Unspecified living kidney donation in the UK: barriers to implementation and delivery
- Healthcare Professionals' Perspective -

1. Background

Over one third of all kidney transplants taking place in the UK today are from living donors. A growing subset of living donors are individuals who choose to donate a kidney to someone that they have not previously met; so called 'unspecified' or 'non-directed altruistic' donors. Over 200 unspecified donations have taken place in the UK to date since this was introduced in 2006 and this type of living donation is becoming more routine, currently accounting for approximately 7% of living donations (1).

Despite this increase, the concept of unspecified kidney donation (UKD) remains uncomfortable for some clinicians, principally due to concerns about the motivations, characteristics and outcomes of these donors. In a recent study of clinicians' views', 78% of French physicians were opposed to the practice of unspecified donation (2). In our previous qualitative work, we have found some evidence that this makes donation more difficult or stressful for some potential donors (3-5). Furthermore, we recently performed a large study of a national cohort of all 148 UKDs in the UK over the first five years of the programme, and compared them with a regional sample of 148 specified kidney donors (SKDs - those who donate to someone with whom they have an emotional relationship) (6). This study did not find an excess of poor psychosocial or physical outcomes in UKDs; however the response rate was 74%, with variable retrospective follow-up, and therefore it is impossible to be certain that donors with significant pathology were not missed- indeed, these are the very donors (for example, with depression) that might be expected to fail to respond. The study did highlight broad regional variations in the numbers of UKDs performed and has highlighted differences in the assessment process, which may explain the differences seen across the country. Indeed, 45% of all unspecified donations were performed in 3 centres. There is some evidence from other studies that attitudes from transplant professionals may be a barrier to donation (7-9). Both living donor nurses and psychiatric assessors involved in UKD have expressed concerns about the lack of practice guidance in this area; lack of clear guidance could be a further barrier to donation (4,5).
Through our qualitative work we have also found that barriers to donation may exist within families where there is tension over the decision to donate altruistically and there may be a role for transplant services to support families in this situation (3). We have recently been awarded a grant from the British Renal Society and

British Kidney Patients Association to explore this. This work is due to commence prior to this study and will inform this research.

The UKD participants in our PPI sessions and previous our qualitative study identified a number of issues in the process that they felt acted as deterrents and may have affected the decision by others to donate (3). They found difficulties in knowing how to make initial contact with the transplant centre. The negative attitudes of transplant professionals were also off-putting and this continued whilst donors were in hospital, with some experiencing ignorance and hostility from ward staff, which made them feel guilty for "choosing to become a patient". The length of the workup process was also commonly an issue, which donors found frustrating. Indeed, when considering living donor chains, most donors would have liked to have participated had it been easier and the timing more predictable. Many were working or had other commitments and the unpredictability of when the donation would take place meant that many were not in a position to oblige. The psychiatric assessment (which is no longer legally mandatory but is considered current best practice) was also a difficult experience for donors who felt that they had to prove their sanity (3).

Unspecified kidney donation is apparently more costly than specified donation, as it is resource intensive, with a large number of enquiries and assessments, and a low proportion that proceed to donate. In Portsmouth (the largest centre for unspecified donation), for example, of 149 referrals, 27 have donated and a further 27 are in work-up, giving a drop-put rate of at least 64%. Nevertheless, a kidney from a UKD may be a particularly valuable resource, since it can be used to provide a high quality, long lasting transplant to those who are otherwise difficult to transplant. The National Kidney Sharing Scheme, for example, involves kidney exchanges between pairs of donor and recipients who cannot otherwise proceed due to immunological incompatibility. A kidney from a UKD can be used to convert these exchanges into a 'chain' primed by the UKD; the UKD donates to recipient A, and her donor dates to recipient B, and so on (Appendix 2). In the US this has resulted in 30 transplants occurring from a single UKD (10). In the UK, 47% of UKDs have been used to prime short chains of two transplants, and the UK Living Donor Strategy aims for 75% to be used for chains, with 3 transplants in each chain, by 2020 (11). Thus, assuming UKDs rise to 200 per year, they would result in 450 transplants annually, which is almost half the current annual living donor transplantation rate. Despite this, no economic analysis of unspecified donation has been performed. This is particularly important since, if it is shown to have a significant economic benefit, extra resources could be allocated by NHS Blood and Transplant, as happened with SKDs over the last decade.

We therefore wish to perform an assessment of healthcare professionals' perspectives on the unspecified donor programme in the UK, in order to determine the extent and reasons for variation in practice and ascertain barriers to donation.

2. Aims

The study will specifically explore healthcare professionals' practice and attitudes to unspecified living kidney donation in transplant centres in the UK.

Research Question:
"Is there variation in transplant professionals' practice and attitudes, which is preventing some unspecified living kidney donations?"

3. Methods

The study will include three arms:

i) Focus groups

ii) Qualitative interviews and

iii) A questionnaire study of transplant professionals (surgeons, physicians, co-ordinators and others involved in transplantation in hospital) working with unspecified donors in the UK.

This is a mixed methods study, drawing on both qualitative and quantitative methods:

i) Qualitative information will be obtained by focus groups and individual interviews with transplant professionals in four centres. Sampling is purposive and centres will be chosen according to their numbers of completed donations, allowing us to sample from two centres which have amongst the highest rates of completed donations (Guys and St Thomas and Plymouth) and two centres whose rates are amongst the lowest (Birmingham and Leeds). These focus groups will contain key staff involved in the unspecified donation process (living donor nurses, psychological assessor, surgeons and nephrologists. These groups will be used to inform the approach in subsequent individual interviews with professionals from each discipline (surgeons, physicians, psychological assessors and donor coordinators). It is anticipated that 60 transplant professionals in total will be interviewed.

ii) Quantitative study: Questionnaires will be sent to all transplant professionals working with unspecified donors across the UK, which will ascertain attitudes towards unspecified kidney donation and current working practices. Both the focus groups described above and the patient representatives will inform the development of a questionnaire that explores working practices, knowledge of donation and staff attitudes incorporating salient points of interest from the data. This will be

supplemented by an existing questionnaire (such as the Organ Donation Attitude [12]), which has been used previously in research to explore the impact of staff attitudes in organ donation.

Participants will be given an information sheet, adequate time to consider the study, and will be asked to give written consent.

If any evidence of distress is elicited in of the different parts of the study, access to a counselor will be offered, an approach we have adopted in a previous study (REC 09-H0804-31). We will ensure that data storage is annonymised and held in a secure fashion, according to Trust SOPs. Trial data will be archived at the end of the study, by our Clinical Trials Office. A trial manager will manage the trial, with help from a research fellow.

The data will be collected by collaborators from the Department of Psychology at Plymouth University. Focus group and individual interviews will be performed at sites most convenient for the healthcare professionals recruited. These may include Guy's and St.Thomas' campus, individuals' homes, or other meeting venues (e.g. professional congresses).

The questionnaire data will be collected by postal or electronic means.

Analysis

Data generated via the focus groups and staff interviews will be analysed via the Framework Approach. The framework approach was developed by the National Centre for Social Research (13). It is a deductive form of analysis that is increasingly being used in healthcare research where the target is to develop practical applications and target policy development. It starts deductively from the aims and objectives identified in the study. However, this approach is grounded and inductive, in that it is heavily based in participants' original accounts and the observations of those studied.

Criteria for acceptance for UKD will be assessed across units in the UK, and requirements for work- up (such as psychiatric assessment) will be compared, in order to determine whether there are significant variations in practice. We will explore this in relation to the number of unspecified donation enquiries and completed donations.

Data from the questionnaire will be analysed using standard statistical tests to compare variations according to demographic factors, individual characteristics and centre effects.

4. Study Steering Committee

There will not be a Data Monitoring Committee, but there will be a Study Steering Committee (SSC), which will have the following responsibilities:

i) To provide advice, through its Chair, to the Chief Investigator, the Project Sponsor, the Project Funder, the Host Institution and the Contractor on all appropriate aspects of the project

ii) To concentrate on progress of the project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question

iii) The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society

iv) To ensure appropriate ethical and other approvals are obtained in line with the project plan

v) To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments

vi) To provide advice to the investigators on all aspects of the project

The SSC will be constituted as follows: An independent chairperson, an independent statistician, one member (not directly involved with the study) from within the Trust, one member external to the Trust, and two service users. An observer from the sponsor and from the CLRN will be invited to attend.

The SSC will meet at 4 to 6 monthly intervals, or more frequently if the Chairperson deems this to be necessary.

There will be a Trial Steering Committee which will manage the project on a regular basis, and which will consist of the members of the project team. This will meet at 3 to 6 month intervals.

5. Data storage

A database will be constructed by the Guys and St Thomas Biomedical Research Centre. Online or paper questionnaires and interview transcripts will be transferred to the database, held on a secure server at either Guys Hospital or Plymouth University, in an anonymised fashion, with password protected access, limited to the study team. Back up will be performed automatically by the Trust systems, and data archiving will be undertaken by the Kings Health Partners Joint Clinical Trials Office, according to their standard operating procedures.

6. Outputs

The data collected will be used together with data from a concomitant NIHR study[1] to achieve several specific outputs, in addition to published manuscripts and conference presentations:

a) A report to NHSBT and the BTS, summarising the findings of the study
b) National guidelines, produced in conjunction with NHSBT and the BTS
c) A protocol for management of those presenting for unspecified donation
d) A report to the Renal Transplant Clinical Reference Group, which reports to NHS England (which commissions transplant services in England), and to the Scottish, Welsh and Northern Irish Departments of Health.

The process for developing these outputs (beyond the first, which will be written by the study team) is as follows:

National Guidelines

The transplant community is small, and there is a widespread desire for guidance on unspecified donation. Existing guidelines on living donation are extensively used by donor teams, and these have been important in changing culture. We recognize that guidelines are not, however, necessarily effective by themselves at changing practice- in this regard, the close liaison that one team member (LB) has with donor coordinators at all transplant centres, and the living donor forum which she organizes, will be vital.
The support of the BTS Clinical Trials Committee for this study is indicative of the close involvement and support of the BTS. There is an existing process for developing guidelines by the BTS, through the BTS Standards Committee. We will convene a small group, including NHSBT and BTS representatives, as well as service users, to draft a guideline, which can be sent to the BTS Standards Committee for consideration. Typically, this is opened for public consultation via the BTS website for a short period, revised and then disseminated to all units.

Commissioners' report

The Chief Investigator is a member of the Renal Transplant Clinical Reference Group (CRG) and has bee involved in drafting Service Specifications for transplantation. He will send a report, which will be drafted with the help of the study team, including service users, to the CRG for discussion and dissemination to NHSE and counterparts in other constituent countries.

[1] Unspecified living kidney donation in the UK: barriers to implementation and delivery - *Potential Donors Study*

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