#### POLICY POL186/9

# Kidney Transplantation: Deceased Donor Organ Allocation

This Policy replaces
POL186/8

Copy Number

Effective

26/01/18

# Summary of Significant Changes

Addition of section on blood-borne positive donor virology.

ODT Duty Office renamed Hub Operations

### **Policy**

This policy has been created by the Kidney Advisory Group on behalf of NHSBT.

The policy has received final approval from the Transplant Policy Review Committee (TPRC), which acts on behalf of the NHSBT Board, and which will be responsible for annual review of the guidance herein.

Last updated: September 2017

Approved on behalf of TPRC: December 2017

The aim of this document is to provide a policy for the allocation and acceptance of deceased donor organs to adult and paediatric recipients on the UK national transplant list. These criteria apply to all proposed recipients of organs from deceased donors.

In the interests of equity and justice all centres should work to the same allocation criteria.

Non-compliance to these guidelines will be handled directly by NHSBT, in accordance with the *Non-Compliance with Selection and Allocation Policies*.

http://www.odt.nhs.uk/transplantation/tools-policies-and-quidance/policies-and-quidance/

It is acknowledged that these guidelines will require regular review and refreshment. Where they do not cover specific individual cases, mechanisms are in place for the allocation of organs in exceptional cases.

Kidneys from deceased donors whose death has been defined by brain-stem death criteria (DBD donors) are allocated through a National Allocation Scheme while kidneys from deceased donors defined by circulatory death (DCD donors) are allocated via a National Sharing Scheme.

This policy predominantly covers kidney only transplantation. Multiple organ transplantations are covered in section 3.

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(Template Version 07/10/08)

Author(s): Kathy Zalewska Page 1 of 11

#### 1. Allocation policy

### 1.1 How allocation policy was developed

Following a study on the factors that influence transplant and patient outcome after deceased donor kidney transplantation,<sup>1</sup> the DBD donor National Kidney Allocation Scheme was developed in 2006 to meet agreed objectives and address issues of inequity of access to transplant.<sup>2</sup>

#### 1.1.1 Kidneys from DBD donors

All kidneys from deceased donors whose death has been defined by brain-stem death criteria are allocated through the national allocation scheme, managed by NHSBT.

The left kidney is allocated to the highest ranked patient on the kidney matching run. Only a centre allocated a kidney for a paediatric, long waiting or highly sensitised patient can request the other kidney based on anatomy, damage, pathology, or perfusion quality.

# 1.1.2 Kidneys from DCD donors

Kidneys from deceased donors defined by circulatory death which meet certain criteria are allocated regionally according to the 2006 DBD donor kidney allocation scheme principles, managed by NHSBT, although one kidney is always offered preferentially to the local transplant centre.

#### If the donor HLA-type is known at the time of offering

One kidney from DCD donors is retained locally and if available, the second 'paired' kidney is shared regionally within four defined regions. If the retained kidney is declined locally it is then shared regionally.

#### If the donor HLA-type is not known at the time of offering

One kidney from DCD donors is retained locally and if available, the second 'paired' kidney will be offered for simultaneous kidney and pancreas transplantation via the Pancreas Fast Track Scheme. If no offer is accepted within 45 minutes OR if at any stage the pancreas is accepted for pancreas only or pancreatic islet transplantation, the kidney will be offered back to the local kidney transplant centre.

In all cases the local team may request either the left or right kidney.

#### 1.1.2.1 DCD donor age criteria

In order to avoid significant changes in centre transplant activity, donor age criteria will be used to manage the 'phasing-in' process of regional sharing. If the donor is aged less than 5 years or greater than 64 years both kidneys will be retained locally. If the retained kidneys are declined locally they are then shared regionally. Regular evidence based reviews will be used to guide potential donor age criteria amendments.

# 1.1.2.2 DCD donor kidney sharing regions

Each donor hospital will be allocated to one of four sharing regions, based on their designated centre as follows:

North	Midlands	South West	London
Edinburgh	Birmingham	Bristol	GOSH
Glasgow	Cambridge	Cardiff	Guy's
Leeds	Coventry	Oxford	The Royal Free
Liverpool	Leicester	Plymouth	The Royal London
Manchester	Nottingham	Portsmouth	St George's
Newcastle	Sheffield		WLRTC
	Belfast		

Where a kidney is shared, offers will be restricted to recipients at centres within the sharing region for the donor hospital.

### 1.2 Allocation scheme principles

#### 1.2.1 Patient prioritisation

All kidneys from deceased donors are allocated via an evidence-based computer algorithm. This is based on five ranked Tiers of recipients who are eligible (as defined below) to receive a particular donor's organs:

Tier	Patients
Α	<ul> <li>000 mismatched paediatric patients - highly sensitised* or HLA-DR</li> </ul>
	homozygous
В	<ul> <li>000 mismatched paediatric patients – others (all except those in Tier A)</li> </ul>
С	000 mismatched adult patients - highly sensitised* or HLA-DR homozygous
D	000 mismatched adult patients – others (all except those in Tier C)
	<ul> <li>Favourably matched paediatric patients (100, 010, 110 mismatches)</li> </ul>
Е	All other eligible patients

<sup>\* ≥85%</sup> calculated reaction frequency (based on comparison with pool of 10,000 donor HLA types on national database)

For donors after circulatory death, if the HLA type is not known at the time of offering, all patients will be prioritised within one tier according to prioritisation criteria for Tiers C, D and E. Paediatric patients are prioritised within Tiers A and B according to waiting time.

Within Tiers C, D and E, patients are prioritised according to a points-based system (highest score first), based on 7 elements, these include:

- Waiting time
- HLA match and age combined
- Donor-recipient age difference
- Location of patient relative to donor
- HLA-DR homozygosity

Author(s): Kathy Zalewska

- HLA-B homozygosity
- Blood group match

#### Waiting times

Number of days of waiting time accrued.

Waiting time is determined from date of first active listing for a graft. Each day on the list accrues 1 point, including all days of suspension from the list.

For the majority of patients, waiting time starts at 0 on the day they are established as 'active' on the kidney transplant list. However, any patient whose previous graft failed within the first 180 days post-transplant starts with a waiting time as it was on the day of that (failed) transplant. The failure must be reported to NHSBT through a follow-up return to enable the waiting time to be calculated accurately.

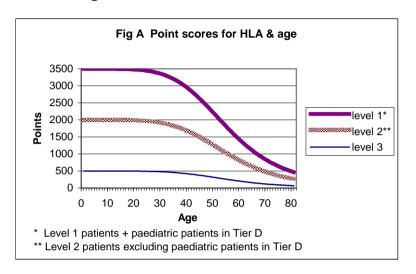
Waiting time is transferable when a patient transfers from one transplant centre to another. The time will be calculated automatically provided the patient has not been 'removed' from the list as part of the transfer. When a patient is notified as 'removed' from the list their waiting time is lost.

### HLA match and age combined

Points are defined as

- 3500 points/(1+(age/55)<sup>5</sup>) for level 1 mismatch patients and paediatric patients in Tier D
- 2000 points/(1+(age/55)<sup>5</sup>) for level 2 mismatch patients excluding paediatric patients in Tier D
- 500 points/(1+(age/55)<sup>5</sup>) for level 3 mismatch patients

Points scored are illustrated in Figure A, and mismatch levels are shown in Table C



### Donor-recipient age difference

Age difference points =  $-\frac{1}{2}$  (donor-recipient age difference)<sup>2</sup>

For example, for a donor aged 60 and a potential recipient aged 20, 800 points are subtracted from the points total for the potential recipient.

#### Location of patient relative to donor

Points are allocated based on the location of the potential recipient as follows:

For donors after brain death

- 900 points for patients at the same centre as the donor
- 750 points for patients at another centre within the local area as defined below:
  - Area A Bristol, Cardiff, London (Guy's, Royal Free, Royal London, St George's and the West London Renal Transplant Centre), Oxford, Plymouth and Portsmouth
  - Area B Belfast, Birmingham, Coventry, Cambridge, Leicester, Nottingham and Sheffield
  - Area C Edinburgh, Glasgow, Leeds, Liverpool, Manchester and Newcastle

For donors after circulatory death

No points are awarded for location

#### **HLA-DR** homozygosity

500 points are allocated for all HLA-DR homozygous patients (where HLA level>1)

#### HLA-B homozygosity

100 points are allocated for all HLA-B homozygous patients (where HLA level>1)

#### Blood group match

-1000 points are allocated for blood group B patients when the donor is group O (Tiers D and E only).

#### **Previous donation**

Please see the *Living organ donors who require a transplant as a direct result of donation* policy for details on prioritising these patients.

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#### 1.2.2 Patient eligibility criteria

Eligibility criteria are primarily based on blood group and HLA match between donor and potential recipient. There are also eligibility criteria relating to highly sensitised patients.

### Blood group eligibility

Patients with blood groups incompatible with the donor's blood group (as defined in Table A) are not eligible to receive that donor's organs. There are restrictions on blood group-compatible (but not blood group identical) patients, detailed in **Table A**.

Table A Donor–recipient blood group matching policy				
Donor	Recipient O	Α	В	AB
0	<b>√</b>	<b>√</b> *	<b>✓</b>	<b>√</b> *
Α	-	✓	-	✓
В	-	-	✓	<b>√</b> *
AB	-	-	-	✓
<ul> <li>* 000 mismatched very highly sensitised (cRF≥95%) adult patients &amp; 000 mismatched paediatric patients only</li> <li>- blood group incompatible</li> </ul>				

#### HLA match eligibility

Donors are HLA-typed at the local H&I laboratory according to the minimum resolution specification agreed by the NHSBT Kidney Advisory Group and are reported to Hub Operations by secure fax.

Patients with HLA types that are not compatible with the donor's HLA type are not eligible to receive that donor's organs. Recipient antibodies reported at the HLA-A, B, C, DR and DQ loci are considered.

The HLA match between donor and recipient is determined on the basis of the HLA-A, B and DR loci only. The numbers of unique, broad level donor antigens not present in the recipient are counted to determine the HLA mismatch level upon which points are based. This is done on the basis of defaulting rare HLA specificities to more common equivalents. The rare antigens and equivalents that are considered are shown in **Table B**.

The rare specificities indicated are 'defaulted' to their more common equivalents so that patients with rare tissue types match with more donors. The defaults are applied (as appropriate) at NHSBT as part of the allocation algorithm. This enables patients with rare specificities also to be considered a match should a donor with the same rare specificity become available.

Table B Defaulting of rare HLA specificities		es
Rare Speci	ificity Common Equiva	lent
A36 A80 A43	A1 A1 A10	
B53 B41 B42 B46 B47 B48 B59 B67 B70 B73 B78 B81 B82 B83	B5 B40 B7 B15 B27 B40 B8 B22 B35 B7 B35 B7 B12 B12	
DR103 DR10 DR9 DR11, DR1	DR1 DR1 DR4 2 DR5	

HLA mismatch grades are determined and then categorised as shown in **Table C**. Patients with a level 4 HLA mismatch with the donor are not eligible to receive the donor's organs through the national allocation scheme.

Table C HLA mismatch levels				
Level	HLA mismatch summary	HLA mismatch combinations included		
1 2 3	000 [0 DR and 0/1 B] [0 DR and 2 B] or [1 DR and 0/1 B] [1 DR and 2 B] or [2 DR]	000 100, 010, 110, 200, 210 020, 120, 220, 001, 101, 201, 011, 111, 211 021, 121, 221, 002, 102, 202, 012, 112, 212, 022, 122, 222		

### Eligibility of highly sensitised patients (HSPs)

HSPs (≥ 85% calculated reaction frequency) are considered for offers of kidneys as follows:

- Level 1 HLA match (000 mismatches) all HSPs
- Level 2 and Level 3 HLA match all local centre HSPs and all other HSPs where all antibody specificities have been identified (i.e. residual sensitisation level = 0)
- Level 4 (all other mismatches) no kidneys are offered for any patients

Note that the HLA match is that based on defaulting of rare antigens.

#### 1.2.3 Additional considerations for paediatric patients

#### Older donors

Paediatric patients and young adults (<18 years at time of active listing) will not be considered for kidneys from donors over 50 years of age.

#### Additional points for long-waiting paediatric patients

For paediatric patients and young adults (<18 years at time of active listing [these patients may still get a growth advantage from early kidney transplantation]) who have a waiting time in excess of 2 years, additional points are allocated in Tiers D and E to improve the chance of being allocated a kidney. It is preferable for paediatric patients to receive a well-matched kidney but in some cases this is not possible and if a patient has not been transplanted within 2 years they are prioritised for any compatible kidney. For patients waiting 2 to 3 years, 2500 extra points are awarded and for patients waiting in excess of 3 years, 5000 points are awarded.

# Patients reaching 18 years old on the transplant list

Patients on the transplant list under 18 years old are classed as paediatric patients for the purposes of the kidney allocation scheme. However, since 15 July 2009, patients registered active on the list prior to their 18<sup>th</sup> birthday but still waiting for a kidney after they reach 18 years, retain their paediatric status and the associated benefits until such time as they are removed from the list for whatever reason, e.g. transplantation. Periods of suspension from the list do not affect this entitlement.

#### Clinically urgent paediatric patients

A child may be priority listed for the next eligible blood group compatible donor (for tiers A–E), aged 50 years and under, regardless of match grade, in the following situations:

- In the event of potential imminent or actual loss of dialysis access without which the child will not survive
- In a child
  - With functioning dialysis but no alternative dialysis access
  - And where dialysis access is likely to become difficult within a short period
  - And when special restrictions are required for a suitable kidney (e.g. size due to anatomical difficulties in the recipient), which significantly restricts the possibility of an appropriate donor
- Options for live related donation have been excluded

Before a child is priority listed an independent review should be carried out by two clinicians from different transplant centres to where the child is listed.

### 1.2.4 Additional considerations for long waiting patients

Patients who have been waiting on the kidney transplant list for 7 years or more, will be prioritised for a deceased donor kidney after any clinically urgent paediatric recipients and before and recipients in Tier A. Long waiting recipients will be ranked by descending total point score. It is anticipated that the length of time on the waiting list that defines a long waiting recipient shall be periodically reviewed and may therefore change over time.

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1.2.5 Allocation of kidneys donated in a domino procedure<sup>3</sup>

In these cases local allocation is appropriate and the kidney should be allocated in advance to a local recipient through Hub Operations at NHSBT.

Local allocation is deemed appropriate because:

- Domino donation is uncommon and equity of access to kidney transplantation is unlikely to be affected by local allocation
- Local allocation provides a better environment for managing the uncertainty associated with domino donation and potentially facilitates improved patient and graft outcomes

### 2. Acceptance of offered kidneys

The receiving centre will undertake HLA cross-matching according to their local policy (based on BTS guidelines).<sup>4</sup> All HLA typing and cross-matching must be undertaken in Clinical Pathology Accredited UK premises.

#### 2.1 Reallocation of kidneys

If a kidney needs to be reallocated because the patient for whom the kidney has been accepted cannot subsequently receive the transplant, the following rules apply:

- If the kidney has not been dispatched to the transplant centre it will continue to be offered for prioritised patients in the usual way
- If the kidney has been dispatched to the transplant centre, it will be offered back for any long waiting patients or patients in Tiers A to D. If there are no suitable patients (nationally or regionally as appropriate), the kidney can be kept by the centre to which the kidney has been dispatched. The centre will select the most appropriate patient from their local list.

Note that when selecting a patient of their own choice, a centre may, in exceptional circumstances, select a patient with a level 4 HLA match or a patient who is blood group compatible but falls outside of the blood group matching criteria specified.

#### 2.2 The Kidney Fast Track Scheme

To optimise the utilisation rate of kidneys available for transplantation a Kidney Fast Track Scheme (KFTS) was introduced for DBD donors on 1 December 2012 and for DCD donors on 1 March 2013.

#### 2.2.1 Kidney Fast Track Scheme offering criteria for DBD donor kidneys

Kidneys from DBD donors will be offered through the Fast Track Scheme if any of the following criteria are met:

- If, at any point, the kidney is deemed to be unusable by a SNOD or a member of the retrieving or transplanting team.
- Five kidney transplant centres decline a kidney-only offer for either donor or organ quality reasons. The reasons given may differ between centres but must relate specifically to the donor or organ quality.
- The organ has accrued six hours of cold ischaemia time and has not yet been accepted for transplantation, or in the case of kidneys that are first offered and accepted as part of a multi-organ transplant (e.g. simultaneous pancreas/kidney, simultaneous islet/kidney or liver and kidney), the kidney should not be Fast-Tracked until the organ has accrued 12 hours of cold ischaemia time.

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### 2.2.2 Kidney Fast Track Scheme offering criteria for DCD donor kidneys

Kidneys from DCD donors will be offered through the Fast Track Scheme if any of the following criteria are met:

- If, at any point, the kidney is deemed to be unusable by a SNOD or a member of the retrieving or transplanting team.
- Three kidney transplant centres decline the kidney for either donor or organ quality reasons.
   The reasons given may differ between centres but must relate specifically to the donor or organ quality.
- The organ has accrued three hours of cold ischaemia time and has not yet been accepted
  for transplantation, or in the case of kidneys that are first offered and accepted as part of a
  multi-organ transplant (e.g. simultaneous pancreas/kidney, simultaneous islet/kidney or liver
  and kidney), the kidney should not be Fast-Tracked until the organ has accrued 6 hours of
  cold ischaemia time.
- If the kidney has been offered and accepted for transplantation but is subsequently declined by the accepting centre after treatment withdrawal but before organ retrieval has begun.

# 2.2.3 Offering via the Kidney Fast Track Scheme

Centres must 'opt-in' to receive offers of kidneys through the KFTS. To qualify, centres must provide NHSBT with a 24 hour fax or single SMS number and have access to the Electronic Offering System.

When a kidney from a deceased donor meets the Fast Track Scheme criteria, the organ will be offered simultaneously to each of the kidney transplant centres that have opted-in to the scheme. Each centre has 45 minutes, from the time of offer, to confirm whether or not they would like to accept the kidney. Failure to respond within the 45 minute window is equivalent to a declined offer. The fast tracked kidney will be allocated to the accepting centre with the highest priority patient listed (according to the National Kidney Allocation Scheme) although that centre may transplant the kidney in to any locally listed patient. Upon inspection, if the accepting centre decides the kidney is unusable, it will be offered to the accepting centre with the second highest priority patient listed and so on, until either the kidney has been transplanted or all accepting KFTS centres have declined the offer of the organ.

#### 2.2.4 If the donor HLA is not known at time of Fast-Track offering

This is likely to be extremely rare for kidneys from DBD donors but may be more common for kidneys from DCD donors. If the donor HLA type is not known at the time of Fast-Track offering a kidney matching run can not be produced and it is not possible to determine which of the accepting centres had the highest ranked patient listed. In such cases, the kidney will be offered to the centre that is first to accept the kidney and so on until the organ is placed.

### 2.3 Blood-borne Positive Donor Virology Scheme

To reduce the length of the donation process the positive donor virology scheme was introduced.

#### 2.3.1 Positive donor virology scheme offering criteria for deceased donor kidneys

The positive donor virology scheme is initiated when NHSBT is notified that a donor has an initial positive result for any of the markers listed below:

- Hepatitis B surface antigen (not Hepatitis B core antibody positive alone, with negative HBsAG)
- Hepatitis C antibody

Author(s): Kathy Zalewska

- HIV 1 and 2 antibody
- HTLV 1 and 2 antibody

#### 2.3.2 Offering via the positive donor virology scheme

Centres must 'opt-in' to receive offers of kidneys through the positive donor virology scheme. When a kidney from a deceased donor meets the positive donor virology criteria, the organ will be offered simultaneously to each of the kidney centres that have opted-in to the scheme. Each centre has 45 minutes, from the time of offer, to confirm whether or not they would like to accept the kidney. Failure to respond within the 45 minute window is equivalent to a declined offer. The kidney will be allocated to the accepting centre with the highest priority patient listed although that centre may transplant the kidney in to any locally listed patient. Upon inspection, if the accepting centre decides the kidney is unusable, it will be offered to the accepting centre with the second highest priority patient listed and so on, until either the kidney has been transplanted or all accepting centres have declined the offer of the organ.

# 3. Allocation policies for multiple and paired organs

### 3.1 Prioritisation of patients requiring a kidney/pancreas or islet/kidney transplant

These patients will be prioritised after Tier A–C kidney only patients (i.e. after 000 mismatched children and 000 mismatched HSP/HLA-DR homozygous adults) for all DBD donor kidneys and for DCD donor kidneys that are offered regionally.

#### 3.2 Allocation of en bloc kidneys

Kidneys from donors aged 4 years and under (before their 5<sup>th</sup> birthday) will be retrieved and offered en bloc (but may be split if appropriate) while kidneys from donors aged 5 years and over will be retrieved and transplanted singly wherever possible. En bloc kidneys will be offered on a centre rather than patient basis to any centre wishing to receive offers of such kidneys.

# 4. Special prioritisation for patients listed for kidney-only transplantation

A patient identified to have missed an offer of a kidney due to a data or administrative error may be awarded special prioritisation in subsequent kidney matching runs. Prior to awarding special prioritisation, approval is required in writing from either the Chair of the Kidney Advisory Group or the Associate Medical Director for ODT NHSBT.

A patient awarded special prioritisation may be ranked above all other non-prioritised patients <u>within their qualifying tier/level</u> (long waiting patients and Tier A to E), of the standard donor kidney matching run. Clinically urgent children and all other higher tiered patients will continue to be ranked higher than a special prioritised patient. Where two or more patients are awarded special prioritisation within the same matching run, they will be ordered first by their qualifying Tier and then by their matching run points score.

Special prioritisation will only be applied until one of the following events occurs:

- The patient receives a single offer of a kidney from an appropriately blood group and HLA matched donor, even if that offer is subsequently declined
- The recipient is successfully transplanted
- The recipient is removed from the kidney transplant list

# 5. Additional waiting time points for patients listed for kidney-only transplantation

A patient identified as having fewer kidney waiting time points than they are entitled to (e.g. due to an administration error within the registration process) may be entitled to additional kidney waiting time points as compensation. Prior to awarding additional waiting time points, approval is required from either the Chair of the Kidney Advisory Group or the Associate Medical Director for ODT NHSBT.

If the patient is known to have missed an offer of a kidney as a result of an administrative error the patient may additionally be awarded special prioritisation described in **Section 4**.

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#### 5.1 Additional waiting time points for patients diagnosed with aHUS

- 5.1.1 Following approval from either the Chair of the Kidney Advisory Group or Associate Medical Director for ODT NHSBT, patients with atypical haemolytic uraemic syndrome (aHUS) who qualify for eculizumab funding and who have not had a previous transplant are entitled to additional waiting time points dating back to the date they commenced dialysis.
- 5.1.2 The additional points awarded to patients with aHUS who have been previously transplanted will depend on how long the previous graft functioned. The patient will be entitled to waiting time points dating back to the date they returned to dialysis following their most recent failed graft if it lasted more than 180 days. If the graft functioned for less than 180 days, the patient is entitled to additional waiting time points equivalent to the date they commenced dialysis. This is consistent with the 180 day rule described in the waiting time section of this document.

#### 6. Exemption request process

If a clinician considers that a transplant candidate is unfairly disadvantaged by the national allocation process, he/she may lodge an exemption request to be considered by the Kidney Advisory Group Exemptions Panel.

- 6.1 The Exemptions Panel will be chaired by the Chair of the Kidney Advisory Group or deputy. The panel will consist of the Chair, his deputy, one representative from each of the four DCD donor kidney allocation regions and one lay member.
- 6.1.1. Where the candidate's consultant is either the Chair or the nominated representative, then an alternate member must be identified, from a different hospital.
- 6.2 The exemption request will be made by electronic means to the Statistical Lead who will circulate, within one working day, the members of the Exemptions Panel who must respond within three working days.
- 6.3 The Chair will decide whether a teleconference is needed.
- 6.4 The decision will be made by majority vote and the Chair will have a casting vote.
- 6.5 The decision may be to decline the request or to award additional points.
- 6.6 The outcome of every request will be presented to the next meeting of the Kidney Advisory Group.
- 6.7 The candidate's consultant may appeal to the Associate Medical Director and the appeal considered at the next meeting of the Solid Organ Advisory Group Chairs Committee.

#### References

- 1. Johnson RJ *et al.* Factors influencing outcome after deceased heart beating donor kidney transplantation in the United Kingdom: an evidence base for a new national kidney allocation policy. *Transplantation* 2010;27:379–86.
- 2. Johnson RJ *et al.* A new UK 2006 kidney allocation scheme for deceased heart beating donor kidneys. *Transplantation* 2010;27:387–94.
- 3. Kidney Advisory Group. Allocation of kidneys donated in a domino procedure, 25th May 2011.
- 4. British Society for Histocompatibility and Immunogenetics/British Transplantation Society document for guidelines on the detection and characterisation of HLA antibodies in renal transplantation. https://bts.org.uk/wp-content/uploads/2016/09/06\_BTS\_BSHI\_Antibodies-1.pdf