

Variation in Practice Patterns for Listing Patients for Renal Transplantation in the United Kingdom: a National Survey

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The authors declare no conflicts of interest.

This article presents independent research funded by the National Institute for Health Research (NIHR) under the Programme Grants for Applied Research scheme (RP-PG-0109-10116). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analyses.

Presented (as an abstract) at the *Joint British Transplantation Society and Nederlandse Transplantatie Vereniging Congress, Bournemouth, 2015; and at the American Society of Nephrology Kidney Week, Philadelphia, 2014*

Research idea and study design: RP, GL, CE, CT, AB, JLF, CB, JC, CD, CW, HD, RJ, WM, DF, RR, PJR; data acquisition: RP, STC, MC; data analysis/interpretation: RP, STC, GCO, RR, PJR; statistical analysis: RP; supervision or mentorship: RR, CE, GL, RR, PJR. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved. RP takes responsibility that this study has been reported honestly, accurately, and transparently; and that no important aspects of the study have been omitted.

Abbreviations

ATTOM	Access to Transplantation and Transplant Outcome Measures
BMI	Body mass index
CKD	Chronic kidney disease
eGFR	Estimated glomerular filtration rate
ESRF	End stage renal failure
LCC	Low clearance clinic
MDT	Multi-disciplinary team
PMP	Per million population
RRT	Renal replacement therapy
WTE	Whole-time equivalent

Abstract

Introduction: Despite the availability of guidelines for the evaluation of candidates for renal transplantation, variation in access to transplantation exists. This national survey investigates whether centre variation exists in the assessment of patients for renal transplantation in the UK.

Methods: An online survey, informed by qualitative interviews, was distributed to all UK renal centres. This survey examined centre approaches to chronic kidney disease service provision, transplant recipient assessment, education provision and wait-listing decision making processes. Centre re-evaluation policies for patients already listed and priorities for future development were also examined.

Results: All 71 renal centres responded. Of these, 83% reviewed pre-dialysis patients in a low clearance clinic. In 26% of centres transplantation was not discussed as a treatment option with all patients. Fourteen centres reported having a dedicated transplant assessment clinic whilst 28% did not have a formal assessment protocol. Age was an exclusion criterion for listing in three centres, all of which had a cut off at 75 years. 83% of centres excluded patients with a high BMI. Cardiac investigations were risk-stratified in 90% of centres. Surgical involvement varied with 11% of centres listing patients without formal surgical review. There was no formal protocol in place to re-evaluate listed patients in 62% of centres.

Conclusions: There is wide variation in UK practice patterns for listing patients for renal transplantation, though its impact on access to transplantation is unclear. The extent to which centre-specific and patient-specific factors affect access to transplantation requires further analysis in a prospective cohort of patients.

Introduction

It is widely regarded that for 'suitable' patients with end stage renal failure (ESRF), renal transplantation confers both better quality of life and life expectancy than dialysis and is the preferred modality of renal replacement therapy (RRT)¹⁻⁴. In light of these benefits, achieving prompt and timely activation on the transplant waiting list is important not least because increasing length of time on dialysis adversely affects graft and patient survival⁵, but also because organ allocation algorithms in many countries (including the UK) give priority to those who have spent greater time on the waiting list when allocating deceased donor kidneys⁶⁻⁷. Thus, centres that achieve earlier listing for transplantation may provide an advantage for their patients compared with centres that take longer.

Various guidelines on the timing of referral for renal transplantation are available from professional organisations across the world⁸⁻¹⁰. Guidelines from the United States Organ Procurement and Transplantation Network (OPTN) Minority Affairs Committee state that the goal for referral should be that all potential candidates are referred for transplant at an estimated glomerular filtration rate (eGFR) above 20 ml/min/1.73m² to favour early transplantation and avoid the development of comorbidities associated with dialysis as well as allowing patients to accrue waiting time that increases their chance of being allocated a donor organ⁸. In comparison the UK Renal Association guidelines recommend that patients with progressive deterioration in renal function suitable for transplantation should be placed on the national transplant list within six months of their anticipated dialysis start date and that pre-emptive transplantation should be the treatment of choice for all suitable patients whenever a living donor is available¹⁰.

The term 'suitable' used in these guidelines often poses a conundrum for clinicians as objective criteria to confirm suitability for transplantation are not clearly defined and hence are open to interpretation. To assist this process guidelines for the evaluation of candidates for renal transplantation have been published by the American Society of Transplantation¹¹, the European Renal Association and European Society for Organ Transplantation¹², the UK Renal Association¹⁰, the British Transplantation Society¹³ and Caring for Australasians with Renal Impairment¹⁴. Despite the availability of clinical guidelines, significant variations in the assessment practices among transplant centres have been reported in the United States as well as Europe¹⁵⁻¹⁷.

To explore this further we undertook a national survey as part of the NIHR funded Access to Transplantation and Transplant Outcome Measures (ATTOM) programme to examine whether variation exists in the organisation of renal services in listing patients, and to describe centre practices in the education and the evaluation of potential transplant recipients as well as exploring how decisions are made in the UK.

Materials and Methods

A structured online and paper-based survey consisting of 96 questions was developed using the results of two qualitative studies carried out within the ATTOM programme^{18,19}. Qualitative studies included 53 patients and 42 healthcare professionals, and explored patients' views and experiences of joining the transplant waiting list and staff members' experiences of listing patients for transplantation. Staff and patients were recruited from a purposive maximum variation sample of nine renal units in the UK. Existing published literature was also reviewed and feedback

sought and incorporated from a group of experts on the ATTOM steering group. Pilot face-to-face interviews with 4 clinicians were conducted using the first draft survey to guide revision to improve instrument face and content validity and usability prior to distribution.

The questionnaire was designed to establish the practice patterns of the unit relating to listing patients aged <75 years for transplantation. Once finalised, both versions (online and paper-based) of the survey were sent to the lead physicians and surgeons of all 71 adult renal centres in the UK in January 2014. Clinicians were invited either to complete the survey personally or to nominate a representative within the unit to respond. It was specified that the respondent's answers should reflect current practice in the unit rather than individual preference.

Statistical analyses were performed using SAS version 9.3. Results for each question were expressed as a percentage of the total number of centres responding to the question. We identified several factors a priori as 'exposure' variables and tested for associations of these categorical variables with care processes using Chi squared test or Mann Whitney test. Given the potential for multiple testing and false positives we only report associations that were significant at $p < 0.01$. In order to measure how much time renal staff were involved in transplantation listing, Whole-time equivalent (WTE) time was asked. An WTE of 1.0 indicates that a person is equivalent to a Whole-time worker, or 2 persons working half-time.

Results

A completed survey was received from all 71 (100%) adult centres in the UK, of which 23 were transplanting and 48 were non-transplanting renal centres. The reported roles of respondents were: Clinical Director (42.3%), Consultant Nephrologist (49.3%), Consultant Transplant Surgeon (2.8%) and 'Other health professional' (5.6%). Forty centres (56.3%) completed the web-based version and 31 centres (43.7%) the paper version of the survey. The responding centres had a total of 6699 patients active on the UK transplant waiting list at the end of 2012 and reported a national workforce involved in listing patients for transplantation which comprised of 488 WTE Consultant Nephrologists, 113 WTE Transplant Surgeons, 57 WTE Associate Specialists, 73 WTE Transplant Co-ordinators and 75 WTE Live Kidney Donor Nurses. The median number of Consultant Nephrologists was significantly greater at transplanting centres (8.5; IQR 8-11) compared with non-transplanting centres (4.5; IQR 3-6), $p<0.001$).

Chronic Kidney Disease Workforce and Organisation

Almost 48% (47.9%, $n=34$) of centres reported seeing all pre-dialysis patients in a dedicated low-clearance clinic (LCC), whilst 33.8% ($n=24$) of centres used a LCC for some of their patients. The remaining 18.3% ($n=13$) of centres did not have a designated LCC service. There was no significant difference between non-transplanting and transplanting centres in terms of the pattern of LCC utilisation. LCCs were mostly joint (consultant with nurse, 48.3%) or consultant-led (43.1%), with only 8.6% of centres having a nurse-led service. When LCCs were present, 30% of non-transplanting centres did not have a specified protocol for referral for transplantation compared with 11.1% of transplanting centres ($p<0.001$).

Transplantation Education

Transplantation was discussed as a treatment option with all patients under the age of 75 in 51 (71.8%) of centres, with other centres reporting a more selective policy. The decision not to discuss was made mostly by a consultant led multi-disciplinary team (MDT) (55%) or solely by a consultant nephrologist (40%). Discussions regarding transplantation were led most often by a consultant nephrologist (64.8%), with nurses leading the discussion in 19.7%, transplant surgeons in 2.8% and 'other' healthcare professionals in 12.6% of centres. Despite reporting a wide range of educational delivery tools, education almost always took the form of a one-to-one consultation (98.6%) where patients were given literature to take home to read (91.5%).

Transplant Listing Pathway and Role of Transplant Surgeons

The clinical setting for transplant assessment varied, with 36.4% of centres utilising a LCC, 21.2% seeing patients in their usual CKD clinic and 19.7% utilising a specific transplant assessment clinic. The remaining 22.7% of centres reported a mix of 'other' clinical settings. The use of specific transplant assessment clinics was similar in non-transplanting centres and transplanting centres, though the frequency varied widely, with clinics occurring monthly or less frequently in 55% of non-transplanting centres, as compared with 100% of transplanting centres running these clinics fortnightly or more frequently, $p < 0.001$. Overall 88.2% ($n=63$) of centres required all patients to be seen by a Transplant Surgeon prior to being listed; of the remaining 8 centres that did not require direct surgical review, 4 centres (1 transplanting and 3 non-transplanting) reported that all patients were discussed with a Transplant

Surgeon, whilst 4 centres reported no surgical involvement in the decision to list for transplantation.

The Assessment Process

Nationally 30% (n=21) of centres did not have a written transplant work-up protocol for recipient assessment, which included 3 transplant centres. Figure 1 shows the frequency with which different investigations were used for the routine assessment of potential renal transplant recipients amongst the 71 centres. Three non-transplanting centres reported having an upper age limit of 75 years (above which patients were only considered in exceptional circumstances for transplantation) whilst all other centres (n=68, 95.6%) did not report any age restrictions. In comparison, Body Mass Index (BMI) was widely used as an exclusion criterion for listing patients, with 81.7% (n=58) of centres excluding patients for transplantation based on BMI. The overall median upper BMI cut off, in these centres was 35 (IQR: 33.25-35), with 36 centres reporting an upper limit of 35, and 5 centres an upper limit of 40 whilst the remaining 17 centres stated a BMI limit between 33-30. The reasons stated for using BMI as an exclusion criterion are summarised in Table 1. These did not differ between centres other than perceived increased cardiovascular risk, which appeared to be more of an issue for non-transplanting (52.5%) than transplanting centres (33.3%), $p<0.01$. All transplanting centres, and 87.5% (n=65) of non-transplanting centres reported stratifying patients by risk when deciding which cardiac investigations to perform. Age (median 50 years; IQR: 50-55)(88%), diabetes (97%), previous cardiovascular disease (91%), and an abnormal ECG (89%) were used to determine risk. Thirty-one centres (44%) conducted some form of 'cardiac stress testing' even in low risk patients whilst significant variation was seen in the first-line investigation of choice

for the assessment of coronary artery disease in high risk patients (Table 2). If a coronary angiogram was deemed necessary for listing a low clearance patient, 5.6% (n=4) of centres reported they would refrain from performing the test until patients were on dialysis to avoid precipitating the need for dialysis, with a further 74.6% stating they would 'sometimes' refrain from proceeding. Only 19.7% reported always proceeding.

Variation was also seen in screening for malignancies with 38% of centres reporting that screening for cancer such as breast, prostate, bladder and colorectal was part of the routine work-up of transplant recipients, in addition to national screening programmes. In contrast, formal psychological or cognitive assessment of all potential recipients was only performed in 7.0% and 5.6% of centres respectively, with 13.1% of centres reporting no access to psychologist or counsellor services.

Decision Making

Overall 76.1% (n=54) of centres utilised an MDT approach when listing patients for transplantation. This proportion was greater amongst transplanting centres where all but one centre (95.7%) used an MDT, compared to 66.7% (n=54) in non-transplanting centres. MDTs occurred more frequently in transplanting centres with a median of 4 meetings a month (IQR 1.25-4) as compared to 2 a month (IQR 1-4; p=0.001) in non-transplanting centres.

If a patient was not deemed suitable for listing for deceased donor transplantation, 76.1% of centres said that they would consider listing them for living donor transplantation if a suitable donor was available. Living donor availability was generally seen as a positive driver for listing, alongside patient enthusiasm, whilst the majority of centres did not perceive socioeconomic factors, including employment

status or level of patient education, as important when deciding whether to list patients for transplantation (Figure 2). Once a decision regarding listing was made, 50.7% of centres reported informing all patients on dialysis, or with CKD stage 5 under 75 years, of the decision, with 78.6% of centres recording all decisions made on transplant suitability on their electronic patient record (EPR). Once recorded on their EPR, only 61.8% of centres performed regular audit of this information. After listing, only 38% of centres reported having a protocol in place to monitor patients activated on the transplant list with the majority of centres (53.5%) reviewing patient suitability annually. Significant variation existed in how centres undertook ongoing surveillance for cardiac disease in asymptomatic patients once listed as shown (Table 3). This was also highlighted in centres' responses to questions on improving listing, with 53 centres (74.6%) either agreeing or strongly agreeing with the need for having a national consensus on cardiac work up, and 52 centres (73.2%) also agreeing that there was a need for a consensus on the entire assessment work-up process (Figure 3).

Inter-Centre Relationships and Future Development

Although 95% of centres reported having a positive relationship with a 'good', 'very good' or 'excellent' relationship with their associated transplanting/non-transplanting centres, one third (n=16) of non-transplanting centres felt that accessing an appointment at their affiliated transplanting centre was a significant source of delay in listing patients.

Factors reported by centres to be most important in improving listing of patients for transplantation included: providing a better evidence base behind necessary assessment work up; improving the commissioning of transplant work up by funders

of the service; and developing a national consensus on the work up of transplant recipients (Figure 3). If extra funding was available, centres stated they would use this to increase the number of transplant co-ordinators and living-donor nurses, increasing the number of operation time slots for transplantation in trusts, and providing administrative support for allied health professionals involved in transplantation would likely improve overall listing and time to listing in their centres (Figure 4).

Discussion

This study provides the most extensive exploration to date of clinical practice patterns within renal centres in listing patients for renal transplantation in the UK; and is the first to account for practice patterns in both transplanting and non-transplanting centres. It provides a comprehensive overview of the transplant-listing pathway including staffing levels, clinic arrangements, provision of patient education on transplantation, decision-making, recipient assessment, surgical review, criteria for listing, and the role of MDTs.

For a national population of 64.1 million²⁰ the number of consultant transplant surgeons reported (1.76 per million population) (pmp) in this survey remains significantly lower than the 2pmp recommended by the Royal College of Surgeons of England²¹. Indeed the number of consultant nephrologists (7.61pmp), transplant co-ordinators (1.14pmp) and living-donor nurses (1.17pmp) are all significantly lower than that recommended by the National Renal Workforce Planning Group and point towards an understaffed service²¹.

Despite the UK Renal Association recommending that CKD patients pre RRT should be managed in a dedicated clinic by a MDT²², this study also demonstrated wide variation in the utilisation of low-clearance clinics nationally, with variation also seen in their implementation and entry criteria. There are many studies, albeit small, which have shown that a dedicated pre- dialysis clinic is associated with improved outcomes and reduced urgent initiation of dialysis²³⁻²⁶. These clinics may provide focused opportunity to assess transplantation potential and more timely discussion of options including live donation and pre-emptive transplantation. Similarly, specific transplant-assessment clinics (used by a fifth of centres) enable joint assessment by physician and surgeon; whilst the evidence of their effectiveness is lacking they may be more efficient at transplant listing.

Irrespective of the type of CKD service in place, a broad range of educational methods were utilised across the UK, with one-to-one education being the main route. A significant proportion of centres (28%) did not discuss transplantation as a treatment option with all patients under the age of 75 years, and nearly 50% of patients who had had a decision made about them regarding transplantation were not informed of the decision made. This is of concern, as a patient-centred approach would require that all options are communicated to a patient and their family where possible. There may be exceptional circumstances where this may not always be feasible, but such instances would be expected to be less frequent than was reported in the present study.

Another important observation from this study was that some centres did not consider surgical review to be an absolute requirement for listing patients for transplantation. Eight centres listed without formal review, four of which cited no

surgical involvement at all. The UK Renal Transplant Service specification stipulates that patients should undergo surgical assessment prior to being placed on the transplant list²⁷, however it should be noted that in the US it is not uncommon to have only a subset of patients evaluated by transplant surgery in a face-to-face encounter. Instead, they selectively evaluate higher risk patients, e.g., those with vascular disease.

Whilst in these centres it might be perceived that informed consent need not be taken by a surgeon and can instead be obtained by an experienced physician. The authors question whether without surgical input, patients can truly make an adequately informed choice and be involved in shared decision-making about transplantation and the associated surgical risks. Chronic understaffing described earlier and the belief that surgical evaluation of every patient prior to listing might reduce/delay access to transplant, may partly explain why centres have adopted such practices, though its impact on outcome is not known.

Several national guidelines recommend that centres should have written criteria for acceptance of patients onto the waiting list^{10, 28}, yet nearly a third of centres reported not having a protocol, including three transplanting centres. The lack of standardisation in these units could lead to variation in assessment, stereotyping, individual clinician bias and personal idiosyncrasies contributing to inequity. It was reassuring that the majority of centres (95.6%) did not use chronological age per se as an exclusion criterion. This figure is higher than that seen in the US, where 66% of centres reported having an upper age cut-off (in a similar study of transplanting centres)²⁹, and acknowledges the notion that age must not be used as a proxy for the assessment of individual need and suitability. It also highlights how clinicians are

aware that chronological age can be very different to biological age in different individuals, and how assessment needs to be tailored on a case-by-case basis to avoid unwarranted age discrimination.

In contrast to age, the majority of centres used BMI as an exclusion criterion, similar to findings from studies from the US³⁰, Canada³¹ and Europe³², with a wide upper BMI limit of 30-40. In the context of an increasingly obese population, such a broad range has the potential to cause variation in access to transplantation. Obese patients are certainly at an increased risk of technical difficulties and peri-operative complications³³⁻³⁴ though evidence in favour of imposing a BMI limit on the basis of more hard end-points (patient and graft survival) is conflicting³⁵⁻⁴⁰. A number of reports from nationwide databases, including the USA, Australia and the Netherlands^{35, 38, 40}, have shown decreased patient and graft survival in obese recipients, whilst others showed no differences in survival between obese and non-obese transplant recipients³⁹. It is unclear in studies where an increase in risk was noted, how much would be mitigated once co-existing cardiovascular disease was accounted for. This raises the notion that if technically feasible, and cardiovascular disease has been ruled out, most patients should be considered for transplantation irrespective of their BMI.

As cardiovascular disease remains the main cause of death in transplant recipients⁴¹, it is unsurprising that most centres invest a great deal of time and resource in its investigation and management. This study showed that most centres stratify patients on their level of risk, though the choice of ensuing investigation varied greatly with no clear consensus irrespective of risk, from non-invasive functional tests to invasive angiography. This variation is likely due to a combination

of factors including lack of evidence on superiority for any one investigation, as well as local cardiac service availability and experience. Centres also differed in their perception of risk associated with angiography in low-clearance patients. Overall this variation has the potential for creating inequity, as centres adopting more intense screening protocols might impede wait-listing for patients with barriers to getting the tests completed.

Another important issue which needs mentioning is the cost implications of changing practice patterns, particularly at a time of receding budgets and rising concern over the cost and value of healthcare. Indeed, it is likely that individual centre practices are in part, a consequence of local infrastructure and availability of service providers, and though instigating some changes may be relatively inexpensive e.g. introducing a written protocol, others e.g. introducing universal invasive cardiac screening for coronary artery disease, may require significant expenditure. Acknowledging this, prior to recommending significant changes to centre practices, it is pertinent to demonstrate the medical efficacy and cost-effectiveness of any proposed changes on access to transplantation which will also assist in ensuring they are long-lasting.

Limitations

Although this study received a 100% response rate across all parts of the UK and though the survey instrument was piloted and refined to enhance relevance, understandability, and usability; some limitations need to be acknowledged. The survey responses were self-reported by self-selecting renal staff e.g. the clinical lead for transplantation, and their responses will not necessarily reflect those of the broader consultant community. Likewise, as only a small proportion (2.8%) of respondents identified themselves as being a transplant surgeon this may have

potentially biased the results due to the under-representation of surgical opinion amongst responders. Equally, we could not check the validity of responses garnered and some of these data were necessarily estimates and so should be regarded with caution. There may also have been a social desirability bias in the responses as respondents may have answered questions to put their centre in a good light. Furthermore, most questions in the survey were multiple-choice questions that invited respondents to select the best possible answer out of the choices available. This approach necessarily limits their responses, although an option to select "other" was provided and the survey was designed following detailed qualitative interviews with patients and staff to identify core domains.

In conclusion there is wide variation in UK practice patterns in listing patients for renal transplantation. Potential causes for this are likely to include variation in international guidelines and a lack of consensus in evaluating patients especially assessing their cardiovascular risk^{10-14, 28}. Differing local population co-morbidity and socioeconomic factors may also be playing a role alongside varying physician attitudes and beliefs towards transplant listing and risk assessment⁴². Future research should be directed at developing a national consensus on recipient work up and in understanding the utility of cardiovascular screening in potential transplant recipients, as well as gaining better long-term outcome data on the impact of obesity and age on transplantation.

There is also a need to understand the impact, if any, of this variation on access to transplantation. In the UK, as part of the NIHR funded ATTOM study, patient variables and the impact of centre variables described in this study, will be further evaluated in a multilevel hierarchical model, in a prospective sample of incident

dialysis patients recruited as part of the ATTOM Study.

Acknowledgments

We would like to thank all clinical directors of the renal units and the additional staff members who responded to the survey.

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Table 1: Reasons for considering raised BMI as a contraindication for transplantation by centres adopting a maximum exclusion criterion

	Transplanting Centre		Non-Transplanting Centre		Overall Nationally	
	N	% (of Centres)	N	% (of Centres)	N	% (of Centres)
Increased post-operative complication risk	16	88.9	34	85	50	86.2
Increased technical difficulty in performing procedure	14	77.8	30	75	44	75.9
Increased cardiovascular risk	6	33.3	21	52.5	27	46.6
Lower Graft survival compared to a normal BMI	6	33.3	9	22.5	15	25.9
Lower patient survival compared to normal BMI	6	33.3	9	22.5	15	25.9
Other (please specify)	2	11.1	10	25	12	20.7
Total	50		113		163	

Table 2: First-line investigation of choice for the assessment of coronary artery disease in high-risk patients

	Transplanting Centre		Non-Transplanting Centre		Overall Nationally	
	N	% (of Centres)	N	% (of Centres)	N	% (of Centres)
Exercise Tolerance Test	5	21.7	1 0	20.8	1 5	21.1
Thallium Stress Test	7	30.4	1 7	35.4	2 4	33.8
Stress Echocardiography	2	8.7	7	14.6	9	12.7
Dobutamine Stress Tc Scan	3	13.0	6	12.5	9	12.7
Coronary Angiography	1	4.3	2	4.2	3	4.2
CPEX Testing*	1	4.3	2	4.2	3	4.2
Other (please specify)	4	17.4	4	8.3	8	11.3

*Cardio-Pulmonary Exercise Test

Table 3: Continued surveillance of cardiac disease in asymptomatic patients on the waiting list reported across UK renal centres

	Transplanting Centre		Non-Transplanting Centre		Overall Nationally	
	N	%	N	%	N	%
No routine surveillance if asymptomatic	6	26.1	13	27.1	19	26.8
All patients screened irrespective of remaining asymptomatic	4	17.4	16	33.3	20	28.2
Surveillance only in high risk groups	12	52.2	11	22.9	23	32.4
Varies, no specific policy	1	4.3	8	16.7	9	12.7
Other (please specify)	0	0.0	0	0.0	0	0.0
Total	23	100.0	48	100.0	71	100.0

Figure Legends:

Figure 1: Bar chart showing proportion of UK Centres performing each investigation as part of their routine assessment of patients under consideration for renal transplantation wait listing at UK renal centres.

Figure 2: Bar chart showing distribution across renal units of responses to the question: **“Please indicate your views on whether the following factors influence the decision to list a patient”** Please indicate how strongly each would influence a decision. Values are expressed as percentage of units (n=71).

Figure 3: Bar chart showing distribution across renal units of responses to the question: **“What is your opinion on the following statements about whether they would improve listing of patients for transplantation?”** Please indicate how strongly you agree or disagree with each of the following.” Values are expressed as percentage of units (n=70).

Figure 4: Bar chart showing distribution across renal units of responses to the question: **“What is your opinion on whether more funding for the following resources would improve overall listing and time to listing in your unit?”** Please indicate how strongly you agree or disagree with each of the following.” Values are expressed as percentage of units (n=70).