

PAPER

Live liver donation, ethics and practitioners: 'I am between the two and if I do not feel comfortable about this situation, I cannot proceed'

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ABSTRACT

This paper discusses the views of 17 healthcare practitioners involved with transplantation on the ethics of live liver donations (LLDs). Donations between emotionally related donor and recipients (especially from parents to their children) increased the acceptability of an LLD compared with those between strangers. Most healthcare professionals (HCPs) disapproved of altruistic stranger donations, considering them to entail an unacceptable degree of risk taking. Participants tended to emphasise the need to balance the harms of proceeding against those of not proceeding, rather than calculating the harm-to-benefits ratio of donor versus recipient. Participants' views suggested that a complex process of negotiation is required, which respects the autonomy of donor, recipient and HCP. Although they considered that, of the three, donor autonomy is of primary importance, they also placed considerable weight on their own autonomy. Our participants suggest that their opinions about acceptable risk taking were more objective than those of the recipient or donor and were therefore given greater weight. However, it was clear that more subjective values were also influential. Processes used in live kidney donation (LKD) were thought to be a good model for LLD, but our participants stressed that there is a danger that patients may underestimate the risks involved in LLD if it is too closely associated with LKD.

BACKGROUND

Despite continuing progress in immunological understanding and transplant capabilities in recent years, the supply of suitable cadaveric livers for transplantation fails to meet demand.^{1 2} This shortfall is increasing annually, resulting in a growing number of patients dying while on the transplant waiting list¹ suggesting that supply rather than medical capability is the greatest obstacle to saving the lives of those on the list. One strategy for increasing supply is to encourage live liver donations (LLDs), a strategy that has worked well for kidneys. LLD is possible because a healthy donor liver will normally regenerate to almost its pre-operative volume,³ and if appropriately matched for blood and anatomical suitability, transplantation is viable. Three hundred and ninety-two LLDs were undertaken in Europe in 2009⁴ and a further 219 in the USA.² LLDs still only account for 0.07%⁵ and 0.03%² of liver transplants in Europe and USA respectively, with great scope for increasing this proportion. Living kidney donation (LKD) now

accounts for approximately 39% of worldwide kidney transplants, and if LLD were similarly successful, this would represent considerable progress to close the supply gap.⁶

LLD is, however, more risky than LKD: it carries a 1 : 2 risk of donor morbidity⁷ and between 0.1% and 2% risk of donor mortality,⁸ even though it also offers significant benefits to recipients. These include optimal transplant timings and a lower associated mortality than the alternative of waiting for deceased donor liver transplant.⁹ Ethical concerns include fears of impaired donor autonomy,¹⁰ external pressures to donate¹¹ and the permissibility of harming one individual to benefit another.¹² Healthcare professionals (HCPs) are essential to the process of guiding donors and recipients through the decision to undertake an LLD. In addition to their responsibility to provide appropriate care to donor and recipient, they often act as guardians of patient autonomy and arbiters of the risks and benefits of the operation. In this respect, their views on the ethics of LLD may influence the decisions made by donors and recipients.

Existing literature suggests that HCPs' support for LLDs is strong if the recipient is a family member but is often significantly weaker if the donor and recipient are unrelated.¹³⁻¹⁵ Some variation is also found in the acceptance levels between different HCPs.¹³ Nevertheless, all research to date on the views of HCPs has used surveys and provides little detail on the strength of, or the justification, for their views. Furthermore, because these studies took place in countries where live organ donation is more common (eg, Japan⁶) or where cadaveric donation rates are high (eg, Spain¹⁶), these results are not necessarily applicable to countries (such as the UK) where cadaveric rates are low.¹ This absence of appropriate research data provides a reason to investigate HCPs' views on the acceptability of LLDs, their justifications for those views and the influence; these may have over the decision-making process in the UK clinical context.

METHODS

The aim of the study was to undertake an empirically informed analysis of the decision making around LLDs in one UK transplant centre, using two research questions: (i) what are HCPs' attitudes towards the ethics of living organ donation? and (ii) how do HCPs' views influence and inform decision making with respect to LLDs?

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Design

Semi-structured, face-to-face qualitatively analysed interviews were undertaken to determine the attitudes and opinions of HCPs in one UK liver transplant centre. Interviews were chosen to enable participants' comments to be clarified and gently probed, thus reducing interviewer bias by favourable interpretation.¹⁷ A topic guide (figure 1) covering the assessment of donor and recipient suitability and HCP opinions was used to ensure consistency between interviews.

Recruitment

The research population included all (approximately 50) HCPs who were involved in a professional capacity with organ transplantations (the transplant 'team') within the liver transplant centre.

Inclusion criteria: worked as a member of the transplant team for a minimum of 6 months (not necessarily at the same hospital) irrespective of whether they had any LLD experience.

Exclusion criteria: unable to organise a mutually convenient time for interview.

Participants were recruited by email during January or February 2012. A reminder email was sent after 2 weeks to all potential participants. Consent was obtained before each interview. Each interview was recorded on a dictaphone, and all were transcribed verbatim according to simple transcription conventions. A favourable research ethics opinion was gained from the BMedSc Population Sciences and Humanities Internal Ethics Review Committee and R&D approval was gained from the relevant NHS trust.

Data analysis

To fulfil the exploratory aim of the research, the data were analysed using conventional content analysis (as described by Hsieh and Shannon),¹⁸ which was chosen because the aim of the analysis was to describe rather than to theorise about the attitudes of the participants. Coding was achieved by ET immersing herself in the data, then noting her impressions and labelling specific segments of data with code words (which described the thematic content). HD independently coded a selection of the transcriptions and ET and HD then agreed the codes. After discussion between ET and HD, categories were then generated

from the amalgamation of multiple similar codes. Similarities between categories were then identified and fundamental themes in the data emerged that represented the views of the participants.

RESULTS

Participants

Seventeen HCPs (from the population of 50) agreed to be interviewed. Gender and professional roles are shown in figure 2. Direct participant experience averaged between two and three LLD procedures. Four participants had no direct experience, but two had extensive experience (following work placements in transplant centres that routinely undertook LLDs). Interviews lasted between 17 and 43 min but averaged 27 min.

Overarching themes

The majority of the data fell into one main theme (Protecting the Donor) and with a lesser theme (Recipient's Decision) accounting for the remainder. There were several categories in the main theme: the respect for donor autonomy, the protection process and the risk of harm. Several subcategories fed into each of these categories. Donor autonomy, for example, was associated with 'volunteering' and 'whose perception?' subcategories. Several categories, subcategories and codes were inter-related, and the data were allocated to the most appropriate category in these cases. A summary of the research results is found in figure 3.

Key findings

The participants' greatest preoccupation was with protecting the donor.

At the end of the day, you're there to protect the donor. (P8)

It's important that we protect the donor. (P16)

Although not all participants referred directly to the need to protect the donor, the issues they raised reflected this concern, which arose from the unanimous recognition of the risks associated with the procedure.

you're having to do harm to an innocent party to benefit somebody else. (P1)

Figure 1 Summary of topic guide.

<u>Summary of Topic Guide</u>
<ul style="list-style-type: none"> • Assessment of participant experience with LLDs. • Why LLD is perceived as a controversial procedure. • Potential benefits of LLD. • Donor Voluntariness. • Assessment of best interests. • Communicating risks. • Understanding of risks. <ul style="list-style-type: none"> • Influence of type of relationship between donor and recipient. • Influence of previous experience on HCP risk perception. • Family reaction to refusal of donor consent to donation. • HCP reaction to refusal of donor consent to donation. <ul style="list-style-type: none"> • Willingness to provide a medical excuse. • Recipient willingness to request donation. • How harm and benefits are balanced. <ul style="list-style-type: none"> • Influence of type of relationship between donor and recipient. • Individual with most decision-making influence (recipient/ donor/HCP). • Assessment of donor and recipient appropriateness for donation.

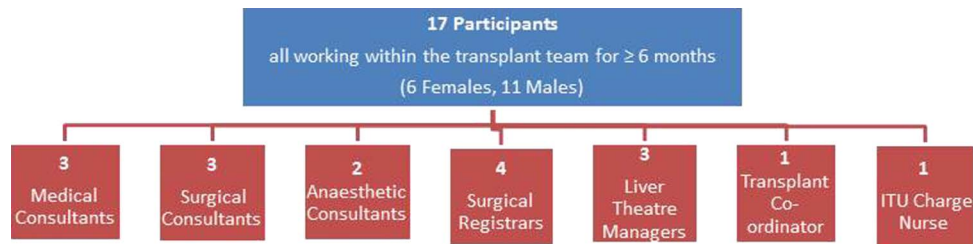


Figure 2 Healthcare professions represented in the study.

I find that on the donor part, you are taking somebody who is completely fit and well and inflicting a massive wound on them, the potential for liver failure on them, the potential for them needing a liver transplant and potentially dying. (P13)

Many participants also thought that if the risks to the donor were manifested, this would harm the HCPs involved too.

If you think how donor deaths have devastated transplant teams, there's also risks to the team that's involved so there's a lot of things to take into account. (P15)

Participants also appreciated, however, the importance of respecting the potential donor's autonomy.

It's the donor that's got the risks I think, so the donor's views and um.. perceptions and motivations, everything has to dominate the whole process I think. (P3)

Although largely preoccupied with the donor, the participants were not oblivious to the wishes of the recipient. Indeed, some

were clear that the recipient had something of a final say, given that their refusal of consent would halt the prospect of an LLD.

As the recipient, I would like to say that I would make the final choice. If everything was to go ahead, I think it should be me because it would be me that would be causing the issues to the donor. (P14)

At the same time, autonomy of both donor and recipient seemed to be regarded as secondary to the willingness of an HCP to undertake the procedure.

I'm the third party in this. I'm between the two and if I don't feel comfortable about this situation, I can't proceed. (P4)

if it becomes clinically impossible, then that's another factor that's taken out of their hands. (P11)

Influential to this willingness for many participants was their own evaluation of acceptable donor risk taking. This seemed to occur prior to the donor's own assessment.

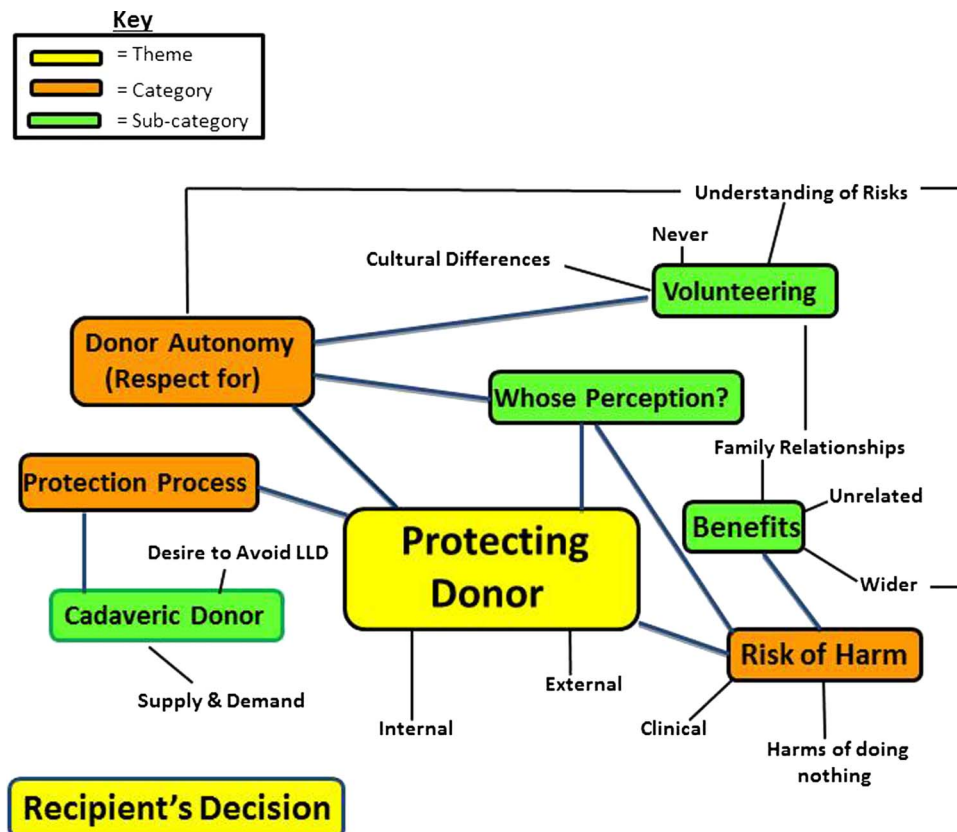


Figure 3 Summary of interview research findings.

You can't offload one risk for another. It is difficult. I think you've got to try to work for the best outcome for the both sides. (P12)

In their attempt to protect the donor from what they believe to be unacceptable risk, many participants suggested a willingness to accentuate the risks involved.

you can project it in such a way that it's not the mere numbers. (P5)

there are ways of putting it across. (P8)

Despite awareness of the potential for donor harm, almost all participants also recognised the possibilities for donor benefit.

I think that there are benefits, but maybe they're harder to quantify and they're a bit less objective in the donor than they are in the recipient. (P1)

These benefits were given greater weight when the potential recipient was a family member, which suggests that the evaluation of the potential risk is not a purely clinical one.

depends how strong the relationship is, the more psychological benefit the donor is going to get from the procedure. (P2)

when they've donated to their children and their children get well, there's nothing better than that. (P13)

In addition to a perceived increase in potential benefits, emotional relationships between the donor and the recipient were also frequently associated with increased levels of donor risk taking, particularly when the donation was from a parent to his or her child.

[parents are] even more prepared to take the risk. For a parent to child, I'm sure a parent would be prepared for risk of death even, if it was to save a child's life. (P2)

The recognition of the emotional complexity of family member live donation led many participants to worry about whether the donor's consent could ever be truly voluntary.

the psychological pressure on yourself as a donor, but also from other family members if you're the match, I think must be horrendous. And in a way, you lose your autonomy. (P13)

Suspensions about donor voluntariness were also tied to ethnicity and, particularly, to concerns about unacceptable financial incentives and external pressures to donate.

I know there are some ethnic groups where they could force family members and force the family members, not ask. Force. (P5)

The participants felt it was important to protect donors from coercion and emphasised the need to separate the assessment of donor and recipient to reduce the opportunities of deliberate or unintentional coercion on the part of either the recipient or an HCB, thereby promoting donor voluntariness.

it's important that the two processes remain separate so there is no conflict of interest. (P6)

Although participants wanted to protect the donor, there was a mixed response to providing a false medical excuse to enable an unwilling donor to withdraw from the donation process. Those willing to do so argued, 'that's all a part of the slightly grey ethics that go with part of being a doctor'; (P1) 'it's probably less harmful for the couple, the donor and the recipient, just to say something medical rather than saying that the donor didn't want to proceed'. (P17) Those unwilling argued, 'I think

when you're trying to protect the person, you need to be honest'. (P11) Nevertheless, patient confidentiality could be used to prevent disclosure of a potential donor's reasons for withdrawing from the process.

That is basically lying and I think that's wrong. I would go back to confidential reasons. (P15)

Although agreeable to the possibility of coercion when the donor and recipient are related, most participants were either wary of, or opposed to, altruistic stranger donation.

it's nice to be nice to other people but it's a strange thing. For me, it's difficult to understand at this moment, I wouldn't consider it really. (P17)

This wariness is consistent, with the participants' perceptions that a close relationship tips the risk equation towards donation. Although strangers are not subject to family coercion, it may be less obvious what they gain from the process of donation to off-set the risk of harm.

Absence of voluntariness was not the only concern raised about the possibility of gaining valid consent to LLD. Participants were also concerned about donors' *understanding* of the associated risks:

Honestly? No. I don't think people understand risks every single day we anaesthetise them. They don't have a clue. (P13)

People, society in general doesn't understand what risks entail. (P15)

Some participants thought there was a widespread misconception that the risks associated with LLDs are similar to those associated with LKD.

People see liver transplantation, live liver donation as the same as being a kidney donor and it's obviously not the same. The risks are much greater and obviously the outcomes can be worse. (P13)

Another way of meeting the shortfall in donated livers and avoiding risks to donors is to increase the number of cadaveric donations. Our participants were mindful of this alternative.

if there were plentiful cadaveric donors, then it would not ever, or very rarely be an issue to be considered or discussed. (P3)

Nevertheless, many recognised that not proceeding with an LLD could be more harmful on balance than proceeding with it.

when there is no option for cadaveric or when we think that with cadaveric donation, he may not make it because of the long waiting list. That's [LLD] an option. (P16)

DISCUSSION

This study only presents the views of participants from one transplant centre and data was not collected on the views of donors or recipients. To the extent that the whole population was invited to participate and only 17 were willing to be interviewed, the sample is self-selected, and we cannot be confident that data saturation was therefore achieved. Consultants or registrars are over-represented in the sample, but they are likely to bear greatest responsibility for proceeding with an LLD. Results should be interpreted in light of these limitations.

Three important themes run throughout the participant interviews. First, this study highlights the benefits and pitfalls of using LKT as a model for the introduction of LLD programmes. Second, while the literature might idealise the decision-making process as a negotiation between all the stakeholders

(ie, donors, recipients and caregivers), HCPs often retain a large degree of control over the process as guardians of the donors' interests. Finally, unpacking how HCPs balance the risks and benefits to donors and recipients is crucial to understanding the acceptability of LLDs to HCPs and their willingness to allow donors to make autonomous choices.

Live kidney donation

It is perhaps inevitable that LKD is regarded as something of a model for LLD. But, mainly due to the significant difference in the degree of risk undertaken with each procedure, the participants were understandably cautious about using LKD as a model for LLD. They were also concerned that patients and their families should not be falsely reassured by the successes and normality of LKD. Its associated risks and benefits are less well understood than LKD, and comparisons made between the two may mask this. Participants did, however, suggest that safeguards introduced in LKD procedures, such as seeing potential recipients and donors separately and together at different phases, could be transferred across to LLD. On balance therefore, although some of the safeguards found in LKD may be usefully transferred to LLD, LKD may not be the best template to introduce patients and families to LLD.

Negotiated autonomy

In agreement with the existing literature on live donation,^{11–19} our data illustrates the complexities and the difficulties encountered when a decision-making process involves three parties: the patient (ie, the recipient), HCP and the donor. In accordance with the literature, participants viewed the situation as ethically clear cut when either the recipient or the donor is unwilling to consent—that is, the LLD ought not proceed—but viewed the decision-making process as less straightforward when the HCP is the only unwilling party. Participants expressed a variety of opinions on the relative influence on the decision-making process of donor and HCP assessment of the risks and benefits in instances where the HCP was reluctant to perform the LLD. Some stated that the donor's opinion was most influential, while others believed that if the consulting doctor was uncomfortable with the donation, the donation ought not proceed, regardless of donor and recipient opinions.

There are two ethical narratives that might justify each view of the decision-making process. On the one hand, since the donor and recipient are those whose bodily integrity are at risk, it is tempting to suggest that the views of the HCP ought to carry little weight in contexts where donor and recipient autonomously consent.¹⁹ Thus, we might expect, as in similar circumstances where a doctor is unwilling to provide treatment, that the onus is on the reluctant professional to refer the patients to another practitioner for a second opinion. On the other hand, the HCP bears liability, regardless of the wishes of the donor and recipient, and is professionally bound to act in the interests of his or her patients (as determined by his or her own professional judgement). In situations where both parties appear to consent, HCPs must assess the extent to which the donor's decision was autonomous (and not the result of undue pressure from the donor or other family members). Additionally, as our participants indicated, HCPs can be affected (both emotionally and professionally) if adverse outcomes (such as donor or recipient harm) ensue, and patients cannot insist on treatment that does not, in the view of the relevant HCP, serve their interests.

For these reasons, it is a mistake to view the decision to undertake an LLD as one determined solely by the wishes of the

donor and recipient. Instead, HCPs must exercise their judgement regarding the balance of harms and benefits between donor and recipient, and this can have a decisive influence over the decision to perform an LLD.

Balancing risks and benefits

There appear to be three major considerations with respect to the way in which HCPs' judgements about benefits and risks are incorporated into the decision-making process. First, our data suggests that although HCPs claim that their assessments are more objective (less clouded by emotion) than those of the donor and recipient, their assessment of risk often reflects their own values regarding the nature of familial relationships. For example, a greater level of risk was judged to be acceptable in the case of an LLD from a parent to his or her adult child than an LLD from an adult child to his or her parent (despite the similar medical risk associated with both cases). Here, the participants seemed to be factoring into their judgement, a view that it is more acceptable for parents to take risks for their children than vice versa. Likewise, in accordance with existing surveys,^{13–15} altruistic (stranger) donation was regarded as too risky, even though the risks are similar to those between relatives or family friends. In this respect, HCPs appear to make judgements about the relative value of particular relationships (eg, parent–child) to donors and then factor the corresponding harm of losing that relationship into their risk assessments.¹⁹ This may be a partial explanation for the readiness with which HCPs are willing to countenance donations by parents as opposed to altruistic donations, since the death of the recipient in the latter case would appear not to harm the donor while it presumably would in the former. This explanation is worrying; however, as the literature on familial live donation suggests that the importance of family relationships to donors is often complex and may undermine the donor's autonomy.¹⁰ In this respect, an HCP's evaluation of the importance of a particular relationship may not reflect the donor's own evaluation of the importance of the relationship. This may be particularly true in contexts where the HCP and donor are from different cultural backgrounds and thus place different emphases on the status and nature of familial relationships. Whether or not HCPs are able to accurately evaluate the significance of the donor or recipient relationship and the incorporation of such evaluations into their risk–benefit assessments belies the ostensibly objective nature of the HCP's advice on the risks to donor and recipient.

Second, the way in which HCPs employ the *balance* of harms and risks between donor and recipient should be made clearer and requires further exploration both empirically and philosophically. In the literature, the debate on the permissibility of LLD is often framed in terms of the balance between benefits and risks,²⁰ but our participants tended to frame the options in terms of those that do the 'least harm'. This difference in emphasis is open to three possible interpretations. The first is that HCPs are straightforwardly applying the Hippocratic norm of 'first do no harm', such that LLD is permissible only when neither participant is harmed, in the sense of being left worse off. Although the donor is harmed in one respect (ie, by exposing them to surgical risks, etc), this harm is outweighed by the avoidance of the alternative harm (psychological harm caused by the recipient's death).¹⁹ The second interpretation is that HCPs are merely redescribing a straightforward utilitarian principle of maximising aggregate wellbeing, such that LLD is permissible only when any harms to the donor (and recipient) are outweighed by benefits to the recipient (and donor). While this justification may account for the bias in favour of performing

LLDs, it fails to account for HCPs' reluctance to allow altruistic donations to occur. Additionally, it seems unlikely that HCPs would evaluate the risks and benefits of LLD without due attention to the separateness of persons. The third interpretation is that HCPs are redescribing a principle of pareto efficiency, such that LLD is permissible only when *both* individuals (taken separately) are better off than they otherwise would have been had the procedure not gone ahead. This interpretation is supported by the different responses of HCPs to familial and altruistic LLD, with HCPs emphasising that the former benefits the donor (through maintenance of a valuable relationship), whereas the latter does not. Of course, it is not clear that familial donors—particularly those who suffer complications—are all-things considered, better-off after LLD. Only donors are likely to be able to accurately evaluate the trade-offs between their own health and the maintenance of an important relationship (and only then in the fullness of time). In this respect, HCPs may systematically overestimate the psychological benefits, which donors received from giving to family members.

Finally, there is considerable disagreement among HCPs as to how risks and benefits ought to be communicated to patients and ultimately incorporated into the decision-making process. There was a range of views over whether the assessment of donor and recipient risks and benefits should be undertaken separately or collaboratively. Some participants favoured the latter, pointing to its openness and transparency and potential for ensuring that both donor and recipient see the risks and benefits from each other's perspective. Some of the participants, however, seemed also to have regarded this as an opportunity to present the overall benefits to the donor in a positive light. Perhaps even more worrying is the tendency disclosed by some of our participants to manipulate the facts in favour of their own views, even if this is done with the honourable intention of protecting either donor or recipient from the harms that the professional finds unacceptable. The coercive potential of this arrangement concerned others. Some pointed to the practice in LKD of seeing donor and recipient separately and together at different stages of the process and suggested that following this tried and tested protocol was the best option. Our participants were, however, conscious that LKD was not always a good model for LLD.

The way in which HCPs view the decision-making process around LLD suggests that LLD programmes should be conservatively introduced. In instances, such as LLD, where a programme is in its infancy (and thus the information available on the potential risks and benefits limited) and where donors are at serious risk of harm (both during and after the operation), HCPs ought to act cautiously with respect to their judgements about the correct balance of harms and benefits between donor and recipient. Conservative guidelines for inclusion might operate in the first instance to constrain the effect of HCP judgement on the decision-making process to those cases where donors and recipients insist upon a risk-laden procedure. In cases where the risks and benefits to donors and recipients appear evenly matched, HCPs who do not wish to proceed should be willing to either refer on to a more sympathetic colleague or seek a second opinion. In cases where donors or recipients appear to be overly cautious with respect to the risks of LLD (or ignore the risk to the recipient of not undergoing the procedure), HCPs ought to refrain from the practice (alluded to by our participants) of manipulating the decision-making process to emphasise the benefits of LLD. Only as more data about the risks and benefits become available, should HCPs be given the freedom to actively encourage donors and recipients to undertake an LLD.

CONCLUSION

LLD is becoming a viable alternative to deceased liver donation and has the potential to radically improve the prognosis for patients requiring liver transplants. Our data suggest, however, that HCPs have a tendency to bring their own values to bear when balancing the potential harms and benefits to recipient and donor (although they may not be aware that they are doing so). We have suggested that LLD might need to be introduced slowly, with tight parameters on the kinds of donors and recipients who are candidates for LLD. This would allow for the collection of more reliable data regarding the risks of the procedure and to investigate how HCPs' judgements about risk ought to be incorporated into the decision-making process. Once these data are collated and accurate assessments of harms and benefits can begin to be made, the range of potential donors may be expanded beyond those with low-risk profiles.

Competing interests None.

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