This Policy replaces

POL186/2

**Copy Number** 

Effective

01/04/14

# Summary of Significant Changes

- · Clarification of policy approval process
- Paragraph 2.2.1 Clarification of Kidney Fast Track Scheme offering criteria for DBD donor kidneys
- Paragraph 2.2.2 Clarification of Kidney Fast Track Scheme offering criteria for DCD donor kidneys
- Addition of paragraph 4 Special prioritisation for patients listed for kidney-only transplantation
- Addition of paragraph 5 & 5.1 Additional waiting time points

## **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: January 2014 Approved by TPRC: March 2014

The aim of this document is to provide a policy for the allocation and acceptance of 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://odt.nhs.uk/pdf/non compliance with selection and allocation policies.pdf

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 local kidney transplant centre policies. This policy therefore relates more to kidneys from DBD donors while briefly outlining some of the allocation arrangements for kidneys from DCD donors in Section 1.1.1.

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

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#### 1. Allocation policy

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.

# 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 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 DCD donors

Kidneys donated after circulatory death (DCD) are not currently allocated through a national allocation scheme. Kidneys from DCD donors are currently allocated according to local kidney transplant centre policies. NHSBT is currently considering the feasibility of a national organ sharing scheme for kidneys from donors after circulatory death.

#### 1.1.1.1 Offering kidney and pancreases from DCD donors

Each year approximately 40 pancreas transplants are performed using organs from DCD donors and many of those are simultaneous pancreas kidney (SPK) transplants. On each occasion a pancreas from a DCD donor aged 65 years or less is considered suitable for clinical transplantation, a single kidney should also be offered with the pancreas. The other (paired) kidney will be offered according to the local kidney transplant centre policy.

Combined kidney and pancreas offers are made through the 2010 National Pancreas Allocation Scheme in the following way:

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

The combined kidney and pancreas will be offered via the National Pancreas Allocation Scheme. If the pancreas is accepted for pancreas only or pancreatic islet transplantation then the kidney will be offered back to the local kidney transplant centre and the kidney will be allocated according to the local kidney transplant centre policy.

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

The combined kidney and pancreas will be offered to the local <u>pancreas</u> transplant centre first and may be accepted on behalf of any locally listed patient. If the organs are declined by the local pancreas transplant centre the kidney and pancreas will then be offered 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 and will be allocated according to the local centre policy.

If the kidney from a DCD donor is not used as part of a SPK transplant then it will be offered for kidney only transplantation. In such cases, the kidney will be first offered back to the local <u>kidney</u> transplant centre. If the kidney has been transported to a pancreas transplant centre that is different from the local kidney transplant centre then the local kidney transplant centre can request that the kidney is transported back. In the interest of optimising kidney utilisation, if further transportation is not deemed practical and the local kidney transplant centre agree, the kidney may be retained by the pancreas transplant centre for kidney only transplantation in a locally listed patient of their choice. In such circumstances no kidney 'payback' will be required.

To be compliant with the current National Pancreas Allocation Scheme policy, pancreas transplant centres are entitled to accept just the pancreas when it is offered with a kidney and in such cases the kidney will then offered to the local kidney transplant centre and may be allocated according to local policy.

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If only one kidney from a DCD donor is available for transplant, the kidney will not be offered with the pancreas and will instead be offered for kidney only transplantation and allocated via local kidney transplant centre policy.

The transplant team who are first to confirm acceptance of a single kidney or combined kidney and pancreas offer may request either the left or right kidney.

#### 1.2 Allocation policy

## 1.2.1 Patient prioritisation

All kidneys from deceased donors whose death has been defined by brain-stem death criteria 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	000 mismatched paediatric patients - highly sensitised* or HLA-DR		
	homozygous		
В	000 mismatched paediatric patients – others (all except those in Tier A)		
С	000 mismatched adult patients - highly sensitised* or HLA-DR homozygous		
D	000 mismatched adult patients – others (all except those in Tier C)		
	Favourably matched paediatric patients (100, 010, 110 mismatches)		
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)

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
- 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 temporary 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.

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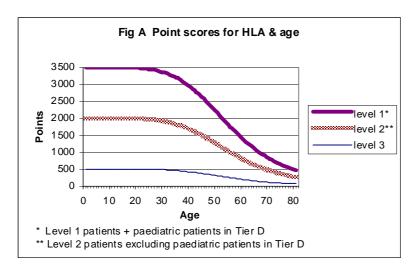
Waiting time is transferable when a patient transfers from one transplant centre to another. The time will be calculated automatically provided the patient has not been 'removed' from the list as part of the transfer. When a patient is notified as 'removed' from the list their waiting time is lost.

# 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 D500 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:

- 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

# **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).

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1500 points are allocated for blood group B patients when the donor is group A2 provided that they have been registered as suitable for such a transplant and their waiting time exceeds 730 days (this is currently a pilot limited to three London centres).

#### **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.

#### 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					
	0	Α	В	AB		
0	ü	ü*	ü	ü*		
Α	-	ü	#	ü		
В	-	-	ü	ü*		
AB	-	-	-	ü		
* 000 mion	antahad biably aspa	itiand or OOO LI	A DD homozygous	adult patients		

- \* 000 mismatched highly sensitised or 000 HLA-DR homozygous adult patients
   & 000 mismatched paediatric patients only
- blood group incompatible

#### HLA match eligibility

Donors are HLA-typed at the retrieving centre according to the minimum resolution specification agreed by the NHSBT Kidney Advisory Group and are reported to the NHSBT Duty Office 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.

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<sup>#</sup> Incompatible except that kidneys from donors of subtype A2 can be allocated to patients of blood group B as part of a pilot scheme in 3 London transplant centres where patients are regularly tested to ensure ongoing suitability for this programme

Table B Defaulting of rare HLA specificities				
Rare Spe	cificity	Common Equivalent		
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, DR	R12	DR1 DR1 DR4 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]	000 100, 010, 110, 200, 210 020, 120, 220, 001, 101, 201, 011, 111, 211			
4	[1 DR and 2 B] or [2 DR]	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 (100, 010, 110, 200 or 210 mismatches) 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

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

## 1.2.4.1 Context

There have been two cases of domino kidney donation (i.e. a kidney removed in the course of a therapeutic procedure in which the patient has asked if the removed kidney could be used for donation) in the past 2 years and, recently, a third that did not proceed to donation. Domino transplants do not require approval from the Human Tissue Authority because the organ is removed primarily for the benefit of the patient from whom the organ is retrieved.

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## **Kidney Transplantation: Organ Allocation**

Previously it has been agreed that domino kidneys are allocated according to national allocation criteria in the same way as kidneys from non-directed altruistic donor kidneys are allocated (i.e. to a recipient on the national transplant list prior to retrieval).

#### 1.2.4.2 Clinical Cases

In the first of the two cases, the kidney was allocated according to national allocation criteria prior to donation and transplanted into a recipient, identified previously, in another centre. The transplant functioned poorly from the outset and subsequently failed after a prolonged period of poor function.

In the second, more recent case, a request was made by the donating centre to allocate the kidney locally. The rationale for this was so that

- An assessment of the kidney could be made at the time of retrieval to ensure that it was viable to transplant
- The logistics of subsequent transplantation/not proceeding to transplantation would be easier to manage, both in terms of informing the potential recipient in the context of local knowledge and minimising cold ischaemic time

After consultation with the Chair of KAG and colleagues within NHSBT, it was agreed that local allocation would be appropriate and the kidney was allocated in advance to a local recipient through the Duty Office at NHSBT. The retrieved kidney was successfully transplanted into the identified recipient and has subsequently functioned well.

A similar approach (i.e. local allocation) was recommended with the third case that was presented to NHSBT but did not proceed to donation at the patient's request.

#### 1.2.4.3 These cases highlight some key points:

- Domino donation is uncommon and equity of access to such kidneys is unlikely to be affected by a change in the allocation system
- Domino donation carries a potentially higher risk of uncertainty about the viability of the retrieved kidney for transplantation in comparison with other living donor kidney scenarios because the retrieval surgery may be complicated by the patient's underlying condition
- In view of this uncertainty, national allocation prior to planned domino donation may not be in the best interests of either donor or recipient in terms of managing both the clinical scenario and the expectations of the potential recipient, particularly if the retrieval and recipient centres are different and/or geographically remote from each other
- 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

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In all cases, offering of kidneys will only continue in the order specified until 20 hours of cold ischaemia time have been accrued, at which point the centre holding the kidney (or the centre to which the kidney has been dispatched) can use the kidney in a patient of their choice.

In either of these cases, the kidney will be offered back to the designated local transplant centre if not required for use at the receiving centre as permitted.

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

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.

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#### 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 patients in Tiers A to D. If there are no suitable patients in Tiers A to D, 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

# 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 or liver and kidney), the kidney should not be Fast-Tracked until the organ has accrued 12 hours of cold ischaemia time.

# 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.
- 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 DBD 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.

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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 was first to accept the kidney and so on until the organ is placed.

## 3. Allocation policies for multiple and paired organs

## 3.1 Prioritisation of patients requiring a kidney/pancreas 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).

## 3.2 Allocation of en bloc kidneys

Kidneys from donors aged 4 years and under 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 within their qualifying tier, Tier A to E, of the standard DBD 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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## **Kidney Transplantation: Organ Allocation**

#### 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, 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.

#### 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, 25<sup>th</sup> 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. <a href="http://www.bts.org.uk/Documents/Guidelines/Active/A6.pdf">http://www.bts.org.uk/Documents/Guidelines/Active/A6.pdf</a>

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