

e-ISSN 2329-0358 © Ann Transplant, 2018; 23: 387-392 DOI: 10.12659/AOT.908660

Received: 2017.12.22 Accepted: 2018.02.10 Published: 2018.06.05

Willingness to Consider Increased-Risk Donors: A Single-Center Experience in Kidney Transplantation

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Background:

The number of Public Health Service increased-risk organ donors (PHS IRD) is growing, largely from an increase

in intravenous drug use overdoses due to the current opioid epidemic.

Material/Methods:

We conducted a retrospective case series review using our single-center data. We reviewed 82 PHS IRD kidney transplant offers between 2015 and 2017, 20 of which were declined. We reviewed outcomes of patients who declined *vs.* accepted PHS IRD offers. We studied the effect of education on these patients' willingness to con-

sider another PHS IRD.

Results:

Twenty patients declined PHS IRD over a 2-year period. They waited on average 9 months for another transplant, and tended to be transplanted with a higher-KDPI kidney than the one originally offered. Patients who declined PHS IRD were more likely to be predialysis, women, and Asian American, and to require an interpreter. Ninety-two percent of patients who received education on PHS IRD after declining an offer stated that they would consider another PHS IRD offer in the future. Four of these patients received a PHS IRD transplant.

Conclusions:

Our results suggest that education of patients may have a positive impact on patient attitudes toward PHS

IRD.

MeSH Keywords:

Kidney Transplantation • Tissue Donors • Transplantation

Abbreviations:

PHS - Public Health Service; IRD - increased risk donor; HBV - hepatitis B virus; HCV - hepatitis C virus;

HIV – human immunodeficiency virus; **SRTR** – Scientific Registry of Transplant Recipients; **DTAC** – Disease Transmission Advisory Committee; **EPTS** – estimated post-transplant survival;

KDPI – kidney donor profile index

Full-text PDF:

https://www.annalsoftransplantation.com/abstract/index/idArt/908660









Background

In 2013, the Public Health Service (PHS) released a guideline which identified organ donors with an increased likelihood of recent hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV) infection, and therefore an increased risk of transmitting an infection to an organ recipient [1]. The number of PHS increased-risk donors (IRD) has been on the rise. Prior to 2010, PHS IRD in the United States comprised 8-10% of all donors; currently, they make up approximately 30% of donors nationally, in large part due to the opioid epidemic [2-4]. These transplants have a similar patient and graft survival when compared with standard-risk donor transplants [5]. Compared with standard-risk donors, PHS IRD are younger, more likely male, more likely to die from anoxia, and less likely to have diabetes or hypertension [5]. In a recent study, Bowring et al. demonstrated that, based on 2010–2014 Scientific Registry of Transplant Recipients (SRTR) data, acceptance of a kidney from a PHS IRD was associated with substantial long-term survival benefit, with a 48% lower risk of death beyond 6 months after accepting a kidney graft from a PHS IRD [6]. Thus, there are excellent data supporting the use of organs from PHS IRD.

Although the PHS IRD Guidelines were developed to protect transplant recipients from the transmission of blood-borne viruses, the actual risk of viral transmission after negative screening tests has proven to be very low. Between 2009 and 2015, only 140 cases of potential donor-related transmission of HIV, HBV, or HCV were considered and reviewed by the Disease Transmission Advisory Committee (DTAC). DTAC attributed 18 such infections to transplants from standard-risk donors (out of 50 066 transplants), and 7 infections to transplants from PHS IRD (out of 8056 PHS risk-identified transplants). This difference in incidence rate was not statistically significant [5].

With an increasing number of patients on the active kidney transplant wait list and an approximately 5% annual death rate on the overall wait list [7], it is imperative that we use as many organs as possible, but this depends on patients being willing to accept PHS IRD offers. The rates of PHS IRD refusals and associated factors have not been well-studied. The purpose of this pilot study was to understand the impact that annual education might have on a transplant candidate's decision-making process, as well as its role in patient acceptance of increased-risk donor organ transplants. To make the education process more targeted, we also aimed to identify characteristics of patients who declined increased-risk kidney offers at our center and to understand the implications of this on patient outcomes.

Material and Methods

We conducted a retrospective case series review from our single-center data. This study does not qualify as human subjects research, as defined by the University of Washington Human Subjects Division. University of Washington Medical Center utilizes an internal communication system for all transplant patients. This database includes a communication entry entitled "Organ Offer", which is to be selected from a dropdown menu whenever a member of the transplant team offers a deceased donor transplant to a candidate on the wait list. We individually reviewed all "Organ Offer" communications over a 2-year period from July 2015 to July 2017 for instances of patients who declined an organ offer due to its PHS IRD status. Ultimately 82 PHS IRD kidney offers were reviewed, 20 of which were declined. Multi-organ offers were excluded from the study. We collected demographic data for these patients, including age, Estimated Post-Transplant Survival (EPTS), sex, ethnicity per self-report, and whether an interpreter was required for communication. For comparison, we also reviewed the demographics for the 62 patients who received PHS IRD transplants between July 2015 and July 2017. These patients' transplant outcomes as of December 15, 2017 were obtained via chart review. Total wait time was calculated in days from the start of dialysis or from the date placed on the wait list, whichever came first. We also calculated the amount of time (in days) from a declined organ offer to a kidney transplant or to the end of the study period on December 15, 2017. We then reviewed DonorNet for the Kidney Donor Profile Index (KDPI) of any declined and accepted kidney offers, as well as the reason for PHS IRD inclusion, if applicable.

PHS IRD education protocol

Every patient at our center receives PHS IRD education at multiple points along the kidney transplant evaluation process. This starts with the transplant nephrologist at the initial visit, and is repeated at the second visit with the transplant surgeon and nurse coordinator. Although the patient is not specifically targeted for education after declining a PHS IRD, this topic is discussed at each yearly medical re-evaluation, typically with the transplant nephrology nurse practitioner. At each point, educators document whether patients indicate that they would decline or consider future PHS IRD offers. Education consists of the definition of PHS IRD, likelihood of viral transmission, window period for viral testing, and the potential risks and benefits of accepting or declining PHS IRD. All PHS IRD discussions in the clinic take place with an in-person or telephone interpreter, as needed. When patients receive a PHS IRD offer, they can consent over the phone prior to coming to the hospital (with a phone interpreter as needed), at which point the risks of this individual PHS IRD offer are discussed in detail with a member of the infectious disease team, and the

Table 1. Patients who declined PHS IRD vs. Patients who received PHS IRD.

Category	Sub-category	Declined PHS IR transplant (N=20)		Received PHS IR transplant (N=62)		Total (N=82)	
Median Age (IQR)		46	(42 to 61.5)	46 (35.75 to 61.25)		46	(36 to 61.25)
Median EPTS (IQR)		25.5	(9.5 to 63)	24.5	(12 to 53.5)	24.5	(12 to 59)
Predialysis			25%	15%			17%
Women		55%		42%			45%
	African American	15%		15%			15%
	Asian American		35%		19%		23%
Ethnicity	Latino American	5%		10%			9%
	White	40%		48%			46%
	Other	5%		8%			7%
Interpreter required		20%		15%			16%

consent form is signed. We did a chart review to determine the date that the study patients were most recently educated on PHS IRD. If the most recent informed consent discussion occurred after declining a PHS IRD offer, we then noted whether they had indicated that they would consider another PHS IRD offer in the future.

Statistical analysis

Descriptive analyses were used to summarize numbers and proportions between groups (those who refused vs. those who accepted an organ offer from a PHS IRD). Numeric variables were summarized with medians and inter-quartile range. Categorical variables were summarized by percentages. Sample size and power of analysis were performed by StatMate, by GraphPad (La Jolla, CA).

Results

Characteristics of PHS IRD "Decliners"

Twenty patients declined donors due to their PHS IRD status during the study inclusion period from July 2015 to July 2017 (Table 1). During this same time period, 62 patients received a PHS IRD kidney transplant at our center. EPTS ranged from 1 to 83 in the patients who declined increased risk donors, with a median (IQR) of 25.5 (9.5 to 63). EPTS ranged from 1 to 98 in patients who received PHS IRD, with a median (IQR) of 24.5 (12 to 53.5). The age of patients who declined a PHS IRD ranged from 21 to 69 with median (IQR) 46 (42 to 61.5). The age of patients who received a PHS IRD ranged from 22 to 71 with median (IQR) 46 (35.75 to 61.25).

Patients who declined PHS IRD were more likely to be predialysis than PHS IRD recipients (25% vs. 15%). Of the patients who declined PHS IRD, 35% identified as Asian American and 20% required an interpreter. By comparison, 19% of recipients of PHS IRD kidney transplants at our center identified as Asian American and 15% required an interpreter. Fifty-five percent of patients who declined a PHS IRD were women vs. 42% of those who received a PHS IRD during the study period.

We did not evaluate for statistical difference among the 2 groups because our pilot study was underpowered for robust analysis. An 80% power to detect a 5% difference would require 590 patients in the group that declined PHS IRD and 1767 patients in the group that received PHS IRD.

Outcomes of PHS IRD "Decliners"

As of December 15, 2017, 1 of 20 patients (5%) who declined a PHS IRD kidney between July 2015 and July 2017 died due to complications from end-stage renal disease. One patient (5%) remained active on the list, and 2 patients (10%) were on hold on the list. The remaining 16 patients (80%) received transplants. Ten of these received a transplant from non-PHS IRD, and 6 ultimately received a transplant from another PHS IRD. The 3 patients who remained on the wait list at the end of the study period had waited on average an additional 532.0 days (17.7 months) since the declined offer. The 16 patients who received a transplant during the study period waited on average 279.9 days (9.3 months) from the declined offer until their transplant. The average total wait time (to either transplant or the end of the study period) was 1651.1 days for patients who declined PHS IRD, and 1184.0 days for patients who received PHS IRD. Of the declined offers, 17 out of 20 (85%)

Table 2. Donor KDPI/PHS IRD status for declined kidneys vs. later-transplanted kidneys.

Offer # (earliest to latest)	Donor KDPI	PHS IRD category	2 nd donor KDPI	2 nd donor PHS IRD category	Δ KDPI between offers	Time between offers (days)
1	7	IVDU*	24	IVDU	17	582
2	7	IVDU	33	IVDU	26	835
3	7	IVDU	17	N/A	10	172
4	20	IVDU	11	MSM***	- 9	88
5	15	IVDU				
6	59	IVDU	25	N/A	-34	701
7	7	Jail time	37	Lack of history	30	606
8	7	IVDU	13	N/A	6	46
9	7	IVDU	12	N/A	5	197
10	8	IVDU	20	N/A	12	233
11	21	IVDU	51	N/A	30	60
12	21	IVDU				
13	16	IVDU	23	N/A	7	96
14	30	Jail time	16	Hemodilution	-14	105
15	41	IVDU	27	N/A	-14	7
16	4	IVDU				
17	4	IVDU	6	IV Steroids	2	188
18	4	IVDU	9	N/A	5	286
19	30	HR Sex**				
20	55	IVDU	73	N/A	18	276

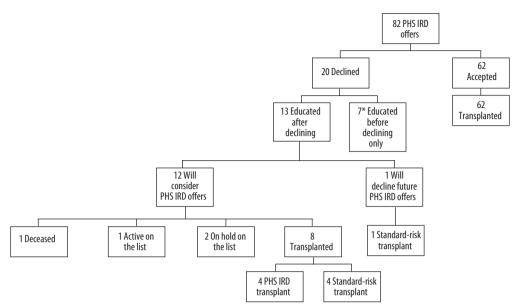
^{*} IVDU - intravenous drug use; ** HR Sex - high-risk sexual behavior; *** MSM - men who have sex with men.

were PHS IRD due to intravenous drug use. One was due to high-risk sexual behaviors, and the remaining 2 were due to serving jail time (Table 2). Of the 6 PHS IRD that were accepted on the second offer, 3 were due to intravenous drug use, 1 was due to high-risk sexual behaviors, 1 was due to inadequate history, and 1 was due to hemodilution. Twelve out of the 16 transplanted patients received a kidney with a higher KDPI than the one originally offered, suggesting worse overall quality (Table 2).

Influence of education on attitudes toward PHS IRD

Of the 20 patients who declined a PHS IRD offer during the study period, 13 received education on PHS IRD after they had declined the initial offer (in addition to education already received prior to declining the offer). This education was provided by the transplant nephrology nurse practitioner in 11 cases

(face-to-face), an infectious disease physician in 1 case (faceto-face), and a transplant surgeon in 1 case (via telephone due to patient request). Twelve out of 13 (92%) patients who had initially declined a PHS IRD verbally indicated that they would consider a future PHS IRD offer after education and discussion. Four of these patients accepted a PHS IRD on a subsequent offer and received a PHS IRD transplant. One of the patients who stated he would consider another PHS IRD declined a PHS IRD offer afterward, although this particular donor had multiple infectious disease risks (intravenous drug use, a man who had sex with men (MSM), and sex with an intravenous drug user). Of the 7 patients who were educated on PHS IRD prior to declining, but not after, 2 subsequently accepted PHS IRD and the remaining 5 received standard-risk transplants. In total, 30% of our patients who declined PHS IRD eventually received a PHS IRD, much higher than the number cited in national data by Bowring et al., at 6.1% after 5 years [6].



^{*} Of those educated only prior to declining PHS IRD, 2 received PHS IRD transplants and 5 received standard-risk transplants.

Figure 1. Flow chart of patients who declined and received PHS IRD during study.

Discussion

For the 20 patients in our center who declined a PHS IRD organ between July 2015 and July 2017, outcomes as of December 2017 included death, waiting another 9 months on average for a kidney transplant, being placed on hold on the wait list, or continuing to wait while active on the wait list for another 15 months after the initial offer. For the 16 patients at our center who received a kidney transplant after declining a PHS IRD, 12 out of 16 received a lower-quality kidney transplant according to KDPI than the one originally offered.

Our standard PHS IRD education practice, which takes place on each yearly medical re-evaluation, was associated with a high willingness to consider future PHS IRD offers. This suggests that there may be a role for targeted education shortly after a patient chooses to decline a PHS IRD. We know that patients often carry apprehensions and misunderstandings regarding PHS IRD [8]. The risk of transmission of viral infection from PHS IRD should be discussed in the context of the risks associated with contracting HCV while on hemodialysis. With an estimated incidence of 0.34% per year, this risk is similar to the risk of contracting HCV from a PHS IRD [9-11]. It should also be considered in the context of the disadvantages of remaining on dialysis rather than receiving an earlier transplant. In 2015, of the approximately 98 000 patients who were on the wait list for kidney transplant (both active and inactive), nearly 5000 (5% of patients) died [7]. At our center, 12 of 13 patients who received education on PHS IRD after declining a PHS IRD offer stated that they would consider another PHS IRD offer in the future. Four of these patients did receive a PHS IRD kidney transplant (Figure 1).

The patients who declined a PHS IRD offer at our center between July 2015 and July 2017 were more likely to identify as Asian American than the patients who received a PHS IRD transplant during the same period. This outcome cannot be fully explained by a language barrier, suggesting that there may be other barriers playing a role. Others have shown that African Americans and Latino Americans experience mistrust during the transplant process [12,13]. Similarly, patients who require an interpreter were more likely to decline a PHS IRD at our center, likely due to both language and cultural barriers. Predialysis patients were more likely to decline PHS IRD, perhaps suggesting that the sense of urgency toward transplant, and therefore willingness to take perceived additional risks, was reduced. Women were also more likely to decline PHS IRD. These demographics should be considered in the design of educational and other interventions aimed at use of organs from PHS IRD.

Our study has several limitations. This study is a retrospective review at a single institution, which limits the sample population. The "Organ Offer" communication entries from which we derived our data are input manually by the user; therefore, we may have missed PHS IRD offers or refusals. Our sample size was too small to draw statistical conclusions. We cannot know whether patients switched from declining to accepting a PHS IRD due to education and increased trust with the transplant team, or due to higher anticipation for transplant after waiting

longer (or some other reason). However, our data show that 92% of patients who previously declined a PHS IRD would at least entertain the idea of accepting a future PHS IRD after a focused discussion.

Conclusions

In this pilot study we have demonstrated that, at our center, comprehensive education of patients on a yearly basis may have a positive impact on patient attitudes toward PHS increased infectious risk donor kidney transplantation, with a large majority of patients who declined PHS IRD stating that they would consider another PHS IRD offer after education.

We noted that women, predialysis patients, Asian American patients, and patients who require an interpreter were more likely to decline PHS IRD kidneys, but our study was underpowered for a robust comparative analysis of these differences.

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Patients who declined PHS IRD waited on average 9 months for another transplant, and tended to be transplanted with a higher KDPI kidney than the one originally offered. Those who remained on the list at the end of the study period had waited, on average, almost a year and a half since they declined the PHS IRD offer.

Future studies are needed to validate our findings in a larger population in order to reduce offer decline rates through identification of modifiable barriers. The education of specific groups regarding PHS IRD organs should be undertaken to avoid longer waiting times, removal from the wait list, or death.

Conflicts of interest

None.

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