Author's response to reviews

Title: Accept or refuse? Factors influencing the decision-making of transplant surgeons who are offered a pancreas: results of a qualitative study

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Author's response to reviews: see over
Reviewer 1

The authors wrote a very interesting paper which resembles very well the current situation in pancreas transplantation. Missing evidence in pancreas transplantation makes it difficult to establish a standard operating procedure when accepting a pancreas. All the following comments are minor essential revisions:
- The lack of evidence should be mentioned clearly in the discussion, evtlly referring to the recent review Curr Opin Organ Transplant. 2013 Feb;18(1):83-8.

  ➔ We have now emphasized the lack of evidence in pancreas transplantation in the discussion and inserted the reference of Maglione et al (2013), p. 18.

- I am missing in the discussion the Pancreas DRI, which is an interesting tool for evaluating the quality of an offered pancreas (American Journal of Transplantation. 2010;10(4):837-845). Is it well accepted in Germany?

  ➔ The donor risk index does not play a role in routine pancreas allocation in Germany and was therefore not explicitly asked for in the interviews. We inserted a footnote to Table 1 (Interview guide), explaining the P-PASS and stating: “The DRI (donor risk index), an alternative prognostic score for pancreas transplantation, is not commonly used in Germany and was therefore not included explicitly in the interview guide” (p. 22).

- In general I am missing in the discussion the analyses of the problems encountered by surgeons, e.g. prognosed ischemia time, DCDs (Am J Transplant. 2012 Aug;12(8):2150-6). Analysing the answers of the interviewees is surely important, but it is probably not enough for a good "take home message" in a surgical journal.

  ➔ This is an important comment. To date, organs of DCDs are not available in Germany and therefore this aspect was not considered. We now pointed this fact out by changing the first sentence of the Methods section accordingly (“In Germany, 163 pancreases from brainstem deceased donors were transplanted in the year 2010 [12] (transplantation from donors after circulatory death is not allowed in Germany)”).

  ➔ A supposedly long cold ischemia time is a reason to refuse offered pancreases, as shown in a quantitative analysis of refusal reasons performed by our group earlier (Loss M et al, Transplantation 2013; 95(9):1134–41), although only 2.5% of refusal reasons pertained to CIT. In the interviews, however, the aspect was not brought up specifically. Obviously it was not considered a major difficulty in the decision-making process. As this is an empirical paper, we are somewhat reserved to discuss aspects which are not part of the results, or to draw conclusions which are not based on the analysis of the interviews.

Reviewer 2

This is a qualitative report on factors influencing the decision making of transplant surgeons who are offered a pancreas. It is a well conducted study and has managed to ask the right questions to an appropriately chosen participants. It has touched on the very topics that make pancreatic transplantation such a demanding procedure like the differences in individual centre’s/person’s philosophy that drives the program.

The only drawback that I thought was apparent was the definition of a high volume centre. This was defined by centres doing more than 5 pancreas transplants a year which is a relatively low number.

  ➔ The reviewer is right that 6 or more transplants seems a low number for defining a hospital to be ‘high volume’. However, it needs to be seen in relation to the numbers of transplants
performed in the single hospitals. Due to the fact that the total number of pancreas transplantations is relatively low in Germany, and as many as 24 centres have a pancreas tx programme, the hospital with the highest volume of pancreas transplantations transplanted only 16 organs in 2010. We inserted a sentence in this sense ("the three hospitals with the highest volume of pancreas transplantations implanted 13, 14, and 16 organs per year, respectively.", p. 4-5). In the statistics of the German Organ Donation Foundation, those centres with >5 transplants are listed giving the detailed numbers of transplants, whereas those with <=5 transplants are just mentioned. That is why we chose the cut-off of >5 pancreas transplantations. As this might not reflect what the term 'high volume' may imply, we deliberately put that term into quotation marks, and we now have added the word 'relative' (p. 5).

Reviewer 3

Major Compulsory Revisions

1. It would be useful to describe the number of pancreas transplants done by the participating centers, how many surgeons in each center performed them, and the experience of the surgeons.

- We have now re-written the first sentences of the Methods section so it becomes clear that the participating centers transplanted 6-16 pancreases each in 2010 (p.4-5).
- As mentioned in the Methods section, the minimum of three years of experience in pancreatic transplant surgery was an inclusion criterion for the interview partners. The first part of the results section gives details of the sample, pertaining to the surgeons’ respective experience ("The 14 transplant surgeons reported to be performing transplant surgery in authoritative positions for 3-15 years. All interview partners with the exception of one reported to be routinely involved in donor surgery of the pancreas as well, being a member of a regional recovery team.").
- We now included the sentence “In most centres, 2-3 surgeons are specialized in pancreas transplantation.” (p. 5)

2. On page three, it should be clarified what the definitions of offered, discarded, and withdrawn signify. I assume that withdrawn from the allocation process means not recovered. I find a 71% frequency of discard to be extremely high, and it is easy to mix this up with not used. For example, in the US about 30% of pancreases are discarded (recovered but not transplanted) but 60% of pancreases are not recovered from donors of other organs.

- In fact, what we meant when writing “discarded” was not “not used”. In order to clarify that passage, we have modified the sentence accordingly ("71% of all offered pancreases are withdrawn or discarded", p.3)
- We added a sentence giving details on the relation of withdrawn and discarded organs (“In Germany, data from 2005-2009 show that 43% of pancreases are withdrawn before recovery because of repeated refusals, and 20% are discarded at the time of intended recovery, or after recovery, mainly due to poor organ macroscopy (Loss 2013)”). As this further lengthens the paper, we leave it to the reviewer and the editor whether or not to maintain this explanation.

3. It would be helpful to present more data about how the medical criteria were identified. How is their relative importance determined? Can the importance be weighted?

- As stated in the results section, the interviewees described that when deciding about the acceptance of a pancreas, different factors need to be weighed against each other. It became clear, throughout the interviews, though, that different factors were not assessed
in relation with each other in a systematic process, but very individually and intuitively for every donor. This is also well illustrated in the quoted term “accumulation of bad gut feelings”. We have inserted a sentence in that sense to the results section, p. 9.

Minor Essential Revisions
None

Discretionary Revisions
1. One concept that should be emphasized is that the implications for allocation efficiency are more profound if the issues affect the post-recovery phase compared to the pre-recovery or initial offer phase. Thus, variations in acceptance behavior based on medical criteria ought to have a much smaller impact (just need to find another more permissive center/surgeon further down the list) than finding a center to accept a pancreas that is already out and judged to be unsuitable, because you are now fighting CIT, possibly distance, and another team having recovered the pancreas.

   ➤ This is an important remark. We took up this recommendation by inserting a sentence which points out this challenge in the discussion of the problem of repeated refusals (“...organs might be refused repeatedly. Consequently a ‘cascade effect’ [20] can ensue, because the refusal of one centre might - consciously or unconsciously - increase the probability of further refusals, as the interview analysis suggests. This is especially critical if the allocation process is still ongoing when the organ has already been recovered. As a consequence, the extended ischaemic time may result in an increase of discarded organs; it can also lead to unequal access to donated pancreases [21]”.

2. While better training for donor surgeons may be indicated, the issue may be as much one of perceived expertise as actual expertise, which may be more difficult to remedy. This seems to be implied in the figure but might be made more explicit in the text. Additional measure to address this might be:
   a. Require that the accepting center send their own team or designate a surrogate surgeon as a condition of acceptance.
   b. Use of visual communication tools to provide information about the pancreas so that it is no longer acceptable for the center to require that they “personally inspect” the pancreas at their center.

   ➤ These are interesting suggestions.
   ➤ a) One could name this option, but it is not really clear whether this would actually remedy the allocation problems identified in this analysis. For example, if a centre with a very restrictive acceptance policy would send their team and then decide that the organ quality is not good enough (for them), the further process would suffer a significant time delay as well (because a new team has to be asked and shuttled to the donor centre). In addition, none of the interview partners brought up this issue, so we are somewhat reserved to elaborate on this question.
   ➤ b) We could address this aspect by adding the following sentence to the end of the discussion (p. 18): “The fact that during the allocation process, the deciding transplant surgeon has to rely on the recovery team’s verbal description of the organ macroscopy seems to hamper a well-informed decision-making, so one may discuss whether visual communication tools such as telemedicine would be helpful for the assessment.” As this was only a discretionary recommendation, and this sentence would further lengthen the paper, we leave it to the editor to decide whether or not to include it in the manuscript.

3. The issue of variation in acceptance by medical criteria is an interesting one. Two important considerations are 1) whether there is variation by center only or by individual surgeons within a center; 2) whether there is inconsistent behavior by individuals from donor to donor. It would be a
difficult sell (and may not be medically beneficial) to advocate universal acceptance algorithms, and
even more difficult to achieve in practice. It would not be unreasonable to expect that centers or
surgeons create their own criteria/algorithms, and to receive feedback about how consistently they
follow them.

- The inconsistency in assessing medical donor characteristics is actually intriguing. As we
  have only interviewed one surgeon per centre, we do not have the data to clarify whether
  the judgments vary between individual surgeons or between centres, which is why we
  have not elaborated on this question. As only 2/14 surgeons report to have institutional
guidelines (see Table 2), we had the impression that these are personal, not institutional,
assessments.

- The interview partners made it clear, though, that every case has to be assessed
  individually, taking into consideration all relevant factors and weighing them against each
  other. This is, for example, well expressed in the quote: “The decision is cumulative: old
  age, pancreatitis, poor circulation, and then - on top of that - maybe overweight. Then you
  add it all up. But refusing it [the organ] just because of a single criterion, we wouldn’t do
  that. (IP 05)”, p. 9. So probably there is inconsistent behavior also from donor to donor. It
  was also clear that this decision is not usually made in a systematic process, or based on
  algorithms, but in an intuitive, subjective process (see also answer to Major Comment no.
  3)

4. There is a suggestion that absolute rule out criteria and criteria that take other factors into
consideration are mutually exclusive, which is not the case. Nearly all center/surgeons are likely
to have both. For donor age, for example, it would not be unusual in the US to have a hard cutoff of 50
and a relative upper level of 40-50 where other factors are also carefully considered.

- The reviewer’s observation of the situation in the US-American centres is interesting. It
does not, however, correspond to our interview results. As shown in Table 2, only 2/14
surgeons reported to have institutional guidelines after all.

5. If possible, I would elaborate on why the surgeons thought P-PASS was not useful.

- In the interviews, we did not ask specifically for reasons why certain donor characteristics
  were or were not seen as useful. It transpired, though, that the reasons for not using the P-
  PASS differed between interview partners. We could insert the following description: “The
  reasons for not using the P-PASS differed between interview partners. One surgeon said he
  had not ‘internalized’ the P-PASS and its prognostic conclusiveness yet, others criticized
  that recent studies question the validity of the P-PASS, some were generally opposed to
  using scores in medicine.” As this paragraph would add to the length of the paper, we leave
  it to the editor to decide whether or not to include it in the manuscript.

6. I think that most experts would view the practice of incorporating need, waitlist size, and the value
of the alternative donor into acceptance decisions as a reasonable one. However, this would
probably depend on the specifics, and whether the practice is evidence-based.

- We fully agree to this view. We have referred to this aspect in the discussion by stating
  “…the fear of endangering the patient’s health by accepting an organ that is not flawless.
The latter is especially important in pancreas transplantation because unlike liver or heart
transplantation, the patient’s condition is usually not life threatening, so there is less
willingness to compromise.” (p. 17)
Reviewer 4

Due to the background that the majority of pancreases offered are not accepted, this study was initiated in order to analyse surgeons’ decisions. The question posed by the authors is well defined and important for those with closely related interests. The methods and data collection are well described. The main medical reasons for acceptance or refusal of the organ were worked out, but also other possible reasons. Strengths and weakness of the study are pointed out and discussed. The results of this study showed how complex the decision of pancreas acceptance is and enabled an interesting insight in this problem. Maybe a better standardization could be developed during the next years in order to utilize offered pancreata better.

- We mentioned the option of a better standardization in the discussion (“One has to discuss whether the allocation process would profit from a better standardization or an evidence-based approach. Particularly younger surgeons who have less experience might benefit from recommendations or guidelines, which can be developed by experts.”, p.18)

Reviewer 5

Major Compulsory Revisions

The manuscript raises a very interesting topic, however the manuscript should be shortened. The paper should be more concise.

- As the reviewer does not name those paragraphs which he feels needed shortening, we were hard put to decide by ourselves which aspects to leave out. Therefore, we decided not to shorten the paper, in order not to risk making the background or the results less understandable to those not so familiar with pancreas transplantation. We would be grateful for the reviewer to name us specifically those passages which, in his opinion, were not concise. We surmise that some aspects that seem to be lengthy or extensive to the reviewer are in fact owed to the qualitative design of the study.
  - E.g. in terms of the presentation of the results, we suspect that it may seem somewhat repetitive to supplement the descriptions of findings with respective quotes from the interviews; however, this is good practice of data presentation in qualitative research.
  - Additionally, the quality criteria for qualitative studies require that the researchers give room also to deviant opinions and findings (see Mays N and Pope C, Qualitative research in health care - Assessing quality in qualitative research, BMJ 2000; 320:50-2), so we also described the participants’ views or practices even if they were expressed only by a minority and contradicted the perspectives of the sample’s majority. This may lead to the impression that the presenting of results is not entirely concise.
  - In addition, Mays & Pope require (“although it adds to the length of research reports”) to give a clear account of the process of data collection and analysis, providing “a clear account of how early, simpler systems of classification evolved into more sophisticated coding structures and thence into clearly defined concepts and explanations for the data collected.” Therefore, we gave a detailed description of the data analysis in the methods section.

The problem of 14 interviews eventually not being sufficiently representative, is addressed, however the problem remains.

- As stated in the discussion, this fact would pose a problem for a quantitative analysis. Qualitative studies, by contrast, follow a different research paradigm and do not aim to
achieve a representative sample. Rather, the aim is to understand processes, and to identify a broad range of possible opinions, perspectives and experiences, that may serve as a basis for later quantitative (representative) data collections.

Minor Essential Revisions
The language should be revised (e.g. pancreata instead of pancreases), some lengthy passages should be written more concisely.

➤ In our experience, the terms pancreases and pancreata are used interchangeably in the Anglo-Saxon medical literature. If the reviewer or the editor prefers ‘pancreata’, the term pancreases can be replaced throughout the whole manuscript. The manuscript has also been checked by a native speaker.

Discretionary Revisions
none