed only within research trials that uniquely require an independent advocate for potential recipients under the provisions of the HOPE Act Safeguards and Research Criteria.⁴ We found that the first cadre of HIRAs who we interviewed were well qualified with regard to professional credentials and were able to articulate their general role and responsibilities as delineated in the HOPE Safeguards and Research Criteria in terms of helping to protect the interests of potential recipients of HIV-infected organs. However many HIRAs expressed a need for more specific guidance about their role, a desire for interaction with HIRAs at other institutions, and some even questioned the need for this position.

In this study, we were able to contact HIRAs at 17 of the 20 institutions who had enrolled HOPE study participants, yet we encountered unexpected difficulties locating HIRAs to interview. In some cases, staff at the transplant centers did not know who the advocate was or were for unclear reasons uncomfortable providing their name and contact information. During the interviews, we learned that filling the role of the HIRA was challenging given the requirement for identifying an individual with experience in transplantation and HIV who was not working with the research team performing HIV D+/R+ transplants. Further, a few sites did not have a HIRA in place at the time we contacted them, while others reported turnover in the role. All of the HIRAs we identified were health care professionals – namely physicians, nurse practitioners, nurses, social workers. This finding contrasts data regarding ILDAs indicating that clergy and laypersons also serve as ILDAs.¹⁴

Given that the role of HIRA is new and not clearly defined, it was not surprising to find variability among HIRAs with regard to professional discipline, training, and practice. Similar variability was documented with early ILDAs, resulting in calls for guidance and standards.^{14,15} In response, the American Society of Transplantations Living Donor Community of Practice clarified required components of the ILDA role, detailed training, and addressed controversies in ILDA role implementation.¹⁶

Our data indicate that the newness of the HIRA role and the lack of guidance or standards is associated with a sense of unease, particularly among those serving as the sole advocate at their institution. Many of those we interviewed suggested that having guidance regarding

qualifications, training, and practice would be helpful as would connecting with other HIRAs. Such guidance should align with the ethical and practical goals hoped for among HIRAs, which arguably need to be more explicitly articulated.

In our study, HIRAs consistently described potential participants as being extremely knowledgeable and enthusiastic about the possibility of receiving an HIV-infected organ. A few HIRAs were concerned that potential participants experienced informational fatigue and questioned whether the role of the HIRA was redundant given all of the other people involved with counseling them. Questions surrounding advocates in high-risk, high-profile research are not new. Independent advocates have been employed in selected research studies involving high or novel risks (e.g., an early artificial heart trial), high-profile experiments (e.g., hand transplants), and those that enroll vulnerable populations (e.g., psychiatric drug research).¹⁷ The role of these advocates, also referred to as ‘independent advocates’, ‘neutral disclosers’, ‘consent monitors’, ‘patient advocates’, and ‘research subject advocates’, is generally to provide an additional layer of protection for prospective participants by serving as a neutral/disinterested third party.¹⁷ In the case of high-risk, high-profile maternal-fetal surgery, advocates were employed to help protect potentially emotionally vulnerable women pursuing maternal-fetal surgery for fetuses diagnosed with spina bifida. Concerned that women having just received a diagnosis of fetal spina bifida would feel compelled to participate in the study, Vanderbilt University Medical Center required expectant parents to consult with an ethicist both before and after meeting with the study team.¹⁷ In the case of the AbioCor artificial heart, an Independent Patient Advocacy Council was put in place at the behest of the company that created the artificial heart. Unlike most examples of advocate use, in which the role of the advocated is focused on the informed consent process, patient advocates in the AbioCor heart trial assisted potential recipients and their families, not only during the informed consent process, but throughout the duration of the trial.¹⁸ In studies of psychiatric medications, ‘neutral disclosers’ were used to ensure potential study participants understood the risks and the benefits of the study and to educate participants on research generally, including the differences between research and clinical care.¹⁹

As mentioned earlier, ILDAs, charged with ensuring the ‘protection of living donors and prospective donors’¹¹ are commonplace in the transplant setting. However, the use of advocates for transplant *recipients* are the exception, rather than the norm. One such example is the Louisville/Jewish Hospital hand transplant program. The program was concerned that ‘when researchers want to engage in such a procedure, the very notion of informed consent is problematic.’^{20,21} To mitigate this potential challenge to informed consent, a potential transplant recipient was required to name an advocate to assist with ‘the process of interpreting the medical information, his own feelings and pressures, and/or questions he might have.’²⁰

For HIV D+/ R+ transplants, the role of the HIRA was ostensibly created to ensure that potential participants understand the risks, benefits, and voluntariness of their decision to accept an HIV-infected organ. While these are of course essential considerations, the added, mandatory HIRA encounter may also inadvertently increase participants’ fear in the research by implying that the study’s risks are so great as to warrant confirmation of their decision to

participate in addition to the usual consent processes that are in place. Furthermore, in light of the fact that most high-risk research studies do not require independent advocates for potential study participants, the HIRA requirement may signal that HIV D+ to HIV R+ organ transplants warrant special protections that could inadvertently be associated with HIV-related stigma. Future work that captures the experiences of potential recipients should explore whether such unintended consequences actually exist.

Nonetheless, given the role of IRBs, investigators, sponsors and institutions to protect the rights and interests of research participants, some might view the role of the independent advocate as not only superfluous, but one that may undermine public confidence in research and the current protections already in place. Others might be concerned that participants could be insulted by the requirement for an advocate, a requirement sometimes ascribed to individuals perceived to be of diminished capacity or particularly vulnerable. As argued in other settings, the use of advocates may divert resources from research contexts in which assistance for vulnerable populations is warranted.^{17, 22}

Regardless of such concerns, since HIRAs are at the interface of the potential recipient and research team, they are uniquely positioned to address ethical and practical challenges in real time to help ensure HIV D+ to HIV R+ organ transplants are responsibly and appropriately performed and examined in practice. However, this potential opportunity cannot be realistically achieved unless patients and HIRAs have opportunities for interaction beyond simply meeting around the time of consent for study participation. This may be difficult to achieve in practice if HIRAs are not currently provided with adequate time and resources to do so, especially since current HIRAs tend to be tasked with this role in addition to other clinical responsibilities. Given these issues as well as the understandable challenges faced in identifying those who have requisite expertise and who are independent from the HIV D+/R+ transplant team at an institutional level, consideration should be given to the possibility of having a central resource at a regional or national level to help fulfill the HIRA role through phone or video consultation. Such a resource could be readily transparent to all of those seeking an advocate for these transplants and would be clearly independent. Of course, it will be critical to assess whether such an approach would be acceptable to potential recipients as well as transplant teams and institutions.

While our data captures the experiences of the first HIRAs, they should be interpreted with some limitations in mind. First, while we were able to interview many of the first cohort of HIRAs, our overall sample was small. However, we achieved informational saturation, suggesting that the sample size was not problematic for this study. Second, while we were able to interview HIRAs from most of the institutions performing HIV D+/R+ transplants, there may be different approaches used at those institutions who did not provide access to their HIRAs. Similarly, there may be different approaches used among this first cohort compared to those that will evolve with experience over time. Accordingly, future work might seek to elicit this information, perhaps using quantitative survey methods. Further, it is important to note that our data are limited to the perspectives of HIRAs themselves. Therefore, research should be directed at garnering the perspectives of others, especially those of potential recipients and transplant teams. Similarly, ethnographic work that might include direct observations of HIRA-potential recipient encounters could be informative.

In conclusion, there are several opportunities to enhance the role of HIRAs in HIV D+/R+ transplants that include the need for a more careful explication of the ethical and practical goals of HIRAs. Resources are also needed to help HIRAs perform their role, including support for time, developing and disseminating guidelines, training materials, and checklists to standardize HIRA-participant encounters. These steps should help to ensure that these transplants are done in an ethically acceptable manner.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Recruitment

Number of Institutions Approved for HOPE Transplants*	Number of Institutions Enrolling Patients for HOPE transplants	Number of Institutions Invited to Participate	Total number of HIRAs identified	Number of Institutions with a HIRA currently in place	Number of HIRAs Interviewed
25	20	20**	27	17	15***

* As of September 15, 2018. Available at <https://optn.transplant.hrsa.gov/learn/professional-education/hope-act/>

** In some instances, several invitations were sent to different staff members at the same institution in an effort to reach the individual(s) serving as a HOPE Independent Recipient Advocate (IA).

*** representing 12 distinct institutions

Table 2.

Characteristics of HIRAs and Encounters

Background	# of Advocates
Nurse, nurse practitioner, or other allied health professional	6
Physician	3
Social worker, ethicist, patient advocate, etc.	6
Member of the transplant team	
Yes	6
No	9
Served as a Living Donor Advocate	
Yes	2
No	13
Number of patients HIRA has met	
>15	2
10–14	1
5–9	5
1–4	7
Meeting Timing	
Before signing consent	4
After signing consent	8
Both	2
Don't know	1
Meeting format	
In person	10
Phone call	3
Both	2
Meeting duration	
<15 minutes	4
15–30 minutes	5
30 + minutes	4
Varies	1
Not reported	1