

Survey of Clinician Opinions on Kidney Transplantation from Hepatitis C Virus Positive Donors: Identifying and Overcoming Barriers

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Abstract

Background Transplant practices related to use of organs from hepatitis C virus–infected donors (DHCV+) is evolving rapidly.

Methods We surveyed US kidney transplant programs by email and professional society LISTSERV postings between July 2019 and January 2020 to assess attitudes, management strategies, and barriers related to use of viremic (nucleic acid testing positive [NAT+]) donor organs in recipients who are not infected with HCV.

Results Staff at 112 unique programs responded, representing 54% of US adult kidney transplant programs and 69% of adult deceased donor kidney transplant volume in 2019. Most survey respondents were transplant nephrologists (46%) or surgeons (43%). Among the responding programs, 67% currently transplant DHCV antibody+/NAT– organs under a clinical protocol or as standard of care. By comparison, only 58% offer DHCV NAT+ kidney transplant to recipients who are HCV–, including 35% under clinical protocols, 14% as standard of care, and 9% under research protocols. After transplant of DHCV NAT+ organs to recipients who are uninfected, 53% start direct-acting antiviral agent (DAA) therapy after discharge and documented viremia. Viral monitoring protocols after DHCV NAT+ to HCV uninfected recipient kidney transplantation varied substantially. 56% of programs performing these transplants report having an institutional plan to provide DAA treatment if declined by the recipient's insurance. Respondents felt a mean decrease in waiting time of ≥ 18 months (range, 0–60) justifies the practice. Program concerns related to use of DHCV NAT+ kidneys include insurance coverage concerns (72%), cost (60%), and perceived risk of transmitting resistant infection (44%).

Conclusions Addressing knowledge about safety and logistic/financial barriers related to use of DHCV NAT+ kidney transplantation for recipients who are not infected with HCV may help reduce discards and expand the organ supply.

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Introduction

Although the kidney transplant waiting list has increased by six-fold in 20 years, deceased and living donations have not quite doubled (1). Unfortunately, kidneys from young donors with expected excellent long-term graft survival were historically discarded because of prior donor hepatitis C virus (HCV) exposure (DHCV positive antibody [Ab+]) or donor HCV viremia as detected by nucleic acid testing (DHCV NAT+). The prevalence of HCV-exposed organs, of which 25% are DHCV NAT+, has increased more than ten-fold in the last two decades as a result of opiate

overdose deaths (2). Although DHCV-exposed kidney use has been increasing, thousands of kidneys have gone unused over a 10-year period (3–5).

Because DHCV Ab+/NAT– kidneys reflect prior, rather than current, infection, viral transmission to recipients is unexpected. In contrast, DHCV NAT+ kidneys result in viral transmission to the majority of recipients (6). Without effective antiviral therapy and given concerns of transmission, transplant clinicians historically confined use of DHCV NAT+ organs to recipients infected with HCV (6,7). The early introduction of direct-acting antivirals (DAAs) has

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permitted safe transplantation of DHCV NAT+ organs to patients without HCV infection (8–14). Trials from the University of Pennsylvania and Johns Hopkins demonstrated that transplantation of DHCV NAT+ kidneys into patients not infected with HCV, followed by 12 weeks of elbasvir/grazoprevir, achieved viral eradication in 100% of patients (8,9). Additional case series have followed, including groups that achieved high levels of viral clearance with shorter courses of DAA treatment, although several patients required retreatment as a result of viral resistance (12,15–18).

Despite this rapidly changing landscape, knowledge and comfort with transplantation of DHCV+ organs has not been systematically assessed. Clinical care and decision making for transplant providers is more complex for DHCV NAT+ kidneys, due to potential concerns about medical and psychosocial risks for the recipients. In addition, programs face concerns about the cost of post-treatment DAA therapy for patients, programs, and the healthcare system. The aim of this study is to examine attitudes and priorities underpinning transplant providers' decisions about transplantation of DHCV+ viremic and nonviremic kidneys into patients without HCV infection and subsequent management.

Materials and Methods

Survey Design

The survey instrument was developed by the study investigators who developed the survey items and refined questions by direct discussion and email between them. The final survey comprised 16 questions (Supplemental Table 1). The survey queries information on participant role at the transplant program (surgeon, nephrologist, coordinator, social worker, administrator, or other) and United Network for Organ Sharing (UNOS) center identifier. Participants were asked about risk perceptions, practices, and protocols in the evaluation and management of DHCV+ transplantation for potential recipients without HCV infection. Respondents from programs that did not perform transplantation of DHCV NAT+ kidneys for patients without HCV infection were asked about perceived barriers to this practice. This study was approved to be human subjects exempt by the Saint Louis University Institutional Review Board (approval number, 30342). The clinical and research activities being reported are consistent with the principles of the Declaration of Istanbul, as outlined in the Declaration of Istanbul on Organ Trafficking and Transplant.

Survey Administration

US kidney adult transplant programs active in 2019 ($N=207$), including surgeons, nephrologists, administrators, coordinators, and social workers, were surveyed. Potential participants at all US kidney transplant programs were derived from the working group's professional connections, and the survey was emailed through the Qualtrics Survey Software. Participants from individual centers who did not wish to participate were asked to share the survey with other potential participants at their center. Surveys received from programs serving only pediatric patients were excluded from the study. Opportunity for self-elected participation through a Qualtrics link was also posted to professional society LISTSERVS, *e.g.*, American Society of

Transplantation (AST) Kidney Pancreas Community of Practice (COP) and AST Transplant Administrators and Quality Management COP, after approval by COP leadership. Links to the survey were distributed between July 15, 2019 and January 24, 2020. The first page of the survey stated the decision to proceed indicated consent to participate. Participants who completed the survey were also invited to enter a lottery for \$10 coffee gift cards (20 cards were distributed). Up to three reminders were provided for nonrespondents.

Statistical Analyses

Each program was represented only once in the analysis. For programs with multiple respondents, we selected one participant to represent the center using a hierarchic algorithm. First, we omitted any survey with missing responses to the questions about whether the center performed DHCV Ab+ /NAT– or DHCV NAT+ transplants for recipients who are uninfected. Next, we omitted surveys submitted by coordinators, social workers, pharmacists, or others in favor of responses from transplant surgeons, transplant nephrologists, or center administrators. Finally, if any programs had more than one response after the above two steps, we retained the survey with the least missing data.

Responses to each survey question were described by either percentages and frequencies or means and ranges, as appropriate. To obtain percentages, we divided the number of program responses (*i.e.*, row totals) by the total number of programs who responded to the question, such that percentages reflect proportions of respondents, as per previous methods (19–22). For questions about DAA therapy, we excluded those respondents from the denominator who reported their program did not perform DHCV NAT+ transplantation for recipients who are uninfected. For questions where participants were asked to “select all that apply,” the denominator for calculating percentages was the number of participants responding to that question. For these questions, column totals exceed 100%. All analyses were performed using SAS for Windows version 9.4.

Results

Survey Participants

We received 173 survey responses, of which 75 came from a program with only one survey respondent, and 98 were from programs with more than one respondent. After limiting to 115 unique program responses (Supplemental Figure 1), we removed surveys from three programs that performed only pediatric transplants, leaving 112 unique programs as the sample size for most analyses. Respondents represented 54% of US adult kidney transplant programs and 69% of adult deceased donor kidney transplant volume in 2019. Participants were most often transplant nephrologists (46%) or surgeons (43%) (Table 1). All UNOS regions were represented. The most commonly represented UNOS regions were Region 2 (14%), Region 3 (13%), and Region 11 (13%).

Transplant Program Acceptance Practices

HCV Ab+ /NAT– donor organs were offered to recipients not infected with HCV by 69% of responding programs,

Table 1. Participant characteristics	
Characteristics	n (%)
Role in transplant center (item denominator=112)	
Transplant surgeon	48 (43)
Transplant nephrologist	52 (46)
Administrator	7 (6)
Coordinator	2 (2)
Other	3 (3)
UNOS region (item denominator=112)	
1	9 (8)
2	16 (14)
3	14 (13)
4	9 (8)
5	10 (9)
6	6 (5)
7	9 (8)
8	7 (6)
9	9 (8)
10	9 (8)
11	14 (13)

UNOS, United Network for Organ Sharing.

including 67% under a clinical protocol or as standard of care, and 2% under research protocols (Figure 1). By comparison, 58% of respondents performed DHCV NAT+ kidney transplantation for recipients not infected with HCV. Transplants from DHCV NAT+ donors to recipients not infected with HCV were performed as a clinical protocol in 35% of centers, whereas 14% performed these transplants as part of standard of care and 9% under research protocols.

Risk Perceptions

The majority of responding programs (64%) reported telling their recipients without HCV infection that there is a <5% risk of HCV transmission from a nonviremic donor, whereas 9% do not specifically discuss transmission risk related to these organs with patients (Table 2). Programs were then queried about patient communication regarding two specific risks after kidney transplantation from DHCV NAT+ (viremic donors) to recipients without HCV infection. First, what is the risk of chronic infection without DAA treatment? More than half of the responding programs (58%) reported a risk >50%, whereas 24% did not discuss—a counseling decision that may reflect not presenting the possibility of transplantation without DAA therapy. Second, what is the risk of chronic HCV infection with appropriate DAA therapy? Nearly all programs (95%) reported that this risk was ≤5%. Finally, on average, programs felt that a mean decrease in waiting time of ≥18 months (range, 0–60 months) justified accepting a DHCV NAT+ kidney transplantation for recipients not infected with HCV.

Patient Eligibility and Concerns

When asked about their program’s criteria for excluding patients without HCV infection from receiving DHCV NAT+ kidney transplants, the most common responses were (allowing selection of all that apply) evidence of cirrhosis (72%), age <18 years (65%), and history of liver disease (49%). Additional, less common reasons included significant allosensitization as determined by calculated panel reactive Ab (10%), history of prior transplant (7%), and no exclusions (6%) (Figure 2).

When asked which patient concerns the participants felt were barriers to the practice of transplanting recipients

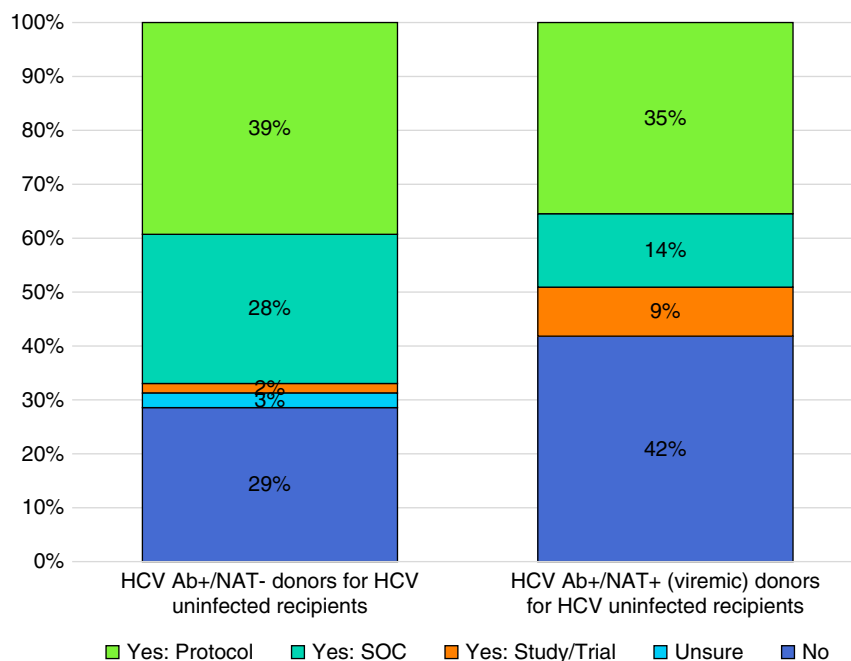


Figure 1. | Acceptance practices related to DHCV Ab+/NAT- and NAT+ kidneys, for recipients who are uninfected. Ab+, positive antibody; DHCV, donors infected with hepatitis C virus; HCV, hepatitis C virus; NAT, nucleic acid testing; SOC, standard of care.

without HCV infection with DHCV NAT+ organs, the most common responses were fear of high out-of-pocket costs for DAA medications (69%) and fear of infection (58%); less common concerns were risk of household HCV transmission (30%) and no concerns (8%) (Figure 3A). When asked which provider concerns the respondents felt were barriers to the practice of transplanting recipients without HCV infection with DHCV NAT+ kidneys, the most common responses were uncertainty about insurance coverage for DAA drugs (72%), fear of high DAA cost for the program (61%), and concern about chronic infection from viral resistance (44%). The least common responses were difficulty monitoring DAA therapy (10%) and no concern (6%) (Figure 3B).

DAA Therapy and Viral Monitoring

For programs that accept DHCV NAT+ organs for recipients without HCV infection, the majority (53%) initiated DAA therapy after discharge, after documentation of recipient viremia (Table 3). By comparison, 21% initiated therapy either at transplant or before discharge, and 14% within 4 weeks of transplant, regardless of viremia. Viral monitoring protocols after transplant from DHCV NAT+ to a recipient without HCV infection varied substantially. The most common protocol (19%) was to test for HCV RNA at transplant days 0 and 1; at DAA treatment weeks 1, 2, 3, 4, 8, and 12; and then, after DAA treatment, continue testing at weeks 2, 4, 8, and 12. Notably, 14% of respondents that reported acceptance of DHCV NAT+ kidneys by their

center were unsure of their program's viral monitoring protocol. Of centers providing this type of transplant, 56% had an institutional plan to provide a complete course of DAA from the transplant hospital if the recipient was declined DAA therapy by their insurance.

Discussion

This first, national survey of US transplant programs was conducted to assess utilization of kidneys from donors infected with HCV in recipients without HCV infection. With donors who are Ab+ /NAT-, the risk of transmission is low and >70% of respondents reported accepting these organs for recipients without HCV infection. This was generally performed as standard of care or under clinical protocols, but seldom as part of a research study. The use of DHCV NAT+ organs is more complex because it requires the administration of DAA therapy, either at the time of transplant or once recipients become viremic. Nationally, 58% of responding programs reported accepting DHCV NAT+ organs for recipients who are uninfected. However, there is a significant diversity of approaches regarding patient education, DAA management, and viral monitoring. Programs also identified barriers to broader use of these organs, including concerns about the cost of DAA therapy to the program, insurance coverage for patients, and the risk of chronic infection due to treatment failure from resistant virus.

Although serologic testing for HCV has been widely available for more than a decade, universal NAT began

Table 2. Risk perceptions

Survey Question	Response, n (%)
What do you tell HCV- potential recipients about the risk of HCV transmission from nonviremic (Ab+/NAT-) donors? (item denominator=107^a)	
<5%	68 (64)
5%–25%	16 (15)
26%–50%	3 (3)
>50%	10 (9)
Do not discuss	10 (9)
What do you tell HCV- potential recipients about the risk of chronic HCV infection after KTx from donors who are HCV Ab+/NAT+ (viremic) without DAA treatment? (item denominator=107^a)	
<10%	14 (13)
10%–25%	2 (2)
26%–50%	4 (4)
51%–75%	6 (6)
76%–85%	2 (2)
86%–100%	53 (50)
We do not discuss this possible risk	26 (24)
In your view, what is the risk of chronic HCV infection due to treatment failure after KTx from donors who are HCV Ab+/NAT+ and appropriate DAA therapy? (item denominator=109^a)	
<1%	51 (47)
1%–5%	52 (48)
6%–10%	2 (2)
>10%	4 (4)
How much reduction in waiting time (months) do you think justifies accepting a KTx from a donor who is HCV Ab+/NAT+ (viremic) for a recipient who is HCV-, versus waiting for another deceased donor organ? Mean (range) (item denominator=108^a)	18 (0–60)

HCV, hepatitis C virus; Ab, antibody; NAT, nucleic acid testing; KTx, kidney transplant; DAA, direct-acting antiviral agent.
^aIndicates the item denominator, based on number of respondents, and accounting for contingent responses.

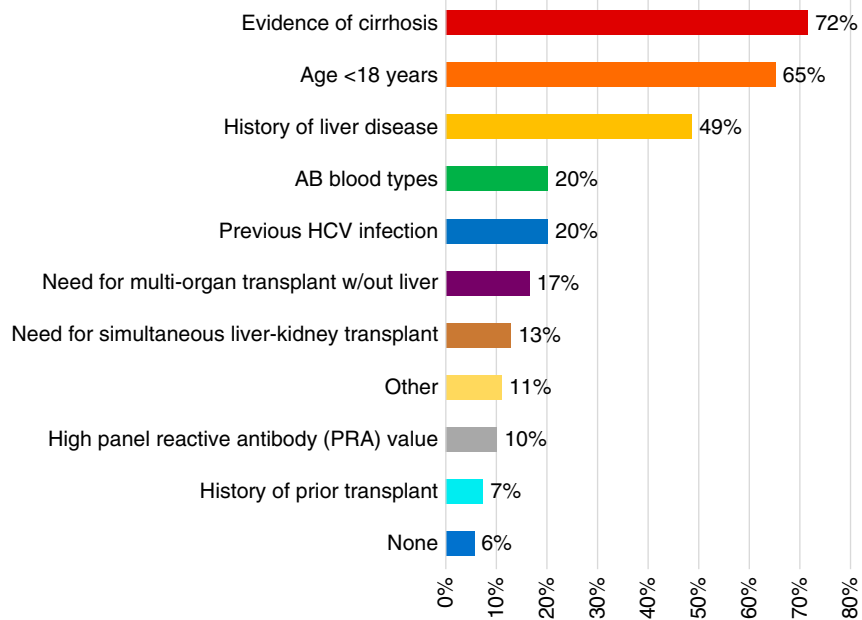


Figure 2. | Program criteria for excluding patients without HCV infection from receiving DHCV NAT+ kidney transplants.

in August 2015, distinguishing viremic and nonviremic donors. A 2017 AST Consensus Conference report on use of DHCV viremic organs for transplantation opined that nonviremic organs without other risk factors are not considered to pose increased risk of HCV transmission (6,23). Studies and case reports have demonstrated that transplantation of DHCV Ab+ /NAT– kidneys into recipients without HCV infection is unlikely to result in transmission (7,24). Despite these encouraging reports, our study showed that almost 30% of transplant centers do not accept DHCV Ab+ /NAT– organs for recipients without HCV infection. Additionally, nearly 30% of the programs tell their potential recipients who are not infected with HCV that the risk of HCV transmission from DHCV Ab+ /NAT– organs is $\geq 5\%$. Accurate information about the true risk of transmission is vital to appropriately counsel recipients, because the majority of educated patients agree to accept these organs, particularly when notified by their transplant providers that risk of HCV is minimal (7). Our survey analysis suggests there is an opportunity to improve utilization through the development of improved patient education tools that accurately report the true risk or, more accurately, the safety and benefit of transplantation with DHCV Ab+ /NAT– organs for all recipients.

DAA therapy for HCV infection has revolutionized the management of HCV in the general population. The availability of pangenotypic treatments has allowed near-universal treatment success, defined as a sustained viral response at 12 weeks after completing DAA therapy. The results from the Transplanting Hepatitis C Kidneys into Negative Kidney Recipients (THINKER) (25) and Exploring Renal Transplants Using Hepatitis C Infected Donors for HCV Negative Recipients (EXPANDER-1) (9) demonstrated the tolerability and efficacy of DAA treatment started before or after DHCV NAT+ kidney transplantation to recipients without HCV infection within a carefully conducted clinical

trial. All patients achieved a sustained viral response at 12 weeks and no treatment-related adverse events were reported (9,25). Although these trials offered encouraging results, both studies were performed in a strict research setting, which included reliable and early availability of DAAs and close patient monitoring. Both pilot trials were industry funded with provision of DAA medications, and no third-party payers were involved. Recently, larger case series have confirmed these results (5,9,12,17,18,25–31).

Despite the published outcomes in clinical studies, the development of safe and effective strategies to use DHCV NAT+ organs is challenging (10). Safe transplantation requires coordination to ensure universal post-transplant testing, access to DAAs for patients who are viremic, and appropriate monitoring to ensure compliance and viral clearance. Barriers to adoption include fear of infection, lack of insurance coverage, and concern about graft dysfunction or death after transplantation (32–35). Among the survey respondents, 42% do not accept DHCV NAT+ organs for candidates who are not infected with HCV. Respondents endorsed apprehension regarding the high cost of DAAs (including out-of-pocket expenses) and uncertainty about the adequacy of patients' post-transplant insurance coverage as barriers to use.

Among respondents, insurance coverage for DAA therapy remains a key impediment. Preemptive therapy with DAAs for patients without HCV infection who receive DHCV NAT+ organs is not reimbursed by many insurance companies, requiring centers to wait to document viremia before obtaining approval or to provide medication from the center. As noted in this survey, 53% programs wait to initiate therapy after documentation of viremia, despite the early initiation practices described in early trials. Even in patients with viremia, approval is not consistent across all health insurance plans and denials occur (36–39). Recently

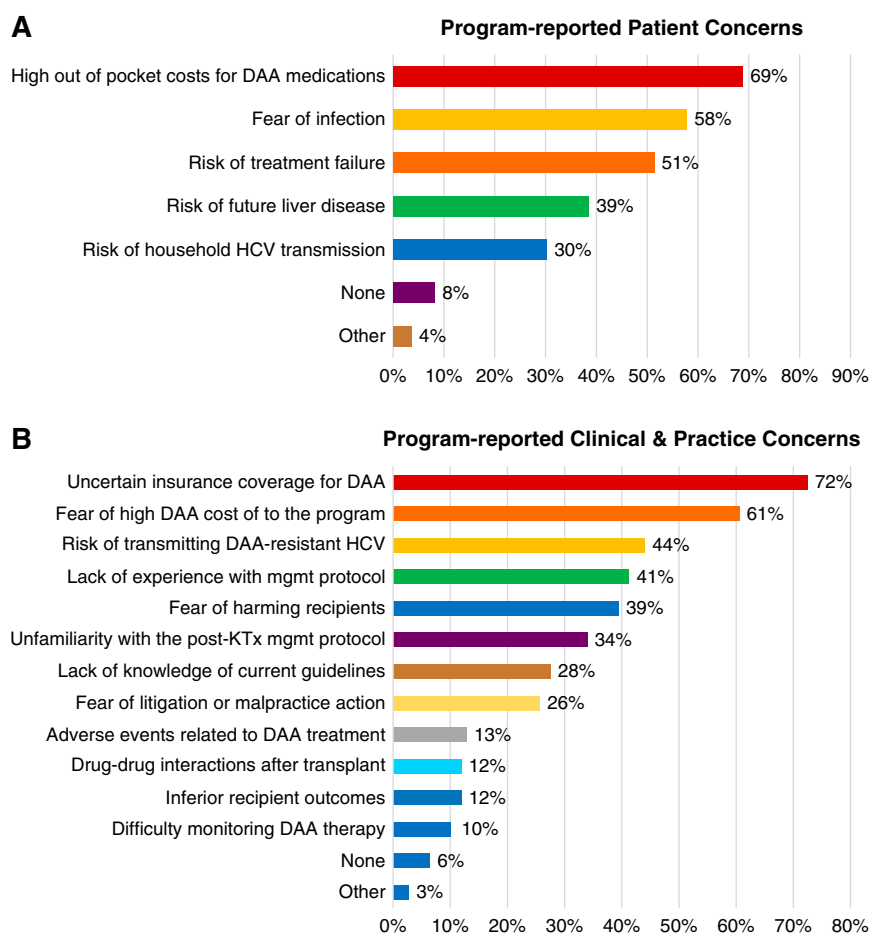


Figure 3. | (A) Program-reported patient concerns related to DHCV NAT+ kidney acceptance for recipients not infected with HCV. (B) Provider-reported clinical and practice concerns related to DHCV NAT+ organ acceptance for recipients without HCV infection. DAA, direct-acting antiviral agent; KTx, kidney transplant; mgmt, management.

two single-center studies reported that the median time for DAA initiation were 76 days and 72 days after transplantation from DHCV NAT+ to recipient without HCV infection, without drug company support (15,27). Adverse outcomes have been reported in patients with delayed initiation of HCV therapy, including the development of fibrosing cholestatic hepatitis (15), that can be fatal. Finally, programs that start DAA before discharge will not receive additional reimbursement for the transplant hospitalization. This will negatively affect overall profitability of deceased kidney transplant in the current era (40). A statement by the Centers for Medicare and Medicaid Services that post-transplant HCV treatment should be covered for all beneficiaries who are Medicare eligible would reduce the risk of payment denial by Medicare intermediaries, and would likely be followed by private insurers. This should include guarantee of payment for DAAs in advance of a documented viral transmission if donor NAT testing was positive.

Despite the high cost of DAA therapy, transplantation of DHCV NAT+ kidneys to recipients not infected with HCV remains a cost saving, especially if dialysis waiting times can be significantly reduced. Two 2018 cost-effectiveness studies showed better outcomes and lower costs with DHCV-infected kidney transplantation to recipients who were

uninfected compared with remaining on dialysis and waiting for a DHCV- organ, from the perspective of the health-care system (31,41). However, payers often do not benefit from the long-term cost savings and the overall benefit of expanding the organ supply. A recent study by our group evaluated the financial breakeven point. Using current pan-genotypic regimens and estimates derived from Medicare payments, payers will reduce 3-year expenditures if waiting times are reduced by at least 11.5 months (42). In this study, respondents on average felt that 18 months reduction in waiting time justifies accepting a DHCV NAT+ for a recipient without HCV infection. Whereas prior studies have documented a reduction in waiting times for recipients, DHCV+ kidney transplants increased by >500% from 2007 to 2018. As more centers use these kidneys, the benefit of shorter waiting time will be diminished; however, this practice should remain cost effective as the cost of DAA medications and the duration of treatment decline (12).

Although DAA treatment ensured excellent allograft function and clearance of donor-derived HCV infection in pilot trials, the optimal timing of DAA therapy in HCV-uninfected kidney recipients from DHCV NAT+ is a topic of debate (9,25). No national guidelines exist regarding the timing of HCV viral screening, management, and treatment

Table 3. DAA therapy and viral monitoring

Survey Question	Response, n (%)
If you accept kidneys from donors who are HCV Ab+/NAT+ for recipients who are HCV–, when do you typically start DAA therapy? (item denominator=72^a)	
Before transplant (on admission or en route)	5 (7)
After transplant, but before discharge	10 (14)
After discharge, but within 4 wk	10 (14)
After discharge, only if HCV viremic	38 (53)
Other	9 (13)
If you accept kidneys from donors who are HCV Ab+/NAT+ for recipients who are HCV–, how long do you believe it is safe to wait to start DAA therapy? (item denominator=68^a)	
At time of transplant	6 (9)
After transplant, but before discharge	8 (12)
After discharge but within 2 wk, regardless of HCV viremia	6 (9)
After discharge but within 4 wk, regardless of HCV viremia	11 (16)
After discharge but only if HCV viremic	32 (47)
Other	5 (7)
How often would you test a recipient of HCV Ab+/NAT+ donor kidney for HCV RNA after transplantation and appropriate 12 wk of DAA therapy? (item denominator=70^a)	
Day 0, post-KTx day 1; DAA treatment weeks 1, 2, 3, 4, 8, and 12; after DAA treatment, continue testing at weeks 2, 4, 8, and 12	13 (19)
Day 0, post-KTx day 1; and at DAA treatment weeks 1, 2, 3, 4, 8, and 12	8 (11)
Post-KTx day 1, weekly during DAA treatment for 12 wk	7 (10)
DAA treatment weeks 4, 8, and 12	11 (16)
DAA treatment weeks 4 and 12	6 (9)
Post-KTx day 1 and at the end of 12 wk of DAA treatment	1 (1)
Other	14 (20)
Unsure	10 (14)
If your program performs a transplant from a donor who is HCV Ab+/NAT+ into a recipient who is HCV– and the patient's insurance declines DAA therapy, do you have an institutional plan to provide a complete course of medication? (item denominator=71^a)	
No	11 (15)
Yes, from the transplant hospital	40 (56)
Yes, through a pharmaceutical company (e.g., grant, research)	4 (6)
Yes, through organ procurement organization	0 (0)
Yes, through the department of surgery or department of medicine	2 (3)
Other	11 (15)
Unsure	3 (4)

Programs that reported not conducting transplant from donors who were HCV Ab+ /NAT+ were omitted. DAA, direct-acting antiviral agent; HCV, hepatitis C virus; Ab, antibody; NAT, nucleic acid testing; KTx, kidney transplant.

^aIndicates the item denominator, based on number of respondents, and accounting for contingent responses.

in the acute setting after kidney transplantation from DHCV NAT+ to recipients without HCV infection. In this study, more than a third of transplant programs start DAA therapy after discharge, but only if the recipients develops HCV viremia. Respondents also did not endorse a standard approach to viremia monitoring post-transplant. Future research is needed to establish optimal clinical practices to inform national standardization of timing of viremia monitoring and DAA treatment in patients who receive DHCV NAT+ organ transplants. These guidelines may encourage further adoption of these protocols in transplant centers nationally.

There are limitations to this study. Respondents were identified by online outreach to US transplant professionals, and not all programs are represented. However, the 54% response rate is similar to or higher than many contemporary studies of transplant program practices, and the responding centers represent 69% of adult deceased-donor kidney transplant volume in the period. The findings represent practices and experiences as they are reported; we

cannot verify how accurately the reports represent actual experience at the center, and we did not have access to direct data such as insurance denials for DAA therapy. Respondents may be more interested in transplantation from donors with HCV infection, which may be biased toward more favorable attitudes than at programs without participating respondents. However, a significant percentage of respondents reported their program did not transplant either DHCV Ab+ /NAT– or DHCV NAT+ kidneys. Even in cases when transplant professionals support the use of DHCV-infected organs, this may not represent the policy of their hospital's senior leadership or local health plans.

In conclusion, this national survey of US kidney transplant programs identified diversity in attitude, monitoring, and treatment knowledge related to transplantation of DHCV NAT+ kidneys to recipients without HCV infection. Differences in transplant teams' attitudes and care protocols may explain variability on acceptance of transplantation from DHCV NAT+ to recipients without HCV across

transplant centers. Reluctance to use DHCV NAT+ organs appears to be driven, in part, by financial and logistic concerns, which may be mitigated by revised payment mechanisms to allow immediate initiation of DAA therapy. This study highlights the need for the improvement of knowledge gaps and standardized protocols regarding the safety and efficacy to expand the organ supply through transplantation of DHCV NAT+ kidneys into patients without HCV infection in the era of DAA therapy and long waiting list times.

Disclosures

K. Lentine serves on the American Society of Nephrology (ASN) Quality Committee and reports personal consulting fees from CareDx and speaker honoraria from Sanofi, outside the submitted work. J. Peipert reports grants from Veloxis, outside the submitted work. R. Forbes reports personal fees from OrthoDiagnostics and Veloxis, outside the submitted work. Schnitzler reports personal consulting fees from CareDx, outside the submitted work. R. Bloom reports grants from Merck (2017–2018) and to Abbvie (2017–2018). R. Mannon serves on the ASN Policy Committee; reports grants from Malinckrodt and Transplant Genomics; personal fees from Hansa, Novartis, Sanofi, and Vitaeris; and grants from Quark, outside the submitted work. D. Axelrod reports personal consulting fees from CareDx and personal advisory board fees from Veloxis and Sanofi, outside the submitted work. All remaining authors have nothing to disclose.

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Author Contributions

K. Lentine, T. Alhamad, M. Schnitzler, and D. Axelrod conceptualized the study and were responsible for funding acquisition, project administration and resources; K. Lentine and J. Peipert were responsible for data curation, analysis, and software; T. Alhamad, Y. Caliskan, S. Chang, M. Schnitzler and K. Lentine were responsible for methodology, investigation, and supervision. K. Lentine, J. Peipert, Y. Caliskan and D. Axelrod wrote the original draft; and T. Alhamad, B. Concepcion, R. Forbes, S. Chang, M. Cooper, R. Bloom, R. Mannon, and M. Schnitzler reviewed and edited the manuscript.

Supplemental Material

This article contains the following supplemental material online at <http://kidney360.asnjournals.org/lookup/suppl/doi:10.34067/KID.0004592020/-/DCSupplemental>.

Supplemental Table 1. Survey instrument.

Supplemental Figure 1. Flowchart of representative survey response selection.

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SUPPLEMENTAL APPENDIX

Table S1. Survey questions, type of response format and response options.

Survey Questions	Response Format	Response Options
What is your role at your transplant center?	Select all that apply	<ul style="list-style-type: none"> • Transplant Surgeon • Transplant Nephrologist • Coordinator • Social Worker • Administrator • Pharmacist • Other
What is your transplant center's UNOS code?	Free response	UNOS code
What is the average waiting time (years) for a KDPI < 85% kidney in your Donation Service Area (DSA) for an unsensitized blood type O transplant candidate? Please slide the bar to indicate the time (up to 1 decimal).	Waiting time scale	0 to 10 years
Does your center accept organs from HCV Ab+/NAT- donors for HCV uninfected recipients?	Select one from options	<ul style="list-style-type: none"> • No • Yes, but only as part of an IRB-approved study and under clinical trial protocol • Yes, under a clinical protocol • Yes, as standard of care under no specific clinical protocol • Unsure
Does your center accept organs from HCV Ab+/NAT+ (viremic) donors for HCV uninfected recipients?	Select one from options	<ul style="list-style-type: none"> • No • Yes, but only as part of an IRB-approved study and under clinical trial protocol • Yes, under a clinical protocol • Yes, as standard of care under no specific clinical protocol • Unsure

<p>What do you tell potential recipients without HCV infection about the risk of HCV transmission from non-viremic (Ab+/ NAT-) donors?</p>	<p>Select one from options</p>	<ul style="list-style-type: none"> • Less than 5% • 5% to 25% • 26% to 50% • More than 50% • We don't discuss this with recipients since HCV Ab+/NAT- is consistent with cure from prior HCV infection.
<p>What do you tell HCV uninfected recipients about the risk of chronic HCV infection after transplantation from HCV Ab+/NAT+ donors without direct acting antiviral (DAA) treatment?</p>	<p>Select one from options</p>	<ul style="list-style-type: none"> • Less than 10% • 10% to 25% • 26% to 50% • 51% to 75% • 76% to 85% • 86% to 100% • We don't discuss this possible risk
<p>In your view, what is the risk of chronic HCV infection due to treatment failure for HCV uninfected recipients after transplantation from HCV Ab+/NAT+ donors and appropriate DAA therapy?</p>	<p>Select one from options</p>	<ul style="list-style-type: none"> • Less than 1% • 1% to 5% • 6% to 10% • More than 10%
<p>How much reduction in waiting time (months) do you think is necessary to justify accepting a kidney from a HCV Ab+/NAT+ (viremic) donor for a HCV uninfected recipient, rather than waiting for another deceased donor organ from a HCV uninfected donor?</p>	<p>Waiting time scale</p>	<p>0 to 60 months</p>

<p>In your view, which of the following are recipient criteria for excluding HCV uninfected patients from receiving kidney transplants from HCV Ab+/NAT+ donors?</p>	<p>Select all that apply</p>	<ul style="list-style-type: none"> • AB blood type • Age < 18 years • Previous HCV infection successfully treated with viral eradication • History of prior transplant • High panel reactive antibody (PRA) value • History of liver disease (such as nonalcoholic steatohepatitis) • Evidence of cirrhosis • Need for simultaneous liver-kidney transplant • Need for multi-organ transplant not involving liver (e.g., simultaneous pancreas-kidney transplant) • None • Other
<p>In your view, which of the following patient concerns are barriers to the practice of HCV Ab+/NAT+ donor to HCV uninfected recipient kidney transplantation?</p>	<p>Select all that apply</p>	<ul style="list-style-type: none"> • Fear of infection • Risk of treatment failure • Risk of future liver disease • Risk of household HCV transmission • High out of pocket costs for DAA medications • None • Other
<p>In your view, which of the following provider concerns are barriers to the practice of HCV Ab+/NAT+ donor to HCV uninfected recipient kidney transplantation?</p>	<p>Select all that apply</p>	<ul style="list-style-type: none"> • Fear of harming recipients over and above the transplant itself • Inferior recipient outcomes • Unfamiliarity with the post-transplant management protocol • Lack of knowledge of current guidelines for transplantation from HCV Ab+/NAT+ donors to HCV uninfected recipients • Lack of experience for transplantation from HCV Ab+/NAT+ donors to HCV uninfected recipients • Risk of transmitting treatment-resistant HCV infection to recipient • Difficulty monitoring DAA therapy • Adverse events related to DAA treatment

- Drug-drug interactions after transplantation
- High cost of DAA treatment to the program
- Uncertain insurance coverage for DAA treatment in light of intentional transmission
- Fear of litigation or malpractice action resulting from HCV transmission
- None
- Other

<p>If you accept kidneys from HCV Ab+/NAT+ donors for HCV uninfected recipients, when do you typically start DAA therapy?</p>	<p>Select one from options</p>	<ul style="list-style-type: none"> • Before transplant (on admission or en route to operating room) • After transplant, but before discharge • After discharge but within 4 weeks, without regard to the development of HCV viremia • After discharge but only if there is a documentation of HCV viremia in the recipient • We do not transplant kidneys from HCV Ab+/NAT+ donors to HCV uninfected recipients • Other
<p>If you accept kidneys from HCV Ab+/NAT+ donors for HCV uninfected recipients, how long do you believe it is safe to wait to start DAA therapy?</p>	<p>Select one from options</p>	<ul style="list-style-type: none"> • Must be started at time of transplant • After transplant, but before discharge • After discharge but within 2 weeks, without regard to the development of HCV viremia • After discharge but within 4 weeks, without regard to the development of HCV viremia • After discharge but only if there is a documentation of HCV viremia in the recipient • We do not transplant kidneys from HCV Ab+/NAT+ donors to HCV uninfected recipients • Other

<p>How often would you test a recipient (initially HCV uninfected) of a HCV Ab+/NAT+ donor kidney for HCV RNA after transplantation and appropriate 12 weeks of DAA therapy? If routine posttreatment testing not specified, indicates no need for testing after DAA treatment unless unexplained hepatic dysfunction develops.</p>	<p>Select one from options</p>	<ul style="list-style-type: none"> • Day 0, posttransplant day 1, and at treatment weeks 1, 2, 3, 4, 8, and 12. After treatment, continue testing at weeks 2, 4, 8 and 12. • Day 0, posttransplant day 1, and at treatment weeks 1, 2, 3, 4, 8, and 12. • Posttransplant day 1 and then weekly during treatment, until completion of 12 weeks. • Treatment week 4, 8 and 12. • Treatment week 4 and 12. • Posttransplant day 1 and at the end of 12 weeks of treatment. • We do not transplant kidneys from HCV Ab+/NAT+ donors to HCV uninfected recipients • Unsure • Other
<p>If your program performs a transplant from a HCV Ab+/NAT+ donor into a HCV uninfected recipient and the patient's insurance declines DAA therapy, do you have an institutional plan in place to provide a complete course of medication?</p>	<p>Select one from options</p>	<ul style="list-style-type: none"> • No • Yes, from the transplant hospital • Yes, through a pharmaceutical company (e.g., grant, research) • Yes, through organ procurement organization (OPO) • Yes, through the Department of Surgery or Department of Medicine • We do not transplant kidneys from HCV Ab+/NAT+ donors to HCV uninfected recipients • Unsure • Other

Figure S1. Flowchart of representative survey response selection.

