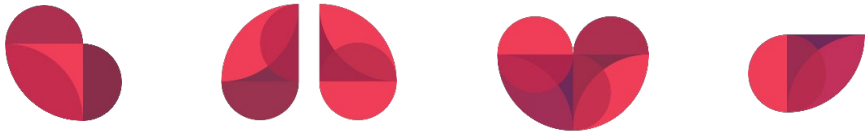

Kidney Donor Risk Decision Support Tool

USER TESTING FINAL REPORT

May 2024 | Dr Sarah White

Centre for Organ Donation Evidence

Acknowledgements and Disclaimers

This research was led, and report written by Doctor Sarah White. The interpretation is theirs alone.

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The study was performed in accordance with the NHMRC Statement on Ethical Conduct in Research Involving Humans 2007, the NHMRC Australian Code for the Responsible Conduct of Research (2007, updated 2015 and as amended from time to time), and the principles laid down by the World Medical Assembly in the Declaration of Helsinki 2008. Ethics approval for this study was obtained from the University of Sydney Human Research Ethics Committee (2023/279).

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Table of Contents

Kidney Donor Risk Decision Support Tool – User Testing Final Report

Aims

The aim of this user testing study was to 1) evaluate the impact of a decision support tool on decisional conflict in decisions related to the medical suitability of kidneys from potential deceased donors and 2) assess the useability of this decision support tool. Unstructured feedback on the usefulness and useability of the tool was also sought.

Methods

This is a mixed-methods study, based on interviewer-led surveys in which participants were asked to give both open-ended feedback and to respond to structured survey questions.

Participants were eligible if they met the following criteria:

Inclusion Criteria

1. Clinicians involved in determining medical suitability
2. Willing and able to comply with all study requirements, including ability to partake in an interview
3. Ability to provide written consent.

Exclusion Criteria

1. Clinicians who are not, or have not previously been, involved in the determination of organ suitability for kidney transplantation.

Potential participants were identified via the relevant organ and tissue donation service in each state and sent an invitation to participate via an email sent by this service. A link to a Participant Information Statement was provided with an invitation to register consent to participate in REDCap (https://redcap.sydney.edu.au/surveys/?s=77T7Y7DTLLAH4ETN).

Individual interviews were conducted using videoconferencing by S White. At the start of each interview, the participant's consent was confirmed and re-checked using a standardised script.

In the first part of the interview, clinicians were presented with two donation scenarios and asked to think aloud their process of determining medical suitability based on the donor characteristics alone. They were then asked to respond to a structured Decision Process Assessment Instrument[1] that queries how difficult decisions were to make and the level of satisfaction with the final decision. They were then invited to enter the donor characteristics into the decision support tool (https://organ-donation-

evidence.shinyapps.io/donor_risk/) and asked to reflect on how the absolute risks presented by the tool changed their view on the medical suitability of the donor and their satisfaction with their original decision.

The second part of the interview addressed the usability of the decision support tool. Interviewees were asked to rate the tool using a Healthcare System Usability Scale[2] and were asked open-ended questions about the usability, visual layout, and areas for improvement of the tool.

Participant interviews were recorded using the Zoom recording feature and later transcribed by the investigator. Participant data were de-identified prior to transcription and analysis.

Respondent characteristics

Demographics

Ten transplant clinicians involved in making kidney donor suitability decisions were interviewed:

- 1 from Queensland
- 3 from South Australia
- 6 from New South Wales

Six had been practicing for 20 years or longer, of whom 4 had at least 10 years of service advising on donor medical suitability. Four had been practicing for less than 20 years (range: 7 to 15 years), of whom 2 had at least 10 years of service advising on donor medical suitability. Only 2 respondents had less than

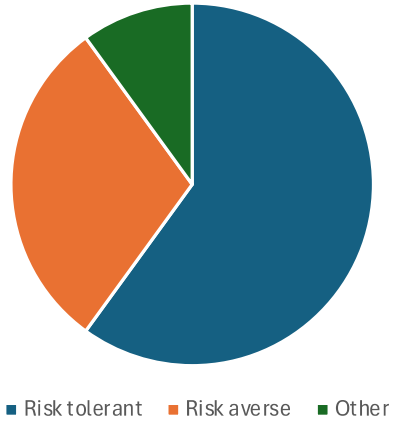
Baseline views on the process of donor suitability assessment

Respondents were asked "Do you consider yourself generally a risk tolerant or risk averse person?" and "How stressful do you find making decisions about donor medical suitability?".

The range of responses to these questions and their correlation with years of experience are shown in Figure 1. Sixty percent of respondents identified themselves as risk tolerant, 33.3% as risk averse, and 1 person as neither (in this case, the respondent stated they were at the mid-point between risk tolerant and risk averse).

There were a wide range of responses to the question "how stressful do you find making decisions about donor medical suitability?". Respondents were prompted that 1 corresponds to decisions that are not-at-all stressful, whereas 100 corresponds to among the most stressful clinical decisions that they make. Half of respondents rated the degree of stress associated with donor medical suitability decisions at 50 or above. There was no evident relationship between self-identified risk tolerance/risk aversion and how stressful the respondent found these decisions.

A



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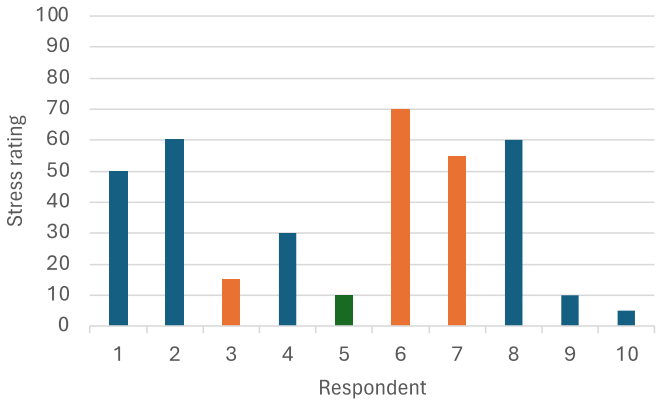


Figure 1: *Responses to the questions (A) "Do you consider yourself a risk tolerant or risk averse person when it comes to making donor suitability decisions?" and (B) "How stressful do you find donor acceptance decisions from 1(low) to 100 (high)?" Blue*

Where do respondents usually go for support in making decisions about biovigilance risk?

Overall, the most commonly cited source of support in making decisions about biovigilance risk was the advice of specialists/clinical experts (oncologists, dermatologist and infectious disease specialists). When limited to the first source of support to which respondents would turn, however, this was most commonly to peers/other transplant clinicians (Figure 2).

Respondents with many (20+) years of practice tended to emphasise the role of peers and hospital specialist contacts in seeking advice around decisions related to biovigilance risk. Younger clinicians (10+ years practicing) tended to go first to the TSANZ Clinical Guidelines and then to their peers (Figure 3).

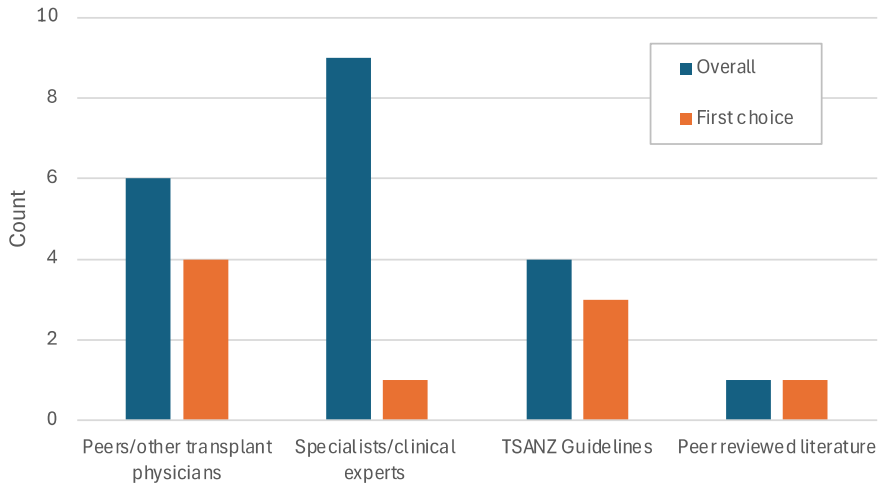


Figure 3: *Responses to the question "Where would you normally go for support in making decisions around biovigilance risk?", overall (allowing for multiple responses) and first response only.*

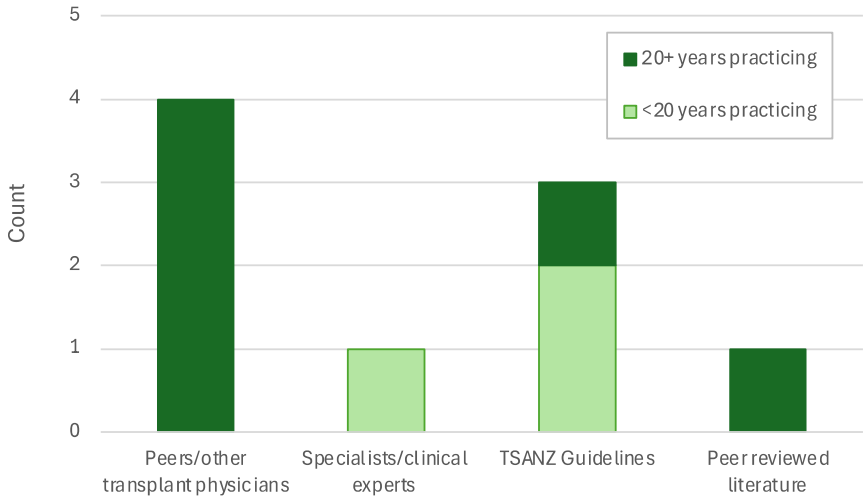


Figure 2: *First response to the question "Where would you normally go for support in making decisions around biovigilance risk?", by number of years of clinical practice experience.*

Case assessments

Assessments of Case 1

The full details of Case 1, as provided to survey respondents, are given in **Appendix A**.

The key elements of the case as they relate to biovigilance risk are as follows:

Medical History and Clinical Conditions	
Past Medical History	Melanoma in situ x 3 (lip – 2015, right shoulder – 2020, abdomen – 2020) MGUS Colonic polyps GORD/Barrett's oesophagus ETOH (4-5 beers + 4-5 wines/night) Other: ICH likely due to post-coital HTN; c/o arm weakness post coitus
HIV	No
HBV	No
HCV	No

Assessment of Case 1 by respondents

Full details of respondents' medical suitability determinations are provided in **Appendix B**.

- The majority of respondents (8 out of 10) indicated that they would accept this donor
- Of the 8 that would accept the donor, 4 had caveats around their acceptance – mainly related to wanting confirmation that the melanomas were in fact in situ
- One respondent said they would decline the donor, on the basis that *"we don't know the recency or number of melanomas. There is also the possibility that the intracranial haemorrhage was due to a melanoma deposit"*
- One respondent abstained from giving a response *"I would need to know more about the melanoma (history of treatment and the nature of those)".*

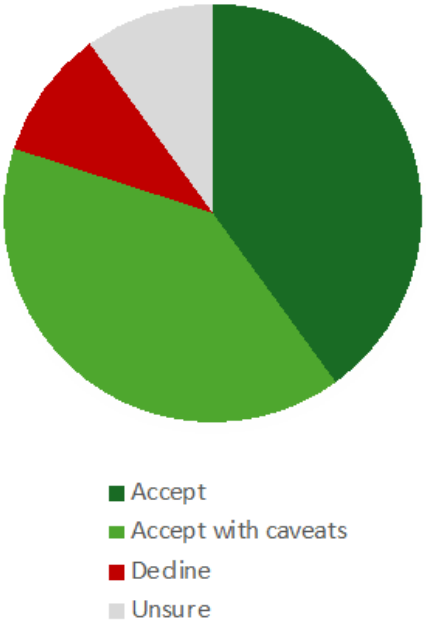


Figure 4: *Donor suitability assessments, Case 1*

Qualitative comments relevant to Tool development and use

- Many respondents emphasised the need in real life to confirm the in situ melanoma diagnosis with pathology records: *"You would also want to confirm that the histology was in fact what they said it was. In my experience, families will often report melanoma which is often in fact SCC or BCC. What the public and clinicians understand to be melanoma are different things,"*

- The fact that there were 3 separate melanomas in the donor history was noted as being of interest by several respondents (see Appendix B) *"The fact that there are 3 melanomas is a bit of a worry. We would ask the ICU team to do a skin check to see if any other lesions have developed in the last 3 years and we would ask a dermatologist to advise."*

- The multiple melanomas in this case example raised the question of how the tool copes with multiple cancers in a donor case history

- In addition, some respondents emphasised the need to check the pathology regarding the colonic polyps in light of the melanoma history and the need for a thorough skin check before proceeding with donation

- MGUS and the history of Barrett's oesophagus raised mild concern amongst several respondents

  "MGUS is common in this age group – as long as the full blood count looks acceptable this wouldn't put me off. I would also want a PCR to know if there is protein in the urine to see if this reflects a monoclonal band of renal significance."

  "Colon polyps are fine; Barrett's is associated with increased risk of malignancy so I would be keen to know when the last scope was done (if one hasn't been done for some time, then I would recommend examination of the oesophagus with some form of imaging prior to donation). I would add Barrett's to my considerations under cancer risk."

- Proteinuria results were not provided as part of the case history; however, urinalysis would have formed part of the decision making for most respondents.

- In this case, there is no reported history of BBV or increased risk behaviours, therefore the result returned for risk of BBV transmission is 0%. However, as pointed out by one respondent, there is always some degree of background residual risk, so the risk is never truly zero *"there is 0% risk of BBV infection (although we know that is not going to be true, because all donors carry some residual risk of viral transmission)."*

Assessments of Case 2

The full details of Case 2 as provided to Survey respondents are given in **Appendix C.**

The key elements of the case as they relate to biovigilance risk are as follows:

Medical History and Clinical Conditions	
Past Medical History	Long history of skin cancers, 2015 onwards. Sept 2021 - e/o BCC R parietal region and full thickness graft, Oct 2021 - parotidectomy & removal lesion left ear. GP - melanoma, back, 2005. Superficial spreading 0.65mm thick showing evidence of regression and arising in a pre-existent dysplastic naevus. No evidence of ulceration. Removed with clear margins (0.7mm). Re-excision in 2010, residual melanoma not found. March 2020 colonoscopy with haemorrhoid banding COPD (ex-smoker)
HIV	No
HBV	No
HCV	No

Assessment of Case 2 by respondents

Full details of respondents' medical suitability determinations are provided in **Appendix D.**

- The majority of respondents (7 out of 10) indicated that they would accept this donor.
- Of those who indicated they would accept the donor, 5 had caveats around their acceptance – mainly related to uncertainty of how to correctly classify transmission risk in this case
- 2 respondents indicated that they were unsure and would need more information about the risks associated with the melanoma history
- 1 respondent indicated they would decline this donor.

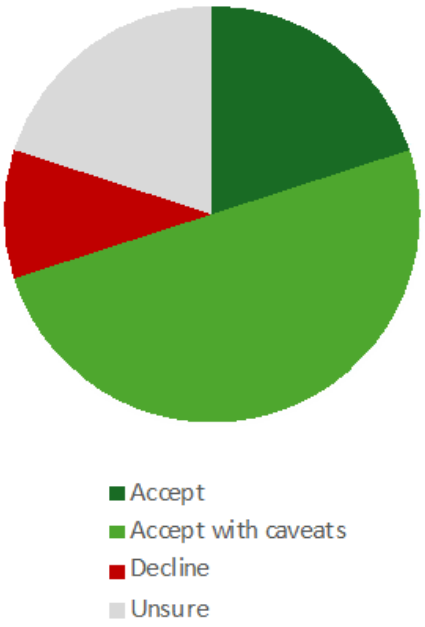


Figure 5: *Donor suitability assessments, Case 2*

Qualitative comments relevant to Tool development and use

- Respondents were less clear on the level of risk that would be associated with this history and more frequently indicated that they would need to speak to a dermatologist/ oncologist. *"It's not quite melanoma in situ, so my first thought would be to look up the TSANZ Guidelines with respect to thickness and type of melanoma and risk of transmission. [looked up the guidelines] The tumour is less than 0.8mm and completely resected - according to the Guidelines, the recommendation in these circumstances is that transplantation should only proceed in extreme circumstances. I would probably therefore be more risk-averse with this donor. I would speak to a dermatologist to get their thoughts on the degree of risk associated with this pathology. I would be concerned that there would be risk of recurrence of greater than 10%."*

- Respondents found it difficult to classify this melanoma history as reported in the context of contemporary cancer staging. They also noted that current guidelines do not make a risk differentiation between T2-T4 melanoma that is <10 or >10 years cancer-free, when there may be a reduced risk associated with a long recurrence-free interval. *"A problem with the TSANZ guideline in this case is that we have T1 N0 completely resected cancer with 20 years cancer free, and the Guidelines*

designate this as high risk. However, a T2-T4 melanoma (>0.8mm) with >10 years cancer free is also designated as high risk. The guidelines do not say the risk is lower if the size if <0.8mm and it is completely resected, but I would have assumed risk would have moved from high to low. There is a problem with the guidelines when it comes to melanomas. I also don't know, from the information presented, whether this cancer fits into a T1 or a T2."

- Three respondents noted that it is unusual for a BCC to have resulted in a parotidectomy. This suggests that it was not a BCC, that it was very aggressive, or that the patient had let it go very far before seeking medical attention. There was no drop-down menu option for this scenario, and it was not possible to include multiple cancers in a single risk calculation. *"SCC/BCC don't concern me; having said that, what is unusual here is that BCCs are generally not invasive, so to have a BCC that leads to a parotidectomy - I would be surprised if the BCC was the cause of the parotid being removed. That is a bit odd and I would want more information about that."*

Decisional conflict assessment

General comments

One respondent noted that, when assessing risk, it is also necessary to factor in the consequences of the risk(s) under consideration: *"It's not just about the absolute risk, it's about the consequences of the risk. If the risk is an infection that can be treated, then that is far less consequential than transmitting a cancer that could be a major issue. The nature of the risk should also come into consideration. Even though the risk of [in situ melanoma] transmission is low, if it did occur the consequences are significant."*

Some respondents referred to the role of collective decision making, noting that – if in doubt – they would reach out to colleagues to come to a unit-level decision on whether to proceed to donation and transplantation. *"This is the kind of thing that I would discuss with my colleagues and we would get a unit level decision because it is not a zero risk and the consequences of transmission are significant. I would seek a collective decision in this case, I don't think this is the kind of decision that an individual would independently make. We would then potentially accept the donor but would go through a careful process of selecting a recipient for this kidney."*

Results of Decisional Conflict Assessment: Case 1

The majority of respondents (9 out of 10) agreed with the risk estimates reported by the tool. The one respondent who did not agree stated: *"if there was clear pathology results, it would be possible to give more definitive risk estimates. Can't say for sure that these were in situ melanomas."*

Another responded provided the following caveat: *"-my only caveat with the tool is that the way you select the skin cancer type, this seems to assume that you only have one skin cancer in the donor history. Someone who has had three - I would be interested in getting a melanoma expert's theories on the cumulative risk."*

No respondent said that the information displayed by the tool changed their view on medical suitability.

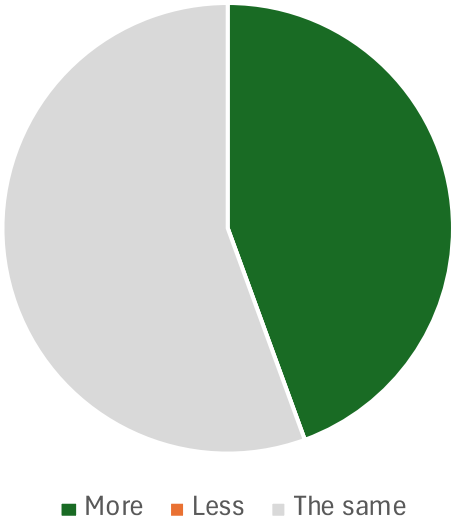


Figure 6: *Proportion of respondents who were more or less satisfied with their original decision after using the tool, or the same.*

Nearly half of respondents said they were more satisfied with their original determination after viewing the results of the tool. The main reason for this was because the tool confirmed their prior beliefs: "It's reassuring having something backing you up, as opposed to just using your intuition."

Table 1 and Table 2 provide the aggregated Decisional Conflict Survey results. Figure 9 shows the individual responses and the directional movement in these after using the Tool.

Total Decision Conflict Scores were calculated as per the methodology described by Dolan[1]. Based on the six questions in the Decisional Conflict Survey, each assessed on a 5 point scale, the possible range for the total Decision Conflict Score is 5 (minimal decisional conflict) to 30 (maximum decisional conflict). Figure 7 shows the Decision Conflict Scores for all respondents for Case 1, before and after seeing the results from the tool. The overall average score was 10.5 without the tool and 10.2 with the tool, a reduction of 2.8%.

There was no observed correlation between years of clinical practice and Decision Conflict Score.

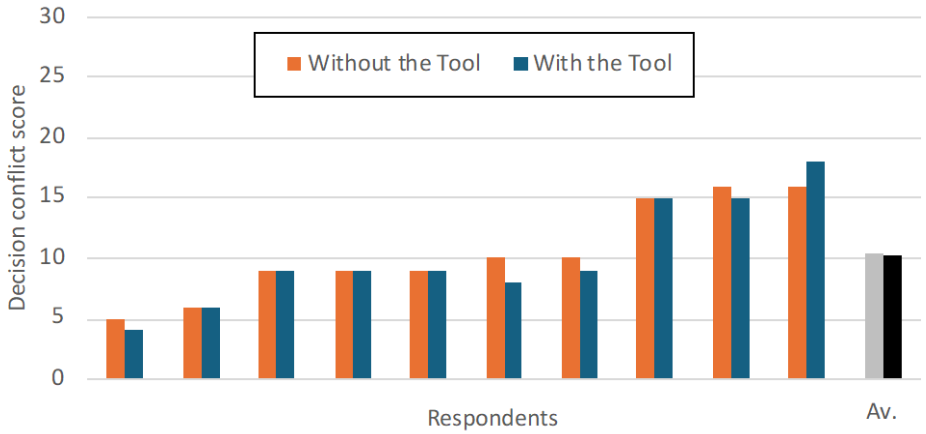


Figure 7: *Total Decision Conflict Scores for Case 1, with and without the use of the Decision Support Tool*

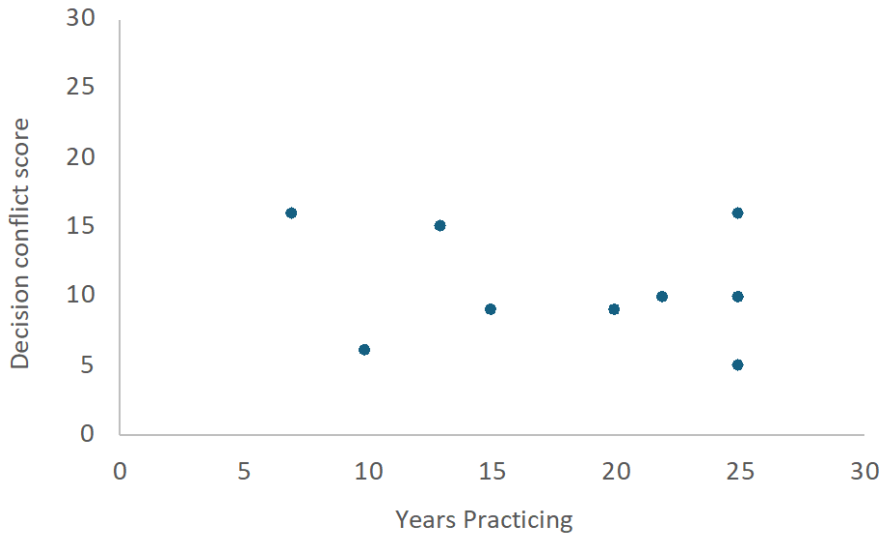


Figure 8: *Correlation between years of clinical practice in transplantation and decision conflict score (without the use of the Decision Support Tool)*

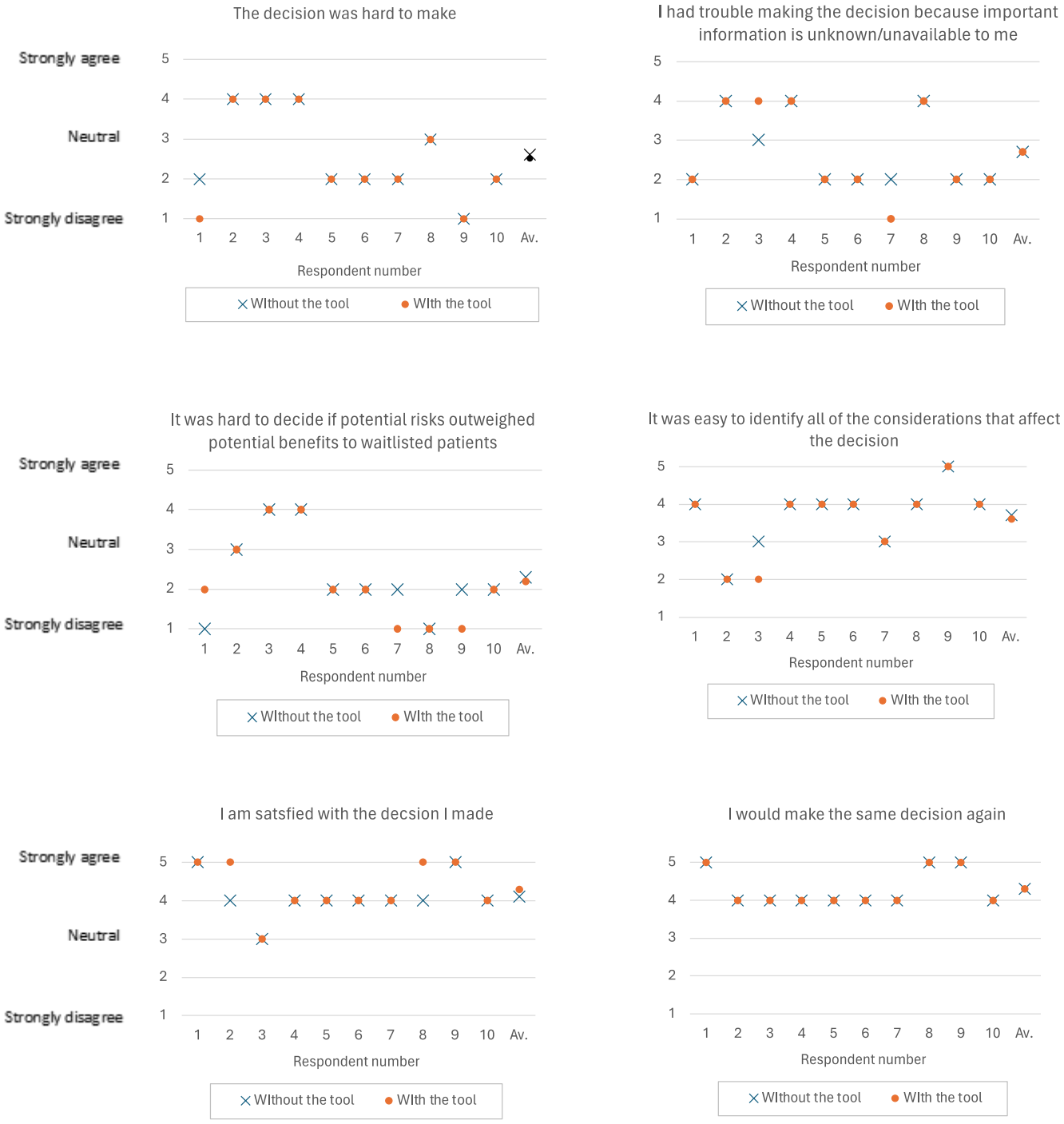
Table 1: *Aggregated responses without the use of the tool – Case 1*

	Strongly Agree	*Agree*	*Neither agree nor disagree*	*Disagree*	*Strongly Disagree*
The decision was hard to make.	n=0	n=3	n=1	n=5	n=1
I had trouble making the decision because important information is unknown/unavailable to me, or is not readily available in the literature.	n=0	n=3	n=1	n=6	n=0
When I made the decision, it was hard to decide if the potential benefits from the donor outweighed the potential risks to people on the waiting list.	n=0	n=2	n=1	n=5	n=2
It was easy to identify all the considerations that affect the decision.	n=1	n=6	n=2	n=1	n=0
I am satisfied with the decision I made.	n=2	n=7	n=1	n=0	n=0
I would make the same decision again.	n=3	n=7	n=0	n=0	n=0

Table 1: *Aggregated responses with the use of the tool – Case 1*

	Strongly Agree	*Agree*	*Neither agree nor disagree*	*Disagree*	*Strongly Disagree*
The decision was hard to make.	n=0	n=3	n=1	n=4	n=2
I had trouble making the decision because important information is unknown/unavailable to me, or is not readily available in the literature.	0	n=4	n=0	n=5	n=1
When I made the decision, it was hard to decide if the potential benefits from the donor outweighed the potential risks to people on the waiting list.	0	n=2	n=1	n=4	n=3
It was easy to identify all the considerations that affect the decision.	n=1	n=6	n=1	n=2	n=0
I am satisfied with the decision I made.	n=4	n=5	n=1	n=0	n=0
I would make the same decision again.	n=3	n=7	n=0	n=0	n=0

Figure 7: *Individual results of the decisional conflict questionnaire – Case 1*



Results of Decisional Conflict Assessment: Case 2

The majority of respondents (6 out of 9 who responded to this question) agreed with the risk estimates reported by the tool. Those who did not agree stated: *"I would think that the risk is lower than 10%. If this is from 2005 - I would put the risk at somewhere between 1 in 100 and 1 in 1000. In my mind, the superficial spreading diagnosis makes it more favourable, but maybe I am wrong."*

"When I choose the option of "cutaneous melanoma <0.8mm completely resected" it suggests at least 10% are estimated to have a transmitted cancer, which I think is an overestimate based on a cancer-free period of 18 years. If the melanoma had been from 6 years ago, that would be quite different to 18 years.

When I enter the BCC option - I don't quite believe the results because this guy lost a gland and an ear...I know BCC doesn't spread, but I am not 100% convinced that wasn't a squamous cell carcinoma. I think that the risk isn't zero from that tumour. It is also very recent (<1 year)."

Three respondents said that the information displayed by the tool changed their view on medical suitability. *"I did say maybe this was a possible donor before, and now I think that determination should have been different."*

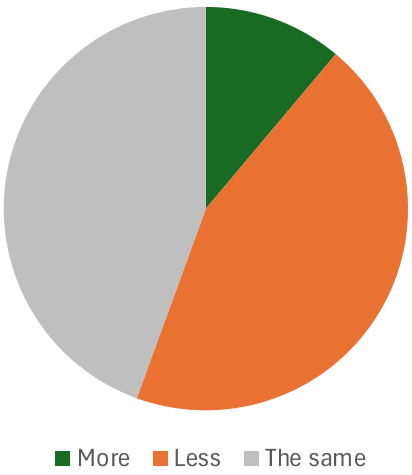


Figure 8: *Proportion of respondents who were more or less satisfied with their original decision after using the tool, or the same.*

Nearly half of respondents said they were less satisfied with their original determination after viewing the results of the tool. The main reason for this was because the tool indicated a higher risk of transmission than had been their assessment.

Many respondents highlighted the lack of the ability to select an option that reflected the long cancer free interval in this case, and felt that the long cancer free interval would be associated with a lower risk of transmission than was indicated by the tool. *"I would have thought that, with the histology in this case, it would be the time from the original cancer that would be important thing and I would want to know the current evidence on risk of recurrence following a 20-year cancer free interval."*

Table 3 and Table 4 provide the aggregated Decisional Conflict Survey results. Figure 13 shows the individual responses and the directional movement in these after using the Tool. More variation in responses with and without the tool is evident compared to Case 1. Some of this variation came from different understandings of what a "superficial spreading" melanoma means. Some interpreted this as equivalent to an in situ melanoma, some as equivalent to a T1 malignant melanoma. The results presented by the tool after selecting the closest available option did not always align with respondent's understanding of this cancer type.

Figure 11 shows the Decision Conflict Scores for all respondents for Case 2, before and after seeing the results from the tool. The overall average score was 13.3 without the tool and 11.8 with the tool, a reduction of 11.3%.

Again, there was no observed correlation between years of clinical practice and Decision Conflict Score.

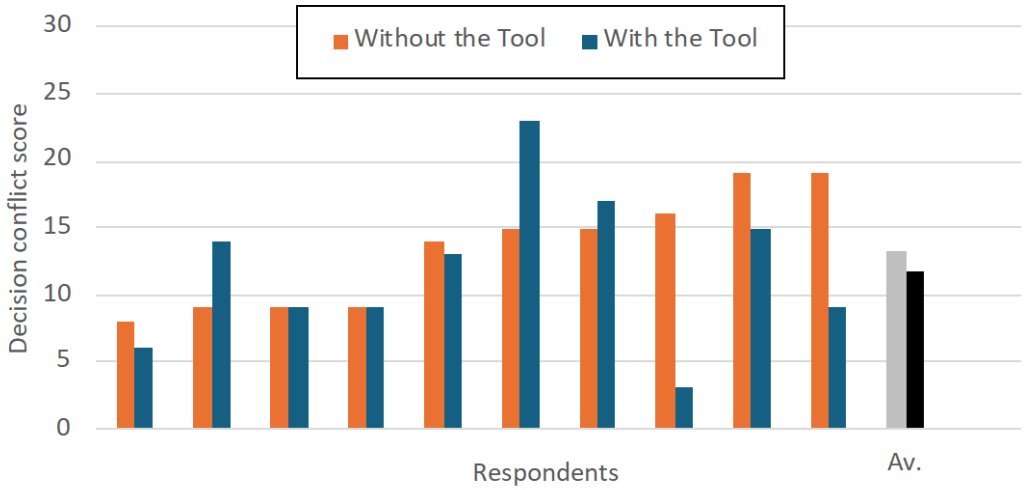


Figure 9: *Total Decision Conflict Scores for Case 2, with and without the use of the Decision Support Tool*

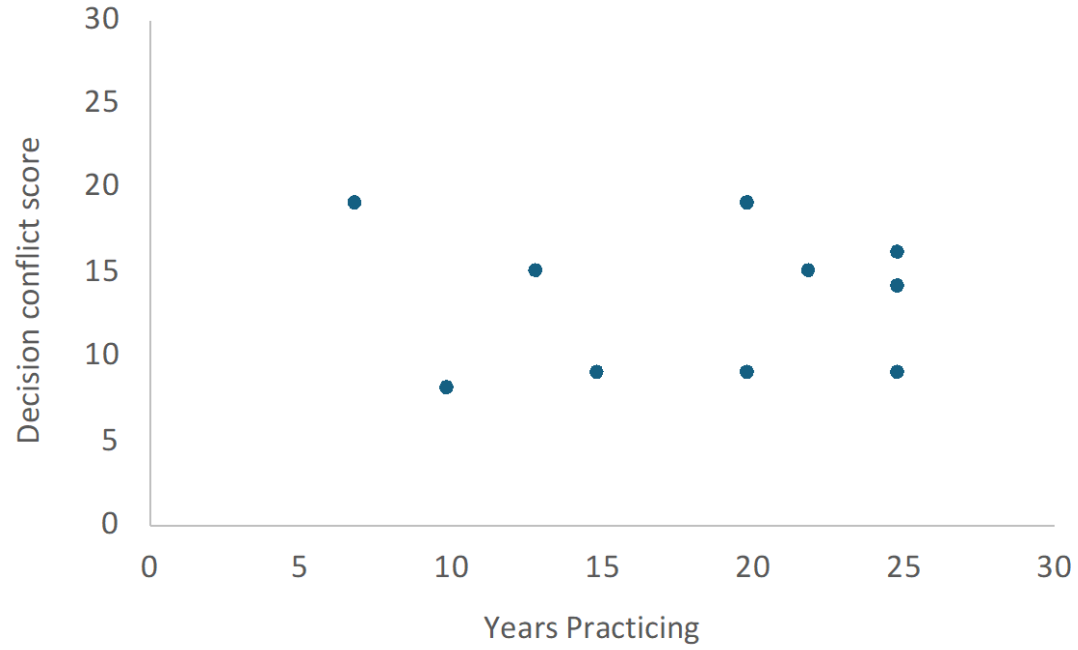


Figure 10: *Correlation between years of clinical practice in transplantation and decision conflict score (without the use of the Decision Support Tool) – Case 2.*

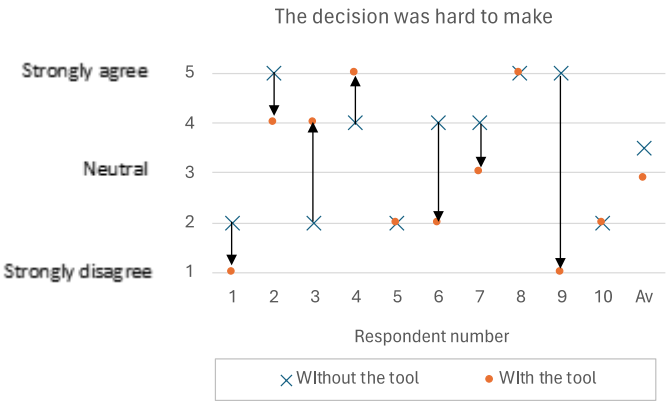
Table 2: *Aggregated responses without the use of the tool – Case 2*

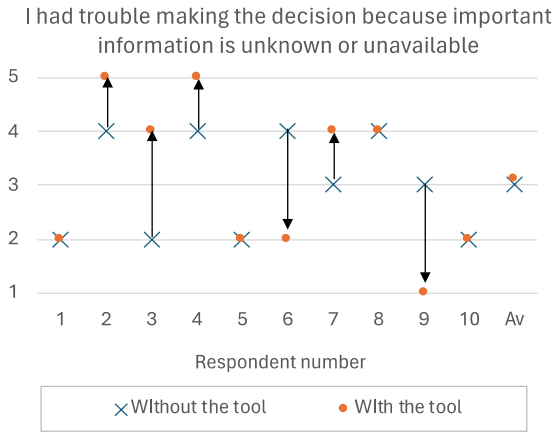
	Strongly Agree	*Agree*	*Neither agree nor disagree*	*Disagree*	*Strongly Disagree*
The decision was hard to make.	3	3	0	4	0
I had trouble making the decision because important information is unknown/unavailable to me, or is not readily available in the literature.	0	4	2	4	0
When I made the decision, it was hard to decide if the potential benefits from the donor outweighed the potential risks to people on the waiting list.	1	1	3	3	2
It was easy to identify all the considerations that affect the decision.	0	7	2	1	0
I am satisfied with the decision I made.	0	5	5	0	0
I would make the same decision again.	0	7	3	0	0

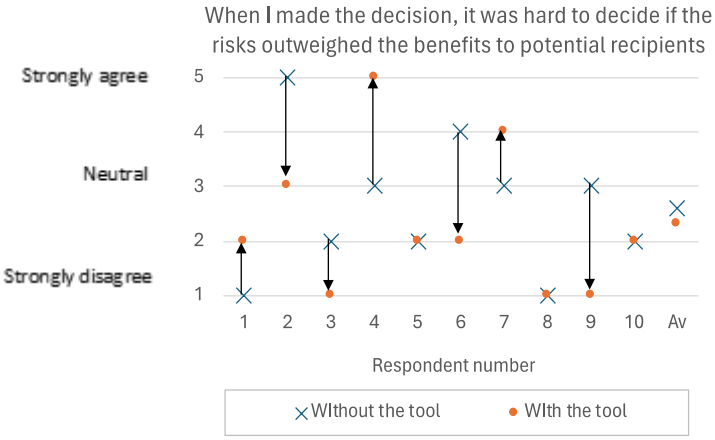
Table 4: *Aggregated responses with the use of the tool – Case 2*

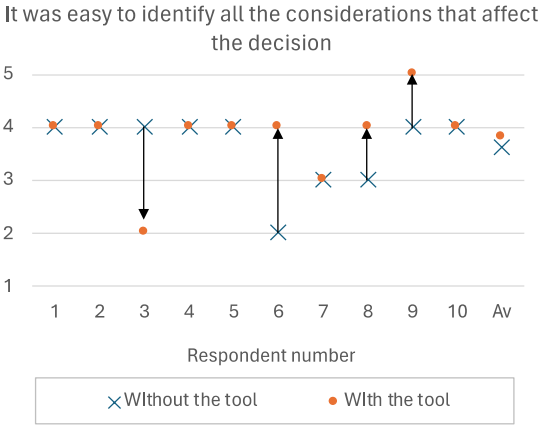
	Strongly Agree	*Agree*	*Neither agree nor disagree*	*Disagree*	*Strongly Disagree*
The decision was hard to make.	2	2	1	3	2
I had trouble making the decision because important information is unknown/unavailable to me, or is not readily available in the literature.	2	3	0	4	1
When I made the decision, it was hard to decide if the potential benefits from the donor outweighed the potential risks to people on the waiting list.	1	1	1	4	3
It was easy to identify all the considerations that affect the decision.	1	7	1	1	
I am satisfied with the decision I made.	2	6	1	1	0
I would make the same decision again.	2	6	1	0	1

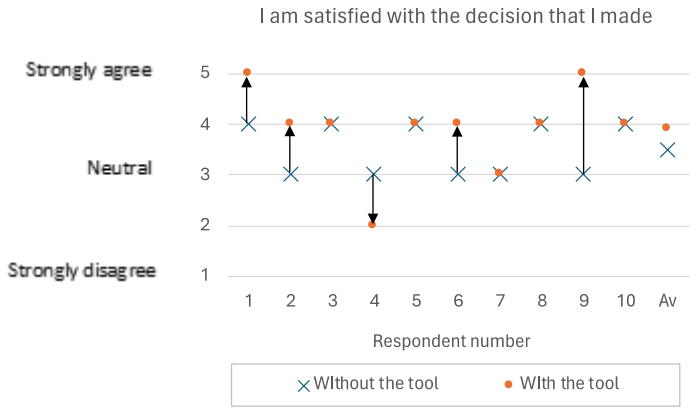
Figure 13: *Individual results of the decisional conflict questionnaire – Case 2*

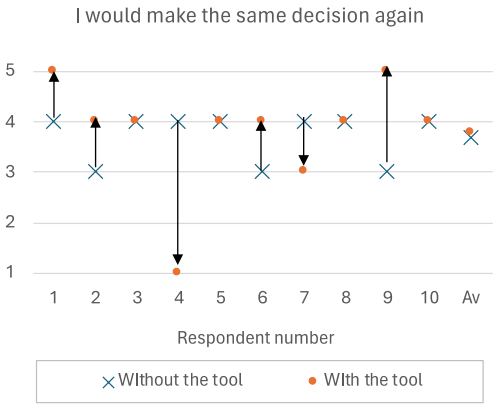












Feedback on System Usability

Decision support tool outputs

For Case 1, the results presented by the decision support tool were largely in agreement with the expectations of respondents.

For Case 2, respondents tended to be surprised by the absolute risk of disease transmission reported by the tool and some felt that it was an over-estimate. The first response of several respondents, based on selecting the option of "Cutaneous melanoma <=0.8mm(T1/N0/M0) completely resected" and seeing lots of red on the pictogram, was to assume something was wrong with the pictogram. Some agreed with the risk estimate of >=10% malignancy transmission, but were still surprised by the results as displayed by the visual array and felt that it conveyed a 90% risk of transmission: *"I don't know why, but I don't have any green people. [expressed surprise at the whole array going red] The risk conveyed seems too high."*

"So… 10% risk of cancer transmission, that's a bit odd. I don't understand that. It's saying at least 100 (10%) are estimated to have a transmitted cancer, but with the little people it is showing almost all of them as being red. It looks more like a 90% risk of transmission."

Others reflected that there wasn't an option to select that matched the scenario presented: *"10% transmitted cancer and no BBV, recommended for use in exceptional circumstances where there is a threat to life. Based on what I have entered, this would not be an acceptable kidney for pretty much anyone on the waiting list... What I think and what the risk support tools states is therefore discrepant. I think that does reflect that I unfortunately can't type in the right field. If I type in "in situ", that comes up with a much more acceptable risk...the trouble is that there isn't a proper category for the cancer type in this case. You would need to ask an expert in oncology/cancer pathology about what the correct category should be. You maybe need other drop-down boxes, starting with melanoma -> histologically proved (y/n/) -> depth -> years cancer free."*

Some respondents were unclear on how the survival estimates were derived and how to interpret these correctly: *"Are the survival estimates based on all-comers/an average recipient? it would be helpful to know who the one and five-year survival estimates apply to. Is this for everyone or is it based on a specific patient profile? Having that in the methodological notes would be helpful."*

Key Points:

- How the Tool conveys high risk of malignancy transmission needs to be revisited
- Some guidance should be provided for scenarios where the drop-down menus don't correspond to the terminology used in the donor history
- Methodological notes need to clarify how the survival estimates should be interpreted – do survival estimates reflect the "average" recipient?

Interaction with decision support tool

Respondents were asked to enter the donor information for Case 2 into the decision support tool and to "think aloud" as they went through this process, commenting on any points of their interaction with the tool that they found confusing, error prone, frustrating, overly manual, requiring undue mental effort, or rigid/inflexible.

Overall, interaction with the tool was smooth and respondents reported only a few issues. The main issue was finding the correct cancer type from the drop-down menu. The first challenge was the number of options to scroll through under skin cancers; the second challenge was that the case information did not perfectly align with the options provided.

Comments/questions included:

- I don't have a terminal creatinine – what should I enter?

- How can I enter multiple cancers? *"The only situation that I am thinking of is where you have a donor with more than one risk factor, but I guess that is too hard to work out the risk for each. For example, you might have someone with a skin cancer who has also had a resected colorectal cancer in the past."*

  "When someone has a history of lots of skin cancers, is it possible to enter multiple cancers? You may well have a person who has a history of invasive SCC as well as melanoma."

- I can't find the relevant category for this melanoma history. *"I don't think the drop-down menu options gives me options that truly reflect the case, so therefore the interpretation of the risk I don't think is accurate."*

  "I am confused about choosing the cancer type. We've got cutaneous melanoma <0.8mm with no time frame, then you have cutaneous melanoma <0.8mm with 10 years cancer free, but there is no cutaneous melanoma <0.8mm with 10 years cancer free."

- Uncertainty that the final category selection was the correct one *"Cutaneous melanoma, <0.8mm completely resected - I would check with a dermatologist whether that is the correct terminology in this case."*

Key Points:

- Interaction with the user interface was positive overall, with very few issues/concerns raised
- The main issue was in relation to finding and selecting the correct skin cancer category, given the large number of options to scroll through.

Feedback on user interface

KDPI

One respondent expressed a preference to remove the temperature thermometer from the KDPI panel, as they felt it might bias acceptance decision where the KDPI was high: *"The biggest problem with the KAPI is*

that it is so age driven and only refers to the donors that are actually being used, so it automatically limits people thinking about using donors in the 70-80 age range when I am sure that you would get benefit from these kidneys. I would avoid having the KDPI being over-emphasised and would take away the colour graphic (temperature scale) as I think that is providing an unconscious bias (not wanting to be in the red zone), pushing you towards thinking of a KDPI of 80 as bad, where I would be very happy with that donor."

However, other respondents reported that they were satisfied with how the KDPI information was presented.

Malignancy and BBV drop-down menus

- The fact that only one cancer can be entered is a limitation where the potential donor has a history of multiple cancers.
- Under "skin cancers" there are a lot of options and it is difficult to find the correct one.
- One respondent suggested moving the drop-down menu for malignancy above the BBV menu, with the rationale that malignancy risk is of greater concern and should therefore be given prominence.

Pictogram/visual array

- Most respondents liked the visual depiction of risk presented by the array.
- However, not all respondents found the pictogram/visual array easy to understand at first glance:

  "I can see a lot of green people…I don't know what that means."

  "I initially had an issue with the pictogram. The key information that I need is in the box below. Though it makes more sense looking at it for longer."

- Correct understanding of the array required a reading of the written results underneath. People got an immediate visual impression of risk from the array, but the actual risk estimate from the text underneath.

- Some respondents – those who are generally not visually oriented in how they comprehend information – found the array did not contribute to their understanding and searched on the page for the written report of risk estimates: *"For me, I think in numbers as much or more than visually, so for me the visual representation doesn't add a huge amount."*

- Some respondents were confused by which risks were being conveyed by the visual array: "*Based on the pictogram, for the outcome of one-year graft survival… actually I don't know what the relevance of one-year graft survival is here, since the outcome I am interested in is cancer transmission."*

- Respondents were comfortable with the way that risk is conveyed by the array for minimal/low/intermediate risk cancers, but were confused by the presentation of high-risk cancers.

- For Case 2, where a high-risk skin cancer option was selected, many respondents interpreted the red figures as indicating that there was a 90% risk of transmitting cancer: *"The picture with all the red makes it look like you have a 93% chance of transmitting malignancy.*"

  "It's saying at least 100 (10%) are estimated to have a transmitted cancer, but with the little people it is showing almost all of them as being red. It looks more like a 90% risk of transmission."

  "What I am seeing is that nearly all of the figures are red, but the number says "at least 100 are expected to have transmitted cancer". I've got nearly 900 showing as red - is that deliberate or not? I was thinking that the red ones, out of 1000, would be the number expected to have transmitted disease. Or is the number at high risk of disease? This is confusing to me - it looks like 9/10 recipients have transmitted cancer. I would only show the proportion with likely transmission in red, with maybe a separate category for the proportion with uncertain transmission."

- The difficulty of conveying statistical uncertainty in a pictogram was discussed: *"If there was some way of incorporating the uncertainty of the risk estimates, I think that would be helpful. Even if it can't be included with the pictogram, if the uncertainty/range/confidence intervals could at least be expressed in the text that would be helpful."*

Risk estimates

- Text not resizing currently – difficult to read (either too small or too large and getting cut off).
- One respondent noted that the default screen shows one-year survival when five-year survival is the more clinically relevant outcome: *"The tool presents both 1 and 5 year graft survival, but in reality we talk in terms of 5-year survival as this is an acceptable outcome for a transplant. I would use the 5-year survival as the default outcome of interest. I am not sure that you would really use the 1-year graft survival."*
- Some respondents indicated they would like to see confidence intervals around the survival estimates *"The 5-year survival estimate looks surprisingly good - I would like to see confidence intervals around the graft survival estimates. Some idea of the strength of the evidence would be helpful."*

Notes on risk estimates

- Few respondents commented on these notes or reflected on their contents.
- One noted that the information was too brief to convey anything meaningful: *"I see that there are notes on risk estimates, it appears that these notes are supposed to link out to further information, but there are no links. This information provided is very brief, it doesn't really say anything, so I was expecting a hyperlink…What I have seen done elsewhere is links to the journal article where the risk score is derived from.*

Having an understanding of the development of the risk scores and whether they have been validated would be important for trust in the tool."

Key Points:

- Respondents queried the fact that only one cancer can be entered.
- Respondents generally liked the visual array but emphasised the need for it to be supported with clear, readable written risk estimates to enable rapid and unambiguous interpretation.
- The current depiction of high-risk cancers by the array led to confusion and the interpretation that there was a >90% risk of cancer transmission.
- There was a request for confidence intervals around the risk estimates to be reported.
- Possible preference for 5-year survival to be presented as the default (instead of 1-year).
- The notes on risk estimates need to convey key information on interpretation, evidences sources, and where to go to find more information.

Relevant clinical information not captured by the tool

Respondents were asked "Based on the donor history you were given, are there other considerations that you would take into account in your final decision regarding medical suitability that are not reflected by this tool?". The following considerations were identified:

Proteinuria / ACR / urinalysis

Most respondents emphasised that they would want to have the results of urinalysis to know whether there is proteinuria present before proceeding with donation. it is routinely available about half the time and would typically be requested for a potential kidney donor. It is necessary for interpreting the risks to kidney donation posed by a history of hypertension or diabetes. Also, in the context of MGUS, proteinuria could indicate a monoclonal band of renal significance.

Smoking

Kidneys from heavy smokers tend to have inferior long term transplant outcomes compared to what we would have predicted on the basis of admission creatinine and patient size. Smoking is of concern from both a malignancy point of view and also as a vascular risk factor. Presence of COPD can be an indicator of heavy smoking history and information on pack-years is relevant to malignancy risk and kidney outcomes.

Multiple cancers

The tool is currently not set up to capture a history of multiple minimal/low-risk cancers (as the tool only allows entry of one cancer, it doesn't reflect the consideration that might be given to other cancers in the donor history).

BMI

Many respondents calculated BMI in their heads while reviewing the case details.

Kidney size

Only raised by one respondent.

Peripheral vascular disease

Only raised by one recipient, who noted that overt vascular disease is something that would be taken into account when determining donor suitability but is not a feature of the KDPI.

Recipient factors

Even though the capture of recipient factors was explicitly out of scope for this tool, several respondents noted that they would take into account whether there might be a suitable recipient for a high-risk donor, such as an older patient or one who was struggling on dialysis, in their determination of medical suitability.

Regarding the relevance of including information on proteinuria and smoking amongst the information presented by the tool, it was noted that high proteinuria will be a barrier to kidney acceptance, as will the combination of diabetes, hypertension and smoking, even if all other indicators are good: "*The triad of death on the donor side for kidney acceptance is diabetes, hypertension and smoking - it is practically impossible to allocate kidneys with all three of these risk factors (especially if DCD). That's another area where I see inconsistencies happening - where smoking or proteinuria are present.*"

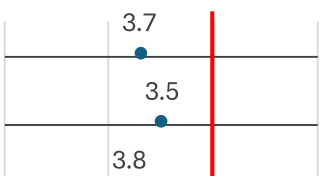
Adapted Healthcare System Usability Scale Results

Based on the adapted Healthcare System Usability Scale[2], and using the scoring methodology recommended by the instrument's authors, the existing version of this decision support tool scores 77%, which indicates good useability with potential for some improvements.

The highest average scores were in relation to tool navigation, ease of use and being able to find information quickly. The lowest scores, indicating particular areas for improvement, are in relation to (i) understanding how the tool creates its risk scores and (ii) with respect to the tool containing all the information that is needed. On the latter point, the comments from respondents included: *"I personally would like to see urinalysis results as this is something that stops donors going ahead. Diabetes and hypertension both cause proteinuria so when they are present you would want to see what is in the urine."*

"Need more information about the cancer background. The ICH could be due to causes other than stroke, such as trauma or malignancy, so we are assuming that it is due to stroke but we don't know. I didn't have the terminal creatinine so I had to enter the information that I had."

"It's got the core information, but sometimes there will be other information that you would need to take into account to make a safe decision. You would have to use this as an adjunct to a full evaluation of the EDR, you couldn't replace the EDR. But specifically for the risk of disease transmission, it's really helpful to fine-tune the risk estimate."



The tool would help me to work more efficiently.

It is easier to make efficient decisions by using the tool.

Qualitative feedback

Question	Average score from 1 (strongly disagree) to 5 (strongly agree)	Qualitative comments
The tool would help me to work more efficiently.	3.7 (range: 2-5)	"I think I would probably reach the same conclusion without the tool, but more slowly." "I think I will always be seeking discussions with colleagues, but sometimes you are making decisions in the wee hours so you might not be able to ring someone then and this tool would help me to feel supported."
It is easier to make efficient decisions by using the tool.	3.5 (range: 2-5)	"It's nice to see that my decision is being backed up by the tool, but I still go through the same mental processes, so it doesn't make those easier" "I would disagree because I would need to go to the computer or on to a new app and often I am getting a call in the middle of the night or when I am driving, when I wouldn't have access to the app."
The tool will help to improve patient outcomes.	3.8 (range: 3-5)	"I think it will improve the consistency of decision making. At the end of the day, it's not up to me, it's up to the transplant nephrologists to accept the organ. If my decision is backed up by a tool that they can see, that's where the improvement in patient outcomes will come from" "You can use the tool when going through the recipient consent process"
The tool fits well with the way I currently make donor medical suitability decisions.	3.7 (range: 2-4)	"Neither agree nor disagree. I tend to make decisions more wholistically" "I would agree because what we do is that we gather as much evidence as possible, and if the evidence is embedded in the tool, that does fit well with that process"
I found the information provided on the screen understandable.	4.1 (range: 2-5)	"I had trouble working my way through the pictograph - I found it more useful to go to the box below. Pictographs aren't my preferred way of communicating information. There were no blue figures in this case, so I was looking between the two boxes trying to find the blue. But also I am not used to it, so I guess you just need to get used to it and be shown how it works." "Yes, with the exception of the issue with the cancer drop-down options not covering the scenario presented" "I think that the way the risk was displayed in the array for the high-risk donor was very confusing. There was 10% risk reported in the text but 90% at risk in the array."
I found it easy to navigate through the tool.	4.4 (range: 4-5)	
I will easily remember how to use the tool.	4.3 (range: 2-5)	
The screen layout makes it easy to see each piece of information.	3.6 (range: 2-5)	"Disagree because of the pictogram - it is a little confusing at first. Otherwise I am happy with the layout." "Some of the cancer details were difficult to locate - I couldn't see all the options that were available to select from"
On the screen, I can find specific information I need quickly.	4.3 (range: 3-5)	"The tiny text is hard on my eyes."
I understand how the tool creates its risk scores.	3.3 (range: 1-5)	"I struggled with the types of the cancers"

		"It wasn't explained - I assume that when people ultimately use the tool there will be some sort of opening preamble and explanation"
The tool's risk scores are consistent with clinical practices and standards.	4.1 (range: 3-5)	"Yes, because it is clearly based on the current guidelines. In that way it is quite helpful, because sometimes you try to read the guidelines but it is a lot to navigate, but having it just pop out the risk and having the multiple domains in one tool is very, very helpful"
The tool contains all the relevant information that I need.	3.3 (range 2-4)	"I personally would like to see urinalysis results as this is something that stops donors going ahead. Diabetes and hypertension both cause proteinuria so when they are present you would want to see what is in the urine."
		"Need more information about the cancer background. The ICH could be due to causes other than stroke, such as trauma or malignancy, so we are assuming that it is due to stroke but we don't know. I didn't have the terminal creatinine so I had to enter the information that I had."
		"It's got the core information, but sometimes there will be other information that you would need to take into account to make a safe decision. You would have to use this as an adjunct to a full evaluation of the EDR, you couldn't replace the EDR. But specifically for the risk of disease transmission, it's really helpful to fine-tune the risk estimate."
I believe that the risk scores are reliable.	3.7 (range 3-5)	"They are reliable based on the current evidence that we have. I would always see these scores as a guide rather than as an absolute, and they are a tool to aid clinical decision making and shared decision making, not the be-all and end-all"
		"I just don't know what was used to general the risk scores. It would be good to include references for where the epidemiological data came from, and some indication of the quality of the evidence."
		"Well I don't know, because I don't know where it has been validated."
		"In terms of validation of the tool, I haven't checked what validation has been performed. I assume there has been a robust process."

Recommendations for User Interface and Risk Reporting

Malignancy drop-down menu

1. Split skin cancers in the drop-down menu into "non-melanoma skin cancers" and "melanoma" so there are fewer options to scroll through and it is faster to find the most appropriate option.
2. Permit entry of multiple cancers or, at a minimum, provide instructions of what to do in the case of a history involving multiple cancers (e.g. enter both separately then focus on the highest risk cancer).
3. Consider adding a check box to indicate whether reported cancer history is histologically confirmed.

Risk reporting / visual array

1. Make the written risk estimates more visually prominent and easier to read. Consider locating these beside or even above the visual array.
2. Ensure the text always resizes to a font size that is readable.
3. Include clearer headings, signposting what is contained in the array and what risks it is trying to communicate.
4. Re-think how high-risk cancers are depicted by the array. Some viewers are interpreting the pictogram for high-risk cancers as conveying a 90% risk of transmitted cancer, instead of "at least 10%".
5. Consider showing 5-year survival as the default, as this is more relevant to clinical outcomes
6. Consider reporting "negligible risk" as an alternative to reporting a 0% risk of transmission when no options for BBV or cancer are selected. This would be a more accurate reflection of the fact that there is always some degree of underlying residual risk of BBV or malignancy transmission.

7. Consider including confidence intervals around the survival estimates.

Inclusion of additional information

1. Several respondents noted the relevance of PCR/ACR results and smoking history. However, these do not form part of the KDPI score and are not currently included in the decision support tool. Suggest including a space to input urinalysis results and smoking status, potentially under the KDPI panel.

2. Several respondents did a mental BMI calculation while considering the donor history. It might be useful to include the results of a BMI calculation in the KDPI panel.

Notes on risk estimates

1. The "notes on risk estimates" section was overlooked by most respondents. Depending on screen size, this section sometimes relocates to under the KDPI panel where the notes may not be visible without scrolling down. They are also very brief for most cancer types and easily dismissed as not adding much that would aid interpretation.

2. Include more detail in the notes on risk estimates and use these notes as an opportunity to describe the degree of uncertainty around risk estimates as well as guiding correct interpretation of the array.

3. Make these notes more visually prominent (or at least ensure they can be seen).

Other/General

1. The inclusion of methodological notes and information on validation will be important for increasing trust in the results presented *"I would like to know what the evidence sources were. From my perspective, I would like to know that the data were drawn from relevant cohorts - ideally Australian data and from recent data. Sometimes evidence can be quite historical and not relevant"*

2. Most respondents indicated that they would want to be able to access the tool via their mobile but would also potentially access it via their computer (i.e. it should be optimised for both platforms). One respondent recommended that the mobile version sort the information into tabs/screens for ease of viewing and use. *"On the road or when at home, I would probably access it on my phone. On the phone, the best format would be if you went from screen to screen entering information - KDPI, then BBV risk, then cancer risk etc."*

   "To be honest, most of our donor work-up has to be done on a laptop or computer, so we would probably use it on computer."

3. Font size is an important consideration – a few respondents indicated they found the smallest text very hard to read.

4. One responded felt that the layout felt crowded towards the left-hand side of the screen *"There is lots of information on the left hand side of the screen and then there is a black area on the right. I would move everything more to the centre to make it look more balanced. The notes on risk estimates could be moved elsewhere possibly."*

Ideally, the tool would be able to generate a summary report that can be copied/printed that contains the following information:

- KDPI
- DCDD/DBDD status
- Stroke death y/n
- Diabetes and hypertension status
- Urinalysis results (proteinuria) and terminal creatinine and GFR
- BMI
- One- and five-year estimates of survival with a functioning graft
- Estimated risk of BBV transmission and notes on interpretation

- Estimated risk of malignancy transmission and notes on interpretation
- Indication of whether malignancy history is supported by histology.

Conclusions

Useability

Responses to the adapted Healthcare System Usability Scale indicate good useability with potential for some improvements, particularly with respect to (i) communication of how the tool creates its risk scores and (ii) the addition of such key information as proteinuria results.

Interaction with the user interface was positive overall, with the main issue relating to finding and selecting the correct skin cancer category, given the large number of options to scroll through. Some guidance should also be provided for scenarios where the drop-down menus don't correspond to the terminology used in the donor history.

How the tool conveys high risk of malignancy transmission needs to be revisited, given the degree of confusion around the interpretation of the visual array where risk of transmission is >10% (which many interpreted as a >90% risk of cancer transmission).

Respondents highlighted the need for more annotation and explanatory information such as methodological notes to clarify how the survival estimates should be interpreted, and the evidence sources they are based on. Confidence intervals or some indicator of the uncertainty around reported risk estimates were also requested. Respondents generally liked the visual array but emphasised the need for it to be supported with written risk estimates to enable rapid and unambiguous interpretation.

Use cases

Clinicians who are new to advising on donor medical suitability

Clinicians with extensive experience in consulting on donor medical suitability did not all agree that they would use this tool or that it would help them to work more efficiently. However, the use case for more junior clinicians who are new to the role of advising on medical suitability, or less experienced in making allocation decisions, was identified: *"I would do everything that I ordinarily do, and then in addition to that I*

would type information into the tool, so that would take me an extra 5 minutes, so that would reduce my efficiency. However, I have been doing this for 25 years so I am sure my approach and needs are different to people who are new to this. This is relevant given that the model in NSW relies on volunteers and there is mounting concern about this model from an insurance perspective and from the perspective of the burden of the task. there will be turn-over in the role and people will come in who are less experienced - a decision aid would be of greater value in that context."

"I think [the tool] may provide reassurance particularly to members of the medical suitability group who are less experienced in the assessment of risk and it may streamline the process in that setting, because particularly after hours it may be difficult to get hold of an oncologist or infectious disease physician who is experienced enough in the area to give a reliable opinion."

"This is a very useful tool which would be helpful particularly for transplant clinicians and receiving clinicians who are not as experienced in doing allocations."

"It's like a comfort blanket, this tool".

Donation nurses/donor coordinators

Donor coordinators could use the tool to rapidly synthesise information and calculate risk estimates, then provide this information to clinicians who will make the final decision on whether to proceed. *"I would see donation nurses using the tool, then calling the state medical directors and being able to quote the risks from the tool. The doctors would still have to go through the process of thinking about the case - for example, I can think of a case where the donation nurses thought it was a vasculytic process that caused the person to become brain-dead, but when we went through the process of thinking about the case (not many people with vasculitis become brain dead), we then determined that they had fungus in their brain. You can input details into the tool, but it's clinical acumen that will figure out that - oh - that story doesn't make sense. Unless you have a highly complex algorithm, that can account for details like vasculitis causing brain death, you still need a clinician to hear the specifics of the story and review the over-arching donor suitability then organ suitability."*

Some respondents noted that they often get calls about donors in the middle of the night or when driving, when they wouldn't be inclined to go to their computer or to enter information into an app. This possibly emphasises the use-case for donor coordinators, who might pre-populate the tool with the donor information prior to making the call so that they can provide the risk estimates as part of the donor information. *"I can imagine that on a phone it would be difficult to correlate information from the EDR to the tool. I would need 2 separate screens to do that. I wonder if it would be easier to be sent the information from the EDR and get the risk estimates from the tool read to be over the phone, asking whether I agree with the risk estimation... Even a screenshot of the output, or when the coordinator has no idea what a certain stage of cancer means, or what an HBV antigen means - if they can input the information and I can finish the rest, or if they can show me different scenarios of risk, that would be helpful."*

Clinicians wanting to rapidly calculate and communicate biovigilance risks

Multiple respondents identified the benefits of being able to more easily calculate biovigilance risks that could then be easily shared with colleagues and in the context of counselling patients: *"Sometimes you try to read the Guidelines but it is a lot to navigate, but having it just pop out the risk and having the multiple domains in one tool is very, very helpful"*

"I think it will be very useful for team members who are making the decision whether to accept donors. If a donor is then accepted and there is some risk associated with that donor, this tool would be very useful in communicating back to the primary nephrologist about what the risks are and quantifying those risks in a really reproducible way. The array would be very helpful to show patients in the context of shared decision making about what level of risk we are willing to accept. Often we discuss the fact that there are risks associated with taking any donor and it would be really good to be able to visualise what that risk is (as long as it really does accurately reflect that risk). I think this will be a really nice way of standardising some of the decision making across the country, which is currently quite person dependent. This will allow more transparent decision making, particularly if it is applied to every donor before offers are made."

"The figure of 0.1% being estimated to have transmitted cancer is a useful number to have for the receiving unit to discuss with the patient."

"We would likely use this in the evaluation of a donor. If we were happy with how the information were displayed, this might be a useful tool for counselling patients in that consent discussion we have with recipients."

One respondent reflected on the role of collective decision-making on complex cases within their unit and the utility of the tool in this context: *"This is the kind of thing that I would discuss with my colleagues and we would get a unit level decision, because it is not a zero risk and the consequences of transmission are significant. I would seek a collective decision in this case, I don't think this is the kind of decision that an individual would independently make."*

Others indicated that it would be useful to be able to enter information into the tool, take a screenshot of the summary results, then share with transplant colleagues if they wanted to seek advice on whether to proceed with donation. *"In South Australia there are 5 people who assess donor medical suitability and we have a WhatsApp group. This is the sort of thing that I could very easily take a screen shot of and then put it on the WhatsApp."*

Others reflected that they found the output on biovigilance risks more useful than the survival estimates: *"I would use it more for determining risk of BBV and malignancy rather than graft survival, perhaps because those biovigilance decisions are harder to make."*

"From my perspective, my role is to say yay or nay to the donor and then to age-restrict it… It's not for me, as the person determining medical suitability, to say whether the donor is suitable for a specific patient - I am just going to say that this donor is suitable for a recipient of a specific age range. Survival outcomes are probably not relevant to me as a medical suitability person."

Value to patients and the system

Consistency of decision making

Respondents reflected on the potential value of this tool in improving the degree of consistency in decision-making: *"I think it will improve the consistency of decision making. At the end of the day, it's not up to me, it's up to the transplant nephrologists to accept the organ. If my decision is backed up by a tool that they can see, that's where the improvement in patient outcomes will come from."*

The value of the tool in making the Clinical Guidelines easier to navigate (and therefore to apply consistently) was also identified: *"…sometimes you try to read the Guidelines but it is a lot to navigate, but having it just pop out the risk and having the multiple domains in one tool is very, very helpful."*

Reduction in decisional conflict

Respondents were asked to reflect on two cases for this survey – one that was relatively straightforward (Case 1) and one that was potentially more complicated (Case 2). The overall reduction in decisional conflict was very small for Case 1, although 44% of respondents were more satisfied with their original determination after it was confirmed by the decision support tool.

For Case 2, decisional conflict scored were decreased overall by 11%. Although the numbers are small, respondents overall found the decision less hard to make with the benefit of the tool and were more satisfied with their decision.

Support for Junior Clinicians

The potential for this tool to be of benefit to junior clinicians in particular was highlighted: *"I think [the tool] may provide reassurance particularly to members of the medical suitability group who are less experienced in the assessment of risk and it may streamline the process in that setting, because particularly after hours it may be difficult to get hold of an oncologist or infectious disease physician who is experienced enough in the area to give a reliable opinion."*

"This is a very useful tool which would be helpful particularly for transplant clinicians and receiving clinicians who are not as experienced in doing allocations."

Barriers to uptake, challenges and risks

Lack of confidence in risk estimates or incorrect/inconsistent risk estimates obtained

A challenge for the tool and for the TSANZ Clinical Guidelines is that they cannot capture every scenario. In addition, cancer terminology and staging are constantly evolving, hence historical pathology notes may be difficult to reconcile with contemporary risk classification. Trying to fit the donor medical history into the range of options presented by the drop-down menus may not always be straight-forward and may yield results that are not considered believable or are incorrect due to the wrong options being selected. *"I found the classification options provided by the tool quite tricky, given that for a melanoma above a certain size [the options] take into account time, but for a smaller size it does not. You would think that a smaller cancer with a long melanoma-free time would have a smaller risk, but that option wasn't there."*

"Based on what I have entered, this would not be an acceptable kidney for pretty much anyone on the waiting list… I think that does reflect that I unfortunately can't type in the right field. If it type in in situ, that comes up with a much more acceptable risk...the trouble is that there isn't a proper category for the cancer type in this case. You would need to ask an expert in oncology/cancer pathology about what the correct category should be. You maybe need other drop down boxes, starting with melanoma -> histologically proved (y/n/) -> depth -> years cancer free."

From the same respondent: *"I think the decision tool is a great idea. I think it is important to have clarity in the cancer field as to which option to select. I clicked on one that I thought was appropriate but it wasn't the one I actually wanted. That could have led to a loss of a donor organ."*

In cases where the donor information cannot be easily aligned with the drop-down options presented by the tool, the tool might not be effective in increasing the degree of consistency in decision-making due to inconsistencies in data entry.

Another factor that will affect confidence in the risk estimates is the quality of the methodological notes and the evidence supporting the risk estimates, and the reporting of validation studies. One respondent expressed that they could not have confidence the graft survival estimates in the absence of information on the recipient characteristics on which those estimates were based. Multiple respondents expressed a desire for confidence intervals or more information on the evidence underlying risk estimates. *"It would be important to know the characteristics of the recipient on which the reported survival estimates are based. If it goes to a 75 year old recipient with cardiac disease the probability of death that would be a very different result to a 50 year old without cardiac disease. The results of any survival model, without the recipient characteristics, would not be valid."*

TSANZ Guidelines become out of date

The Decision Support Tool relies on the TSANZ Clinical Guidelines recommendations on malignancy in donors to stay up to date with current clinical evidence and practice. The tool also needs to be updated with revised risk estimates each time the TSANZ Guidelines undergo an update to this section.

However, there may be a lag between an emerging/evolving clinical consensus around the transmission risk associated with a specific cancer history and an update to the Guidelines being drafted, approved, and released. Where this is the case, the risk estimates presented by the tool will generally tend to be more conservative than current thinking.

In Case 2 used in this survey, the case history described a potential donor with a history of a 0.65mm superficial spreading melanoma that was resected nearly 20 years ago with no recurrence. This prompted discussion from several respondents about the limitations of the current TSANZ Guidelines with respect to donors with a distant history of melanoma. Under the current guidelines, T1 malignant melanoma is designated as high risk regardless of the recurrence-free interval; however, several respondents indicated that this should be revised.

This issue will generally affect cancers currently designated as "high risk" of transmission, where the consensus has shifted towards a down-graded risk estimate due to improved treatments or greater

evidence on transmission risk. A high-risk designation arguably presents the most difficult scenario for decision making around donor medical suitability and is likely to result in not proceeding with kidney donation. Misclassification in this circumstance, confirmed by the Decision Support Tool, carries some risk of lost donation opportunities.

One way to approach this would be to include, in the "explanatory notes" section, a note for all high-risk cancers prompting the reviewing clinician to seek expert advice on transmission risk.

The tool interface should also prominently display which version of the TSANZ Guidelines is the source of risk estimate and when the risk estimates were last updated (what year).

Donor cancer history cannot be confirmed

Sometimes an exact cancer diagnosis and histological information are not available – for example for donors who were diagnosed and treated overseas. It may also be the case that a history of cancer reported by the next of kin, particularly a history of skin cancer, may be misreported as malignant melanoma when it was not, and vice versa.

Based on the 2 cases presented to respondents to this survey, a significant proportion of the decisional conflict around each case was due to the uncertainty around the medical history – especially whether the reported in situ melanomas were, in fact, in situ. Most respondents were reluctant to take the case information on face value. In one case, this uncertainty resulted in a determination to decline the kidney:

"The thing that worries me in the melanoma in situ...the thing is that we don't know much about the actual degree of the histology for the melanoma - the recency or number of melanomas. There is also the possibility that the intracranial haemorrhage was due to a melanoma deposit. To me this is a high-risk donor. I would not accept due to the risk of melanoma. I would need much more information about the melanoma in situ and would be very reluctant to accept this person as a donor."

It may be helpful for the tool to include a box to tick if the cancer history has been confirmed by pathology reports. This would not change the final risk estimate, but would indicate the degree of uncertainty around the diagnosis and the cancer type selected.

The risk estimates presented by the tool might not be helpful where there are doubts around the medical history.

Applicability to donors <18 years

The KDPI is known to have limitations, especially when reported for donors <18 years. A decision may need to be made regarding whether the tool is applicable for donors <18 years and whether the information provided (KDPI and graft survival estimates) is sufficiently accurate. It may be helpful to include a note on the interpretation of results where the donor is <18 years.

Tool is used to rule out potential donors inappropriately

In cases where malignancy history is incorrect, ambiguous, or misinterpreted as high or unacceptable risk, the risk estimates generated by the tool may be used as a rationale for not proceeding with donation when there may have been potential recipients for the kidneys.

One respondent emphasised that the tool should not be used to filter out potential donors prior to clinician review: "*We wouldn't want this tool to stop the call coming from Donatelife - we wouldn't want Donatelife to be using the tool as a way to make a decision not to proceed with donation. I see this as a clinical tool on the transplantation side rather than the donation side, and it shouldn't be used as a tool to rule things out. You never know, there could be a patient who is running out of dialysis access who would be prepared to take this risk. You wouldn't want that chance to have been ruled out by someone who had used this as a filtration tool at the beginning*"

Legal and Security risks

One respondent queried the medicolegal implications of using the tool as well as the data security risks: *"Many of us are concerned about the medical liability - will this help us in terms of improving our decision making*

and will it have a legal implication if using the tool. That is, if the tool says one thing and the decision made by the clinician is different and there is an adverse outcome, who is to blame? The security of the data being imputed should also be considered. Who owns this tool?"

Appendix A

DONOR REFERRAL CASE 1

Donor characteristics	
Age	64
Gender	Male
ABO	A+
Weight (kg)	80
Height (cm)	176
Primary Cause of Death	Intracranial haemorrhage
Patient Admission Summary	R hemiparesis with subsequent deterioration CTB – L thalamic haemorrhage with intraventricular extension
Mechanical Ventilation	Invasive
Pathway	DCD

Medical History and Clinical Conditions	
Past Medical History	AF (Rivaroxaban) PPM 2017 Melanoma in situ x 3 (lip – 2015, right shoulder – 2020, abdomen – 2020) MGUS B12 deficiency Colonic polyps GORD/Barrett's oesophagus ETOH (4-5 beers + 4-5 wines/night) Other: ICH likely due to post-coital HTN; c/o arm weakness post coitus Medications: Irbesartan, Rabeprazole, Rivaroxaban, Ezetimibe, Vit D, BL Osteoblast
HIV	No
HBV	No
HCV	No
Cancer	Melanoma in situ x 3 (lip – 2015, right shoulder – 2020, abdomen – 2020)
Hypertension	Yes
High Cholesterol	Yes
Diabetes Mellitus	No
Smoker	No
Observations	

Reading Date	BP (Arterial)	MAP (Arterial)	Temp (°C)	Urine Output
05/12/2022	124/65	84	35.6	60

Biochemistry				
Reading Date	Urea	Creatinine	eGFR	Comment
19/07/2021	4.2	84	84	Historic
04/12/2022	.	81	88	Admission
05/12/2022	4.7	72	>90	Terminal

Urinalysis - unavailable

Appendix B

Respondent	Risk tolerant/ averse	Assessment	Comments on cancer history	Other concerns
1	Tolerant	Accept	The melanoma in situ is irrelevant as it is low risk The colonic polyps - do we know anything about them, have they been biopsied? The Barret's oesophagus is always a potential concern - is there anything pre-cancerous? Noted he is a non-smoker He doesn't have an overwhelming cancer-like picture.	Hypertension and high cholesterol but no diabetes - there would be a question about how well he had been controlling his hypertension. Do we have a urine dipstick to see if there is evidence of proteinuria? I would like a urinalysis
2	Tolerant	Accept (with caveats)	A melanoma in situ - in general we are happy with melanoma in situ, but if it was an actual melanoma I would be concerned. MGUS - I would refer to the guidelines but I think this is fine. Same with colonic polyps.	I would calculate their BMI. Often people get worried about potential donors with lower BMI and alcohol use, but this person doesn't appear to have a low BMI. Cause of death is intracranial haemorrhage which portends some increased risk. DCD is associated with delayed graft function. I would be a bit worried about hypertension in terms of poorer graft function in the recipient.
3	Averse	Decline	The thing is that we don't know much about the actual degree of the histology for the melanoma - the recency or number of melanomas. There is also the possibility that the intracranial haemorrhage was due to a melanoma deposit To me this is a high risk donor. Would not accept due to the risk of melanoma. I would need much more information about the melanoma in situ and would be very reluctant	

			to accept this person as a donor….Even with clear pathology I would be hesitant to accept these kidneys given a recent, multisite melanoma history.
4	Tolerant	Unsure (need more information)	The things that concern me about this donor are the DCD pathway (which should be ok) and the 2 pre-malignant lesions - the MGUS and multiple episodes of melanoma in situ. While I think this patient probably has good kidneys, and would certainly have usable kidneys, those 2 premalignant lesions make me a little concerned, particularly the melanoma. I would refer to the guidelines and discuss with colleagues whether to take this, and I would need to know more about the melanoma (history of treatment and the nature of those) and to seek further advice around the nature of that. We all have grave concerns about the transmission of melanoma through transplantation, but I have probably got a bias because we actually had a case of this so past experience makes us more concerned (more so because there are multiple episodes)
5	Neither	Accept	Sounds like every single donor that comes my way. I would accept.
6	Averse	Accept (with caveats)	History of AF and or melanoma in situ, which has occurred on multiple occasions. Has an MGUS. It would be important to know the pathology on the colonic polyps. There are a few things that probably need a bit more information. It would be useful to have pathology on his melanoma in situ, confirming that the pathology was as described. Melanoma in site per se is not a deal-breaker, but it needs to be confirmed. The next thing

			would be the MGUS - I would want to know when the diagnosis was made and who made it. Colonic polyps - it would be useful to confirm the donor and family history, when the scope was done, what the pathology showed and what was the plan for follow up. The key thing is just checking the melanoma in situ story and getting a bit more information to make sure the diagnosis is as described. I would want to know that the intensivist has performed a full examination to make sure there are no lesions of concern at the time of donation. If it is confirmed that it is melanoma in situ and the polyps are clear, then it is unlikely that the cause of this persons ICH is metastatic melanoma and then I think it would be ok to proceed with transplantation.	
7	Averse	Accept (with caveats)	They have had melanoma in situ x 3, most recently in 2020 - I think the lifetime recurrence event is 1% for melanoma in situ, so we would normally accept the donors and counsel the recipients. The melanoma is a relative contraindication but wouldn't rule this out. The fact that there are 3 melanomas is a bit of a worry. We would ask the ICU team to do a skin check to see if any other lesions have developed in the last 3 years and we would ask a dermatologist to advise. Depending on what other organs are being considered, a CT might be done - we would be reassured if a CT had been done with no evidence of metastatic disease. It's partly related to their age. Would counsel the recipient that there is a bit of a risk.	Would be the upper end of the age spectrum for us, so they would need to be medically pretty good for us to take them on. No other viral risks. Not a smoker, no diabetes - it sounds like they are at the upper end of the age range for use, but they don't have any vascular disease or diabetes and their kidney function is normal, blood group A so should be able to find a suitable recipient.

8	Tolerant	Accept	Melanoma in situ x3 in different locations is curious – I would want to see the pathology. If they were indeed melanoma in situ then it wouldn't stop me from going ahead, but it is unusual to get 3 melanoma in situ and I would want to get a melanoma expert's views on the cumulative risk. MGUS is common in this age group, as long as the full blood count looks acceptable this wouldn't put me off. I would also want a PCR to know if there is protein in the urine to see if this reflects a monoclonal band of renal significance. Colon polyps are fine; Barret's is associated with increased risk of malignancy so I would be keen to know when the last scope was done (if one hasn't been done for some time, then I would recommend examination of the oesophagus with some form of imaging prior to donation). I would add Barrets to my considerations under cancer risk.	
9	Tolerant	Accept (with caveats)	We would want to make sure that the melanoma in situ is in fact an in situ. The fact that there are 3 of them is of interest. The Rivaroxaban and the stroke are not really a surprise, the rest of it looks pretty reasonable.	noted that the urinalysis is not available - that is one of the first things I would ask for. ACR should be a standard part of the assessment of potential kidney donors
10	Tolerant	Accept	Apart from being an extended criteria donor with all the comorbidities, the thing that comes closest to excluding them as a donor is the melanoma. I am reassured that it is only melanoma in situ, and I am a little bit reassured that it has not been a very recent melanoma in situ. One thing that does concern me a bit is those two in 2020 that were almost	It's a shame urinalysis is not available, as in this situation where there is hypertension - and in most situations - it is nice to know whether there is proteinuria.

	synchronous but in 2 different locations. So I would very carefully explore the colonic polyps to make sure that they were assessed recently and to make sure there is no hint of malignancy there and the colonoscopies were up to date. I would want to make sure there was a thorough examination of the skin to make sure there are no suspicious lesions before proceeding.

Appendix C

DONOR REFERRAL CASE 2

Donor characteristics	
Age	70
Gender	Male
ABO	A
Weight (kg)	85
Height (cm)	183
Primary Cause of Death	Intracranial Haemorrhage – Spont SAH
Patient Admission Summary	SAH WFNS V Fisher IV SAH CTB: SAH w ventriculomegaly with significant intraventricular bleeding, tracking to 4th ventricle, blood left sided predominant.
Mechanical Ventilation	Invasive
Pathway	DBD

Medical History and Clinical Conditions	
Past Medical History	Long history of skin cancers, 2015 onwards. Sept 2021 - e/o BCC R parietal region and full thickness graft, Oct 2021 - parotidectomy & removal lesion left ear. GP - melanoma, back, 2005. Superficial spreading 0.65mm thick showing evidence of regression and arising in a pre-existent dysplastic naevus. No evidence of ulceration. Removed with clear margins (0.7mm). Re-excision in 2010, residual melanoma not found. March 2020 colonoscopy with haemorrhoid banding COPD (ex-smoker)
HIV	No
HBV	No
HCV	No
Cancer	Malignant melanoma (2005)
Hypertension	No
High Cholesterol	No
Diabetes Mellitus	No
Smoker	Ex-smoker

Observations				
Reading Date	BP (Arterial)	MAP (Arterial)	Temp (°C)	Urine Output
10/02/2022	140/62	88	35.1	160
11/02/2022	108/44	65	35.0	20

Biochemistry				
Reading Date	Urea	Creatinine	eGFR	Comment
17/10/2021	5.8	78	87	Historic
10/02/2022	6.4	66	>90	Admission

Urinalysis – unavailable

Appendix D

Respondent	Risk tolerant/ averse	Assessment	Comments on cancer history	Other concerns
1	Tolerant	Accept (with caveats)	Malignant melanoma in 2005 is of concern, as is the fact they are an ex smoker Melanoma on the back - no ulceration is good, noted removal with clear margins and reexcision with melanoma not found. 0.65mm I would need to refer to the TSANZ guidelines. I think that puts him into the high risk group (above 0.5mm is a problem), but it is almost 20 years since the original melanoma was diagnosed. He's had lots of other skin cancers and colonoscopy with haemorrhoid banding - that's fine. Based on the information I have, I would put the cancer transmission risk in the low category, but I wouldn't be as comfortable as saying minimal risk.	the problem with the kidneys are the fact that he is an ex-smoker and this history of melanoma Urine output has dropped off, blood pressure is good, temperature is fine and renal function is ok I would say the kidneys are acceptable, but I would confirm with a transplant nephrologist.
2	Tolerant	Accept (with caveats)	Long history of skin cancers. BCC in the parietal region with parotidectomy. I am not concerned about BCC spread locally without distant mets History of melanoma 0.65mm, regression in a pre-existing dysplastic naevus that was excised and reexcised in 2010 (15 years ago), which I think puts this in the TSANZ high risk category (but not unacceptable risk) however I would refer to the guidelines rather than relying on my memory.	70 year old male, blood group A - slightly older than case 1, portends more of a risk of death censored graft loss for the recipient No hypertension, no diabetes, but an ex-smoker
3	Averse	Accept (with caveats)	The history of skin cancer is of concern, however what we have here is mainly BCCs and I assume that is actually proven histologically. Then we have a melanoma from 2005. Superficial spreading with regression, no visible ulceration and clear margins, re-excision with no melanoma found.	

			A few years ago I would have still said no, but i think this would probably be ok to go ahead, but still with recipient consent. I would accept for an older recipient because of the donor age. I would explain the recipient that there was a small risk of melanoma being transmitted. I would say that a risk of <1% would be a fair/safe estimate of the risk of melanoma transmission. Based on the pathology notes, there are some atypical melanocytes extending to within 0.3mm of the lateral margin, which is a bit more concerning, but I would still accept with informed consent since the melanoma is from 2005 with no residual melanoma found in 2010.
4	Tolerant	Unsure (need more information)	Apart from donor age, this looks good so I am thinking this is a feasible donor, but again the history of melanoma is an important factor. It's different in the sense that it was a one-off lesion in the distant past, so I would need to know that the donor did not have any suspicious skin lesions at the moment. I would be more likely to favour accepting this donor due to the distant history of the melanoma, even though it was malignant melanoma. I am not sure of the evidence base for that - the previous case had multiple in situ melanomas quite recently, but this is a historical malignant lesion. I don't know if someone has been melanoma free for 20 years if there is less risk of transmission - I would suggest that the risk is lower than the previous case because the cancer is so historical. I would need to know what treatment they had and to seek expert advice on risk of recurrence.
5	Neither	Accept	History of skin cancer (melanoma 2005, superficial spreading no evidence of ulceration), colonoscopy. Yes, I would accept.

6	Averse	Unsure (need more information)	Long history of skin cancers. BCC removed 5 months ago and his parotid taken out and removed left ear. I would assume that we would have pathology report confirming that this was a BCC and not something else and giving the reasoning for the parotidectomy. All that information would need to be clarified. Superficial spreading melanoma invading into the dermis level 2, 0.65mm. Pathology report says that the margins are clear but that there are also atypical cells within 0.3mm of the margins. But they obviously looked again in 2010 and did not find any residual melanoma. The key issue is really in regard to the risk from the melanoma. I would need to look up the risks specific to superficial spreading melanoma. It's not quite melanoma in situ, so my first thought would be to look up the TSANZ Guidelines with respect to thickness and type of melanoma and risk of transmission. [looked up the guidelines] The tumour is less than 0.8mm and completely resected - according to the Guidelines, the recommendation in these circumstances is that transplantation should only proceed in extreme circumstances. I would probably therefore be more risk-averse with this donor. I would speak to a dermatologist to get their thoughts on the degree of risk associated with this pathology. I would be concerned that there would be risk of recurrence of greater than 10%. He has had a colonoscopy - it would be interesting to know what was see there. One of the questions here is whether his cerebral bleed is caused by metastatic disease	Kidney function looks reasonable - historical eGFR suggests there may be a little bit of kidney disease. He is also an ex-smoker so has risks from a lung perspective. Would want to make sure his lung x-ray looks ok
7	Averse	Accept (with caveats)	History of skin cancers. BCC with parotidectomy and removal of part of ear - as long as these were fully excised that would not be a problem. Melanoma in 2005, superficial spreading 0.65mm, not ulceration, clear margines. Re-excised in 2010 - that is unusual.	

			They have had a colonoscopy and are an ex smoker. No viral risk factors, no hypertension, no diabetes, normal creatinine. Medically, we would be happy. The melanoma is a bit trickier. It is a much higher risk melanoma than the previous one and it is usual that it wasn't re-excised at the time, but reassuring that the reexcision down the track didn't show any residual disease. It's also quite a long time ago - 20 years without recurrence. You've got a higher risk melanoma, but a lot of time has elapsed. For us this would be potentially appropriate, but we would probably seek advice. We would do a skin check to make sure there are no other lesions or evidence of local recurrence and we would probably recommend a CT scan, based on the age and smoking history, to get an idea of the degree of vascular calcification and also looking for evidence of distal metastatic disease. If the CT looked ok we would offer to specific selected recipients with counselling about the risks.	
8	Tolerant	Accept (with caveats)	The melanoma is from ~20 years before, although this doesn't exclude residual melanoma and there are adverse features and depth of concern. Superficial spreading with regression - regression is actually an adverse prognostic feature and I had a case just like this and talking to a melanoma expert, that was a problem. Regression means that they have had an immune response to it, and potentially it was deeper than 0.65 because there is fibrosis suggesting the tumour regressed. After 18 years it is probably cured, but I couldn't say that with 100% certainty. Skin cancers include BCC with parotidectomy and removal of lesion on the left ear - you don't do this for benign cysts and it unusual to do a parotidectomy for a BCC so although BCCs don’t metastasise, it is extreme to remove the parotid. This tells you that it is either an	Age 70 is getting up there but is certainly within the range of what we see. ICH is fine, ventilated DBD is fine, blood pressure fine. There was an episode of oliguria, associated with hypotension - that's ok in the context. Earlier biochemistry shows normal kidney function, but I would be interested to know the terminal creatinine as they could be going into acute kidney injury. COPD is fine except that it is a sign of heavy cigarette exposure. It would be helpful to know the number of smoking pack years. I would want to know the terminal creatinine.

			aggressive tumour of the person does not attend much medical care and they let this go too far. I would proceed with donation, but I would request the surgeon retrieving the kidneys to palpate for lumps and look for black spots. To the receiving teams I would spell out the details of the melanoma because we couldn't exclude potential for spread, and I would raise the BCC in case this was misclassified.	
9	Tolerant	Decline	SCC/BCC don't concern me; having said that, what is unusual here is that BCCs are generally not invasive, so to have a BCC that leads to a parotidectomy - I would be surprised if the BCC was the cause of the parotid being removed. That is a bit odd, and I would want more information about that. Superficial spreading melanoma of 0.65mm - that is quite a reasonable size. I would be quite concerned about that given the size. I think that this is a donor that I would be concerned about accepting on the basis of the malignant melanoma. I would probably be saying no, based on my understanding of the risks associated with that.... I would probably put it to the wider group - I wouldn't knock it back outright, but I would want to be absolutely clear about the melanoma transmission risk.	
10	Tolerant	Accept	We have a superficial spreading melanoma nearly 20 years ago without recurrence, but with a history of other skin cancers (SCC/BCC). I would think this donor is suitable and I would proceed.	The potential donor is slightly older (70) but has the advantage of going down a DBD not a DCD pathway. Normal urine output, blood pressure and renal function but we don't know about proteinuria. No hypertension, hyperlipidemia or diabetes The main comorbidities are around smoking.

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