

OPEN

Designing a Liver Transplant Patient and Family Decision Support Tool for Organ Offer Decisions

Cory R. Schaffhausen, PhD,¹ Marilyn J. Bruin, PhD,² Sauman Chu, PhD,² Warren T. McKinney, PhD,¹ Jack R. Lake, MD,³ Srinath Chinnakotla, MD,⁴ and Ajay K. Israni, MD, MS^{5,6}

Background. For liver transplant candidates on the waiting list, deciding to accept a donor organ with known or potential risk factors can be stressful and can lead to declined offers. Current education for patients and family often takes place during transplant evaluations and can be overwhelming and result in low retention and poor understanding of donor quality. **Methods.** In the first phase, we sought to understand provider experiences when counseling patients about donor risks and donor offers. We conducted interviews and focus groups with liver transplant providers at 1 local center and at a national clinician conference. Twenty providers participated: 15 hepatologists and 5 surgeons. The provider feedback was used to create an initial outline of content that is consistent with decision support frameworks. In a second phase, graphic design collaborators created mockups of a patient-friendly tool. We reviewed mockups with 4 transplant coordinators and 9 liver transplant candidates for feedback on clarity and utility to prepare for an organ offer. Patient responses allowed a comparison of perceived readiness to receive an offer call before and after viewing mockups. **Results.** We identified themes relating to the offer process, repetition and timing of education, and standardization and tailoring of content. The results indicated a gap in available education after the evaluation session, and information specific to offer decisions is needed. Patient feedback emphasized the need to review the offer process before a real offer. **Conclusions.** Patients and providers responded favorably to a patient tool addressing existing gaps in education while waiting for a donor offer. Additional patient, family, and provider feedback will guide the development of an interactive tool to prepare patients and families for an offer decision.

(*Transplantation Direct* 2021;7: e695; doi: 10.1097/TXD.0000000000001140. Published online 27 April, 2021.)

INTRODUCTION

In 2016, over 13700 end-stage liver disease patients were waiting for a liver transplant in the United States. A persistent organ shortage contributed to over 2600 patients dying or becoming too sick to transplant while waiting.¹ Lai et al² describe 5680 patients over 5 y who died or were delisted and had at least 1 declined liver offer

(84% of all candidates who died or were removed from the list). This finding was not a result of poor organ quality as 55% of this group had at least 1 high-quality liver offer. While many offers are declined on behalf of a candidate, some candidates decline offers that are extended to them. A majority of centers (57%) report contacting patients who decline an offer to provide additional patient education,³ but a future offer may never come.

Received 8 December 2020. Revision received 21 January 2021.

Accepted 31 January 2021.

¹ Hennepin Healthcare Research Institute, Minneapolis, MN.

² College of Design, University of Minnesota, Minneapolis, MN.

³ Division of Gastroenterology, Hepatology, and Nutrition, University of Minnesota, Minneapolis, MN.

⁴ Department of Surgery, University of Minnesota, Minneapolis, MN.

⁵ Department of Epidemiology and Community Health, University of Minnesota, Minneapolis, MN.

⁶ Department of Medicine, Hennepin Healthcare, University of Minnesota, Minneapolis, MN.

Funding comes from the Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute grant K12HS026379 (C.R.S. and W.T.M.). Work supported by the AHRQ R01 HS 24527 (A.K.I.). This research was also supported by the National Institute of Health's Center for Advancing Translational Sciences, grants TL1R002493 and UL1TR002494 (W.T.M.).

The authors declare no conflicts of interest.

A.K.I., C.R.S., and S.Chu. participated in research design. C.R.S. and M.J.B. participated in data acquisition. C.R.S., W.T.M., and M.J.B. participated in data analysis/interpretation and article writing. A.K.I., J.R.L., S.Chi., and S.Chu. participated in supervision or mentorship.

Supplemental digital content (SDC) is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal's Web site (www.transplantationdirect.com).

Correspondence: Cory Schaffhausen, PhD, Hennepin Healthcare Research Institute, 701 Park Ave, Shapiro 5, Minneapolis, MN 55415. (schaf390@umn.edu).

Copyright © 2021 The Author(s). *Transplantation Direct*. Published by Wolters Kluwer Health, Inc. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

ISSN: 2373-8731

DOI: 10.1097/TXD.0000000000001140

Decision support frameworks outline many elements to support decisions and 1 element to support an organ offer decision is communicating risks.⁴ Candidates may decline offers with an increased risk of infectious disease transmission, such as donors designated as “Public Health Service (PHS) increased risk.”⁵ These comprised 19.5% of all donors in 2014.⁶ Other common reasons for declined offers include increased risk of graft failure due to age or comorbidities.^{7,8} Patients have little time to decide and are often risk-averse, despite the fact that the estimated <1% risk of infectious disease⁹ is often significantly lower than the risk of waiting for another offer.¹⁰ The second element of decision support is communicating the offer process and how donor organs are evaluated before being offered to patients. Candidates and families are currently provided with a broad range of education materials during transplant evaluations. This education may include the steps of the offer process; however, this evaluation period is overwhelming to patients and retention is often low.¹¹ Little is known about education specific to organ offers as prior reports of how education is provided to transplant candidates have omitted this topic.^{12,13} Decision aids have been pilot tested to address the limited understanding of donor quality observed with transplant patients.¹⁴ However, past decision aids are no longer public. Although many patients would prefer shared decision making for organ offers, the time constraints for an offer decision and varying patient preferences suggest shared decision making could best be facilitated before a real offer.¹⁵

We sought to understand how centers provide education and counseling related to donor quality and organ offer decisions. In the first phase, we sought qualitative and questionnaire input from transplant providers in the United States to identify gaps in current education. The results describe opportunities to improve education, and the data were used to create an outline of content. In the second phase, we created mockups of the visual layout for a new decision support tool to prepare transplant candidates and families for an organ offer decision and completed pilot evaluations of the mockups with liver transplant candidates and transplant coordinators. The process was intentionally iterative, including user testing of prototypes and incorporating stakeholder feedback, which is consistent with human-centered design best practices.¹⁶ Results from each phase will be used to develop and test a public, interactive tool that is available to patients, caregivers, and providers to prepare for an organ offer.

PARTICIPANTS AND METHODS

The study was approved by the Hennepin Healthcare Institutional Review Board and The University of Minnesota Review Board. Provider participants gave written, informed consent. Before recruiting patient participants, coronavirus disease 2019 (COVID-19) restrictions required a change to virtual interactions and interviews, and written consent was waived after providing participants with a study description. Each interview was between 30 and 60 min; focus groups were 45–90 min. An overview of phases of stakeholder feedback is provided in Figure 1.

Phase 1: Developing Information Content With Hepatologists and Surgeons

Local participants were a convenience sample of hepatologists and surgeons recruited at the University of

Minnesota-Fairview (UMNF) clinic. National participants included hepatologists and surgeons and were purposively recruited to ensure that there was at least 1 participant from each Organ Procurement and Transplantation Network region. Focus groups of national participants included a mix of hepatologists and surgeons in each group. Before participating, local and national participants completed a printed questionnaire. The questionnaire included demographics questions and multiple-choice questions about patient education and donor offers.

We conducted semistructured one-on-one interviews and focus groups. First, UMNF hepatologists and surgeons were interviewed one-on-one to collect pilot data and to finalize the questionnaire and discussion guide. Next, we conducted focus groups with national participants during the 2019 Liver Meeting of the American Association for the Study of Liver Diseases (AASLD). The AASLD focus groups were conducted in Boston, MA, in a hotel conference room.

National focus groups were only conducted during breakfast or lunch due to AASLD restrictions on affiliate events. Meals were provided. Discussions followed a structured guide that was developed with transplant physician feedback (A.K.I., S. Chi, and J.R.L.) and revised following pilot interviews. The participants and discussion topics were selected with a methodological orientation of phenomenology to understand the experience of counseling patients about organ offers.¹⁷ The guide included questions about current practices, challenges faced when discussing donor quality with candidates, engaging family and caregivers, implementation barriers, and potential content for a new patient decision support tool (Table S1, SDC, <http://links.lww.com/TXD/A320>).

Phase 2: Feedback on Visual Mockups With Patient and Transplant Coordinator Pilot Interviews

Using data from surgeons and hepatologists, we created an outline of potential content for the decision support tool. Graphic design collaborator (S. Chu) assisted with the design of a patient-friendly visual layout to begin additional stakeholder feedback. The layout depicted a series of website pages with text, images, and navigation buttons, and mockups of the design were created as static images. We conducted additional pilot interviews with a convenience sample of UMNF liver transplant candidates and pretransplant and transplant coordinators to review the mockups of the graphic layout. At the UMNF clinic, pretransplant coordinators assist with patient education during transplant evaluations and transplant coordinators are on call and are the primary staff to present patients with an offer. The coordinators were recruited via email, and interviews were conducted in-person or via video conference. Before liver transplant candidate interviews, mockups were refined on the basis of coordinator feedback.

Liver transplant candidates were recruited via mail and follow-up phone calls. Candidates were on the UMNF waiting list. Non-English speakers and candidates who were unable to give consent were excluded. Patients participated in interviews remotely via video conferencing (Zoom). Participants first completed a demographics and health history questionnaire. The moderator (C.R.S.) shared a screen to display the mockup images. Participants viewed each page sequentially and read text aloud. Participants were instructed to use a think-out-loud protocol¹⁸ to share feedback if the content was

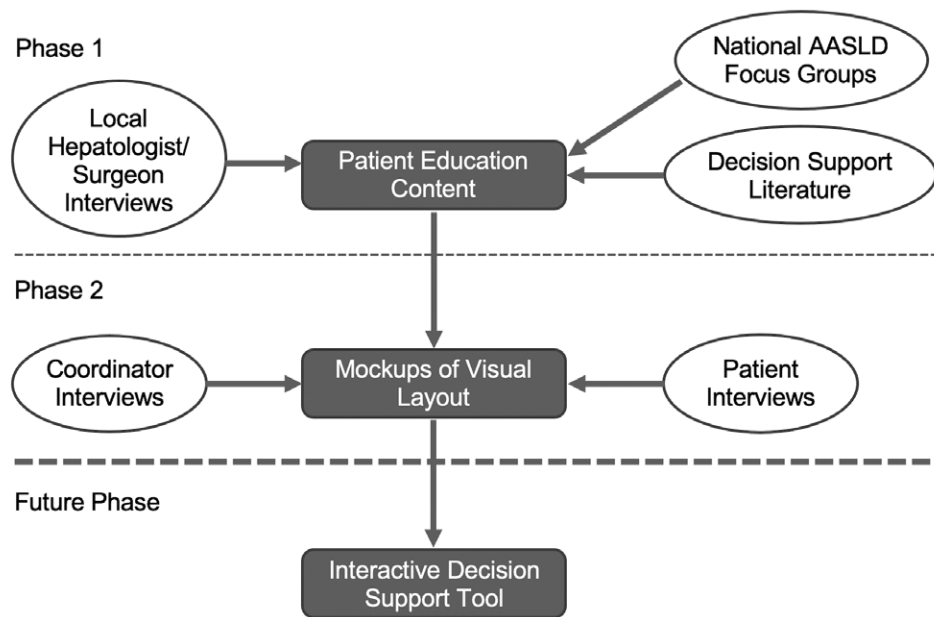


FIGURE 1. Overview of the stakeholder input process and future work to develop an education tool to prepare patients for an organ offer decision. AASLD, American Association for the Study of Liver Diseases.

confusing or lacked sufficient details as well as if the content was helpful or relevant to making decisions. Annotations with suggested improvements were added directly to mockup images, and refinements to mockups were made on the basis of patient feedback. Preinterview and postinterview questions were included to help assess comfort with decisions before and after viewing the decision support tool (Table S2, SDC, <http://links.lww.com/TXD/A320>).

Analysis

Discussions were audio recorded and transcribed. Phase 1 transcripts and field notes were open coded and axial coded through inductive, thematic analysis.^{17,19} Codes were used to organize relevant quotes but were not quantitatively analyzed. Multiple analysts reviewed data. Dedoose coding software (Dedoose, Hermosa Beach, CA) was used to organize data and identify supporting quotations. C.R.S., M.J.B., and W.T.M. developed themes and discussed supporting data to reach agreement. Phase 2 transcripts for the discussion of mockups were used to verify feedback for recommended changes. Patient transcripts for the discussion questions before and after viewing mockups were coded by C.R.S., and excerpts were reviewed by M.J.B. The analysis identified excerpts that reflected the utility or limitations of viewing the decision support tool.

The methods shown in Table S3 (SDC, <http://links.lww.com/TXD/A320>) includes additional details for reporting interviews and focus groups using Consolidated criteria for Reporting Qualitative research guidelines.²⁰

RESULTS

Results from 33 participants are reported. The phase 1 study participants and questionnaire responses are summarized in Table 1, including 15 hepatologists and 5 surgeons. The study participants in phase 2 are summarized in Table 2, including 9 liver transplant candidates and 4 coordinators.

Phase 1: Developing Information Content With Hepatologists and Surgeons

Four themes from hepatologist and surgeon feedback are described, with a focus on the content of an education tool and implementation: (1) preparing for an offer includes becoming familiar and comfortable with the offer process; (2) providing education outside of the evaluation fills a gap and may improve retention; (3) prioritize reinforcing high waitlist mortality and the benefit of receiving a transplant; (4) standardization and tailoring to patients and centers are both valued. Table S4 (SDC, <http://links.lww.com/TXD/A320>) includes additional quotations illustrating the main themes.

Theme 1: Preparing for an Offer Includes Becoming Familiar and Comfortable With the Offer Process

Preparing for an organ offer includes a broad range of steps. Understanding donor quality and risks from donor types is important; however, to be prepared, patients must also be familiar with the match process, backup offers, logistics of receiving a call and preparing for surgery, and other actionable steps for patients and family. Participants discussed a proposed concept to include ≥ 1 practice offers to share an example of what an offer call might sound like. Providers prioritized communicating to the patient the process in which the surgeon and care team review offers before proceeding, specifically within the context of donation after circulatory death (DCD) donors. If the offer is presented to a candidate, the care team determined that the DCD donor is an opportunity for the specific candidate and is considered a benefit over additional waitlist mortality risk. Knowing the provider's assessment of the potential benefit to a patient can increase the comfort of patients to consider donor organs with increased risk.

"I would present it as getting patients ready to receive offers as opposed to educating patients on types of donors ... because it's not just like the PHS high risk, I'm hoping it's the whole process." [AASLD focus group]

TABLE 1.
Phase 1 participants and questionnaire responses

	Total sample size (N = 20)	
	Hepatologist (n = 15)	Surgeon (n = 5)
Local interviews (n)	2	2
National AASLD participants, n total (n available to join focus groups)	13 (11)	3 (2)
National AASLD participant regions (n)		
Region 1	0	1
Region 2	2	0
Region 3	1	2
Region 4	1	0
Region 5	2	0
Region 6	1	0
Region 7	1	0
Region 8	1	0
Region 9	1	0
Region 10	1	0
Region 11	1	0
International	1	0
Male, % (n)	73% (11)	40% (2)
Based on your experience, what donor characteristics are most likely to be declined by a candidate?, % (n)		
PHS increased risk	80% (12)	60% (3)
Older age	33% (5)	0
DCD	46% (7)	0
Split/partial	7% (1)	0
Hepatitis C NAT+	40% (6)	60% (3)
Donor malignancy	27% (4)	20% (1)
Fatty liver	7% (1)	0
Imported graft/long CIT	0	0
Other	7% (1)	0
At your center, who makes the first call to a patient for an organ offer? ^a % (n)		
Surgeon/fellow	23% (3)	33% (1)
Pretransplant coordinator (local)	15% (2)	66% (2)
Transplant coordinator (local)	46% (6)	100% (3)
Transplant coordinator (vendor/third party)	15% (2)	33% (1)
Other	8% (1)	0
At your center, who provides education to patients/family before an organ offer about donor quality or risk factors? % (n)		
Hepatologist	73% (11)	80% (4)
Surgeon	73% (11)	80% (4)
Pretransplant coordinator	67% (10)	60% (3)
Transplant coordinator (local)	27% (4)	60% (3)
Social worker	8% (1)	20% (1)
Class/support group leader	23% (3)	40% (2)
Other	8% (1)	0
At your center, what types of education/content are provided before an organ offer about donor quality or risk factors? ^a % (n)		
In-person counseling	92% (12)	100% (3)
Handouts	77% (10)	100% (3)
Online links/text	8% (1)	33% (1)
Online videos	8% (1)	33% (1)
Support group discussions	31% (4)	0
Classes (internal/third party)	31% (4)	66% (2)
Other/not sure	0	0

^aNot collected for local pilot interviews.

AASLD, American Association for the Study of Liver Diseases; CIT, cold ischemia time; DCD, donation after circulatory death; NAT, nucleic acid test; PHS, Public Health Services.

“I think really trying to do some sort of role playing where people get a dry run at it before it really happens, in the heat of battles ... makes an awful lot of sense.” [Interview]

“We tell the patients, ‘We would never use a liver for you if we don’t think it’s a good use of the liver.’ ... They want to know that they can trust you and that you’re going to give them a good organ and they don’t really necessarily need to know all the details of that.” [AASLD focus group]

Theme 2: Providing Education Outside of the Evaluation is a Gap and May Improve Retention

Centers described current practice to schedule education efforts around transplant evaluations. This practice can begin the informed consent process, but providers acknowledged that retention is often low for education during evaluations. Education after patients have completed evaluations can

TABLE 2.
Characteristics liver transplant candidates in phase 2

	Local candidates (UMNF) ^a
Interview participants (n)	9
Age, mean (SD)	51 (12.5)
Sex, n (%)	
Male	7 (78%)
Race, n (%)	
Black	0 (0%)
White	8 (100%)
Hispanic	0 (0%)
Other	0 (0%)
Education, n (%)	
Less than high school	0 (0%)
High school	1 (13%)
At least some college	4 (50%)
Graduate education	3 (38%)
Annual household income, n (%)	
<\$15 000	1 (13%)
\$15 000–\$30 000	0 (0%)
\$30 001–\$45 000	0 (0%)
\$45 001–\$60 000	1 (13%)
\$60 001–\$75 000	0 (0%)
>\$75 000	5 (63%)
Declined to answer	1 (13%)
No. of household members, mean (SD)	3.0 (1.5)
Form(s) of insurance, n (%) (multiple selections allowed)	
Private	7 (88%)
Medicare	3 (38%)
Medicaid	0 (0%)
Not Insured	0 (0%)
Other	0 (0%)
Self-reported health status, n (%)	
Excellent	0 (0%)
Very good	2 (25%)
Good	3 (38%)
Fair	2 (25%)
Poor	1 (13%)
Has had previous transplant, n (%)	0 (0%)
Currently on the waiting list, n (%)	
Yes	8 (100%)
No	0 (0%)
Not sure	0 (0%)

^aIncomplete data from 1 participant other than sex. UMNF, University of Minnesota-Fairview.

reinforce retention and address changing priorities over time; however, scheduling and implementation are challenging and can be aided through online and printed materials for off-site review.

“It’s already an overwhelming day.... Maybe once they’re done with their eval and the time that they’re ready to become active on the waitlist is a better time.” [AASLD focus group]

“Again, you have to recognize it is a dynamic process. There should be regular check-ins and things like that.” [AASLD focus group]

“I think if you have a video or a web-based module or something. Then it would become infinitely easier. Because then we could just build into our workflow.” [AASLD focus group]

Theme 3: Prioritize Reinforcing High Waitlist Mortality and the Benefit of Receiving a Transplant

Participants considered PHS increased risk donors as a persistent challenge in educating patients and family members due to required labeling and risk aversion. Repeated education can provide consistent reinforcement of the low clinical risks from PHS increased risk donors and high waitlist mortality. Other donor types, such as DCD donor, in which actual post-transplant risk is higher, were described differently. Assessing risk from a DCD donor is complex, and participants preferred communicating information about risks in general terms that are presented at appropriate health literacy and numeracy levels. Rather than communicating detailed risks for DCD donors, a priority was communicating high waitlist mortality as well as the offer process described in Theme 1.

“The PHS stuff. If you would call those increased opportunity donors instead of increased risk, we would not even be here talking today.” [AASLD focus group]

“If you do not get a transplant, you might die, but if you do get a transplant, you just have an increased risk of a complication, but we can manage that complication and you might not die right away.” [AASLD focus group]

“I really encourage you to think about the numeracy burden of statistics ... if what they are saying is just a whole bunch of gibberish up front, no matter of how important it is, it is just not going to stick.” [AASLD focus group]

Theme 4: Standardization and Tailoring to Patients and Centers are Both Valued

An education tool provides an opportunity to standardize how information is presented across centers and by multiple providers at a center during long periods of waiting. A preferred approach incorporated online and print materials as a supplement to provider discussions. Standardized content can reduce variability; however, the flexibility to explain concepts in multiple ways was viewed as beneficial. Providers described important needs to tailor information to specific patients, such as considering the potential risks of DCD donors for appropriate candidates. Discussions also included the potential to tailor content to center practices, such as those that do and do not perform living donor liver transplants.

“People are wait listed for two years, whatever median time ... so despite our best efforts to have a standardized or an attempt at having a standardized education process when they first get sick, a lot of that falls by the wayside because we don’t have a repeat process for continued education.” [AASLD focus group]

“I mean that goes into listing the right patients for the right organs instead of just listing everybody for everything” [AASLD focus group]

“Some people have a different way of explaining it that maybe patients respond to better.” [Interview]

Outline of Education Content

The initial content outline (Table 3) for a decision support tool to prepare patients for an offer decision was informed by multiple sources, including provider feedback from interviews and focus groups and decision support literature (see Figure 1). Content was included that described the donor pool and donor quality to address known limitations in patients’ understanding of donor quality.¹⁴ Standardized information provides a general overview of risks and benefits (Theme 3) and a general overview of the offer process (Theme 1). The

TABLE 3.**Outline of content for a patient education tool to prepare for organ offers**

Section	Outline of standardized content	Opportunities for tailoring content to a candidate or center
Donor pool	<ul style="list-style-type: none"> Organs offered to candidates have been selected from a large donor pool. Poor quality organs are not offered. Your doctor reviews the donor's history and considers the quality to be good. Accepting a larger donor pool can reduce waiting and improve survival. 	
Donor profile	<ul style="list-style-type: none"> Quality can depend on age, weight, and other factors. The donor history can result in a potential risk of disease transmission. All organs are tested for infections. Infections from organs that test negative are extremely rare. Donors with a potential exposure to infectious disease are: often younger, higher quality than average, an opportunity to expand the donor pool. 	<ul style="list-style-type: none"> Optional details specific to PHS increased risk donors.
Donor match	<ul style="list-style-type: none"> You must be a blood type match to get an offer. Your blood type can affect waiting time. Your priority depends on MELD scores. A match first depends on having a matching blood type. 	
The call	<ul style="list-style-type: none"> When you get a call, you will have to decide quickly. You can learn more so you are prepared. <ul style="list-style-type: none"> Learn what medical terms you might hear. You can practice what an offer might sound like. 	<ul style="list-style-type: none"> Optional glossary of medical terms for donor organ types Optional animations and audio to hear what an offer could sound like (a "practice" offer).
What is right for you	<ul style="list-style-type: none"> You can consider the risks and benefits that match your values. Discuss any doubts about a donor type early. This will help you prepare. In almost all cases, candidates who accept a donor organ have higher survival than those who decline. <ul style="list-style-type: none"> View risks of waiting compared with the risks for some common donor types. 	<ul style="list-style-type: none"> Optional summary of average risks from infectious disease and average waitlist mortality in the United States. Optional patient-specific and region-specific waitlist outcomes calculator maintained by the Scientific Registry of Transplant Recipients.
Being prepared for an offer/actions you can take	<ul style="list-style-type: none"> Waiting can be stressful, but you and your caregiver can take some actions now to be prepared. Patients and caregivers can take the following steps to prepare. (Review a list of actions.) 	<ul style="list-style-type: none"> Evaluate methods to include actions focused on living donors for centers offering living donor transplants.

MELD, Model for End-stage Liver Disease; PHS, Public Health Services.

outline addresses standardization and tailoring of content (Theme 4) through combined use of standard content and available tailored content. Finally, the outline includes content to respect personal values and reinforces caregiver support, which are elements that are consistent with decision support frameworks.⁴

Visual Layout Mockups

A visual layout with patient-friendly graphics was developed to appeal to visual learners and to graphically convey important concepts. Based on the themes derived from providers, a tool was designed to review pages sequentially and to present each topic in an overview with available "Learn More" options for additional detail. Each topic of the content outline was represented graphically, and a simplified home-page is shown in Figure 2.

Feedback of Mockups

Pilot patient interviews provided preliminary feedback to understand how patients perceive their readiness to receive an offer call and how the decision support content would be used or improved. Patient experiences varied, for example, 2 candidates had previously accepted an offer that was ultimately not transplanted, but most had no experience with an offer call. Patients reported varying confidence in making a decision; however, responses consistently indicated gaps in knowledge of potential donor quality. Feedback on the decision support tool informed refinements of the wording used (eg, using "doctor" rather than "provider"). Feedback on the overall content was positive, and responses suggested a functioning tool would be a benefit to patients on the waitlist and their

caregivers. A comparison of excerpts from before and after viewing mockups is shown in Table 4. Feedback from coordinators was consistent and supported the potential benefit of a functioning tool. Example coordinator quotes are included in Table S5 (SDC, <http://links.lww.com/TXD/A320>).

DISCUSSION

The study results highlight important gaps in current patient education practices. The content of the tool has been designed to address these gaps and improve patient wellbeing during a stressful time receiving an offer, reduce the resources required to consent patients and present offers, and could potentially improve utilization for donor types that are disproportionately discarded (eg, PHS increased risk). Specifically, the content and implementation of the decision support tool can: (1) provide education as an ongoing process rather than primarily during evaluations, (2) provide a broad overview of the steps of the offer process to reduce stress during a real offer that may lead to risk-averse behavior, (3) provide an opportunity to practice what an offer would sound like, (4) provide information on waitlist mortality to compare against donor risks, and (5) reinforce the process of providers reviewing each offer before contacting a patient.

Themes from provider feedback provide evidence for a holistic educational intervention, in particular, to provide decision support both for donors with risks known to be high (DCD) and donors with risks perceived by many patients to be high (PHS increased risk). In this case, education is often tailored to candidates who are appropriate to consider for DCD donors (Theme 4). Patient feedback reinforced the low



FIGURE 2. An example of the design of a patient-friendly visual layout representing sections from the content outline (color image converted to grayscale).

retention of education from the evaluation period related to donor risks. Patients may benefit from both (1) repeated reviews of waitlist mortality risk and the risk of complications and (2) an understanding of the offer process, including the review of offers by surgeons before presenting an offer to patients. However, these are distinct education goals and are described in Themes 1 and 3.

The content of the decision support tool is intended to prepare patients and families for a real offer decision and could be revisited while on the waiting list for an offer. This approach differs from a decision aid to use at the time of an offer for a specific donor organ.²¹ Because of the urgent time response requirements, the lack of time and increased stress may be barriers to receiving support during an offer discussion. Candidates can prepare for this decision in advance.¹⁵ Existing decision support frameworks provide guidance, such as how to provide facts, clarify values, and guide deliberation.⁴ The content shown in Table 3 provides facts about the donor match, donor quality and risks, and the logistics of receiving a call and preparing for surgery. The section *What is Right for You* can support patients as they clarify values. Several sections direct candidates to discuss questions and

concerns with their care team and encourage them to receive additional guidance.

Patient education and consent is regulated by the Centers for Medicare and Medicaid Services and centers document compliance for education requirements.²² This is one potential factor for including extensive education sessions during a transplant evaluation, even before a center determines the suitability of the candidate to undergo transplant. Future education efforts could be focused on candidates who are listed for transplant and are most in need of preparing for an offer. Candidates could review materials over time as individual health conditions, waitlist priority, and values and perspectives change. Some family members and caregivers may not participate in the evaluation but do contribute to medical decisions, in particular, for patients who may become frail or cognitively impaired as Model for End-stage Liver Disease scores increase. These caregivers would be able to review materials with patients, better understand priorities, and support decisions.

Providers described challenges from a lack of standardization and shared examples of local efforts to create tailored educational content for specific patient demographics (see

TABLE 4. Patient excerpts from phase 2 pilot interviews

Before review of decision support tool

"My understanding is my coordinator will call and tell me that they have a liver waiting for me or they have a match ready, and that's really all I know about that."
 "I would say I would be readily accepting of [an offer] because like I said, I would be pretty sick by the time I got a dead donor."
 "I haven't learned about any kind of risk factors, as far as how it would relate individually to me."
 "One thing that never occurred to me is the possibility of [being] informed that there's a liver available and then being told ... that there might be some risk.... And then I would have to decide whether or not to accept, whether the benefits outweigh the risk. And the idea of having to make that decision had never crossed my mind until just now."
 "I feel a lot of mixed feelings about it, which translate into, for me stress and anxiety."

During or after review of decision support tool

"Yeah, that is the big one. You want to have [the education] done ahead of time."
 "I like it. It's well laid out. I really like the illustrations."
 "The writing is simple enough, it's not too packed with information, it's just the basics and it's brief enough, but it covers all the information."
 "I'm terrible in the moment asking questions ... because my brain kind of freezes up. And so this is good, I like this [practice offer] concept a lot."
 "I wish I had been told a lot of this because like a lot of my family had questions similar to this for me and I'm just like, 'I don't know; all I know is that we're banking on a living donor and if that doesn't work out then I'm not really sure.'"
 "And for me, I think it's helpful to have it driven home that before an offer is even made, your doctor has looked at this and thinks it's a good idea for you— because I personally put a lot of faith in my doctor"
 "The feeling I get from these pages is that if you need one and you're offered one, you better take it, because you might not get offered again."
 "It has decreased my anxiety and just kind of organized things in my brain, I guess, more."

Theme 4). For example, several participants described translating materials into multiple languages most common to the center's patients and, in some cases, hosting non-English transplant classes (see additional quotes in Table S4, SDC, <http://links.lww.com/TXD/A320>). Prior studies have demonstrated the benefit of patient counseling tailored to cultural needs.^{23,24} In addition, participants described a perceived benefit to allowing variability in the way education was presented. For example, if providers use different explanations to convey the same concept, some patients may benefit from hearing the information in multiple ways. In addition to center variability, user preferences may also vary. Incorporating both text and graphical displays of patient risks and other donor quality concepts can be a benefit to multiple learner types.

Standardized transplantation education directed at Centers for Medicare & Medicaid Services requirements has been provided for kidney transplant candidates,²⁵ and several participants indicated an interest in a similar tool specific to kidney candidates (data not shown). Developing additional organ-specific versions is an area of future work. Additional research is warranted to balance the degree of standardization with the needs of individual patients and centers. Participants noted that current practice varies widely by center, and providing a tool with opportunities to tailor content may reduce barriers to adoption.

A potential implementation approach based on provider feedback would contribute to the potential improvement in education. The decision support tool can provide a core of standardized content and also methods to allow optional and tailored content to meet specific needs. Standardized content can be formatted for printable versions of the information. The interactive tool used for future testing will include support for desktop and mobile viewing. This content can be a supplement to in-person counseling during evaluations or follow-up visits. Creating future versions tailored to language and cultural needs would increase the impact for diverse patient populations. The content outline (see Table 3) includes opportunities to tailor content to individual patients, for example, with the integration of an optional Scientific Registry of Transplant Recipients (SRTR) risk calculator to estimate waitlist outcomes for specific patient characteristics and locations.²⁶ The focus groups reviewed existing waitlist calculators and discussed the potential for integration into a patient tool for those seeking detailed risk estimates. Patient feedback was positive after discussing the potential of an integrated risk calculator with personalized waitlist risk information. Given the integration of an existing SRTR risk calculator, future work will evaluate providing the final tool as a publicly available decision support tool on the SRTR website. This approach will facilitate sustainable maintenance and updates to risk information.

Several centers had recently begun a protocol for hepatitis C positive donors in negative recipients. Provider participants expressed an interest in including education related to these new policies, and few patients reported awareness of new hepatitis C transplant options. The outline was developed before the COVID-19 pandemic, and the transplantation field is rapidly evolving to understand the impacts on patient safety and policy.²⁷ In addition, regulations related to PHS increased risk donors are changing, with potential impacts on informed consent.²⁸ These recent developments suggest a potential benefit of using portions of standardized

content to rapidly adjust to changes in the field. For example, future content for the offer tool could include discussions of exposure to COVID-19 virus and the related donor and recipient risks. This allows for rapid and consistent dissemination across centers and uses a format that is suited to telehealth visits if needed.

The combined studies include a number of important limitations. The recruiting methods resulted in a smaller number of surgeon and coordinator participants. This limits the generalizability of results. The study included only pilot interviews with patients at 1 local center. Pilot interviews included a sample biased toward insured and highly educated patients. Although the content has been developed for appropriate medical literacy and using a medical decision support framework, the evidence of gaps even for patients with high education reinforces the potential benefit for more diverse patient groups. Additional feedback from coordinators, diverse local and national patients and their caregivers, and other providers will be important future work to develop an interactive tool and is beyond the scope of the current analysis. Focus group transcripts did not indicate individual speaker identities; therefore, the analysis did not compare feedback across provider types or regions.

In conclusion, current patient education during transplant evaluations can be suboptimal with poor retention. The time spent waiting for an offer can be long and include dynamic changes in patient's condition and perspectives. An education tool designed for repeated review after an evaluation may provide an opportunity for continued support and patient and caregiver engagement. Data from patient and provider feedback support the development of new tools to prepare patients for an offer decision. An educational tool for offer decisions can support patients and families with information about the donor match, donor quality and risks, and the logistics of receiving a call and preparing for surgery.

REFERENCES

- Kim WR, Lake JR, Smith JM, et al. OPTN/SRTR 2016 annual data report: liver. *Am J Transplant*. 2018;18:172–253.
- Lai JC, Feng S, Roberts JP. An examination of liver offers to candidates on the liver transplant wait-list. *Gastroenterology*. 2012;143:1261–1265.
- Mataya L, Aronsohn A, Thistlethwaite JR Jr, et al. Decision making in liver transplantation—limited application of the liver donor risk index. *Liver Transpl*. 2014;20:831–837.
- Légaré F, O'Connor AC, Graham I, et al. Supporting patients facing difficult health care decisions: use of the Ottawa Decision Support Framework. *Can Fam Physician*. 2006;52:476–477.
- Goldberg DS, Blumberg E, McCauley M, et al. Improving organ utilization to help overcome the tragedies of the opioid epidemic. *Am J Transplant*. 2016;16:2836–2841.
- Kucirka LM, Bowring MG, Massie AB, et al. Landscape of deceased donors labeled increased risk for disease transmission under new guidelines. *Am J Transplant*. 2015;15:3215–3223.
- Rodrigue JR, Hanto DW, Curry MP. Patients' willingness to accept expanded criteria donor liver transplantation. *Am J Transplant*. 2011;11:1705–1711.
- Volk ML, Tocco RS, Pelletier SJ, et al. Patient decision making about organ quality in liver transplantation. *Liver Transpl*. 2011;17:1387–1393.
- Kucirka LM, Singer AL, Segev DL. High infectious risk donors: what are the risks and when are they too high? *Curr Opin Organ Transplant*. 2011;16:256–261.
- Volk ML, Goodrich N, Lai JC, et al. Decision support for organ offers in liver transplantation. *Liver Transpl*. 2015;21:784–791.
- Brown J, Sorrell JH, McClaren J, et al. Waiting for a liver transplant. *Qual Health Res*. 2006;16:119–136.

12. Wilson R, Brown DR, Boothe MA, et al. Improving the delivery of patient education about kidney transplant in a transplant center. *Prog Transplant*. 2012;22:403–412.
13. Ashcroft P. Adapting patient education for potential liver transplant recipients in a climate of chronic donor organ shortfall. *Prog Transplant*. 2009;19:59–63.
14. Volk ML, Roney M, Fagerlin A. Pilot test of a patient decision aid about liver transplant organ quality. *Liver Transpl*. 2014;20:850–855.
15. Op den Dries S, Annema C, Berg AP, et al. Shared decision making in transplantation: how patients see their role in the decision process of accepting a donor liver. *Liver Transpl*. 2014;20:1072–1080.
16. Altman M, Huang TTK, Breland JY. Design thinking in health care. *Prev Chronic Dis*. 2018;15:E117.
17. Patton M. *Qualitative Research and Evaluation Methods: Integrating Theory and Practice*. Sage Publications Ltd; 2015.
18. Beatty PC, Willis GB. Research synthesis: the practice of cognitive interviewing. *Public Opin Q*. 2007;71:287–311.
19. Maxwell J. *Qualitative Research: An Interactive Design*. Sage; 2005.
20. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007;19:349–357.
21. Kilambi V, Bui K, Hazen GB, et al. Evaluation of accepting kidneys of varying quality for transplantation or expedited placement with decision trees. *Transplantation*. 2019;103:980–989.
22. Centers for Medicare & Medicaid Services. Hospital conditions of participation: requirements for approval and re-approval of transplant centers to perform organ transplants. *Federal Reg*. 2007;72:15198–15280.
23. Gordon EJ, Caicedo JC, Ladner DP, et al. Transplant center provision of education and culturally and linguistically competent care: a national study. *Am J Transplant*. 2010;10:2701–2707.
24. Gordon EJ, Reddy E, Gil S, et al. Culturally competent transplant program improves hispanics' knowledge and attitudes about live kidney donation and transplant. *Prog Transplant*. 2014;24:56–68.
25. Waterman AD, Hyland SS, Goalby C, et al. Improving transplant education in the dialysis setting: the “explore transplant” initiative. *Dial Transplant*. 2010;39:236–241.
26. Hart A, Schladt DP, Zeglin J, et al. Predicting outcomes on the liver transplant waiting list in the United States: accounting for large regional variation in organ availability and priority allocation points. *Transplantation*. 2016;100:2153–2159.
27. Michaels MG, La Hoz RM, Danziger-Isakov L, et al. Coronavirus disease 2019: implications of emerging infections for transplantation. *Am J Transplant*. 2020;20:1768–1772.
28. Jones JM, Kracalik I, Levi ME, et al. Assessing solid organ donors and monitoring transplant recipients for human immunodeficiency virus, hepatitis B virus, and hepatitis C virus infection—U.S. Public Health Service guideline, 2020. *MMWR Recomm Rep*. 2020;69:1–16.