

Pilot Test of a Patient Decision Aid About Liver Transplant Organ Quality

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Prior studies have shown that patients are reluctant to accept donor-specific risks, and transplant professionals lack an effective and time-efficient means of obtaining informed consent. We designed and pilot-tested a Web-based patient decision aid (DA) on organ quality. The DA was administered to 53 liver transplant candidates (median Model for End-Stage Liver Disease score = 14, range = 7–26), and they took a mean of 15 minutes to complete it. Questions about knowledge and attitudes were asked before and after the DA. Subjects' knowledge improved, with 53% and 60% correctly answering questions about hepatitis B virus and human immunodeficiency virus transmission before the DA and 94% and 100%, respectively, correctly answering them afterward ($P < 0.001$). The accuracy of mortality prediction also improved from a mean 3-month mortality estimate of 22% before the DA to 12% afterward ($P < 0.001$). After the DA, subjects felt that it was more likely that they might be offered a less-than-perfect liver ($P = 0.001$), and they were more likely to consider accepting such a liver ($P < 0.001$). In conclusion, implementing a Web-based patient DA is feasible and improves knowledge among liver transplant candidates. The use of this tool may decrease candidates' reluctance to accept extended criteria organs. *Liver Transpl* 20:850–855, 2014. © 2014 AASLD.

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Not all liver allografts are of equal quality. We conceptualize organ quality as an overarching concept with 2 primary subdomains: risk of graft failure and risk of disease transmission. Donor characteristics such as age, cause of death, steatosis, and ischemia time can make the difference between 20% and 40% rates of graft failure within the first 3 years after transplantation.¹ Furthermore, the quality of available organs appears likely to worsen in the coming years. The donor pool is aging, more donors have experienced stroke as the

cause of brain death, and the use of donors after cardiac death is increasing.² Thus, issues of organ quality are increasingly relevant for every liver transplant candidate.

Although organ quality is a spectrum, the term *extended criteria donor organ* is used to refer to an organ with a higher-than-average risk of graft failure or disease transmission. Each time that an extended criteria donor organ offer is made, the patient and the physician are faced with a difficult choice: to accept the offer or to wait in the hope that a better liver 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

Additional Supporting Information may be found in the online version of this article.

Abbreviations: CDC, Centers for Disease Control and Prevention; DA, decision aid; HIV, human immunodeficiency virus; MELD, Model for End-Stage Liver Disease.

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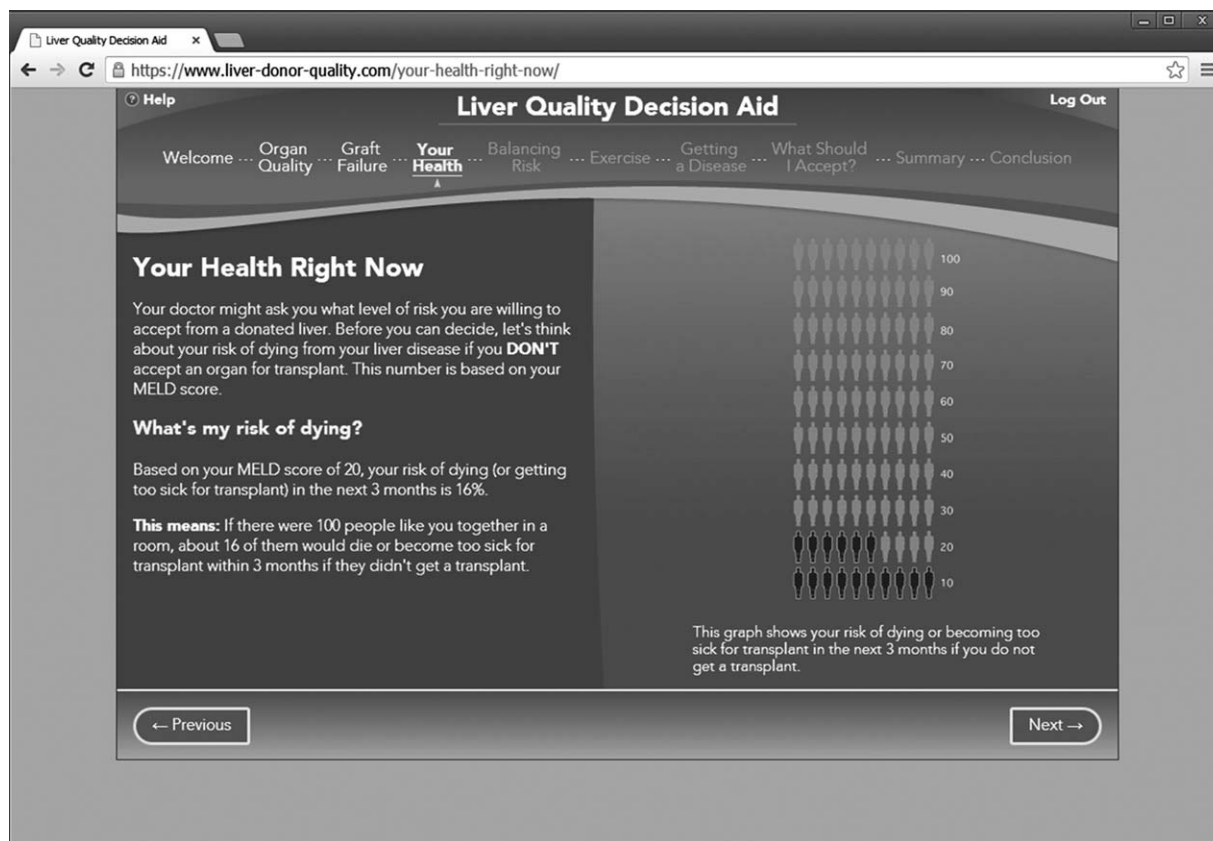


Figure 1. Presentation of the waiting-list mortality risk based on the patient's MELD score.

with uncertainty, and communicating the various risks to the patient can be challenging.^{3,4} Yet, it is critical that patients understand this information because our prior work has demonstrated that patients want to be involved in the decision about what type of organ they receive: 83% of those surveyed indicated that they would prefer an equal or dominant role in the decision.⁵

Ideally, discussions about organ quality should begin during the transplant evaluation so that the candidate is prepared for the potentially middle-of-the-night decision of whether or not to accept an available liver. However, this is easier said than done at a busy transplant clinic with other competing priorities. Our previous work highlighted not only patients' desire for involvement in decision making but also their poor understanding of issues of organ quality and preconceived notions and biases about the topic.⁵ Transplant professionals are in need of a tool to educate patients and satisfy requirements for informed consent in a time-efficient manner. Therefore, we designed and pilot-tested a Web-based patient educational tool and decision aid (DA) about liver transplant organ quality. Our goal was to provide patients with information that can supplement their discussions with their physicians and to test whether receiving this information would make patients more informed about the risks and benefits or change their attitudes about accepting an extended criteria liver.

PATIENTS AND METHODS

Design of the DA

The design of the DA was based primarily on results from our prior study⁴ and a study by Rodrigue et al.,⁵ who found that the majority of liver transplant candidates (1) assume that any organ offered to them will be of good quality, (2) do not understand the inherent tradeoff between organ availability and organ quality, and (3) are resistant to accepting anything but a very high quality organ. The template was written by the first author (M.L.V.) and revised by a health writer with expertise in health literacy. Design features were also based on state-of-the-art knowledge about best practices in patient DAs, with input from experts in graphic design, human factors engineering, and decision psychology. Examples of these best practices include the use of absolute risks, pictographs, plain language, and tailoring.^{3,7}

The beginning of the DA is focused on addressing knowledge gaps (eg, the definition, risk factors, and health implications of graft failure). Because the literature suggests that the primary determinant of whether or not to accept an organ should be the candidate's risk of dying while he or she is waiting,⁸ we present the 3-month wait-list mortality risk in a graphical format (Fig. 1). This risk is tailored to the individual candidate and is based on his or her most recent Model for End-Stage Liver Disease (MELD)

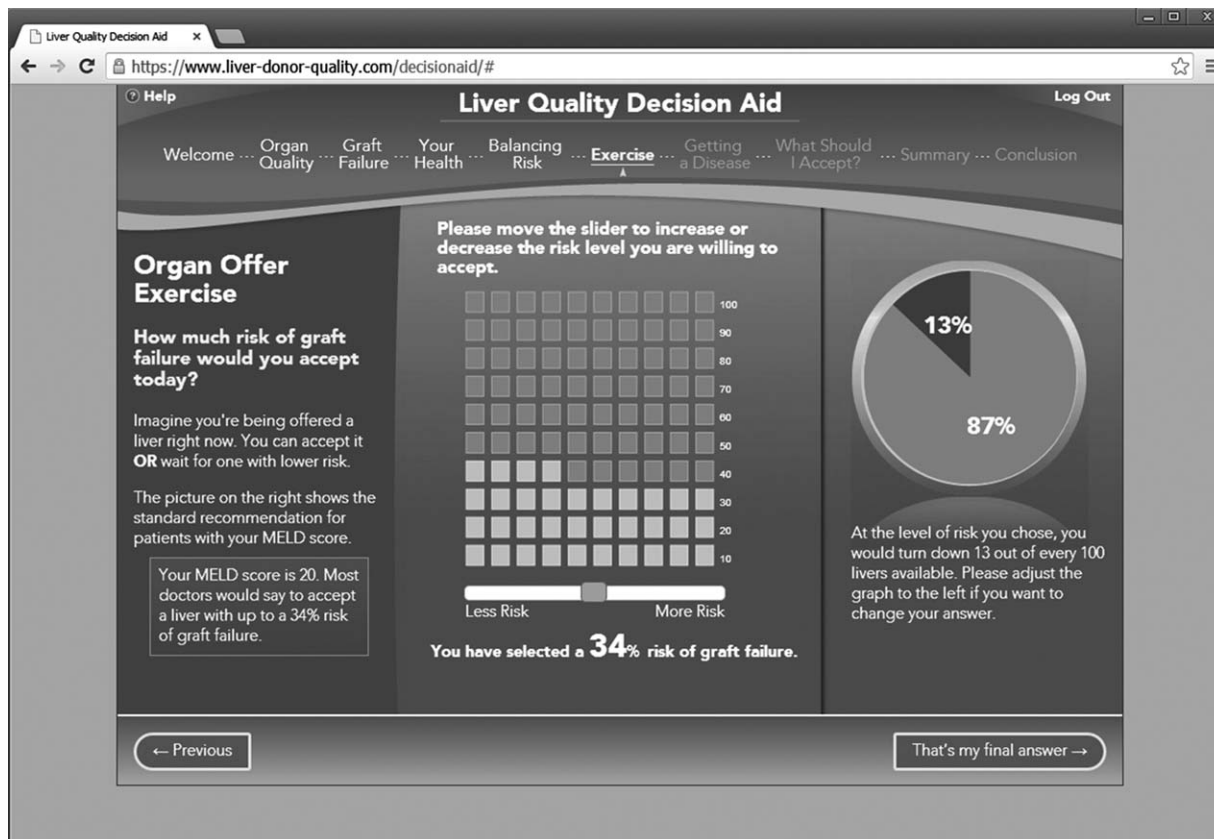


Figure 2. Risk tolerance exercise used to emphasize the tradeoff between organ quality and organ availability.

score (which was entered into the DA by a research coordinator to ensure the accuracy of the input).⁹ This information then sets the stage for framing the tradeoff between organ quality and organ availability and leads to an interactive organ offer exercise. In this exercise, the patient is able to adjust his or her risk tolerance for organ quality and see how this tolerance affects organ availability. As shown in Fig. 2, the initial settings are tailored to the individual patient on the basis of the most recent MELD score.⁸ This is done because our prior work and a long history in psychology have demonstrated that patients are anchored to the initial value that they see.¹⁰ Finally, the DA concludes with a discussion about the risks of disease transmission from organ transplantation. The DA recommends that all patients accept Centers for Disease Control and Prevention (CDC) increased-risk organs as well as organs from donors with hepatitis B core positivity. The rationale for this recommendation is that any patient sick enough to justify the 5% to 10% 1-year risk of perioperative mortality associated with liver transplantation should be willing to accept the numerically much smaller risk of disease transmission.^{11,12}

Preliminary usability testing was conducted with clinic staff (nurses, transplant hepatologists, and surgeons) and 5 patients, and we revised the program to reflect their comments. The pilot version of the DA can be seen online.¹³

Study Design

The aims of this pilot study were to demonstrate that the DA (1) is usable by liver transplant candidates, (2) increases patients' knowledge, and (3) decreases candidates' reluctance to accept organs of less-than-perfect quality.

Approval for the performance of this study was obtained from our institutional review board. Adult patients (18 years old or older) on the waiting list for liver transplantation at our center were approached at the clinic for participation. We included only subjects already on the waiting list, who at our center had already undergone extensive pretransplant education, including discussions with an attending surgeon about organ quality. The exclusion criteria were grade 2 or worse hepatic encephalopathy (assessed during the pre-enrollment screening of medical records and again in person during the initial contact) and previous participation in any of our prior studies on organ quality. We also excluded candidates listed primarily for MELD exceptions such as hepatocellular carcinoma in order to simplify the interpretation of the results for this initial pilot test. After informed consent was obtained, the DA was administered in 1 of 2 formats according to patient preference. Patients could either use an iPad provided at the clinic or access the DA on a secure Web site from their home computer.

Outcome Measures

Usability measures, including the completion rate and the time spent per subject, were calculated from the Web site. The interactive features of the DA provided an additional opportunity for data gathering: participants provided their final risk tolerance after the organ offer exercise and also indicated whether they would be willing to accept CDC increased-risk and/or hepatitis B core-positive organs. Those who would not accept CDC increased-risk or hepatitis B core-positive organs were asked to provide open-ended comments about their reasons for not accepting them. Finally, the impact of the DA on knowledge and attitudes was assessed with a pre/post design, with survey items administered immediately before and after the DA. The full version of this survey can be seen in the supporting information.

Knowledge Questions

The following knowledge questions were used:

1. Out of 100 people with the same severity of liver disease as you have, how many do you think die during a 3-month period on the waiting list?
2. True or false: It is possible to get human immunodeficiency virus (HIV) from a liver transplant, even if the donor tested negative.
3. True or false: If the donor has been exposed to hepatitis B in the past, the liver is not usable.

Attitude Questions

Attitudes were measured with the following questions:

1. Imagine that an organ becomes available. How likely do you think the surgeon will be to offer you this organ if it is less than perfect?
2. Would you ever consider accepting a less-than-perfect liver?
3. How confident do you feel in your ability to make a decision about whether to accept or turn down a liver?
4. How confident do you feel in your ability to discuss these issues with your doctor?

Statistical Analysis

Statistical analysis was performed with a matched *t* test for attitudes measured on a 6-point scale as well as waiting-list mortality estimates before and after the DA. McNemar's test was used to compare true/false and yes/no questions before and after the DA. The primary outcome measure was the attitude toward accepting extended criteria organs. On the basis of our prior data, we a priori hypothesized a 20% improvement in the likelihood of accepting a less-than-perfect liver. Thus, a sample size of 53 subjects would provide 90% power to detect this difference with a 2-sided *t* test for matched pairs with a repeated measures correlation of 0.3.

TABLE 1. Demographic Characteristics of 53 Wait-Listed Patients

| | |
|------------------------------|------------|
| Median age (years) | 56 (20-67) |
| Male sex (%) | 55 |
| Race/ethnicity (%) | |
| White | 87 |
| Black | 4 |
| Hispanic | 7 |
| Other | 2 |
| Median laboratory MELD score | 14 (7-26) |
| Primary diagnosis (%) | |
| Alcohol | 15 |
| Viral | 32 |
| Cryptogenic/fatty liver | 23 |
| Other | 30 |

NOTE: Ranges are shown in parentheses.

RESULTS

Participant Characteristics

Seventy-two liver transplant candidates on the waiting list were approached for participation. Fifty-six (78%) were enrolled, and 53 of those candidates (95%) completed the study. The 3 candidates who did not complete the study had begun the DA in the waiting room before their visit and chose to leave the clinic immediately afterward without completing it. The clinical and demographic characteristics of the 16 patients who chose not to participate appeared identical to those of the participants (data not shown). Demographic and clinical characteristics of the participants are shown in Table 1. Fifty-one of the 53 participants (96%) completed the DA on an iPad at the clinic, and 2 (4%) completed the DA online from home. The time spent taking the DA ranged from 7 to 28 minutes, with participants spending an average of 15 minutes.

Risk Preferences

After going through the organ offer exercise, participants were willing to accept liver allografts with a median risk of graft failure of 28% 3 years after transplantation. Participants who spent more time on the DA tended to be more risk-averse; each extra minute was associated with a 0.4% lower tolerance of graft failure risk ($r^2 = 0.15, P = 0.004$). Seventy-nine percent of the participants were willing to accept CDC increased-risk organs, and 76% were willing to accept hepatitis B core-positive organs. Sixteen patients were unwilling to accept 1 or both of these forms of an increased risk of disease transmission, and the reasons that they provided included the following: the feeling that they were healthy enough to wait for a higher quality organ ($n = 6$), concerns about the cost and side effects of the pills required to receive a hepatitis B core-positive organ ($n = 3$), the desire to confer with their physician ($n = 1$), not wanting to risk infecting anyone else ($n = 2$), and simply not being

TABLE 2. Survey Responses Before and After Use of the DA

| | Before DA | After DA | P Value |
|--|-------------------|-------------------|---------|
| Knowledge | | | |
| 3-month mortality risk | 22% risk of death | 12% risk of death | <0.001 |
| Possible to get HIV from a transplant | 60% correct | 100% correct | * |
| Hepatitis B virus donor not usable | 53% correct | 94% correct | <0.001 |
| Attitudes [†] | | | |
| Likelihood that surgeon will offer you a less-than-perfect organ | 3.74 | 4.40 | 0.001 |
| Willingness to consider a less-than-perfect organ | 3.53 | 4.60 | <0.001 |
| Confidence in ability to decide | 4.72 | 4.98 | 0.12 |
| Confidence in ability to discuss with physician | 5.66 | 5.58 | 0.10 |

*The P value could not be calculated because there were 0 incorrect responses after the DA was used. If 1 subject had responded incorrectly, the difference between pre-DA and post-DA results would have been significant at $P < 0.001$.

[†]Attitudes were graded on a 6-point Likert scale.

comfortable with any risk/wishing to have a liver of the best quality possible (n = 4).

Impact of the DA on Knowledge and Attitudes

Survey responses after the DA demonstrated improvements in knowledge, as shown in Table 2. When they were asked if HIV could be transmitted via organ transplantation, 60% answered yes (true) correctly before the DA, and 100% answered correctly afterward. Similarly, 53% responded correctly before the DA that hepatitis B core-positive organs could be used, whereas 94% responded correctly to this question after the DA. The accuracy of mortality predictions also improved, although not in the direction that we had anticipated. We had hypothesized that underestimation of waiting-list mortality risk might be a factor in candidates' reluctance to accept extended criteria organs. However, the subjects initially estimated a mean 3-month mortality estimate of 22%, which was inappropriately high for this group, which had a median MELD score of 14. After the DA, the mean estimate decreased to 12% ($P < 0.001$).

Attitudes about organ quality were also influenced by the DA, as shown in Table 2. After the DA, subjects felt it more likely that they might be offered a less-than-perfect liver ($P = 0.001$), and they were more likely to consider accepting such a liver ($P < 0.001$). These differences appeared similar across MELD scores. For example, among patients with MELD scores < 15 (n = 30), the willingness to accept a suboptimal liver improved from 3.7 to 4.9 ($P < 0.001$), whereas this willingness improved from 3.2 to 4.2 ($P = 0.03$) among participants with MELD scores of 15 or greater (n = 23). Subjects' confidence in their ability to make the decision or discuss it with the surgeon did not change.

DISCUSSION

This pilot study has demonstrated that a patient DA can improve liver transplant candidates' knowledge about organ quality and decrease candidates' reluctance

to accept extended criteria organs. The DA is intended not to replace patient-physician discussions but rather to augment them. Organ quality is a complex topic, and when a physician is counseling a patient, it could be useful for the patient to have already gained some knowledge and to have spent time considering the risks and benefits. For example, despite prior explicit counseling about CDC increased-risk organs at the clinic, 40% of the patients in this pilot study did not realize before they used the DA that they could get HIV from a liver transplant.

This study also extends our prior work in understanding how patients think about organ quality. It confirms that many patients hold a preconceived bias against donor-specific risks. However, contrary to our hypothesis, an underestimation of mortality risk was not a factor influencing this bias. Conversely, most patients overestimated their mortality risk. Furthermore, despite extensive education and a strong recommendation to accept CDC increased-risk and hepatitis B core-positive organs, 21% and 24% of the subjects remained unwilling to do so. We conclude that education can mitigate but not completely eliminate patients' unwillingness to accept donor-specific risks, even when doing so might improve their chances for survival. This conclusion, along with strong patient preferences for involvement, supports the importance of comprehensive informed consent in organ acceptance decisions.

It is unclear why the DA did not lead to improvements in subjects' confidence in their ability to make the decision or discuss it with the surgeon. We were able to conduct brief follow-up interviews with 5 subjects who subsequently underwent transplantation, and they all expressed that the DA was helpful to them at the time of the organ offer. We speculate that many patients may not have fully appreciated the complexity of the subject before they completed the DA. Additionally, a certain lack of confidence may be entirely appropriate for such high-risk, low-certainty decisions.

It is important to emphasize that this was a small pilot study at a single center, and the findings may not apply to other patient populations. The limited number of questions about patient knowledge prevents a detailed investigation into domains of knowledge. Furthermore, pre/post study designs tend to exaggerate effect sizes in comparison with randomized trials. Finally, this pilot study assessed intermediate endpoints only. Further studies are now required before this tool is used in clinical practice; such studies will need to be multicenter and randomized and should address the impact of the DA on the actual decisions made. Future studies should also assess how patient preferences change over time as the severity of their liver disease changes, and they may also explore the impact of family involvement on these decisions. Family involvement may be particularly important for patients with significant encephalopathy, which was an exclusion criterion for this study. However, this is a feasibility study and suggests that this DA may ultimately serve as a useful educational tool.

In summary, this DA is usable by transplant candidates, improves their knowledge about organ quality, and decreases their reluctance to accept extended criteria organs. If validated in future studies, this could be a useful tool for the transplant community to satisfy ethical requirements to inform patients about organ quality issues in a time-efficient manner.

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