Deceased donor kidney offer review schemes oversight committee – update

1.0 Background

There are three offer review schemes (ORSs) currently active in UK deceased donor kidney transplantation:

1) decline of offers from apparently 'ideal' kidney donors

2) discard of kidneys retrieved from apparently 'ideal' donors

3) decline of offers from standard criteria donors to high priority recipients (defined as one or more of the following: 000 MM, cRF 85% or more, waiting time >7 years)

The definition of 'ideal' kidney donors has been discussed previously at KAG and agreed. A report from a short term working group examining the deceased donor kidney ORSs was presented at the last KAG (KAG(18)40). Broadly, the STWG considered how to categorise responses from centres to letters sent out through the ORSs and what oversight of the ORSs was required.

KAG agreed with the recommendation of the STWG, and an oversight committee has been formed. The KAG Chair also asked the committee to draft a code of practice for offer acceptance and transplantation of deceased donor kidneys. This is an update from the oversight committee.

KAG is asked to consider this document, and to discuss any required changes, as needed.

2.0 The committee, its remit, and structure

After receiving expressions of interest from colleagues, the following were invited to join the committee by Chris Callaghan (chair, Guy's Hospital, London - CC): Professor Lorna Marson (Edinburgh), Dr Imran Saif (Plymouth), Dr Gareth Jones (Royal Free Hospital, London), Mr Adam Barlow (Leeds), and Julia Mackisack (lay

member). The remit of the committee is to examine and grade written responses from units after being contacted through the ORSs.

Grading will be red / amber / green, as per KAG(18)40. The process will be as follows:

- initial letters will be sent out to units from CC (or the Chair of KAG)
- unit responses will be sent to all members of the oversight committee, including the core donor data form with patient-identifiable details removed and the letter from CC. Units will be anonymised.
- the committee will be asked 1) 'Given the donor information and the unit's response, do you have on-going significant concerns about the decision to decline / discard this kidney?' (yes = amber, no = green) 2) 'If you answered 'yes' to 1), do you have significant concerns that the standards for acceptance and transplantation of deceased donor kidneys have been breached?' (yes = red, no = amber)
- if the responding unit is Edinburgh, Guy's, Leeds, Plymouth or RFH then CC will subsequently email the relevant member individually to ask them not to vote. If the unit is Guy's, CC will not vote.
- when voting, members will reply to CC alone, in order to ensure that independent decisions are reached. CC will cast a vote before emailing the group.
- each member will have one vote for 1) (and 2) if they answered yes to 1)), to be cast within three working days.
- 'amber' grading decisions will be made on the basis of majority or tie for 1). Three responses will be needed for a quorum. For 'red', a majority of the responding committee votes will be needed. A tie would lead to further discussions within the committee.
- the outcome of the vote will then be emailed to all members. Members will be asked to keep these decisions confidential. The unit will be informed of the committee's decision.

A 'red' grade implies that the standards for acceptance and transplantation of deceased donor kidneys has not been adhered to, leading to notification of the

ODT Medical Director for further consideration. This is defined further below (4.0).

3.0 Collation and analysis of 'amber' grades

A statistically valid mechanism is required to determine if the frequency of amber responses is higher than is acceptable. Discussions have been had with Sally Rushton, NHSBT Statistics and Clinical Studies, who is examining the possibility of using CUSUM curves or funnel plots to analyse this. An appropriate baseline and denominator are being investigated. It is expected that reports will be generated for the ODT Medical Director and KAG every six- or twelve-months, and that triggering units will be written to by the ODT Medical Director, as per current policies for graft loss or patient mortality CUSUM triggers.

4.0 Code of practice for acceptance and transplantation of deceased donor kidneys

Aims:

1. To define minimum acceptable standards with respect to accepting an offer of a deceased donor kidney
2. To define minimum acceptable standards around transplantation of a deceased donor kidney.

Failure to meet these standards, if identified via the ORSs, would be defined as a 'red' incident, and would be escalated to the Medical Director of ODT for further consideration and/or investigation.

Standards:

1) 24-hour access to both a consultant transplant surgeon & nephrologist for opinions and decisions on organ offers

2) No organ offer should be declined without appropriate consideration of the donor, the organ, and the patient for whom it has been offered (e.g.

the patient's HLA sensitisation status, HLA mismatch, match points, time on dialysis, time on the wait list)

3) No offer should be declined for a patient in Tier A (new Kidney Offering Scheme) without a discussion between the on-call consultant nephrologist and transplant surgeon

4) No named-patient offer should be declined solely for centre logistical issues (e.g. inability to access theatres, lack of ward or ITU beds, lack of surgeon availability)

The committee also defined behaviours which can be considered to be good practice, but which do not meet the level of concern necessary to warrant being defined as a 'red' incident if they do not take place.

Good practices:

1) If a named-patient offer is declined, specific reasons for offer decline should be recorded in the patient's records, noting the requirement for appropriate anonymisation of donor details as per NHSBT / BTS guidance

2) If an offer is declined after it is initially accepted, this should occur as soon as possible in order to maximise the chances of other units and patients to utilise that organ. Once an organ arrives at an implanting centre it is recommended that the organ be inspected and a decision made on suitability for transplantation within 4 hours.

3) If an organ is declined for centre logistical reasons (e.g. inability to access theatres, lack of ward or ITU beds, lack of surgeon availability) then an incident should be logged in the both Trust and NHSBT incident reporting systems. Consideration should also be given to transfer of the patient and organ to another centre, especially for Tier A patients.

5.0 Changes to the names of the ORSs

Recent experience in ORSs in other organs has demonstrated that use of the term 'ideal' donor can create confusion in units when a letter is sent. Donors identified through schemes 1) and 2) in 1.0 are not without any adverse risk factors. Instead, these donors are judged to have few significant risk factors. It is therefore proposed that schemes 1) and 2) are re-named 'higher quality donor' ORSs.

6.0 Summary

The make-up, remit, and structure of the new oversight committee of the deceased donor kidney ORSs are described. The proposed definitions of red, amber, and green grades are outlined. A change to the names of the ORSs is also suggested.

KAG is asked to consider the above proposals.

Chris Callaghan, NHSBT National Clinical Lead for Abdominal Organ Utilisation, on behalf of the Oversight Committee