# Live liver donors' information needs: A qualitative study of practical implications for informed consent

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***Background.*** *As live donor liver transplantation is increasingly used to expand the donor pool, concerns remain regarding how best to obtain live liver donors' informed consent. This study assessed donors' information preferences and their perceptions of informed consent.*
***Methods.*** *Cognitive interviews were conducted with donors by telephone about how knowledge items in a new survey instrument were material to informed consent, between November 2011 and April 2012. Thematic analysis was used to analyze qualitative data until reaching saturation.*
***Results.*** *Twenty-nine liver donors participated (85% participation). Donors commonly reported being unable to understand or retain much information disclosed during education. Donors preferred information about major donation risks, eg, death and minor risks that would likely affect their daily lives, eg, wound infection. Donors expressed less interest in information about their rights, confidentiality, or the medical procedure itself. Donors' preferences varied regarding statistical information. Many perceived the disclosure of risk information to be excessive, and rationalized risks they believed to be uncommon or not serious. Donors were disappointed by the brevity of the postdonation hospital stay.*
***Conclusion.*** *Our findings suggest that the complexity and volume of disclosed information during evaluation were difficult for donors to adequately comprehend. Donors' lack of appreciation for the seriousness of complications may undermine their ability to provide informed consent. Future research should develop effective methods of information delivery to enhance informed consent. (Surgery 2016;160:671-82.)*

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Given the shortage of organs for patients in need of liver transplantation, adult-to-adult live-donor liver transplantation (LDLT) has come to be proffered as an excellent treatment option. Approximately 4% of liver transplants are from living donors.[1] Despite the better health outcomes afforded to patients by LDLT, live liver donors undergo major medical health risks, and relatively little is known about long-term health outcomes for donors. LDLT raises serious ethical concerns about unnecessarily harming donors for no direct medical benefit to themselves (nonmaleficence).[2] Transplant clinicians and policy makers require that living donors are well informed to ensure their autonomous decision-making and to ethically justify the procedure.

Despite attention to the importance of living donors' informed consent, numerous studies and systematic reviews report that donors desire more information prior to donation,[3,4] while donors in other studies acknowledge having received all the information they needed to make the decision to donate.[5-7] Furthermore, donor candidates report gaps in knowledge about the risks of donation[4,7-12]

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and experience anxiety over a perceived lack of information provided.[9,10] Little is known, however, about donors' specific information needs about live liver donation,[4,13,14] and even less is known about why such information is important to them and to their decision-making process.[14]

Understanding donors' information needs and how they use desired information is essential for modifying education processes that optimize comprehension for informed consent. As part of the process of developing and refining a survey instrument to assess the quality of donors' comprehension about living donation, we conducted cognitive interviews to assess donors' information preferences about LDLT and informed consent experiences. This article presents donors' information needs, their rationales for preferring certain types of information over others, and their perceptions of risk disclosure and medical care provided before and after donation.

## MATERIALS AND METHODS

**Setting and donor evaluation process.** We conducted cognitive interviews with live liver donors who had previously donated a liver segment at Northwestern Memorial Hospital (NMH) (Chicago, Illinois) between November 2011 and April 2012. Potential liver donors at NMH proceed through 4 phases of evaluation. In phase I, donors participate in group education in which PowerPoint (Microsoft, Redmond, WA) presentations are given by a transplant surgeon about living donation. Thereafter, potential donors undergo blood tests for ABO compatibility testing.

In phase II/phase III (same day), about a week later, donors receive a psychosocial assessment by the social worker, independent living donor advocate, or psychiatrist or psychologist and a history and physical by a physician. Further testing (eg, blood, special protocol magnetic resonance imaging [MRI]) is conducted to assess suitability for donation. The independent living donor advocate discussion entails an informed consent conversation about the risks, benefits, alternatives, voluntariness of donating, etc. A multidisciplinary team reviews all relevant information about the donor, such as the anatomic complexities of the MRI, and makes a decision as to whether the donor will be cleared for donation. The donor is then informed about the decision, and if cleared to donate, the donor is expected to take a "cooling off" period, for approximately 10 days, to reflect on whether he or she wants to proceed with donation.

In phase IV, the last phase of the evaluation, which occurs several days before the living donor procedure, the potential donor and transplant nurse discuss preoperative instructions, donation risks, and specific details of the recipient operation. If potential donors prefer to proceed, the operation is usually performed 2 days later. Disclosure of the risks, benefits, procedures, and alternatives of donation occurs throughout this process through discussion with clinicians and distribution of booklets on the live liver donor transplant process.

Throughout the evaluation process, the living donor surgeon meets with the living donor 3 times, first by telephone, when living donors call the donor hotline for their first encounter, again in person, during the donor medical/surgical evaluation (phases II/III), and lastly in person 2 days before the scheduled operation to discuss the operative risks (phase IV). Donors are informed in phase IV that the mean hospital stay is 2 days after donation to avoid in-hospital infections.

Potential donors and recipients are always educated about the possibility of waiting for a deceased donor graft (Expanded criteria donors/Donation after circulatory death) or a split liver. They are given extensive data on the regional availability of these resources. Additionally, at phase IV of the evaluation process, the transplant surgeon and coordinator again discuss with potential donors and recipients the possibility of cancelling the living donation in the event that a deceased donor graft becomes available. In the past 5 years, 3 LDLTs were cancelled due to availability of a deceased donor organ (in one case a split) and subsequent deceased-donor liver transplant.

After donation, living donors are followed extensively. Living donors are discharged after 2 days in the hospital and stay at a nearby hotel (located 4 blocks from the hospital) for 2–3 nights (longer for out-of-state living donors) to reduce the likelihood of nosocomial infections. NMH provides transportation between the hospital and the hotel. Living donors return for follow-up care at 1 week, 1 month, 3 months, 6 months, 1 year, and 2 years postdonation.

**Study population.** Donors were eligible to participate if they were English-speaking, age ≥21 years, and had donated within the last 3 years. This time frame was selected to enable participants to comment on whether their postoperative experiences matched expectations set in the informed consent process, considering that complications can arise up to 6 years postdonation.[15] Eligible prior donors were mailed a letter inviting participation, followed by a telephone call 1–4 weeks

thereafter. As many as 7 attempts were made to interview donors by phone.

**Cognitive interviews.** Cognitive interviews were conducted to develop a new survey instrument, the Evaluation of Donor Informed Consent Tool (EDICT), to assess live liver donor candidates' comprehension about donation as part of the informed consent process. The final EDICT items and its performance have been previously described; in the study by Gordon et al, more than a year's number of participating living liver donor candidates were provided a copy of the EDICT before donating and were assessed again after donating.[16]

EDICT instrument items pertained to standard consent domains (eg, procedures, risks, benefits, alternatives, voluntariness) that were tailored to the live liver donor context necessary for potential donors to comprehend for providing informed consent to donate. The preliminary item set included 112 items derived from Centers for Medicare and Medicaid Services (CMS) regulations, Organ Procurement and Transplant Network (OPTN)/United Network for Organ Sharing guidelines for donor informed consent, literature reviews, liver-donor consent forms, and an expert panel feedback.

Cognitive "think aloud" interviews were conducted to pretest EDICT's items for understanding by eliciting donors' feedback about each item's meaning, clarity, wording, and preferences for retaining items in the instrument using standard techniques.[17,18] Respondents were also asked open-ended questions about the kinds of information liver donor candidates need to know to give informed consent, how risk information should be presented (eg, using statistics to convey the likelihood of a complication or simply presenting the fact that donors might experience a complication), and demographics. Thus, by describing their information needs, donors shared broader concerns, beyond the EDICT items, about the informed consent process that informs the present paper.

Cognitive interviews thereby enabled the development and refinement of additional instrument items. Cognitive interviews were conducted in an iterative fashion, whereby analysis of initial interview data among a first subgroup of participants entailed subsequent refinement of EDICT items, then a round of additional interviews and analysis, and so forth, until reaching saturation—the point at which no new information emerged.[19]

A trained, master's-level research staff (JM) conducted the interviews by telephone. Interviews lasted between 45 and 90 minutes and were audio recorded and supplemented by hand-written notes. The study was approved by Northwestern University's Institutional Review Board, and verbal consent was obtained prior to each interview.

**Medical chart review.** Living donors' medical charts were reviewed for postdonation complications (eg, Clavien grade, number of readmissions at 30 days and at 1 year, returns to the operating room, endoscopic retrograde cholangiopancreatography [ERCP], and percutaneous transhepatic cholangiography [PTC]) to ascertain whether donors with complications reported some information needs over others.

**Qualitative analysis.** Select portions of interviews pertaining to information needs and the informed consent process, rather than comments on fine-tuning specific EDICT item wording, were transcribed verbatim by JM (who was trained by social scientist EJG). Notes and transcriptions were analyzed iteratively and inductively for emergent themes and patterns using the constant comparison approach.[20,21] Data collection occurred until reaching thematic saturation—when no new themes emerged, and saturation was attained after the 20th interview, which commonly occurs in qualitative research.[19] Themes and patterns were explored and verified during the remaining 10 interviews. Analysis was performed by hand by 1 researcher (JM) and verified by another (EJG) through discussion and reaching consensus. Illustrative quotations are provided below. Themes reflect the concerns voiced by participants; participants who did not comment may or may not have been in support of that theme.

**Statistical analysis.** We used descriptive statistics to assess the mean (SD) distribution of complications across the sample and of demographic variables. Mixed-methods analytic techniques were used to assess whether donors' articulation of themes was associated with their experience of complications, as one might expect that donors with complications would be more likely to express greater information needs.[22] Chi-square tests were performed to assess presence of complications by themes with sufficient samples. As donors had relatively few complications, analyses dichotomized Clavien complications into none versus $\geq 1$ and none versus ERCP and PTC combined. All tests were 2-sided and used a 5% significance level. SPSS software (version 18; SPSS, Inc, Chicago, IL) was used to run analyses.

## RESULTS

**Participant demographic characteristics.** Twenty-nine ($n = 29$) of the 34 live liver donors contacted

**Table I.** Participant characteristics

| | N* | % |
|---|---|---|
| Sex | 29 | |
| Female | 17 | 59 |
| Male | 12 | 41 |
| Age, y, mean (SD) [Range] | 42 (10.8) [21–59] | |
| 21–30 | 5 | 17 |
| 31–40 | 8 | 28 |
| 41–50 | 11 | 38 |
| 51–60 | 5 | 17 |
| Race | 29 | |
| White | 25 | 87 |
| Asian | 1 | 3 |
| Other (Latino) | 2 | 7 |
| Other (mixed) | 1 | 3 |
| Ethnicity | 29 | |
| Non-Hispanic | 25 | 86 |
| Hispanic or Latino | 4 | 14 |
| Marital status | 29 | |
| Married/domestic partner/civil union | 19 | 66 |
| Never married | 5 | 17 |
| Member of an unmarried couple | 3 | 10 |
| Divorced | 2 | 7 |
| Education level | 29 | |
| High school graduate | 3 | 10 |
| Some college/ Associate's degree | 8 | 28 |
| Bachelor's degree | 12 | 41 |
| Graduate degree | 4 | 14 |
| Doctorate (PhD, MD, etc) | 2 | 7 |
| Employment status | 28 | |
| Employed for wages | 22 | 79 |
| Self-employed | 5 | 18 |
| Homemaker | 1 | 3 |
| Total annual household income | 26 | |
| $15,000–$20,000 | 3 | 11 |
| $20,001–$35,000 | 2 | 8 |
| $35,001–$50,000 | 1 | 4 |
| $50,001–$65,000 | 2 | 8 |
| $65,001–$80,000 | 1 | 4 |
| $80,001–$100,000 | 5 | 19 |
| More than $100,000 | 12 | 46 |
| Mo since donating, mean {median} (SD) [range] | 19.0 {18.0} (9.7) [5–38] | |
| 1–6 | 3 | 10 |
| 7–12 | 5 | 17 |
| 13–24 | 13 | 43 |
| 25–36 | 7 | 23 |
| 37–38 | 1 | 3 |
| Relationship to liver recipient | 28 | |
| Spouse | 4 | 14 |
| Parent | 7 | 28 |
| Sibling | 2 | 7 |
| Cousin | 3 | 10 |
| Aunt/uncle | 2 | 7 |
| In-law | 1 | 3 |
| Friend | 8 | 28 |
| Stranger | 1 | 3 |

*Number of respondents varies because some respondents did not answer all queries.

(85%) completed the interview. No respondents refused to participate, but 5 donors who indicated interest were subsequently unable to complete interviews. The average age was 42 years, and most participants were white (87%), females (59%), and held at least a bachelor's degree (62%; Table I). Donors had donated on average (mean) 19 months (range: 5–38; median: 18 months) before the interview. No demographic differences were observed between those who participated and those who were unable to complete interviews.

**Emergent themes.** The following section presents 4 themes: comprehending information, information needs, perceptions of risk disclosure, and donor care. Illustrative quotations are presented in Table II.

*Difficulty comprehending information about living donation.* All donors reported that the evaluation process was marked by an abundance of new information, and they felt "bombarded" with it. Donors noted that the information was sometimes too detailed, too scientifically complex, or simply too much to process. Donors also explained that the medical information was difficult to understand and retain. Because donors found it challenging to learn complex information, they managed information intake by focusing on the information they considered most important. Specifically, donors reported seeking information about postoperative complications and expressed less interest in information about donor rights (eg, confidentiality, right to opt out) or the medical procedure itself.

*Information preferences.* All donors were interested in receiving information about major complication risks. However, they preferred information about major risks that affected their decision to donate and common complications that could affect their daily lives. Moreover, donors expressed ambivalence about the use of statistical information in donor education.

MAJOR ("MAKE OR BREAK") COMPLICATIONS. Several donors explained that they preferred to be informed mostly about complications that would

**Table II.** Illustrative quotations

| *Theme/subtheme* | *Illustrative quotations by theme, subtheme, and presence of complications* | *Complication* |
|---|---|---|
| Difficulty comprehending information about living donation | | |
| | "There's a lot of information that gets thrown at you in a pretty quick time, so I remember there was some stuff that got to me, some stuff I didn't remember at all. I'm not sure what did and what didn't." (Male, 23, donated to parent, #1,019) | PTC |
| | "I went through the material that [the transplant team] had provided. I mean they even provided too much material. They provided two scientific journal articles that were impossible to understand and read, even though I think I got what they were pointing at. But one seemed to contradict the other a little bit… there were certain factors in there that I highlighted and underlined because I really didn't understand them." (Female, 39, donated to husband, #1,014) | PTC |
| Information preferences | | |
| Major ("make or break") complications | "I mean I knew what the risks were, but I guess I didn't know all of the risks. Like for me personally, it was 'Well what are my chances of dying, and what are the chances of [the recipient] dying?' That was the thing I wanted to know the most… I didn't really think about the other complications." (Female, 39, donated to uncle, #1,011) | N/A |
| | "[I wanted to know] things that have happened, how often they happened… what are my chances of the liver won't function right after removing the right lobe?" (Male, 22, donated to cousin, #1,013) | PTC |
| | "To me that was the biggest risk, was that I would die. I don't know that I felt that there were any other major risks." (Female, 46, donated to stranger, #1,002) | PTC |
| | "I don't think you always need the statistic [on the likelihood of complications], but when it comes to the probability of dying I think it's definitely important." (Male, 23, donated to parent, #1,019) | PTC |
| Common complications that impact daily life | "I had this eye infection from hell that I got right away, it looked like I had pink eye. They had seen it before I was officially released from the hospital… It took 3 months to clear because my body was so busy, I guess, fighting [for] the liver… I also got these weird rashes that I guess are not uncommon when you've had a major trauma to your body… I felt very surprised by all that. So when I was thinking complications, I was thinking more the bigger deal stuff, but this little stuff really was annoying. I wish I did know more about that. Doesn't mean I wouldn't have done it [donated], but I wish I would've known more about it, I wouldn't have been as nervous [when the infections occurred]." (Female, 46, donated to stranger, #1,002) | PTC |
| | "You know, how the [postdonation] fatigue is going to affect you… it could affect your concentration, and being able to put together concepts… So they tell you that while your liver is growing… the body is giving all these resources to the growing liver, so yeah, there's not so much resources going everywhere else. But I did not understand that it was gonna take me so long… I couldn't even watch TV and understand what was going on, it was really, really that bad." (Female, 43, donated to parent, #1,035) | PTC |

(*continued*)

**Table II.** (*continued*)

| *Theme/subtheme* | *Illustrative quotations by theme, subtheme, and presence of complications* | *Complication* |
|---|---|---|
| | "The big thing that I wanted more information [about was] more of after the surgery, more from a nutrition perspective. What food should I be eating? My liver is burning 4,000 calories… I even asked [the transplant team] and they're just like, 'Oh, you just eat anything.' I'm like, well, no, you can't just say you eat anything… am I supposed to be doing Blizzards [milkshakes]? (Male, 49, donated to friend, #1,039) | N/A |
| Ambivalence about statistical information | "I like stats, I'm an odds person. I wouldn't remember 65%, but I'd remember "pretty good chance." (Male, 22, donated to cousin, #1,013) | PTC |
| | **"**Keep it general, people don't remember exact statistics." (Male, 31, donated to parent, #1,042) | N/A |
| | "Not specific numbers, but maybe 'high' or 'low' likelihood? The statistic is not as important as the risk itself." (Female, 48, donated to friend, #1,009) | PTC |
| | "[Risk of donor liver failure is] an important thing that the donor [should] be aware of, but… that could be accompanied with a likelihood. (Male, 29, donated to friend, #1,027) | N/A |
| | "Maybe it's good for people who are thinking about donating to look at the actual statistics. But from my perspective, after donating, the actual statistics… it's kind of interesting, but it's not really that critical. Is there a risk? Yes or no? Is the risk low or high? Whether it's 9% or 13% from my perspective is kind of insignificant." (Male, 49, donated to friend, #1,039) | N/A |
| Disinterest in knowing the medical procedure | "I'm a little indifferent [to the fact that I could need a blood transfusion]. I'm pretty much assuming they're [the transplant team] gonna be able to take care of me." (Male, 31, donated to parent, #1,042) | N/A |
| | "I mean, I don't know if some people would care [whether they're in the ICU], but if I knew I was in the hospital, I wouldn't really care – like Intensive Care Unit, General Unit, whatever." (Male, 23, donated to parent, #1,019) | PTC |
| | "I am not going to be deciding whether to – in fact I'm happy that I have a breathing tube, because if I stop breathing, I want you be to be able to resuscitate me… I would expect it to be already implicit with the surgery… You might have a little sore throat or something [afterwards], but that's not gonna make or break my decision, for sure." (Female, 47, donated to sibling, #1,040) | N/A |
| | "Because [members of the transplant team] know what part they have to remove, how big they have to remove. They know what they're doing, what they have to do. They let us know how [much] is gonna be taken." (Female, 43, donated to sibling, #1,008) | PTC |
| Donor rights and confidentiality | "I'm trying to think of the possibility that before a transplant that [confidentiality] would really be relevant to me. Because in my circumstances I was donating to my mom, I wouldn't really care." (Male, 31, donated to parent, #1,042) | N/A |
| | "I really don't care… I was a donor to my husband, so I knew all his test results." (Female, 42, donated to husband, #1,029) | N/A |

(*continued*)

**Table II.** (*continued*)

| *Theme/subtheme* | *Illustrative quotations by theme, subtheme, and presence of complications* | *Complication* |
|---|---|---|
| | "Their [donors'] main concerns are gonna be pinpointed to what's gonna happen to them. I don't think they really care that their information's shared [with the recipient]… if they're there for that recipient, they're not gonna hide anything anyway." (Male, 53, donated to in-law, #1,032) | Readmission within 30 days for drainage of bile leak, Clavien Grade 3a, ERCP |
| Perceptions of risk disclosure | | |
| Excessive risk information | "Just before I donated, [the surgeon] came and talked to us… and he came in the room and he asked me if I was ready, and I said, [upbeat tone] 'Yeah I'm ready!' And I was smiling or whatever, I guess I was too pleasant. Well he said to me – he got very angry, and he said, 'Well I don't think you're taking this seriously enough. Don't you realize you could die? Your life could be over!' is what he said to me, and I said [softly], 'And I understand that, but you need to understand that if something happens to my husband, my life is over anyway. So I'm willing to do this.' He wasn't being mean, he was afraid I guess that I wasn't understanding the seriousness of all this." (Female, 58, donated to husband, #1,046) | N/A |
| | "A lot of this stuff [risk information] you don't need to get into… I knew what my mission was, and I knew what I wanted to do, and no one was gonna talk me out of it. Actually I think I had to talk the doctors into doing it… It bothered me that they tried to talk me out of it. (Male, 59, donated to wife, #1,023) | PTC, Clavien grade 2, Clavien grade 3b, operating room readmission for hernia repair |
| Rationalization of donation risks | "[Postdonation depression is] something that is gonna come down the road. You don't wanna scare somebody off, and that's a scare-off, with the depression and all that other stuff. I'd dump that, they'll find out eventually. And they may not have a problem!" (Male, 59, donated to wife, #1,023) | PTC, Clavien grade 2, Clavien grade 3b, operating room readmission for hernia repair |
| | "I'm just afraid that [the item stating that 'Little is known'] would frighten people, possibly… I think that people that want to give, that really, that are thinking about donating… they need to know everything about what's gonna happen, that's why I think these questions [about risk] should stay. But I think you should probably try to give them as much information as you can without scaring the crap out of them." (Female, 58, donated to husband, #1,046) | N/A |
| | "I'd say that they do know a good amount about [liver donation], otherwise they wouldn't be doing it." (Female, 24, donated to friend, #1,003) | PTC |
| | "True… just because it's only been happening for 12 years, but I don't feel like it's fair to call that much attention to that." (Male, 29, donated to friend, #1,027) | N/A |
| | "I'm sure they've been doing it for a long time. But I don't think I would have that in there, telling people we don't know long-term effects… I guess you're kinda telling someone up front, 'We don't know down the road whether you're gonna have issues.'" (Male, 40, donated to parent, #2,001) | N/A |
| | "I don't really believe that little is known any longer, because it's like 30 years now or something, but you need to have that factor of just you don't know." (Female, 39, donated to husband, #1,014) | PTC |

(*continued*)

**Table II.** (*continued*)

| *Theme/subtheme* | *Illustrative quotations by theme, subtheme, and presence of complications* | *Complication* |
|---|---|---|
| | "When I donated, I remember that Northwestern had a really good success rate with it, and I know that they had been doing it for a while, and they were one of the hospitals in the country that had done the most." (Female, 49, donated to cousin, #1,043) | PTC |
| Perceptions of postdonation care | | |
| The shock of hospital discharge | "I got one freakin' night [in the hospital]. That's bullshit, by the way [laughs]. I understand why you only get the one night, but let me tell you, that is not easy. I totally get why they do it… They're worried about you getting diseases that are hard to fight off. So the head dude said… 'I can cure you of anything you catch at the hotel, but I cannot guarantee I can cure of anything you might get here'… While you're in the process of trying to get better it's not fun. You go to a hotel, and it's just a regular bed, not a hospital bed, so you're trying to get up, and your stomach has no stomach muscles, and it's very painful." (Female, 46, donated to stranger, #1,002) | PTC |
| | "I would make sure the donor knows they're only going to be in the hospital two nights, because I was shocked at that!… Because I was terrified that they sent me home that soon. I was really scared… it was so close after surgery, and I had this tube coming out of me, and I was terrified to go home." (Female, 39, donated to friend, #1,020) | PTC |
| | "For me personally, knowing that they wanna get you out very quickly is very important. As far as knowing that they're gonna take care of you if something happens, then they're gonna keep you, I think that's very important, too." (Female, 39, donated to husband, #1,014) | PTC |
| | "Well, they told me I would stay two nights. And I know that they try to get people out of there pretty fast. I ended up staying three [nights], because I was throwing up, and it was pretty terrifying. My husband was like, 'She is *not* leaving this hospital until you get this under control' [laughs]. But I know they do want you out of there." (Female, 48, donated to friend, #1,009) | PTC |

*N/A*, Not applicable.

"make or break" their decision to donate. As most donors noted, only the risks of major complications, like liver failure or death, could have had such an effect on their decisions. By contrast, donors considered details with no bearing on their decision to donate as less important; this included information about postdonation fatigue.

COMMON COMPLICATIONS THAT IMPACT DAILY LIFE. Some donors desired a pragmatic approach to information disclosure that described the types and duration of likely and common complications that could adversely affect their daily lives during recovery. They also preferred information about other post-transplant situations (eg, temporary changes in cognitive or bodily functions, nutrition issues) that would require significant medical attention. One donor described postoperative infections that she would have liked to have been prepared for, even if they would not have affected her decision to donate. Similarly, another donor described experiencing an unanticipated delayed cognitive functioning following the transplant, which she attributed to the donation. Still other donors expressed broader concerns about everyday life post-donation regarding daily nutrition.

DISINTEREST IN UNCOMMON OR LESS SERIOUS COMPLICATIONS. Donors offered guidelines on complications that they did not want to learn about. Donors were disinterested in complications that seemed unlikely to occur or that they believed would cause only minor inconvenience. Many donors

downplayed the seriousness of complications that were perceived as either uncommon or not immediately life-threatening, including bile leaks or the need for a blood transfusion, believing that these complications posed insignificant risks. Donors reported that serious but uncommon or low-severity risks (eg, infection) were not substantial enough to merit their attention.

AMBIVALENCE ABOUT STATISTICAL INFORMATION. Donors expressed concerns about the use of statistics in the education process. In some cases, donors considered statistics helpful for concisely conveying specific risks and the likelihood of adverse outcomes. Others, however, voiced strong aversion to the use of percentages, asserting that statistics were difficult to understand. Donors opposed to statistics felt that statistics went beyond some people's comprehension. Most donors, however, fell somewhere between these 2 extremes. They struggled to digest statistical information but did not come to a clear conclusion about the use of statistics in donor education. When considering our proposed survey items that included frequencies and percentages, donors became highly ambivalent.

DISINTEREST IN THE MEDICAL PROCEDURE. Overall, donors expressed little interest in details about the medical procedures involved in donating. For example, donors were disinterested in where they would stay in the hospital (the intensive care unit), whether they would be intubated during the operation, or whether they might need a blood transfusion or colonoscopy. Donors perceived that these procedures and their risks were unlikely to entail complications. Several donors explicitly or implicitly conveyed that the transplant team would handle "routine" aspects of the procedure. Further, donors described such information as having no effect on their decisions to donate. For example, when asked about the amount of the liver that is typically removed for donation, one donor reported having had no idea and explained that the transplant team was expert enough to decide how much to take.

DONOR RIGHTS AND CONFIDENTIALITY. Donors expressed disinterest in explanations of confidentiality and donor rights, despite the transplant team's required efforts to inform donors of their rights. Most donors ($n$ = 20) donated to a family member and stated that they were comfortable sharing their confidential health information with the recipient. Donors did not believe that keeping their health information confidential from their recipients was important, because recipients were family members who were emotionally intimate and because donors were focused on the health outcomes of donation (eg, whether they would experience complications).

*Perceptions of risk disclosure.* Donors perceived the disclosed risk information to be excessive. Many donors downplayed the seriousness of risks and rationalized these risks, often by deferring to the expertise of the transplant team.

EXCESSIVE RISK INFORMATION. Donors reported that the transplant team's disclosure of risk information seemed excessive and made them feel uneasy. They disliked being repeatedly warned of donation risks and having to justify to the team their reasons for donating. Some donors misunderstood the transplant team's cautionary approach and perceived the team as trying to discourage them from donating. For example, one donor explained that he had committed to donating to save the life of his wife (the recipient) and reported feeling uncomfortable with the transplant team's attempts to ensure he understood the risks.

RATIONALIZATION OF DONATION RISKS. In reference to the survey instrument items pertaining to risk, some donors reported that the risks were either overblown or too shocking, even though they derived from CMS regulations and OPTN guidelines.[23,24] Donors stated that some risks were insignificant and that mentioning them would only "scare" potential donors from donating. Some donors discouraged us from including items in the survey instrument that stated, for example, "I may feel depressed, anxious, or emotionally distressed before, during, or after donation."

Although donors acknowledged the need to inform potential donors of the risks of donation, they preferred a softer approach. Donors downplayed the relevance of risks and thus rationalized the riskiness of donation. Donors' rationalizations were especially strong in response to the item stating, "Little is known about how donating affects liver donors' health in the long-term." Although most donors understood the statement to be true, they reported maintaining trust in the safety of the live liver donor procedure because it has been performed for what they perceived as a "long time." Moreover, many donors relied on the expertise of the transplant team to justify their rationalizations. Risk information was less important to them because they trusted the transplant center's reputation for success.

*Perceptions of postdonation care.* Donors reported that their experiences of care after donation did not meet their expectations. Donors expressed dismay, "shock," and "terror" at the brevity of their hospital stay postdonation (≤48 hours). Although

donors recognized why the stay was brief—to prevent hospital-acquired infections—they reported feeling too vulnerable to be discharged so soon after the donation. Some donors also felt afraid of being discharged because they had already experienced complications and were readmitted to the hospital shortly thereafter. Other donors explained they had to "beg" and bargain with the transplant team to stay and receive the care they had expected postdonation. Donors expected closer supervision from the transplant team and desired quicker access to information about addressing unanticipated complications following donation.

**Complications.** Living donors had few complications: Clavien grade 1 ($n$ = 1), grade 2 ($n$ = 3), grade 3a ($n$ = 3), grade 3b ($n$ = 2); readmission within 30 days ($n$ = 2) and 1 year ($n$ = 1); operating room returns ($n$ = 5 [but 4 times for 1 patient]); ERCP ($n$ = 2); and PTC ($n$ = 18). There was no significant relationship between having a Clavien complication or ERCP/PTC and expressing the theme of "rationalization of donation risks" or expressing an "information preference" overall, except that donors with an ERCP/PTC complication were less likely to express an "information preference" ($P$ = .02).

## DISCUSSION

This qualitative study assessed live liver donors' informational needs and experiences of informed consent for liver donation. Overall, our study found that donors had serious concerns about the amount and type of information disclosed, unmet information needs, and conflicting perceptions about risk information, and they experienced unmet expectations about postoperative care. In a systematic review, we previously identified donors' knowledge gaps about risks and their unmet information needs about LDLT,[4] though studies have not detailed donors' specific information needs or concerns about consent. The present study advances understanding of informed consent for LDLT by describing in-depth *what* information donors preferred to learn and suggesting *why* donors have knowledge gaps.

Some donors reported being either unable or unwilling to learn the information. Donors had gaps in knowledge because they could not meaningfully process the large amount of complex information disclosed to them. Donors found the complexity and volume of information disclosed during the evaluation process too difficult to comprehend, and retained only a portion of the disclosed information. Moreover, donors chose not to learn about information they perceived as superfluous to their decisions to donate.

We found incongruities between donors' expectations for informed consent and actual experiences of care. Donors disliked the transplant team's heavy emphasis on the riskiness of donation. Donors reported not seriously considering most risks of complications and, instead, placed great trust in the transplant team that liver donation was a safe enough procedure to undertake. Donors believed that less probable risk outcomes could be ignored because the transplant team was expert enough to prevent those outcomes from occurring. Donors reported perceiving the transplant team as being so successful that the disclosed risk information seemed highly unrealistic.

Other research studies have similarly found that donors downplayed major risks[3,14] and perceived risk information as excessive.[25] Additionally, donors in other studies have reported that risk information is "not important in their decision [to donate],"[4] because they wished to save the recipient's life.[13,26] Although the sample was too small for subanalyses, the donor's relationship to the recipient may have played a role in their minimizing of risks. A factor contributing to this pattern of ignoring "routine" risks was donors' expressed familiarity with operative risks. Other research similarly found that donor candidates "perceived themselves as experienced in surgeries or medical issues."[4]

Additionally donors disliked their swift hospital discharge (within 48 hours of the transplant), and the team's seemingly casual response to minor postoperative complications. Early discharge is our transplant center's standard of care. Discharge is not to "home" but rather to a Residence Inn hotel proximal to the hospital with daily phone contact with a physician (Dr Baker [coauthor] who is the director of the Liver Living Donor Program).

Although the 2-day duration of stay is designed to reduce the possibility of infection, better preoperative education may be needed to set expectations. That is, donors expected contradictory forms of care: autonomy in the preoperative period and protectionism in the postoperative period. Notably, donors' lack of concern with some risks suggests their expectation of paternalism from the transplant team, which may have undermined donors' informed consent.

The discrepancy between expectations and experiences suggests that donors may need to be better prepared for their postoperative care. These findings suggest that donors may not have

sufficiently understood the seriousness of risks associated with donation and may not have been adequately prepared for the team's postoperative interactions. From a traditional ethics perspective, donors' limited appreciation for the seriousness of donation risks may compromise their ability to provide informed consent.[3,4] However, our findings may challenge the value clinicians place on risk information believed to be material to patients' decisions. Providing donor candidates with more information about risks, therefore, might not be a viable strategy to enhance informed consent.

The informed consent process requires open communication to facilitate education and comprehension. However, communication may become inhibited when donors perceive the transplant team to be "working against" their donation or trying to "scare" them. Clinicians should be careful to avoid language that might create undue fear in donors[4] and should cultivate empathy between themselves and donors to improve risk communication.[27] Additionally, clinicians should better explain the importance of risk disclosure about LDLT and help potential donors understand how to interpret the risk information.[28]

Still, the question arises as to how clinicians should handle the situation of donors desiring less information. One option may be for clinicians to make potential donors aware of the availability of information on the various types of risks and then ask them what risk information they do and do not desire. As informed consent is the means by which donors express their autonomy, then donors can express their right not to be informed.[29] This patient-centered approach to information disclosure may be perceived as "softer," because the donor guides the pace and content of information disclosure according to his or her information preferences.

Although donors desired specific types of information that they perceived were not provided, delivering more information may not necessarily optimize the informed consent process. Therefore, the most crucial information should be delivered more effectively, through the development of decisional aids.[30,31] Layering information in decisional aids, ranging from basic to more complex, in-depth explanations, could satisfy patients' information preferences for more or less information and clinicians' obligations to disclose risk information. Health information technology interventions can enhance informed consent by improving patients' objective comprehension of medical procedures, decreasing patients' anxiety levels, and increasing satisfaction with care.[32] Such interventions are appropriate for accommodating various learning styles and information needs that donors discussed, such as varied preferences relating to the use of statistical information.

Contrary to expectations, we found no significant relationships between presence of complications and themes of "rationalization of donation risks" and having expressed an "information preference," except that donors with an ERCP/PTC complication were less likely to express an "information preference." A larger sample size may better illuminate the distribution of themes among donor participants.

This study's strengths include a relatively large sample of adult-to-adult live liver donors and a qualitative and mixed-methods approach that provided in-depth insights into donors' perceptions of informed consent and their breadth of experiences with donating. Our participation rate was comparable with other qualitative studies of live liver donors.[13,14]

There are, however, study limitations. Findings from this single-center study may not be generalizable to donors at other transplant programs, particularly as the informed consent and care processes likely vary across programs in both structure and content of information disclosed, as other research shows in the kidney donor context.[33,34] Participants comprised a highly educated and socioeconomically established group, which may not generalize to other living donors. This finding, however, is consistent with other studies.[25,35]

Additionally, given the retrospective design, participants' comments may be limited by recall bias, though comments spanned positive, neutral, and negative experiences. Further, there is selection bias by interviewing only those who have donated. It is unknown how the LDLT recipient outcomes influenced donors' responses. Future research should assess information needs and preferences of live liver donors at other programs.

In conclusion, live liver donors perceive problems with information disclosure as part of the informed consent process and have unmet information needs. To prevent information overload while also helping potential donors to better appreciate the import and meaning of donation risks in their lives, innovative approaches are needed to simplify and convey risk information in a comprehensible manner, such as through the use of decisional aids.

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