

# Patient Decision Making About Organ Quality in Liver Transplantation

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It is challenging to discuss the use of high-risk organs with patients, in part because of the lack of information about how patients view this topic. This study was designed to determine how patients think about organ quality and to test formats for risk communication. Semistructured interviews of 10 patients on the waiting list revealed limited understanding about the spectrum of organ quality and a reluctance to consider anything but the best organs. A computerized quantitative survey was then conducted with an interactive graph to elicit the risk of graft failure that patients would accept. Fifty-eight percent of the 95 wait-listed patients who completed the survey would accept only organs with a risk of graft failure of 25% or less at 3 years, whereas 18% would accept only organs with the lowest risk possible (19% at 3 years). Risk tolerance was increased when the organ quality was presented relative to average organs rather than the best organs and when feedback was provided about the implications for organ availability. More than three-quarters of the patients reported that they wanted an equal or dominant role in organ acceptance decisions. Men tended to prefer lower risk organs (mean acceptable risk = 29%) in comparison with women (mean acceptable risk = 35%,  $P = 0.04$ ), but risk tolerance was not associated with other demographic or clinical characteristics (eg, the severity of liver disease). In summary, patients want to be involved in decisions about organ quality. Patients' risk tolerance varies widely, and their acceptance of high-risk organs can be facilitated if we present the risks of graft failure with respect to average organs and provide feedback about the implications for organ availability. *Liver Transpl* 17:1387-1393, 2011. © 2011 AASLD.

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Deceased donor liver allografts vary widely in quality. Donor characteristics such as age, cause of death, steatosis, and ischemia time can make the difference between 20% and 40% rates of graft failure 3 years after transplantation.<sup>1</sup> Furthermore, organ quality appears likely to worsen in the future. The donor pool is aging, more donors have experienced stroke as the cause of brain death, and the federally funded Organ Donation Breakthrough Collaborative is promoting the expansion of the donor pool with extended criteria donor (ECD) organs, which carry higher risks of graft failure.<sup>2</sup> Thus, issues of organ quality are increasingly relevant for every liver transplant candidate.

Each time that an organ offer is made, the patient and physician are faced with a difficult choice: to accept the offer or to wait in the hope that a better one will come along. For patients with end-stage liver disease, this decision could mean the difference between life and death. For physicians, this decision is fraught with uncertainty and requires the balancing of numerous patient and donor factors. Furthermore, communicating this complex risk/benefit tradeoff to the patient can be challenging. Ideally, discussions about organ quality should occur prospectively during the transplant evaluation.<sup>3</sup> However, this is easier

Abbreviations: ECD, extended criteria donor; MELD, Model for End-Stage Liver Disease.

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said than done in a busy transplant clinic. These discussions are made even more difficult by our limited understanding of how patients perceive organ quality. How much risk of graft failure are patients willing to accept, and what factors influence their decisions? What are the critical knowledge deficits and cognitive biases that must be addressed in physician-patient conversations?

In this study, we investigated how candidates for liver transplantation consider issues of organ quality. In addition to presenting an overview of patients' decision-making process, we aimed to (1) test various presentation formats for communicating risks to patients and (2) determine which patient factors might be associated with an increased willingness to accept higher risk organs.

## PATIENTS AND METHODS

Because of the limited prior knowledge about this subject, we employed a mixed methods approach consisting of qualitative and quantitative components.<sup>4</sup> These methods are complementary: qualitative data are richer and more nuanced and allow the detection of findings that do not necessarily fit with researchers' preconceived notions or hypotheses. Quantitative data, on the other hand, allow the testing of specific inferential hypotheses.

Both portions of the study were performed with adult patients at a transplant clinic who were already on the waiting list for liver transplantation. At our center, all patients receive an extensive education about the transplant system, including a half-day group education class, before their placement on the waiting list. Additionally, each patient has at least 1 individual appointment with a transplant surgeon, who routinely discusses the topic of organ quality. Specifically, at each of these appointments, the surgeon explains that organ quality is on a spectrum and describes organs with a higher than average risk of graft failure (eg, donation after cardiac death organs).

### Qualitative Methods

Semistructured interviews of adult patients on the waiting list for liver transplantation at our center were conducted by the primary author (M.L.V.). The patients were enrolled from the transplant clinic; the exclusion criteria were significant hepatic encephalopathy (West Haven grade 2 or higher) and an inability to converse in English. This study was approved by our institutional review board, and informed consent was obtained for the interviews and audio recording. The questions were initially open-ended but progressively grew more focused on patients' understanding of organ quality and preferences for accepting higher risk organs. Probes were used to elicit further details. The interviews also included questions about patients' perceptions of their risk of dying on the waiting list

and their opinions about the organ allocation system. The interviews were recorded, transcribed, and imported into NVivo 7 (QSR International, Doncaster, Australia), which is a qualitative data analysis package allowing the manipulation and organization of text from transcripts. The analysis was performed with methods of qualitative description.<sup>5</sup> First, codes representing analytically meaningful categories were assigned to segments of the text. Second, these segments were organized together so that patterns and themes could emerge. Interviews were conducted until the transcripts no longer revealed new and relevant information.

### Quantitative Methods

The findings from the qualitative portion of the study were then used to inform the development of a quantitative Web-based patient survey. Patients on the waiting list for liver transplantation were enrolled from the transplant clinic to complete the survey on a study laptop computer. Patients with limited computer literacy were assisted by a study coordinator who was trained in survey administration. Those with significant hepatic encephalopathy were excluded, as were subjects from the qualitative portion of the study. Among those approached, the participation rate was 82%. Informed consent was obtained from all subjects, and the entire protocol was approved by the institutional review board.

The survey consisted of 3 sections: (1) education about the spectrum of organ quality and the implications of graft failure, (2) the elicitation of patient preferences about the level of graft failure risk that they would accept, and (3) the covariates hypothesized to influence patient decisions. These covariates included the following:

1. Demographic and clinical characteristics, which included the Model for End-Stage Liver Disease (MELD) score.
2. Patients' quality of life, which was measured with a visual analogue scale.<sup>6</sup>
3. Patients' belief in control over their own health, which was measured with a validated scale called Locus of Control and has been shown in other fields to affect risk-taking behavior.<sup>7</sup>
4. A validated scale measuring trust in physicians.<sup>8</sup>
5. Patients' knowledge of the MELD-based allocation system, which was measured by the percentage of correctly answered questions.
6. Patients' estimates of their risk of dying in the next 3 months on the waiting list for transplantation.
7. Patients' estimates of the probability of receiving a transplant in the next 3 months.
8. Patients' expectations about their survival and quality of life after transplantation.
9. Patients' emotional distress due to waiting for an organ, which was measured with a

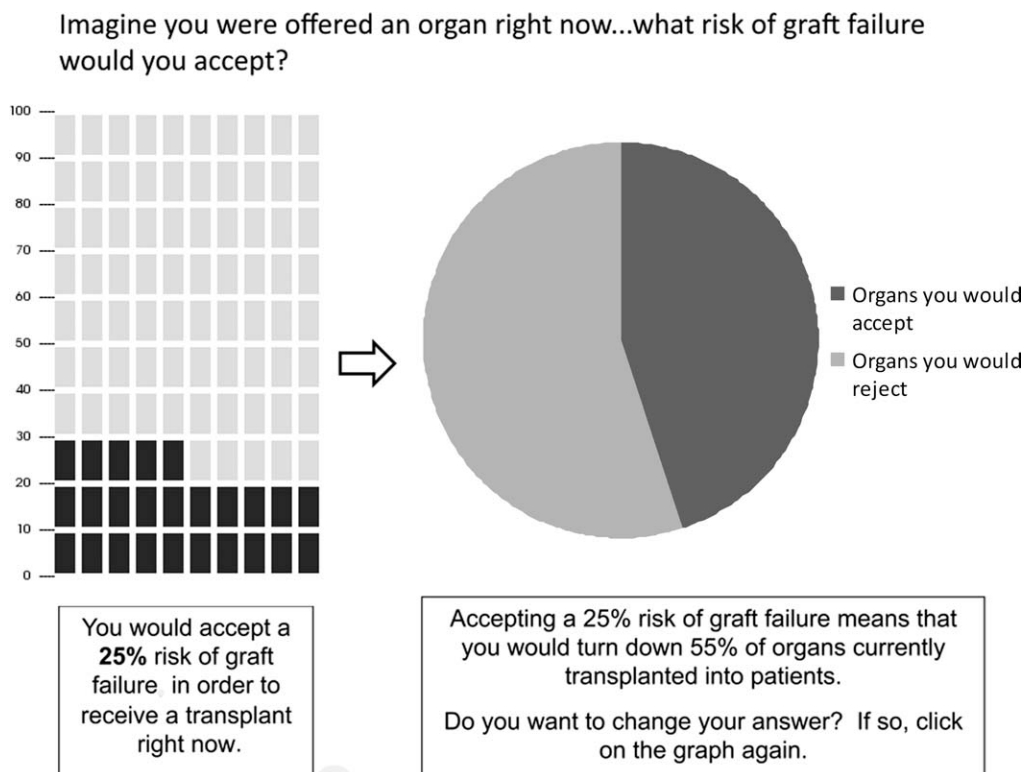


Figure 1. Tool for eliciting patient preferences about the risk of graft failure.

standardized scale called the Positive and Negative Affect Schedule.<sup>9</sup>

10. A validated scale of numeracy, which reflected patients' comfort and ability to work with numbers (similar to the concept of literacy).<sup>10</sup>

To elicit patient preferences, patients were instructed to imagine being offered a transplant right then and were asked to indicate what risk of graft failure at 3 years they would be willing to accept. Responses were recorded with an interactive graphical tool that visually represented in a pictograph format how many organs out of 100 would fail. An example of this preference elicitation tool is shown in Fig. 1. The pictograph format was chosen because pictographs have been shown to improve the understanding of risk information in other clinical settings.<sup>11,12</sup>

With a computerized random number generator, patients were randomized to receive 2 different versions of this elicitation tool: in one version, the initial pictograph showed the risk of graft failure with the best quality organs (19% at 3 years), and in the other version, the initial pictograph showed the risk of graft failure with average quality organs (25% at 3 years). This randomization was performed to determine whether the patients' responses were anchored to the initial graph that they saw. After the initial preference elicitation, the patients were provided feedback about how their preferences would limit the number of organs available to them (see the pie chart in Fig. 1, which was not visible in the initial elicitation). They were then asked whether they would like to revise

their answers; data were collected before and after the feedback to determine whether this feedback influenced preferences.

Finally, a possible bias against lower quality organs was tested by the presentation of a discrete choice scenario with a logically correct answer: (1) staying on the waiting list with a 20% risk of dying or (2) accepting a lower quality liver with a 20% risk of dying but an improved quality of life.

The statistical analysis was performed with non-parametric methods because the preliminary analysis of the data revealed that the patient preferences did not fit a normal distribution, and linear residuals demonstrated significant heteroskedasticity. A Spearman correlation was used for interval independent variables, a Mann-Whitney test was used for dichotomous independent variables, and a Wilcoxon signed-rank test was used for paired samples. Because of the exploratory nature of this analysis and the relatively few predictors of subject preferences on bivariate testing, a multivariate regression was not performed. Calculations were performed with Stata/SE 11.0 (Stata-Corp, College Station TX). The required sample for detecting medium-sized associations between patient factors and preferences for organ quality was 84 subjects when  $\beta = 0.8$  and 2-tailed  $\alpha = 0.05$  were assumed.<sup>13</sup>

Finally, we re-approached 20 patients who had remained on the waiting list and had taken the initial survey at least 6 months previously to determine whether their preferences remained stable over time.

During this period, we continued to recruit new participants; thus, our final sample size was 95 subjects.

## RESULTS

### Qualitative Results

Several themes became apparent after 10 wait-listed patients (4 men and 6 women) were interviewed (median MELD score = 14). First, even though they had received a prelisting education about the spectrum of organ quality, these wait-listed patients had a very poor understanding of the subject. They attempted to dichotomize organs into good and bad ones, and they assumed that any organ that they would be offered would be good: "They're not going to offer it if it's not

transplantable," and "Just knowing this hospital and its reputation, I would think they would be looking only at good quality organs." This view was even held by a patient who had previously been called for a transplant that was canceled because of concerns about the organ quality. Despite this experience, she indicated that when she was offered another one, "I'm sure it will be good—we should be checking them out first." Most patients were initially resistant to receiving anything but the best quality organ: "Well, I'd like to get a liver from an 18-year-old football player"; "I would think that 5% risk [of graft failure] would be the norm, but I'm not sure I would want more than that"; and "If I'm going to be sliced and diced, I'd rather get something that will last me a long time." These qualitative findings affected the design of the quantitative survey and led specifically to the emphasis on the spectrum of organ quality and the testing of methods for mitigating patients' initial biases.

### Quantitative Results

Demographic characteristics are shown in Table 1 for the 95 wait-listed patients who participated in this portion of the study. The median age was 55 years, 65% were male, and the median MELD score was 13. The mean laboratory MELD score was slightly lower for the participants versus our overall wait-listed population (13 versus 15,  $P < 0.001$ ), and the participants were less likely to be Hispanic (1% versus 7%,  $P = 0.02$ ); however, the other demographic characteristics were representative.

The results for the various psychological metrics are shown in Table 2, which provides an overview of the group's mental and emotional states at the time of the survey. The patients' numeracy was similar to that of

**TABLE 1. Demographic Characteristics of the 95 Wait-Listed Patients in the Quantitative Study**

Median age (years)	55 (19-70)
Male sex (%)	65
Race/ethnicity (%)	
White	87
Black	9
Hispanic	1
Other	3
Median laboratory MELD score	13 (6-23)
Hepatocellular carcinoma exception (%)	8
Primary diagnosis (%)	
Alcohol	18
Viral	29
Cryptogenic/fatty liver	22
Other	31

NOTE: Ranges are shown in parentheses.

**TABLE 2. Results of Psychological Metrics**

Metric	Median Score	Interpretation/Comment
Numeracy	4.2	The scale goes from 1 to 6; the scores were similar to those of other populations.
Positive and Negative Affect Schedule	4	The scale goes from -27 to +27; positive values reflect more positive feelings than negative feelings.
Quality-of-life visual analogue	65	The scale goes from 0 to 100; the results reflect moderate impairment in the quality of life.
Perceived risk of dying on the waiting list in the next 3 months	5% (0%-80%)	Patients perceived a low chance of death on the waiting list.
Perceived chance of receiving a transplant in the next 3 months	10% (0%-100%)	Patients perceived a slightly higher chance of transplantation.
Trust in physicians	5	The scale goes from 1 to 6; the results reflect high trust in physicians.
Knowledge	Correct answers to 67% of the items	97% understood that their MELD score influenced their chance of transplantation; only 67% knew this about their willingness to accept high-risk organs.
Locus of Control	4	The scale goes from 1 to 6; scores greater than 3 reflect the perception that health is not within the patient's control.

NOTE: Higher scores reflect better numeracy, more positive affect, better quality of life, more trust, more external locus of control, and so forth. Ranges are shown in parentheses.

the general population with a median score of 4.2 on a 1 to 6 scale.<sup>10</sup> Their affect was on the positive end of the spectrum with a median score of 4 on a -27 to +27 scale. Their quality of life was moderately impaired with a median score of 65 on a 0 to 100 analogue scale. Eighty percent of the patients expected that their quality of life would improve after transplantation by a median of 15 points. They perceived a relatively low chance of dying on the waiting list in the next 3 months (median risk = 5%, range = 0%-80%) and believed that they had a 10% chance (median; range = 0%-100%) of receiving a transplant in the next 3 months. Their trust in physicians was high with a median score of 5 on a 1 to 6 scale. They correctly answered 67% of knowledge questions about factors that would influence their chances of receiving a transplant. In particular, 97% understood that their MELD score would influence their chance of transplantation, whereas only 67% responded that their chances would be influenced by the quality of the organ that they were willing to accept. Finally, this group had a relatively external locus of control with a median score of 4 on a 1 to 6 scale (the higher number reflected their belief that their health was outside their control).

### Risk Preferences

After the patients had completed the preference elicitation tool, the mean risk of graft failure that they were willing to accept for a particular organ was 32% 3 years after transplantation. There was significant between-patient variability in risk preferences, as shown in Fig. 2. The majority of the patients preferred relatively low-risk organs: despite feedback that stringent acceptance criteria could shrink the pool of organs available to them, 58% would accept only organs with a risk of graft failure of 25% or less at 3 years, whereas 18% would accept only organs with the lowest risk possible (19% at 3 years). A bias against lower quality organs was demonstrated by their responses to the following scenario: subjects were asked to choose between (1) continuing on the waiting list with a 20% chance of dying and (2) accepting a lower quality liver with a 20% chance of dying but an improved quality of life. In this discrete choice scenario with a logically correct answer (accepting the liver), 42% preferred to stay on the waiting list. Nonetheless, a sizable minority were willing to accept much higher risks, up to nearly 100% in some cases, in order to receive a transplant. Patients reported a strong desire to be involved in decisions about organ acceptance, with 83% wanting an equal or dominant role in the decision.

Among the 20 patients re-approached after a mean of 16 months (range = 6-30 months), the group's risk preferences were not significantly different [the mean acceptable graft failure risk was 34% on the initial survey and 33% on re-approach ( $P = 0.3$ )]. However, the individual preferences were not particularly stable, and there was only a modest correlation between the

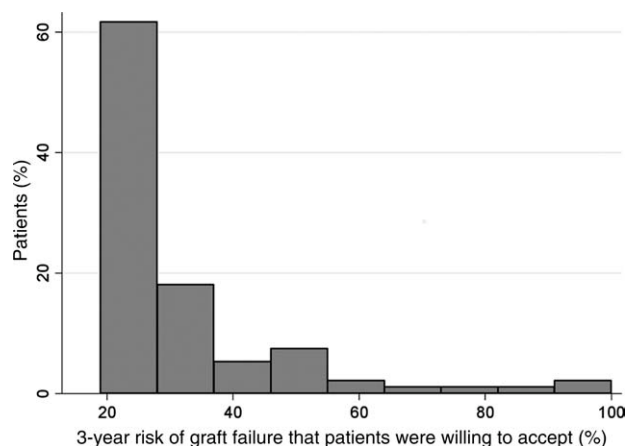


Figure 2. Histogram demonstrating the variability between patients in terms of the 3-year risk of graft failure that they were willing to accept ( $n = 95$ ). The displayed preferences are those stated by patients after they had the opportunity to reflect upon the implications of organ availability (see the pie chart in Fig. 1).

initial and re-approach values (Spearman's  $\rho = 0.24$ ). Changes in preferences were not associated with either changes in the MELD score (which increased by a mean of 1 point in this group;  $P = 0.1$ ) or the time from the initial survey to re-approach ( $P = 0.9$ ).

### Impact of the Presentation Format

The format for presenting information did have a significant impact on patient preferences. The absolute risk of graft failure that patients were willing to accept was modified by the initial graphical presentation; those initially shown a graph with a 19% risk of graft failure (the best organ scenario) would accept up to a 26% risk on average, whereas those initially shown a graph with a 25% risk of graft failure (the average organ scenario) would accept up to a 29% risk on average ( $P = 0.001$ ). This experiment demonstrated the psychological bias of anchoring to the initial number seen. Patients were also influenced by feedback about organ availability. During the initial preference elicitation, the mean risk of graft failure at 3 years that patients were willing to accept was 28%; this increased to 32% once they were given pie chart feedback (as shown in Fig. 1;  $P = 0.003$ ). Among the 67 patients who initially preferred organs with no more than a 25% 3-year risk of graft failure, 13 (19%) indicated that they would accept a risk greater than 25% after they had received this feedback. Conversely, among the 28 patients who initially would accept organs with more than a 25% 3-year risk of graft failure, only 2 (7%) reduced their risk tolerance after they had received the feedback.

### Correlates of Risk Preferences

Among the patient demographics and clinical characteristics, only sex was associated with risk preferences, with men preferring lower risk organs in comparison with women (the 3-year graft failure risk tolerance

after feedback was 29% for men and 35% for women;  $P = 0.04$ ). In particular, neither laboratory MELD scores nor MELD exceptions for hepatocellular carcinoma were significantly associated with their risk preferences ( $P = 0.2$  and  $P = 0.1$ , respectively), nor were their perceived chances of dying or getting a transplant. Among the psychological factors hypothesized to correlate with patient risk preferences, only the belief in control over one's health demonstrated a statistically significant association: patients with more external locus of control were more likely to accept higher risk organs ( $P = 0.04$ ). When patients were asked directly what factors would influence their decisions about organ acceptance, the most common response was quality of life (85%), and this was followed by trust in the transplant team (79%).

## DISCUSSION

This study of patient decision making about organ quality in liver transplantation has 3 main findings. First, many patients entered discussions about organ quality with an inherent bias against the acceptance of organs with higher risks of graft failure. This finding was demonstrated most clearly by their responses to the discrete choice scenario: 42% would choose to stay on the waiting list instead of accepting a lower quality liver that would improve their quality of life and would not increase their chance of dying. This bias against lower quality organs was partially mitigated when the organ quality was presented with respect to average organs rather than the best organs and when feedback was provided about the implications for organ availability. Second, risk tolerance was highly variable between individuals and was not particularly stable over time. Third, an individual patient's risk tolerance was associated with sex and beliefs about control over his or her health and not with the severity of liver disease. Although these findings need to be confirmed in future studies, they provide much needed information about ways to counsel patients about issues of organ quality.

How involved should patients be in decisions about organ acceptance? Some would argue that this decision is too complicated for patients to contemplate. On the contrary, we contend that patient involvement is important for many reasons. First, from an ethical standpoint, few would dispute that patients have the right to know the quality of the organs that they are receiving.<sup>3</sup> Physicians routinely counsel patients about risks and benefits of medications and procedures, and organ quality should be no different. Second, from a legal standpoint, there may be ramifications for transplant centers that do not adequately inform their patients.<sup>3</sup> Third, from the standpoint of outcomes, patient involvement in decision making is associated with improved survival<sup>14</sup> and improved medication compliance in the setting of renal transplantation.<sup>15</sup> Finally, the patients want to be involved. In our study, 83% of the patients reported that they would prefer an equal or even dominant role in decid-

ing whether to accept a higher risk organ. Thus, it is incumbent upon the transplant community to respect the autonomy of patients by involving them in these discussions.

Despite these arguments, a number of logistical challenges remain. First, although general issues of organ quality can and should be discussed in advance,<sup>16</sup> the real decision happens when an organ offer is made. This event often occurs in the middle of the night under less than ideal circumstances for informed consent discussions. Second, although the primary decision should focus on risks and benefits for the individual patients, transplant physicians must also consider the impact on other patients on the waiting list, which can at times pose an ethical dilemma. Third, findings from our study suggest that patient preferences are significantly influenced by the presentation format and are relatively unstable over time. Thus, we do not recommend that patients simply be asked to decide on their own (nor do patients want this). Instead, we suggest that patients be guided through the decision and provided with a clear recommendation that they can then accept or reject. Furthermore, the preferences of patients will need to be readdressed frequently as their clinical condition changes. We are currently in the process of developing a patient education tool for this purpose, and we are building upon our findings in this study as well as previous work demonstrating that complex risk communication is best done (1) with graphs, (2) with absolute risks rather than relative risks, and (3) with contextual information (to account for innumeracy).<sup>17-19</sup> This education tool is intended as something that patients can use at home; in this way, it will not interfere with the flow at a busy transplant clinic but can set the stage when the actual organ offer occurs.

This study was limited by its single-center nature and the inclusion of relatively few patients with very high MELD scores. The unstable nature of high-MELD patients provided logistical challenges for their enrollment: they often missed clinic appointments because they were admitted to the hospital, and they either died or received a transplant quickly. Therefore, the findings in this study cannot necessarily be generalized to patients with different sociodemographic characteristics and more severe liver disease. Another limitation was the use of a preference elicitation tool that had not been previously validated. When this study was begun in 2008, no literature existed on this topic in liver transplantation. Recently, another group conducted a study on patients' willingness to accept ECD organs.<sup>20</sup> Although that study dichotomized organs into standard organs and ECD organs, the authors found similar results: a large proportion of patients expressed a reluctance to consider ECD organs. The strengths of our study included the mixed methods approach and the testing of various presentation formats. These design features allowed us to develop an understanding of the best ways to communicate with patients instead of simply describing their preferences. Finally, it is important to note that both

of these studies focused on organ-specific risks of graft failure and not disease transmission. The literature for kidney transplantation suggests that patients have similar biases about disease transmission risks.<sup>21,22</sup>

In summary, our patients expressed a strong desire to be involved in decisions about organ quality and demonstrated widely varying levels of risk tolerance. We found that risk tolerance was not associated with disease severity, but it was significantly influenced by the presentation format. These findings suggest that when organ quality is being discussed with patients, the risks of graft failure should be presented with respect to average quality organs, and feedback should be provided about the relationship between organ quality and availability. Future work on developing validated patient education tools will aid transplant physicians in these discussions.

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