Kidney Assessment and Recovery Centre (ARC) – Pilot Manual.

Kidney ARC to Accepting Transplant Centre

Index

1. Summary of changes

2. Introduction

3. Glossary

4. Roles and Responsibilities

5. Arrival of donor Kidney at Kidney ARC

6. Kidney accept/decline/offering during NMP

7. Kidney transport

8. Follow-up and data returns

9. Associated documents and references

1. Summary of changes

New document

2. Introduction

An Assessment and Recovery Centre (ARC) is a dedicated facility separate from the accepting transplant centre where a deceased donor kidney is assessed prior to transplant. At the ARC, the kidney will undergo ex-situ normothermic machine perfusion (NMP), which allows the kidney to be maintained under controlled physiological conditions to assess function, improve preservation, and allow potential reconditioning prior to transplantation.

The Kidney Assessment and Recovery Centre Pilot aims to:

- Test the feasibility and safety of providing a national kidney machine perfusion service to support increased deceased donor kidney utilisation
- Establish the logistics and governance arrangements for this new organ journey pathway
- Generate mechanisms for robust audit and data collection to be able to monitor ARC performance and impact
- Create a sense of national ownership of the ARC programme as a service provided by some, for the benefit of all, to offer equity of access to all transplant recipients

Any additional information around the ARC programme including links to Kidney Passport (FRM 8225) and patient information leaflets can be found here Assessment and Recovery Centres programme - ODT Clinical - NHS Blood and Transplant

3. Glossary

Term	Definition
Kidney Assessment and Recovery Centre (ARC)	Specialist centre who will undertake kidney machine perfusion on behalf of the accepting transplant centre.
Normothermic Machine Perfusion (NMP)	An ex-situ organ preservation method where a deceased donor kidney is continuously perfused at normal physiological temperature with oxygenated perfusate, enabling ongoing metabolism, and functional assessment prior to implantation.
Abdominal Normothermic Regional Perfusion (A-NRP)	Technique to restore the circulation to the abdominal organs in situ following circulatory arrest for the purpose of transplantation
Donation after Brainstem Death (DBD) donor	Deceased donor who donates organs following confirmation of death by neurological criteria
Donation after Circulatory Death (DCD) Donor	Deceased donor who donates organs following confirmation of death by circulatory criteria

4. Roles and Responsibilities

Role	Responsibility in ARC pathway
Coordinator - Accepting transplant centre	Communicates between Hub Operations, Specialist Nurse and Kidney ARC to coordinate acceptance and transport of donated kidney
Coordinator – ARC	Mobilises ARC perfusion team and continues to support communication between Kidney ARC Clinical lead / kidney ARC preservation team / Transplant centre
Accepting transplant centre	Transplant centre that has accepted donor kidney for a recipient. Maintains communications between Hub Operations and ARC centre to support transplant pathway.
Accepting Transplant Surgeon	Kidney Transplant Surgeon from the accepting transplant centre who makes the decision to accept kidney for transplant for their recipient.
Kidney ARC Lead Surgeon	Leads the kidney perfusion team at the Kidney ARC. Liaises with Accepting Transplant Surgeon to support decision to transplant. Undertakes or oversees the assessment and clinical decision making on viability of donor kidney on NMP.
Kidney ARC Organ Preservation Practitioner	Trained to set up and prime NMP circuit, initiate perfusion and monitor perfusion indices and kidney physiology including troubleshooting under guidance of Kidney ARC Lead Surgeon.
Hub Operations	NHSBT Hub Operations provide a link in the transplant process between the Organ Donation Services Teams, the National Organ Retrieval Service, the ARC and Accepting Transplant Centres. Hub Operations supports the organ donation and transplantation community by matching and allocating organs from deceased donors.
Specialist Nurse (SN)	Nurse who supports potential donor families and the operational processes of deceased organ donation.

5. Arrival of donor Kidney at Kidney ARC

5.1 Arrival of Kidney at Kidney ARC
5.2 Ex vivo machine perfusion of Kidney
5.3 Crossmatch material and vessels
5.4 Sampling of Kidney including routine biopsy and microbiology
5.5 Urgent histopathology
5.6 Additional samples

5.1 Arrival of Kidney at Kidney ARC

Refer to SOP 6886 *Kidney Assessment and Recovery Centre (ARC) – Pilot Manual - Donor Hospital to Kidney ARC* for a description of the clinical pathway prior to arrival of kidney at the ARC.

On arrival at ARC, the kidney must be correctly identified against 3 pieces of **donor** personal identifiable information (PID). Crossmatch material should remain on melting water ice. Accompanying paperwork should remain secure in kidney box inside a waterproof envelope.

The kidney should be visually inspected by the Lead ARC Surgeon and FRM8225 *Kidney ARC Passport* started.

If organ damage is noted on inspection and not documented on the Kidney Donor Information (HTA – A FRM 4121) form, this should be reported to the NHSBT Patient Safety Team, in line with SOP3888- *Reporting an Organ Donation or Transplantation Incident to NHSBT.*
Tell us about an incident - ODT Clinical - NHS Blood and Transplant
Images of any damage should be uploaded to TransplantPath directly. Information on the use of TransplantPath can be found here
TransplantPath - ODT Clinical - NHS Blood and Transplant including INF1833 – *TransplantPath users: Uploading Files, Images and Video* (**INF/)**

If the kidney is considered suitable for perfusion after visual inspection, the circuit can be prepared and primed.

5.2 Ex situ Kidney Normothermic Machine Perfusion (NMP)

Kidney perfusion is undertaken as per the ARC's local perfusion protocols.

The following points must be followed to maintain traceability, sterility and accurate identification of the kidney and its associated samples and documentation at all times:

- Each perfusion setup should take place in a dedicated room where possible. If this is not possible, the room must be segregated appropriately to reduce the chance of cross contamination and maintain traceability of organ and samples.

- Place ARC Kidney label (FRM 8240) on kidney ice box. All documentation (witnessed donor blood group, HTA-A) as well as donor lymph, spleen and blood to remain in this ice box during time at the ARC.

- When at the ARC, the kidney should be monitored by the designated members of the ARC team.

If new organ damage is caused and or visualised at any point during the machine perfusion process, this must be documented on the Kidney ARC Passport FRM8225, and reported in line with

SOP3888- *Reporting an Organ Donation or Transplantation Incident* as described in section 5.1

5.3 Crossmatch material

All crossmatch material (lymph, spleen and blood) accompanying the kidney from the donor hospital must be stored safely at the ARC on melting water ice in a kidney organ box. The ARC personnel must regularly check the box and replenish ice if there are signs of melting.

The organ box must be labelled on arrival with *ARC Kidney Transport Label* (FRM8240) ensuring donor number is visible externally on the box. This must be cross checked with any accompanying samples, and placed on the box.

5.4 ARC routine sampling protocol- microbiology

As part of the ARC process, there is a requirement for routine microbiology sampling.

All microbiology samples processed in ARC must be undertaken under donor PID so that results can be assigned to the correct donor record.

All microbiology samples must be processed at the ARC as quickly as possible following sampling. This includes abdominal organ transport fluid testing and blood cultures taken from NMP circuit.

Sample to be taken	Taking of the sample	Storage of sample	Area to process	Area responsible for reporting and sharing result with Hub Operations
Abdominal Transport fluid microbiology (see section 5.4.1)	Sterile pot/s 30-40mls (minimum 20ml)	Process as soon as possible (maximum 18 hours if refrigerated)	ARC	ARC
Blood culture from NMP circuit (see section 5.4.2)	Blood culture bottle (minimum 10ml per bottle) taken from NMP circuit	Process within 4 hours of sampling	ARC	ARC

The ARC must record details of all samples taken on the Kidney ARC Passport FRM8225.

ARC centres must identify person/s in their centre who are responsible for reporting results appropriately to Hub Operations where clinically indicated (See section 5.4.1 and 5.4.2).

Hub Operations have the responsibility to communicate availability of all reports received to all transplanting centres as per SOP4938 *OTDT Manual 5: Managing and Sharing Clinical Information*.

Samples that accompany the kidney from the donor centre e.g. lymph and spleen are to remain on ice and be processed at the accepting transplant centre

5.4.1 Abdominal transport fluid
As per UK Standards for Microbiology Investigations B 62 - *Abdominal organ transport fluid testing* (link Document library), abdominal transport fluid samples must be taken when the kidney is unpacked at the ARC. The sample must be collected in sterile pots 30-40mls (minimum 20ml) and sent for urgent processing as soon as possible. It **must be processed within 18 hours** of collection if the sample is refrigerated. Samples must be clearly labelled with 3 pieces of donor PID, date/time of collection, and type of sample.

Positive Abdominal Transport fluid must be reported by the ARC as per MPD1338 – *Positive Transport Fluid* on FRM5964 – *Transport Fluid Alert Form.* Commensal organisms and negative results do not require reporting.

5.4.2 Blood culture from NMP circuit
Blood culture samples of the NMP circuit fluid must be taken and placed in blood culture bottles at the end of NMP.

As per UK Standards for Microbiology Investigations S12 - *Sepsis and systemic or disseminated Infections* (link Document library)**,** blood culture samples should be sent for urgent processing, as Soon as possible after collection within a **maximum of 4 hours** from sample collection. Samples must be clearly labelled with 3 pieces of donor PID, date/time of collection, and type of sample.

If there is no growth on NMP circuit cultures, there is no requirement to share results. Any other results of the cultures from NMP circuit must be communicated as soon as possible by the ARC see by uploading results to TransplantPath and verbally communicating to the Hub Operations as soon as they are available. (01179 757580).

5.4.3 Kidney stand down at ARC
If the kidney is stood down for transplant at the ARC and samples are in process, they must:

- Continue with the processing of abdominal transport fluid as this could have implications for other recipients
- Stand down all other processing

5.5 Urgent Histopathology
If there are findings indicating the need for urgent histopathology examination identified at the ARC, SOP5735 *New Findings Made at Transplant Centres Requiring Histopathology Assessment.*(Policies and guidance - ODT Clinical - NHS Blood and Transplant) The ARC has the same responsibilities as a 'Transplant Centre' as defined in the SOP.

- The ARC Coordinator is responsible for informing the Hub Operations of the need for urgent histopathology and the plan for processing.
- Hub Operations have responsibility this is communicated urgently following their processes.
- If the ARC cannot process histopathology on the sample, they must inform Hub Operations immediately. Hub Operations will follow own processes to escalate and communicate to relevant individuals and advise ARC of next steps.

5.6 Additional samples

If any additional non-microbiological samples are taken as per the clinicians' judgement during the NMP assessment, these must be processed at the accepting transplant centre.

If any additional microbiological samples are taken as per the clinicians' judgement during the NMP assessment, these must be processed at the ARC and results reported to NHSBT Hub Operations as describe in section 5.4.

All samples must be labelled clearly with 3 pieces of donor PID, the type of sample, and the date and time of collection and placed in the kidney ice box. Any additional samples must be clearly identified on the Kidney ARC Passport (FRM8225).

6. Kidney acceptance/decline/offering during NMP

6.1 Assessment criteria of kidney on NMP
6.2 Kidney ARC offering and allocation
6.3 Kidney not accepted or deemed not for transplant

6.1 Assessment criteria of kidney on NMP

The ARC team must continually monitor the kidney throughout the perfusion process, recording all applicable details in Kidney ARC Passport FRM8225.

Primary criteria			
	'Pass' values	'Consider' values	'Fail' values
Macroscopic appearance at one hour	Evenly perfused	Patchy	Mottled/ purple/ black
Renal blood flow (RBF) or intra-renal resistance (IRR) at 1 hour	RBF at 1 hour > (pressure*weight)/71.1 Or (simplified, where perfusion pressure is 75mmHg): RBF at 1 hour in mL/min > kidney weight in grams	-	RBF at 1 hour < (pressure*weight)/71.1 Or (simplified, where perfusion pressure is 75mmHg): RBF at 1 hour in mL/min < kidney weight in grams
Secondary criteria			
	Associated with primary function	Associated with delayed graft function	
Lactate trajectory	Decrease from baseline	Rise, plateau, fall Continuous rise from baseline	

6.2 Kidney ARC offering and allocation

After 2 hours on NMP, the Lead ARC clinician will assess the kidney utilising the assessment criteria in section 6.1.

- The kidney must meet 'Pass' and 'Consider' values for the kidney ARC offer to be made.
- If 'Fail' criteria are identified the Lead ARC Surgeon can deem the kidney not transplantable and proceed to section 6.3

ARC must follow directions on the Kidney ARC passport (FRM8225) ensuring relevant sections as directed on the passport are uploaded to TransplantPath including images (if able). See section 5.1 for advice regarding upload to TransplantPath.

ARC must contact Hub Operations by phone on 01179 757580 to ask them to send out Kidney ARC Offer.

- The kidney ARC offer will only be sent to those fast-track centres that have opted IN to receive Kidney ARC offers.
- The kidney ARC offer will only be sent to ARC opt in centres within 4 hours travel distance of the ARC.
- Centres will have 45mins to respond to the kidney ARC offer.

The Lead ARC Surgeon must be available to discuss the offer with any interested centres. The decision to transplant remains the responsibility of the accepting transplanting surgeon.

Hub Operations will allocate the kidney according to POL186 *Deceased Donor Kidney Distribution and Allocation* and inform the centre who has been allocated the kidney. The ARC as a centre itself, may express an interest as part of this offering process, and will be placed at the bottom of the allocation sequence.

6.2.1 ARC and Accepting Centre communication

Hub Operations will inform a transplant centre when they have been allocated the kidney. The accepting centre must then contact the ARC to facilitate ongoing communication, agree length of time kidney to remain on NMP, agree requirements for updates and approximate time that kidney will leave the ARC. Once timings agreed between ARC and accepting centre, the ARC can arrange transport of kidney via Hub Operations, see section 7.

NOTE
Kidney can remain on XVIVO Kidney Assist for a maximum of 6 hours.

NOTE
The accepting centre has the responsibility to ensure the recipient receiving the ARC kidney for transplant is adequately informed and consented in line with local processes

6.2.2 Accepting centre decline

If the accepting centre declines the kidney at any point, they must inform Hub Operations and the ARC as soon as possible.

Hub Operations will reallocate to the next centre if more than one centre showed interest in the ARC offer. Once a new centre has been allocated the kidney; they should establish communication with the ARC as outlined in section 6.2.1.

If there is no acceptance of the kidney proceed to section 6.3.

6.3 Kidney not accepted or deemed not suitable for transplant

If there is no acceptance of the kidney ARC offer, or the kidney is stood down for transplant at any point whilst at the ARC, then the ARC has the responsibility to:

- Remove the kidney from NMP
- Inform Hub Operations of stand down
- Hub Operations will proceed to research offering should there be donor consent/authorisation in place
- Hub Operations will advise of placement for research and the ARC must package the kidney and support transport arrangements as advised
- If there is no research consent/authorisation, or if the kidney is not accepted for research, the ARC must dispose of the kidney ensuring HTA-B form (FRM6295) is completed
- The ARC must ensure all samples accompanying the kidney are disposed of in line with local processes
- The ARC must ensure a complete copy of the Kidney ARC Passport (FRM 8225) is uploaded to TransplantPath and store a hard copy locally

7. Kidney transport

7.1 Arranging transport
7.2 Preparing kidney for transport
7.3 Releasing kidney for transport

7.1 Arranging transport

NOTE
There will be no peripheral blood sample for laboratory ('wet') crossmatch for kidneys from ARC.

Once the accepting centre confirms their intention to transplant, the ARC and accepting transplant centre must agree a time for the kidney to be removed from NMP, and the timings for transport.

The ARC must contact Hub Operations to arrange transportation of the kidney from the ARC to the accepting transplant centre. Note the response time for transport is minimum time of 60 minutes. Hub Operations will require the following information:

- 3 pieces of donor PID
- Collection location for the kidney
- Delivery location
- Kidney box number
- Confirmation of collection time

7.2 Preparing the kidney for transport

Once the kidney is removed from NMP, it must be packed into the ARC labelled kidney box with the following:

- Kidney (with coloured sling indicating left or right)
- Lymph and spleen
- Sufficient melting water ice
- Paperwork must include :
  - HTAA form,
  - Witnessed donor blood group
- Transport box must be labelled with relevant (left or right) Kidney ARC transport label (FRM8240) which must be attached to the box handle
- Hub Operations will confirm delivery address with the ARC when arranging transport

A completed copy of Kidney ARC Passport (FRM 8225) must be uploaded to TransplantPath prior to the kidney leaving the ARC. There is no requirement to send a hard copy with the kidney.

NOTE
No microbiology samples should travel with the kidney to the accepting transplant centre. These should all be processed at the ARC (as per section 5)

7.3 Releasing the kidney for transport

The responsible person in the ARC for releasing the kidney for transport must:

- Confirm the identity of the person collecting the organ. This should be done through proof of identification via a badge of the transport company, with photographic evidence of the transport personnel.
- Confirm the type of organ that is being dispatched, the intended destination and the required time of arrival.
- Check that the organ transport box is structurally intact and fastened securely.

- Record the date and time of handover to transport personnel, and sign, print and date the record on locally held documentation.

For traceability, records of organs released for transport must be stored for 30 years.

8.0 Follow-up and data returns

8.1 Kidney ARC Passport FRM 8225 instruction – Kidney transplanted
8.2 Routine recipient follow-up
8.3 Kidney ARC Passport FRM 8225 instruction – Kidney stand down
8.4 Kidney ARC microbiology results

8.1 Kidney ARC Passport FRM8225 – Kidney transplanted

Original copy of FRM8225 should remain at the ARC.

A completed copy of FRM8225 must be uploaded to TransplantPath before the kidney leaves the ARC. The ARC must retain the original for their own records.

8.2 Routine recipient follow-up

The accepting transplant centre must follow current processes for routine recipient follow-up.

8.3 Kidney ARC Passport FRM8225 – Kidney stand down

If the kidney is stood down at the ARC, then it is the responsibility of the ARC to complete Kidney ARC passport FRM8225 as fully as possible and ensure this is uploaded to TransplantPath once complete. The ARC must retain a copy of the completed form for their own records. The ARC must ensure completed HTA-B form is returned to NHSBT.

8.4 Kidney ARC microbiology results

The kidney ARC must have a local process in place to ensure results of microbiology tests are reported to Hub Operations as soon as they are available as described in section 6.1

All results must include 3 forms of donor PID and indicate type of sample.

If there is no growth on the NMP circuit blood cultures, there is no requirement to share results. Any other results of the cultures must be communicated as soon as possible by the ARC by uploading the results to TransplantPath and verbally communicating to the Hub Operations (01179 808075) who will disseminate the results according to established processes.

Positive abdominal organ transport fluid must be communicated in line with MPD1338 – *Positive Transport Fluid.*

9. Associated documents and references

POL186 - *Kidney Transplantation: Deceased Donor Organ Allocation*
SOP3888 - *Reporting an Organ Donation or Transplantation Incident to NHSBT*
SOP6886 - *Kidney Assessment and Recovery Centre (ARC) – Pilot Manual - Donor Hospital to Kidney ARC*
SOP4938 - *OTDT Manual 5: Managing and Sharing Clinical Information*
SOP5735 - *New Findings Made at Transplant Centres Requiring Histopathology Assessment*
MPD338 - *Positive Transport Fluid*
FRM8225 - *ARC Kidney Passport*
FRM8240 - *ARC Kidney Transport Label*
FRM4121- *Kidney Donor Information (HTA – A)*
FRM6295 - *Human Tissue Authority – Research (HTA - B)*
FRM5964 - *Transport Fluid Alert Form*
INF1866 - *Introduction to Kidney transplantation and the Assessment and Recovery Centre (ARC)*
INF1833 - *TransplantPath users: Uploading Files, Images and Video*
UK Standards for Microbiology Investigations B 62 - *Abdominal organ transport fluid testing*
UK Standards for Microbiology Investigations S12 - *Sepsis and systemic or disseminated infections*

Training Plan for Documents:

Type of Change	< new document >	
	Trainee new to the process	**Trainee trained to the previous revision.**
Stakeholders who require training	External to NHSBT document - Kidney ARC pilot centres and kidney transplant centres. No training to NHSBT employees	N/a
Knowledge required prior to training	Nil	N/a
Critical aspects of process	New process to support Pilot kidney ARC pathway for processes in the ARC to Transplanting Centre>	

Training Plan:

	Trainee new to the process	**Trainee trained to the previous revision.**
Recommended Training Method	<Training methods for each role/department identified e.g.: • Read only >	< n/a>
Assessment	<How assessment of competency is evidenced e.g.: • Transplant centre director communication to indicate centre are adequately trained	<n/a
Cascade Plan	ARC champion network	< n/a • >

Training Score – Training Plan Risk Matrix (Collapsible – Click ▶ icon to open/close)
Use the *Training Plan Risk Matrix* to identify the training method and assessment required.

The *Process Criticality Score* is determined by the potential impact on donor/patient safety and/or product quality using the table below for guidance:

	Impact on Donor, Patient safety or product quality
1. Negligible	A process whose failure, in full or in part, **cannot** impact product quality, patient/donor safety or the ability to supply products/services.
2. Minor	A process whose failure, in full or in part, **may**: (i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align) (ii) result in the discard of a small number of replaceable products and/or (iii) result in an inconvenient delay to the supply of products/services (e.g. delay of 1-3hrs of non-urgent product/service).

3. Moderate	A process whose failure, in full or in part, **may**: (i) indirectly impact product quality, patient/donor safety (e.g. harm only results where failures in more than 1 process align) (ii) result in the discard of a medium number of replaceable products and/or (iii) result in a temporary delay to the supply of products/services (e.g. delay of 4-12hours of non-urgent products/services).
4. High	A process whose failure, in full or in part, is **likely** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
5. Very High	A process whose failure, in full or in part, is **certain** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
Process Criticality Score	<3>

The *Criticality of Change Score* is determined by assessing the nature of change(s) and complexity of the process using the table below for guidance.

	Change to Trainee(s)
1. Negligible	An existing process to which no material changes are made. E.g. format changes, minor clarifications of existing practice, fixing typos.
2. Minor	An existing process to which new information is added but where changes to existing knowledge and practices are minimal. E.g. clarifications that tighten existing practices
3. Moderate	An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform. E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks
4. High	A new process of moderate complexity, OR An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
5. Very High	A new process of high complexity, OR An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.

Criticality of Change Score	<4>

Training Plan Risk Matrix:

Process Criticality →

Criticality of Change ↓	1. Negligible	2. Minor	3. Moderate	4. High	5. Very High
1. Low	1	2	3	4	5
2. Moderately Low	2	4	6	8	10
3. Moderate	3	6	9	12	15
4. High	4	8	12	16	20
5. Very High	5	10	15	20	25

	Trainee new to the process	**Trainee trained to the previous revision.**
Process Criticality Score	<3>	
Criticality of Change Score	<4>	<n/a>
Training Score	<12>	<n/a>

Recommended Training Method and Assessment:

Training Score	Level of Risk	Examples of Training Methods	Examples of Assessment
1 - 3	Low	Read only	Record on FRM511 only
4 - 8	Manageable	Email, team brief, word brief	Knowledge/Observation Check & FRM511
9 - 14	Medium/Significant	Formal training package	Knowledge/Observation Check & FRM511 or FRM5076
15 - 25	High	Practical	FRM5076 or equivalent