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Assessing Consensus Between UK Renal Clinicians on Listing for Kidney Transplantation: A Modified Delphi Study

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Background. It is well recognized that there is significant variation between centers in access to kidney transplantation. In the absence of high-grade evidence, it is unclear whether variation is due to patient case mix, other center factors, or individual clinician decisions. This study sought consensus between UK clinicians on factors that should influence access to kidney transplantation. **Methods.** As part of the Access to Transplantation and Transplant Outcome Measures project, consultant nephrologists and transplant surgeons in 71 centers were invited to participate in a Delphi study involving 2 rounds. During rounds 1 and 2, participants rated their agreement to 29 statements covering 8 topics regarding kidney transplantation. A stakeholder meeting was used to discuss statements of interest after the 2 rounds. **Results.** In total, 122 nephrologists and 16 transplant surgeons from 45 units participated in rounds 1 and 2. After 2 rounds, 12 of 29 statements reached consensus. Fifty people participated in the stakeholder meeting. After the stakeholder meeting, a further 4 statements reached agreement. Of the 8 topics covered, consensus was reached in 6: use of a transplant protocol, patient age, body mass index, patient compliance with treatment, cardiac workup, and use of multidisciplinary meetings. Consensus was not reached on screening for malignancy and use of peripheral Doppler studies. **Conclusions.** The Delphi process identified factors upon which clinicians agreed and areas where consensus could not be achieved. The findings should inform national guidelines to support decision making in the absence of high quality evidence and to guide areas that warrant future research.

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Kidney transplantation is widely considered to be the optimum treatment for many patients with established renal failure. However, the number of patients requiring a kidney transplant far exceeds the number of available organs.[1] In this context, it is important that clinicians make evidence-based decisions regarding benefits of transplantation, when deciding which patients should be assessed for transplantation and which should join the waiting list.[2] The decision to waitlist patients for transplantation is influenced by many clinical factors and much work has gone into producing guidelines to ensure patients have access to available treatment options.[3] In the absence of high-grade evidence to support or discourage transplantation in specific patient groups, many of the recommendations draw on "expert opinion." It is possible that the lack of a strong evidence-based produces variation in practice between individual clinicians, which in turn contributes to variation between renal units in terms of listing policy for kidney transplantation.[4] Although several factors have been identified which influence clinicians' decision making,[5] it is unclear whether there is majority consensus between clinicians on many aspects of the transplant preparation process.

A survey of clinical practice across UK transplant centers confirmed variations in practice and identified areas where there is disagreement, such as the assessment of cardiovascular comorbidity, body mass index (BMI) and age.[6] This study informed a large UK wide research program, Access to Transplant and Transplant Outcome Measures (ATTOM). One of the aims of ATTOM is to investigate how to improve equity of access to kidney transplantation across the United Kingdom by systematically assessing patient- and center-specific factors influencing access to transplantation. Access to Transplant and Transplant Outcome Measures involved 5 workstreams,[7] one of which encompassed the 5 studies shown in Figure 1,[8] including the current Delphi consensus process. All studies investigated factors which may influence clinicians' decisions to list patients for kidney transplantation.

The current study aimed to use a Delphi approach to seek consensus between individual clinicians on factors they deemed important when making a decision whether or not to list a patient for kidney transplantation.

MATERIALS AND METHODS

Design and Setting

The study followed a modified Delphi process with clinicians from renal units in the United Kingdom. The Delphi approach is a formal consensus method recommended by the National Institute for Health and Care Excellence for enhancing effective decision making in healthcare.[9] The approach aims to enhance collective decision making by keeping individuals' responses anonymous from one another and reducing the effect of dominant individuals on the group decision.[10] There are several types of Delphi method which vary in their design;[11] a modified Delphi method using questionnaires was chosen for this study. The method was modified as the research team started with a set of preselected items to form the basis of the first questionnaire round. Two questionnaire rounds were performed. Anticipating that some questions would not reach consensus within 2 rounds, a further opportunity to reach consensus was provided in the form of a stakeholder meeting. The ATTOM study received ethical approval from Cambridgeshire Central Research Ethics Committee (ref: 11/EE/0120).

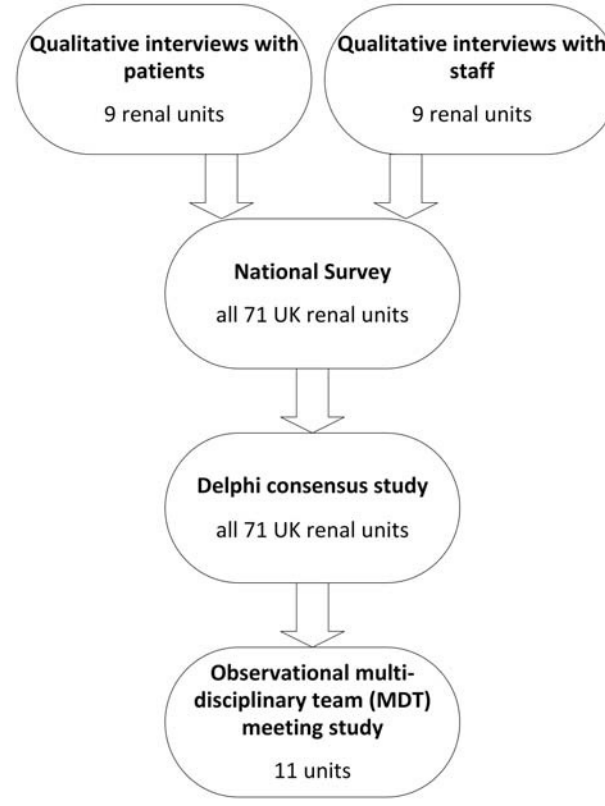

FIGURE 1. A diagram showing the 5 studies carried out within ATTOM workstream 1.

Participants

Consultant nephrologists and consultant transplant surgeons from all 71 UK renal units (23 transplanting and 48 nontransplanting units) were invited by email to participate in the study. Consultant grade clinicians were invited to take part as they represent staff who take overall responsibility for decisions about whether patients are listed for kidney transplantation. It was not possible to identify every practicing nephrologist in the United Kingdom along with reliable contact details, so in an attempt to recruit as many consultant nephrologists as possible, email invitations were sent to clinical directors at each unit, with a request for them to forward details to their consultant colleagues. Clinicians were considered to have given informed consent to participate if they responded to the invitation.

Questionnaire Items

The development of the initial Delphi questionnaire was informed by the results of a survey of all UK renal units, which aimed to identify variation in practice patterns in the process of waitlisting for kidney transplantation.[12] This survey found significant variation in the reported age limit for transplantation, the reported BMI cutoff, the investigations deemed necessary during transplant workup and the indications for such investigations. From 71 centers, 30% did not use a written transplant protocol, and 24% did not use multidisciplinary team (MDT) approach for transplant decision making.

One additional item identified from a related qualitative study (Pruthi R, personal communication) exploring individual

clinician views about listing was also added. Free-text comments were also allowed in the survey to allow participants to explain the reasons for their responses.

Twenty-nine items were identified for round 1 of the Delphi process, representing 8 broad themes (need for a written protocol, recipient age, recipient BMI, cardiac assessment, peripheral vascular disease, malignancy, compliance, need for MDT). Statements were drafted by the research team with expert advice from consultant nephrologists and transplant surgeons to ensure that they were clear and comprehensible. Statements were formatted into an online questionnaire using the software **SurveyMonkey** (http://www.surveymonkey.com) (see **Supplemental Digital Content,** http://links.lww.com/TXD/A79).

Procedure and Analysis

Round 1

Potential participants received an email with a web link to round 1 of the Delphi along with information about the aim of the study and eligibility criteria. Participants were asked to indicate their level of agreement with each statement by using a 9-point Likert scale (1, strongly disagree; 9, strongly agree). Free-text boxes were provided for any participant comments. Participants were given 6 weeks to respond. The median and interquartile range (IQR) for each statement were calculated using Microsoft Excel 2010. Group consensus agreement was defined a priori as a median group rating of 8 or more of 9. Median and IQR were used as measures of consensus because they are less susceptible to influence by outlying responses. Items achieving consensus agreement in round 1 were accepted. Items not achieving consensus agreement were circulated back to the participants for reconsideration in Round 2.

Round 2

Only participants who completed all statements in round 1 were invited to take part in round 2. Participants were sent a personalised email with a web link to the round 2 questionnaire. An attachment gave participants the results of round 1 with the average group score for each statement along with the participant's original response. Participants could give the same answers to Round 2 as given in Round 1, or could

TABLE 1.

Results from the Delphi process

		Median score (IQR)	
	Delphi rounds 1 and 2 responses; 0-9 (0, strongly disagree; 9, strongly agree)	**Round 1**	**Round 2**
1	A written transplant work-up protocol is needed for assessment of patients to be listed for kidney transplantation	8 (7-9)	—
2	There should be an upper age limit of 80 years for listing for transplantation	5 (2-8)	5 (2-7)
3	There should be an upper age limit of 75 years for listing for transplantation	4 (2-7)	4 (2-6)
4	There should be an upper age limit of 70 years for listing for transplantation	2 (1-4)	2 (1-3)
5	There should be a maximum BMI exclusion criterion of 40 kg/m^2	6 (2-8)	6 (3-8)
6	There should be a maximum BMI exclusion criterion of 35 kg/m^2	5 (3-8)	4 (2-7)
7	There should be a maximum BMI exclusion criterion of 30 kg/m^2	*2 (1-3)*	*2 (1-2)*
8	There should be a minimum BMI exclusion criterion of 20 kg/m^2	*2 (2-5)*	*2 (2-4)*
9	There should be a minimum BMI exclusion criterion of 18 kg/m^2	5 (2-6)	4 (2-6)
10	The minimum cardiac work-up undertaken for patients being assessed for transplant listing should include at least an ECG and ECHO	7 (5-8)	7 (5-8)
11	The minimum cardiac work-up undertaken for patients being assessed for transplant listing should include a stress test	*3 (2-4.75)*	*2 (2-5)*
12	Cardiac assessment for patients undergoing listing for transplantation should be stratified by risk	8 (8-9)	—
13	Asymptomatic CAD identified on pretransplant workup should be revascularized before listing for transplantation	5 (3-7)	5 (3-6)
	In the evaluation of lower limb peripheral vascular disease, Doppler studies should be done for:		
14	Asymptomatic older patients	5 (2-7)	5 (2.75-7)
15	All patients with diabetes	7 (4-8)	7 (5-8)
16	Symptomatic patients	9 (8-9)	—
17	Asymptomatic patients with poor peripheral pulses	8 (7-9)	—
18	Patients with asymptomatic bruit	8 (5.25-8)	—
19	History of smoking	6 (4-8)	6.5 (4-8)
	Patients should be routinely screened for malignancies as part of transplant assessment workup. All patients should be screened for:		
20	Prostate (men)	7 (5-8)	6 (3.5-8)
21	Breast (women)	8 (6-8)[a]	6 (4-8)
22	Cervical (women)	8 (7-8)[a]	7 (4-8)
23	Skin	7 (5-8)	—[b]
24	Colorectal	5 (3.25-8)	5 (3-7)
25	Bladder	5 (3-7.75)	—[b]
26	Lung	6 (4-8)	—[b]
27	Poor compliance (taking medication and/or clinic attendance) should be a factor which influences listing for transplantation	8 (7-8)	—
28	An MDT approach is needed when discussing all patients for listing for transplantation	7 (4-8)	8 (6-9)
29	An MDT approach is needed when discussing complex/borderline patients for listing for transplantation	9 (8-9)	—

Shading indicates consensus agreement; shading of scores indicate the round in which consensus was reached. Underlining indicates consensus disagreement after round 2.

[a] Two results from round 1 were not considered to have reached consensus agreement because clinicians written responses indicated misinterpretation of the statements—these were reworded for round 2.

[b] Three questions were not included in round 2 because they were felt to be too complex.

change their earlier answers, and were given 5 weeks to respond. Up to 3 reminders were sent to nonresponders. Again, group consensus agreement was defined as a median score of 8 or more of 9. Consensus disagreement was defined as a median score of 2 or fewer of 9.

Stakeholder Meeting

Results from rounds 1 and 2 were presented to the attendees of the National Health Service Blood and Transplant Renal Transplant Services annual meeting in March 2015. Renal Transplant Services is a national forum representing all units providing renal transplantation services in the United Kingdom, as well as other transplant stakeholders (eg, histocompatibility laboratories, commissioners and patients). The group was asked to vote on 3 statements that had not reached consensus in the previous rounds to see whether discussion helped to achieve consensus. The 3 statements were those that had greatest variation based on the IQR of responses in Rounds 1 and 2 (Table 1). Participants were asked to vote anonymously for 1 option using electronic voting pads. Open discussion was recorded by field notes made by members of the research team. Three other members of the team (R.P., R.R., and G.O.) coordinated discussions and presented data to the group.

RESULTS

Participation in rounds 1 and 2 is shown in Figure 2. A total of 167 participants from 49 renal units responded to round 1, which represents about a quarter of the nephrologists and surgeons and two thirds of the renal units in the United Kingdom (Table 2).[11] The number of clinicians responding in each unit varied from 1 to 13 (median, 2). The recruitment method did not allow enumeration of the number of clinicians who received an invitation to participate in the study.

Figure 3 summarizes the outcomes of rounds 1 and 2.

TABLE 2.

Clinical speciality of participants who responded to round 1 and characteristics of the renal units in which they worked

Individual clinicians	No. responses (%)
Clinical specialty	
Nephrology	136/550[a] (25)
Surgery	24/150[a] (16)
Renal unit representation	**No. responses (%)**
Of all UK renal units	49/71 (69)
By UK region	
England	36/53 (68)
Wales	2/4 (50)
Scotland	9/9 (100)
Northern Ireland	2/5 (40)
By type of unit:	
Transplanting	19/23 (83)
Nontransplanting	30/48 (63)

[a] Total consultants in Nephrology (550) and Transplant Surgery (150). Data from workforce survey by the Royal College of Physicians.[12]

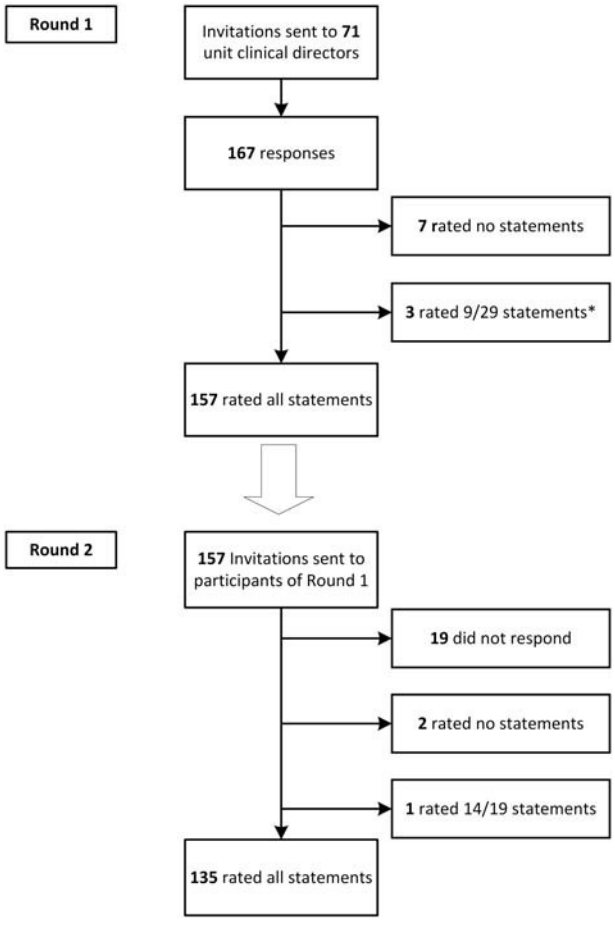

FIGURE 2. A flowchart showing responses to the Delphi in rounds 1 and 2.

Round 1

Seven (24%) of the 29 statements obtained consensus agreement in round 1 (Table 1 and Figure 3). These included agreement between participants over 3 broad themes: (1) that written protocols should be used for assessment of patients for transplantation, (2) that cardiac assessment should be stratified by risk, and (3) that poor compliance with treatment should be a factor taken into consideration when assessing patients for waitlisting. Many participants provided free-text comments, especially regarding patient age and BMI. Many

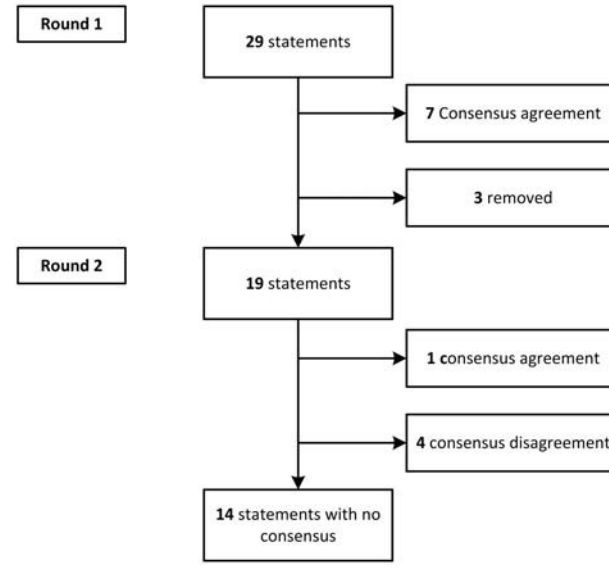

FIGURE 3. A flowchart showing the results of rounds 1 and 2.

felt BMI was an unhelpful measure and were reluctant to make decisions about listing based on BMI alone. Several emphasized that listing decisions were based on individuals patient circumstances and that cutoff values for age or BMI would not apply to everyone and such single-variable values were, therefore, unhelpful.

The statement concerning screening for malignancies in round 1 was perceived as lacking in clarity, and it was amended for round 2. Three items, relating to specific malignancies (skin, bladder, and lung) were removed from round 2 as they were felt to be too complex. Two statements regarding malignancy had reached consensus, but the free text comments indicated that some had misinterpreted the statements. These were amended and included in round 2. No new topics of interest were identified.

Round 2

In round 2, 157 clinicians who rated all statements in round 1 were invited to take part and 135 completed all statements (Figure 2); the response rate for nephrologists was 91% and for surgeons, 73%. Respondents came from 45 (63%) renal units; representing 17 (71%) transplant units and 28 (58%) nontransplant units. Between 1 and 13 (median, 2) responses were received for each unit.

One statement in round 2 reached consensus agreement (Table 1 and Figure 3). Participants agreed that MDT meetings were useful for all patients being considered for listing for transplantation, rather than for complex patients only. In addition, 4 statements reached consensus disagreement with scores of 2 or fewer. For the remaining statements, scores appeared to change in the direction of consensus (agreement or disagreement), indicating that participants had been influenced by the group score. However, wide variation remained in all responses (Table 2).

Nineteen participants did not respond in round 2, and 3 were not invited to take part in round 2 because they did not fully complete round 1 (Figure 2). This meant that the 2 groups in each round were not the same. To account for this difference, results were reanalyzed, removing data contributed by these 22 participants from round 1 (Table S1, http://links.lww.com/TXD/A79). This made no difference to the consensus decisions indicated by the process.

Fewer free-text comments were provided in Round 2. No participants reported having problems with understanding the questionnaire. Participants shared similar views to Round 1, providing comments regarding BMI and age and the need to assess patients on an individual basis.

Stakeholder Meeting

An attendance list was collected for the stakeholder meeting. Seventy people attended the meeting with 15 transplant surgeons and 16 nephrologists present, and of these, 13 (42%) had taken part in the previous 2 rounds. The remainder of the audience consisted of other professionals including histocompatibility laboratory leads, researchers and statisticians, and 8 patient representatives. All attendees were invited to vote on 3 statements concerning BMI, age, and asymptomatic coronary artery disease (CAD) revascularization.

The results indicated similar variability in opinion as for the previous rounds (Table 3). Between 24 and 50 participants voted for each question, indicating that not all responses were from clinicians.

TABLE 3.

Responses in the round 3 stakeholder meeting for 3 of the statements that did not reach consensus in round 2

Statements	Options	n (%)
(1) The maximum BMI exclusion criterion for listing for transplantation for most patients should be:	BMI 30 kg/m^2	3 (6)
	BMI 35 kg/m^2	24 (48)
	BMI 40 kg/m^2	23 (46)
	Total vote	50 (100)
(2) The upper age limit for listing for transplantation for most patients should be:	80 years	27 (61)
	75 years	16 (36)
	70 years	1 (2)
	Total vote	44 (100)
(3) Asymptomatic CAD identified on pretransplant workup should be revascularized before listing for transplantation.	Agree	10 (42)
	Disagree	9 (38)
	Neither	5 (21)
	Total vote	24 (100)

Shading indicates consensus agreement; Underlining indicates consensus disagreement; No consensus was reached for question 3.

Participants voted for a BMI cutoff of 35 or 40 kg/m^2, and most votes were evenly divided between these options (Table 3). In discussion, some surgeons highlighted examples of cases where they would undertake transplantation on patients with a BMI over 40 kg/m^2 (such as in younger recipients). Others felt that BMI was not a useful measure to assess risk of transplantation. Several highlighted that assessment for transplantation required a holistic process rather than consideration of separate clinical factors. Overall, attendees felt that it was appropriate to undertake transplantation in patients with a BMI of up to 40 kg/m^2.

Most attendees (61%) voted for an upper age cutoff of 80 years (Table 3) although in discussion, many felt that it was inappropriate to have a specified age limit because there were always exceptional cases. Some specifically mentioned that a patient's biological age rather than chronological age should be considered. However, with a limited supply of organs, attendees suggested that there was a need to maximize a kidney transplants life expectancy and this ultimately disadvantages older patients, who may be predicted to die more often with a functioning kidney transplant. Attendees agreed that an age limit of 80 years was most appropriate out of the choices provided, although it was felt that age alone was not useful as a factor to influence decision making.

Lastly, participants' views were split over whether patients with asymptomatic CAD should undergo cardiac revascularization (Table 3). In the final group discussion, transplant surgeons appeared more likely to agree with this statement than nephrologists. Some perceived a trend toward lower rates of revascularization, driven by cardiologists, such that nephrologists now have an increased influence on this process. Some suggested that a randomized controlled trial would be helpful in assessing the need for revascularization. No consensus was reached on this statement.

Overall, the discussion led to agreement on 2 of the 3 statements presented to the audience (Table 3). This equated to consensus agreement for 2 of the statements presented in rounds 1 and 2 (BMI cutoff 40 kg/m^2 and age cutoff 80 years) and consensus disagreement for 2 other statements (BMI cutoff should not be 30 kg/m^2 and age cutoff should not be 70 years).

DISCUSSION

To our knowledge, this is the first study using a consensus approach to elicit the views of senior transplant clinicians on the factors influencing listing for kidney transplantation. Using a modified Delphi approach, clinicians were invited to take part in 2 rounds, via a web questionnaire, and results were presented at a stakeholder meeting. Clinicians reached consensus on several of the statements included in the Delphi rounds. They agreed that a written transplant workup protocol should be followed and that cardiac assessment should be stratified by risk. There was agreement that peripheral vascular Doppler ultrasound studies were useful for symptomatic patients with poor peripheral pulses and patients with an asymptomatic arterial bruit. Clinicians felt that patient compliance with treatment should be considered when making a decision to list and that an MDT approach to the listing decision should be used for all and not just for complex patients. Clinicians did not support BMI cutoffs of over 30 kg/m^2, over 35 kg/m^2, or under 20 kg/m^2. They were also against an age limit of 70 or 75 years, acknowledging that age must not be used as a proxy for the proper assessment of individual need and suitability for transplantation. Lastly, clinicians felt that a cardiac stress test was not required for minimum cardiac workup for patients in general.

This study has several strengths. It was open to all consultant renal clinicians in the United Kingdom, and all renal units were contacted to encourage participation. A significant number of clinicians replied in round 1, and there was minimal dropout in round 2. As well as collecting ratings of agreement, participants were also able to write comments in the free-text boxes provided. These boxes captured data that helped to explain variation in some responses but also to improve the questionnaire for round 2. The content of the Delphi was informed by a recent national survey of all UK renal units and therefore asked about current issues that were relevant to all UK renal clinicians. The Delphi approach also enabled participants to contribute and to receive group feedback while remaining anonymous to one another. A Delphi approach has been used in many other settings, including for selecting healthcare quality indicators[13] and outcome measures in clinical studies.[14]

There are also limitations to the study and points to consider. The proportion of clinicians recruited in the United Kingdom was moderate (25% of nephrologists and 16% of surgeons), although the study did capture data from 69% of renal units, and included a reasonable mix of nephrologists and surgeons from both transplant and nontransplant units. The study was part of a national research program involving all renal units in the United Kingdom, and this may have led the clinicians with links to the project to be more likely to respond. These points may have relevance to the generalizability of the findings, as the participants may be from research-active renal units and have greater knowledge of the study. In addition, it should be noted that clinicians were asked to base their answers on "an ideal world" rather than what was feasible for their renal unit, which is usual in Delphi studies but has implications for the applicability of the findings in practice. The stakeholder meeting was opportunistic but enabled us to engage with a mixed audience of senior surgeons and nephrologists, as well as a wider group interested in kidney transplantation, importantly including patient representatives. However, due to the need to ensure confidentiality, it was not feasible to exclude patients' responses from voting.

Those statements that reached consensus in the present study can be compared with current recommendations and may help inform future guidelines. New topics where clinicians were in agreement included the need for patient compliance with treatment, and use of multidisciplinary clinical teams in decision making. Within the survey, patient compliance was not explicitly defined and therefore clinicians made their own judgment about what constitutes evidence of "poor" compliance. However, agreement on the statement indicated that clinicians felt this was an important factor to consider. This is supported by worldwide data where although clinicians report that perceived compliance influences their decision making, they also recognize that it is difficult to define and may not be predictive of future behavior.[5] If considered for guidelines, further thought is required as to how clinicians would assess compliance to avoid discriminating against patients and making them aware of the requirements to adhere to medication after transplantation.

Those statements on which there was consensus disagreement in the Delphi process included limits for BMI and age. Clinicians stressed that considering 1 factor in isolation was unhelpful. When statements relating to BMI and age cutoff approached consensus agreement, feedback from clinicians suggested that these should only be approximate guidelines. Clinicians felt that a BMI limit of 40 kg/m^2 could be a guideline for listing, although this limit was higher than reported in existing guidelines where a BMI over 35 kg/m^2 is considered a contraindication.[15,16] Other guidelines and publications state that age alone should not be a contraindication.[15,17]

Although consensus was achieved for some statements, others indicated significant variation in clinicians' views. The diversity in views is likely to reflect variation between units in their approaches to listing and is also reflective of the scarcity of evidence in some areas.[18] Further research is needed before recommendations can be incorporated into guidelines. For example, clinicians need to know the impact of BMI on patient outcomes after transplant and the cost-effectiveness of different cardiac work-up pathways.

In summary, this study adds to available data on individual clinicians' views on factors influencing kidney transplant listing decisions and identifies areas of consensus. The findings can be used to inform the content of guidelines where consensus was achieved and, by highlighting topic areas with noticeable variation, indicate areas where further research and policy development are needed. The findings also reflect the uncertainty surrounding the absolute and relative risks of events that may preclude listing, such as cardiac events that are relevant to the BMI and CAD statements. There is a paucity of adequate contemporary observational data for these issues and even as higher-grade studies are considered, there remains a role for registry-based observational work that will help define the absolute risks and thus guide more powerful randomized clinical studies in this area.

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