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Post-transplant survey to assess patient experiences with donor-derived HCV infection

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Abstract

Background: Despite increased utilization of hepatitis C virus-infected (HCV+) organs for transplantation into HCV-uninfected recipients, there is lack of standardization in HCV-related patient education/consent and limited data on financial and social impact on patients.

Methods: We conducted a survey on patients with donor-derived HCV infection at our center transplanted between 4/1/2017 and 11/1/2019 to assess: why patients chose to accept HCV+ organ(s), the adequacy of their pre-transplant HCV education and informed consent process, financial issues related to copays after discharge, and social challenges they faced.

Results: Among 49 patients surveyed, transplanted organs included heart (n = 19), lung (n = 9), kidney (n = 11), liver (n = 4), heart/kidney (n = 4), and liver/kidney (n = 2). Many recipients accepted an HCV-viremic (HCV-V) organ due to perceived reduction in waitlist time (n = 33) and/or trust in their physician's recommendation (n = 29). Almost all (n = 47) felt that pre-transplant education and consent was appropriate. Thirty patients had no copay for direct-acting antivirals (DAA) for HCV, including 21 with household income <\$20 000; seven had copays of <\$100 and one had a copay >\$1000. Two patients reported feeling isolated due to HCV infection and eight reported higher than anticipated medication costs. Patients' biggest concern was potential HCV transmission to partners (n = 18) and family/friends (n = 15). Overall almost all (n = 47) patients reported a positive experience with HCV-V organ transplantation.

Conclusion: We demonstrate that real-world patient experiences surrounding HCV-V organ transplantation have been favorable. Almost all patients report comprehensive HCV-related pre-transplant consent and education. Additionally, medication costs and social isolation/exclusion were not barriers to the use of these organs.

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AUTHOR CONTRIBUTIONS

KP involved in conceptualization, data curation, writing—original draft, revision. CRS and SIR involved in conceptualization and data curation. CL, NL, KM, and VP involved in conceptualization and writing—original draft. SA involved in conceptualization, writing—original draft, revision.

CONFLICT OF INTEREST

SA: Consultant for Merck, unrelated to the data presented in this paper. The other authors of this manuscript have no conflicts of interest to disclose.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

Keywords

consent; DAA cost; donor-derived HCV; education; HCV organ transplant

1 | BACKGROUND

The use of organs from hepatitis C virus (HCV)-infected donors has increased nationally in an attempt to reduce the disparity between the number of people awaiting an organ transplant and the number of organ donors available. According to the Organ Procurement and Transplantation Network, in 2019, approximately 4500 persons died on the waitlist, while another 5751 were removed as they became too sick for transplant.¹ Since the unfortunate opioid epidemic began, there has been a sharp rise in the number of overdose deaths. Concomitant with this rise, the number of HCV-infected (HCV+) organ donors has also significantly increased. The transplant community has thus been investigating the use of HCV+, and more specifically HCV-viremic (HCV-V), organs to help combat the donor shortage. HCV-V organs are those organs that test positive for HCV by nucleic acid amplification testing and may be either HCV antibody positive or negative. HCV-V donors are associated with an almost 100% transmission of HCV infection to the recipient.

In the United States, there are two types of health insurance, that is, a. government health insurance (like Medicaid, Medicare and Children's Health Insurance Program) and private health insurance. Health insurances do not cover 100% of medical costs. While all plans must cover some essential benefits, remaining costs are shared between insurance recipient and company. The share incurred by the individual varies greatly by type of insurance, policy, and even by state. One type of shared cost is the copayment, or "copay," which is a fixed amount an individual pays for a specific service or prescription medication.²

Since the advent of direct-acting antiviral (DAA) treatment,³ there has been an increase in the use of HCV-V organs for transplant,⁴⁻⁸ mostly within the clinical trial setting but also as part of real-world clinical practice protocols in which patients are responsible for the cost of DAA therapy,^{9,10} which can be considerable.¹¹ Recent reports suggest excellent short-term outcomes with use of HCV-V organ transplantation.^{6-8,12-17} In the clinical trials reported, patients were provided DAA free of cost and access to prompt and immediate DAA therapy was easily feasible. In the real-world scenario,^{9,10,18} transplant centers work with patients' insurance companies to get approvals and authorizations prior to initiating DAA therapy. There is concern that not all patients may be financially able to pay for DAA therapy or drug approvals may be denied. Additionally, there is concern regarding the level of patient understanding at time of acceptance of HCV-V organ transplant as well as the potential social and ethical implications for the patient.^{19,20} Physicians and policy makers want to ensure patients are receiving appropriate and thorough education to allow for informed consent, and that high treatment costs and/or other patient perceptions and experiences are not barriers to care. While all agree that HCV-V organs should only be transplanted with explicit patient consent,²¹ no standardization of consent forms or guidance regarding content has been developed to date.

At our institution, we developed a clinical practice protocol for transplantation of organs from HCV+ donors. This policy was initiated in April 2017 and is ongoing. It includes a two-step consent process.¹⁸ First, all patients aged 18 years and older who are able to provide informed consent and are either undergoing evaluation for an organ transplant or are currently waitlisted are approached for a detailed discussion regarding the use of HCV+ organs. A standardized patient information form is both discussed and provided at the time of discussion. Transplant infectious diseases (TID) consultation is available as well. Once consented, the patient's waitlist status in UNet is changed to "accepting HCV organs." The education and consent process discuss outcomes of untreated HCV, financial liability, routes of HCV transmission, as well as benefits in terms of reduced waitlist time and excellent short-term outcome data. The key elements included in the consent form are outlined in Table 1. Patients are seen by TID both at time of transplant admission as well as in clinic. DAA is generally started in the outpatient setting following insurance approval though exceptions are made based on clinical status or if a prolonged hospital stay is expected.

For the current study, our goal was to understand why patients chose to accept HCV-V organ(s), to assess the adequacy of our pre-transplant HCV education/informed consent process, and to elaborate on financial issues related to copays after discharge. We also aimed to learn more about patients' social experiences, such as perceived social isolation/exclusion, after receiving an HCV-V organ. We hypothesized that by better understanding our patients' experiences we could optimize the quality of education we provide and the consent process for HCV-V organs pre-transplant.

2 | METHODS

2.1 | Study design

As part of an institutional quality improvement project, all adult patients who underwent transplantation with an HCV-V organ at the University of California San Diego from 4/1/2017 to 11/1/2019 were surveyed. Patients with pre-transplant chronic HCV infection and those who received HCV-non-viremic organs were excluded. The survey was administered over the phone or in person during transplant clinic visits. For those patients whose first language was Spanish, surveys were conducted either by a fluent research team member or using the hospital's interpreter services. None of the research team members who conducted the survey were directly involved in the respondents' clinical care. The survey was completely voluntary and confidential.

We developed the survey instrument based on other published surveys that specifically addressed donor-derived infections in organ transplant recipients.^{22–25} The survey was tested internally and modified prior to patient administration. The survey was built, and all responses were directly recorded into REDCap, a secure web application for building and managing online surveys and databases. A copy of the survey instrument is included as a Figure S1.

The survey consisted of 36 questions and took approximately 20 minutes to complete. The survey aimed to first understand participant demographics (age, gender, education, household income, and type of health insurance), and obtain details about each participant's

transplant (organ, time on waitlist, and transplant year). We then asked questions to better understand what most concerned patients about HCV-V organ transplantation, and factors that made them more or less willing to accept such organs. The last section asked questions regarding their post-transplant experiences – social exclusion/isolation, fear of HCV transmission, financial impact, and their overall impression of the education and consent process. Questions pertaining to patients' impressions were asked on a Likert scale. For each section, we also had open-ended questions to allow patients to further elaborate on details regarding their experiences and to suggest ways to improve consent, education, and the transplant process. Patients could skip any questions if they did not wish to answer.

We obtained approval from our center's IRB to perform the surveys and for our research plan. Per the IRB, verbal consent was obtained from each patient prior to starting the survey.

2.2 | Statistical analysis

All statistical analyses were performed using SPSS v.26. Due to a lack of divergent responses, we report most results as descriptive outcomes only. When comparing demographics and reasons for accepting HCV-V organs and post-transplant experiences, however, we divided the respondents into those who received kidney transplants alone, that is, those with an option to remain on dialysis and not in urgent need of an organ, and those who received non-kidney and/or dual transplants. All continuous variables were compared using one-way analysis of variance and categorical and frequency data were analyzed via chi-square. We also performed a univariate analysis using linear regression to compare median copays for DAA dependent on participant's household income and medical insurance. We used $P < .05$ as a cut-off for statistical significance.

3 | RESULTS

Between 4/1/2017 and 11/1/2019, a total of 70 patients were transplanted with HCV+ (either viremic or non-viremic) organs at our institution. Of these, six patients had a pre-transplant history of HCV infection, seven received non-viremic organs and two were deceased at the time of the survey. Of the remaining 55 transplant recipients, three did not wish to participate in the survey and three could not be reached despite multiple attempts. We discuss results based on the 49 patients that were surveyed. One patient declined to continue the survey midway through administration; however, the completed answers were included in the analyses. All surveys were administered between 11/2/2019 and 12/31/2019.

3.1 | Baseline demographics

As noted in Table 2, the median age of respondents was 63.0 years (IQR 54–68). The majority were male ($n = 41$, 83.7%) and Hispanic ($n = 24$, 49.0%). The median annual household (HH) income range was \$20–\$49 999; almost half of the cohort had a HH income of <\$20 000 ($n = 21$, 42.9%). All participants in the survey had medical insurance—the most common was government insurance ($n = 41$, 83.7%), although almost a third had dual coverage with both government and private insurance ($n = 19$, 38.8%). Most patients had a high school or equivalent degree ($n = 18$, 36.7%) or had completed college/trade school ($n = 17$, 34.7%). Religious affiliation was reported as Catholic ($n = 19$, 38.8%), spiritual ($n =$

8, 16.3%), or not religious (n = 6, 12.2%). These demographics did not differ when groups were separated into those who received kidney-only and non-kidney/dual transplants (data not shown).

3.2 | Transplant details

Survey respondents had undergone heart (n = 19, 38.8%), lung (n = 9, 18.4%), kidney (n = 11, 22.4%), liver (n = 4, 8.2%) as well as combined heart/kidney (n = 4, 8.2%) and liver/kidney (n = 2, 4.1%) transplants. The majority of transplants were performed in 2019 (n = 27, 55.1%). In terms of transplant waitlist time, most non-kidney/dual transplant organ recipients were awaiting transplant for 3 months or less (Table 1). However, significantly more kidney-only transplant recipients were waiting for >24 months (n = 9, 81.8%) ($P < .001$). More than half (n = 26, 56.5%) of the respondents first heard about HCV-V organ transplantation during the transplant evaluation process, generally from their transplant coordinator (n = 26, 53.1%). A third of those receiving kidney-only transplants (n = 4, 36.4%) heard about HCV-infected organ transplantation more than 2 years after being listed.

3.3 | Reasons for accepting HCV-V organ transplants

The potential decrease in waitlist time (n = 33, 67.3%) was the most cited reason for accepting an HCV-V organ, followed by increased donor pool (n = 29, 59.2%) and confidence in their doctor's recommendation (n = 29, 59.2%). About half of the patients (n = 22, 44.9%) reported that they felt "too sick to wait" for an HCV-uninfected organ. In open-ended questioning, nine patients specifically stated that knowing HCV was more than 95% curable was the primary reason for them to accept an HCV-V organ. When asked which factors they most considered prior to accepting an HCV-V organ, 21 (42.9%) cited risk of HCV acquisition. Another 13 (26.5%) were concerned about acquiring another infection, in particular, human immunodeficiency virus (HIV) or hepatitis B virus (HBV). A small group (n = 8, 16.3%) was concerned that HCV-V organs may be of "inferior" quality. Nearly a fourth of patients (n = 11, 22.4%) stated that the donor's potential history of drug use factored into their decision to accept an HCV-V organ; five (10.2%) and four (8.2%) participants were concerned about potential history of incarceration or sex work in the donor, respectively. (See Figure 1, panel A and B).

When the groups were divided into those receiving kidney-only and non-kidney/dual transplants, the potential decrease in waitlist time was still the most common cited reason for accepting an HCV-V organ (kidney: n = 10, 91%, non-kidney/dual transplant: n = 23, 61%) ($P = .058$). However, significantly more people in the non-kidney/dual transplant group selected confidence in their doctor's recommendation (n = 26, 68%) ($P = .01$) and too sick to wait (n = 21, 55%) ($P = .01$) as reasons to accept an HCV + organ than the kidney-only transplant group (n = 3, 27% and n = 1, 9%, respectively). There was no statistical difference seen between the two groups related to factors considered prior to accepting an HCV-V organ. (Figure S1).

3.4 | Patients' perceptions of their HCV-related education and consent

Almost all participants reported that the education provided (n = 47, 97.9%) and the consent process (n = 46, 95.8%) prior to transplant were appropriate and adequate. One patient

responded that the education was “definitely not” adequate, however, declined to elaborate further. In open-ended questioning, several felt they needed more information regarding sexual transmission risk (n = 3) and wanted more specifics about the factors that are associated with HCV infection in the donor (n = 3). One patient each requested more information on potential DAA adverse events and overall cost of DAA therapy. (See Figure 1, panel D). Overall perceptions did not differ when groups were separated into those who received kidney-only transplants and other (data not shown).

3.5 | Patient cost associated with HCV treatment

All patients were asked about their copays for HCV treatment, and whether the cost of DAA therapy was higher than they had anticipated. Among 48 respondents, seven could not recall their HCV-related copay. Among all others, 30 (73.2%) stated that they had no copay and that the total cost of DAA was covered by their health insurance. Other patients (n = 10, 24.3%), noted a copay of <\$100. The majority of patients with sole government insurance, 17 (77.3%) had no copays compared to four (50.0%) of those with private insurance and nine (52.9%) with both government and supplementary private insurance. Notably, one patient had a copay between \$1000 and \$5000. When we cross-tabulated average copays to annual household income, we found that 80% of those patients who reported annual household income of <\$20 000 had no copay for DAA. There was no statistical difference in median copays when we compared the type of medical insurance or household income by univariate analysis (data not shown). Of all the respondents, eight (16.3%) felt that the costs of DAA were higher than they anticipated. Among these, one had no copay, three had a copay of <\$100, one had a copay of \$100-\$1000, one of \$1000-\$5000 and one could not recall his copay.

3.6 | Social experiences with HCV-V organ transplantation

Patients were most concerned about HCV transmission to a partner (n = 18, 36.7%) or friend/family member (n = 15, 30.6%). Only two (4.0%) respondents experienced social isolation/exclusion. One of the two patients specified in open-ended questioning that she had isolated herself from others due to concern for viral transmission. A third of patients (n = 17, 34.7%) reported no negative experiences related to the HCV-V organ or DAA. (See Figure 1, panel C). When the groups were divided into those receiving kidney-only and non-kidney/dual transplants, there was no statistical difference found between the groups in regards to experiences post-transplant. (Figure S1).

Overall 97.9% (n = 47) of all participants had a positive experience with HCV-V organ transplantation. Additionally, 91.7% (n = 44) stated that they would willingly accept an HCV-V organ again if they needed another transplant. (See Figure 1, panel D).

4 | DISCUSSION

To the best of our knowledge, this survey is the first of its kind, regarding real-world experiences with HCV-V organ transplantation from the patient’s perspective. All patients in this study underwent transplantation with HCV-V donor organs using a clinical practice protocol at our center¹⁸ and were not part of a clinical trial. We make several important

observations about HCV-V organ transplantation from the patient's financial and social perspective. First, patients at our center accepted an HCV-V organ as they believed it would shorten their waitlist time, thought that HCV was likely curable, and had confidence in their doctors' recommendations. Second, patients felt that the pre-transplant education/consent provided at our center was adequate and appropriate, although an added emphasis on transmission risk to others was needed. Third, insurance covered the cost of DAA for the majority of our patients. And lastly, social isolation/exclusion was not a significant challenge faced by our HCV-V organ recipients.

As HCV-V organ transplantation moves out of clinical trials and becomes more routine in clinical practice, there are concerns regarding adequate patient education and informed consent.^{19,20,26,27} At our center, HCV + organ transplantation is routinely first discussed by transplant coordinators during the organ evaluation period and/or while on the waitlist. Transplant coordinators attend educational seminars led by TID physicians to increase their comfort with this information, and to empower them to initiate such discussions with patients. Further details regarding HCV+ organ transplantation are also included in patients' pre-transplant education classes. To ensure all patients receive the same information, we developed a standardized patient information form that discusses details of HCV infection, transmission, and treatment as well as risks associated with untreated HCV and of treatment failure. Patients may also choose to meet with the TID team for counseling prior to updating their listing status in UNet. In the immediate post-transplant period, all patients are seen by TID to discuss the next steps pertaining to their new HCV-V organ. DAA is prescribed by the TID team and the patient is followed closely in the inpatient and outpatient setting.

At our institution, the pre-transplant discussion is standardized to include five key areas: (a) a brief description of HCV infection and its prevalence in the United States, (b) a discussion regarding epidemiological risk factors for HCV infection in organ donors, (c) details regarding treatment of HCV, costs (including financial liability), side effects and cure rates, (d) an explanation of HCV transmission risk based on whether the transplanted organ is HCV-V or non-viremic, and (e) details of HCV-related complications including end-stage liver disease, hepatocellular carcinoma, and death with untreated infection. We evaluated the quality of our HCV-related education and consent process by directly asking patients how prepared they felt for their post-transplant experiences. By surveying those who had undergone HCV-V organ transplantation, we could further understand where our education was lacking. Almost all patients thought the education they received was adequate and prepared them well for the post-transplant period. A few patients did, however, cite the need for further education on HCV transmission risk from them to others. Our survey demonstrates that these five core features should be present in all patient education materials/consent forms when using HCV-V organs for transplantation. Furthermore, an emphasis should be placed on discussing sexual and non-sexual transmission risk in the post-transplant period.

In previous surveys conducted on waitlisted patients, willingness to accept HCV-V organs under any circumstance has been low.^{22,28} Concerns cited have been centered around HCV cure rates, organ quality, costs, and stigma.^{22,28} Recent publications highlight almost 100% sustained virologic response rates and similar graft outcomes when compared to

HCV-uninfected organs.^{4,6,7,13,29} However, there are limited data published regarding patients' financial and social challenges. Historically, there have been relatively high rates of insurance denials for HCV treatment costs,^{30–32} with denial rates nearing 50% for Medicaid patients. This was not the case for transplant patients treated at our center who received HCV-V organs, with no insurance denials reported and most copays that were financially feasible for patients. The majority of patients who could recall their copays stated that they paid <\$100. One patient reported a copay of >\$1000. Our transplant pharmacists help identify patient assistance programs that can help with allaying the cost, if needed. Similarly, prior data on non-transplant patients³³ noted high rate of stigma experienced by patients with HCV and an association between stigma and adverse health outcomes and health access measures.³⁴ We did not study stigma in our survey but asked about social isolation/exclusion as a result of the HCV infection. Only two of the 49 patients experienced social isolation/exclusion (one was self-imposed), suggesting limited social barriers to the use of HCV-V organs for transplantation.

There are several limitations to our study. It represents a single-center experience, which may not be generalizable nationally. Recall bias is possible as all patients were surveyed in 2019 and may have been treated for acute HCV infection anytime between 2017 and 2019. Selection bias may also play a role, as we were not able to survey eight eligible patients, thus reducing our sample size. In addition, although surveys were not performed by providers directly involved in patient care, participants may still have felt pressured to participate or provide more positive responses. Although perceptions of HCV+ organ transplantation were positive across the organ groups, only a limited number of liver and lung recipients were included. We excluded patients with a history of pre-transplant HCV infection; therefore, this study cannot comment on that population's financial and social experiences, which may differ from an HCV-uninfected recipient.

5 | CONCLUSION

Our data represent the first real-world look at patients' experiences with HCV-V organ transplantation and the experience thus far has been highly favorable. We found that: patients were most interested in seeing a reduction in waitlist time with use of HCV+ organs; our pre-transplant HCV education/informed consent process was appropriate and patients were able to make adequately informed decisions regarding receipt of HCV-V organs; in general patients did not face financial hardship when they were treated with DAA in the outpatient setting; and patients were most concerned about transmitting HCV infection to their loved ones. Thus, we have identified key components of patient education and informed consent for HCV+ organ transplantation. We plan to update our education and consent materials to better address these patient concerns. Lastly, almost all patients were pleased with the process and outcomes and would accept HCV-V organs if needed in the future. These data may thus help alleviate patients' concerns pre-transplant and increase acceptance of HCV-V organs. This survey also provides physicians with added real-world evidence to support their use. Larger scale studies are still needed to better understand the patient perspective nationally.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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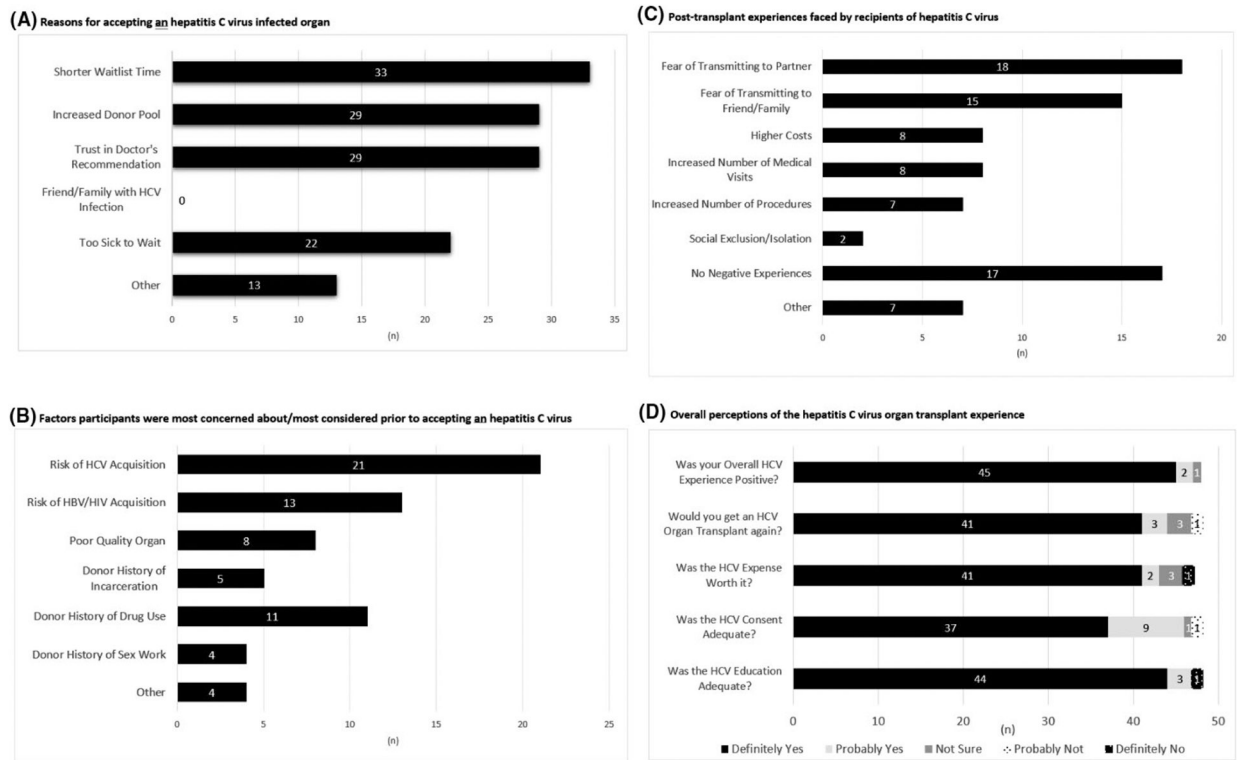


FIGURE 1. Panel (A) outlines reasons patients chose to accept an HCV organ. Panel (B) discusses factors patients most considered/were most concerned for prior to accepting an HCV organ. Panel (C) details the challenges patients faced post-transplant that they attributed to their HCV organ. Panel (D) shows a Likert scale assessment of patients’ perceptions of the education, consent process, and overall experience with HCV-V organ transplantation. The total number of patients who responded for all panels was 48. All patients could select multiple responses to each question from panels (A)-(C)

TABLE 1

Key elements in UCSD's HCV organ transplantation consent form

Key elements in HCV consent document

1. Description of HCV infection, natural history in the immunocompetent and immunosuppressed populations, and prevalence in the US
 2. Discussion regarding epidemiological risk factors for HCV infection in organ donors
 3. Details regarding treatment of HCV, costs (including financial liability), side effects and rate of sustained virologic response
 4. Explanation of HCV transmission risk based on whether the transplanted organ is HCV-viremic or non-viremic
 5. Details of HCV-related complications including fulminant hepatic failure, end-stage liver disease, hepatocellular carcinoma, and death with untreated infection
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TABLE 2

Baseline characteristics of study patients with donor-derived HCV infection

Baseline characteristics (n = 49)		
	(n)	(%)/IQR
Age (median), IQR		
63.0	54–68	
Gender		
Male	41	83.7%
Female	8	16.3%
Race/Ethnicity		
White	17	34.7%
Hispanic	24	49.0%
Black	4	8.2%
Pacific Islander	2	4.1%
Asian	2	4.1%
Other	1	2.0%
Annual household income		
<\$20K	21	42.9%
\$20–49.9K	11	22.4%
\$50–100K	7	14.3%
>100K	4	8.2%
Decline to Answer	6	12.2%
Health insurance		
Government	23	46.9%
Private	8	16.3%
Both	18	36.7%
Highest education level		
Less than HS	4	8.2%
High School/GED	18	36.7%
Some College/Trade	17	34.7%
Bachelors	8	16.3%
Advanced Degree	2	4.0%
Current employment		
Full-Time	2	4.1%
Part-Time	5	10.2%
Disabled	19	38.8%
Unemployed	6	12.2%
Retired	17	34.7%
Organ(s) transplanted		
Heart	19	38.8%
Lungs	9	18.4%
Kidney	11	22.4%

Baseline characteristics (n = 49)

	(n)	(%)/IQR
Liver	4	8.2%
Heart/Kidney	4	8.2%
Liver/Kidney	2	4.1%
Year transplanted		
2017	6	12.2%
2018	15	30.6%
2019	27	55.1%
Time on Waitlist prior to transplant		
<3 mo	16	32.7%
3–6 mo	5	10.2%
6–12 mo	6	12.2%
12–24 mo	9	18.4%
>24 mo	13	26.5%

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