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

Donor Hospital to Kidney ARC

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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	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 of donor kidney pre-perfusion, cannulation of kidney and placing on NMP circuit.
Kidney ARC Organ Preservation Practitioner	Organ Preservation Practitioner trained to set up and prime NMP circuit, initiate perfusion and monitor perfusion indices and kidney physiology.
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. Eligibility and Exclusion Criteria for Kidney to ARC

5.1 Donor referral, consent/authorisation and assessment
5.2 Kidney ARC eligibility criteria
5.3 Kidney ARC exclusion criteria
5.4 Considerations

5.1 Donor Referral, Consent/Authorisation and Assessment

SN will follow established processes for deceased donor referral, approach, consent/authorisation and characterisation. There is no change to these processes for the ARC pilots.

5.2 Kidney ARC Eligibility criteria

- DBD and DCD kidneys at point of fast track
- The ARC consultant will consider factors which are likely to include but are not limited to:
    - perfusion characteristics (fair, poor, patchy),
    - complex anatomy or damage,
    - AKIN (1-3),
    - cold ischaemia time or kidneys awaiting histopathology results.

The ARC can express interest during the FastTrack offer. Once all transplant centres decline the kidney offer; it will be allocated to the ARC closest to the location of the organ.

5.3 Kidney ARC Exclusion criteria

- Kidneys deemed unsuitable by the ARC team.
- Referral to an ARC to perfuse on behalf of an accepting centre.

5.4 Considerations

Kidney ARC cannot be requested during routine offering. A kidney can only be accepted into an ARC once fast track offering has been exhausted for direct transplant.

Organ acceptance is based on clinical judgement and can vary between Clinicians and Transplant Centres.

ARC must inform Hub Operations if they are unexpectedly unavailable during their rostered-on period.

An ARC team must include a Lead Surgeon, an assistant to support the perfusion and a team member responsible for coordination.

6. Kidney Offering and Allocation

6.1 Kidney ARC availbility
6.2 Offering and allocation
6.4 Kidney accepted by ARC with no recipient

6.1 Kidney ARC availability

The Kidney ARC must inform Hub Operations if the ARC becomes unexpectedly unavailable during their rostered-on call period.

6.2 Offering and allocation

Hub Operations will offer kidneys according to POL186 – *Kidney Transplantation: Deceased Donor Organ Allocation* and proceed to fast track once a fast track trigger is met.

ARC centres must respond clearly to Hub Operations within the 45 minutes for the fast track offer with a firm decision if they would like to:

- Accept the organ for transplant
- Accept the kidney for perfusion in an ARC without an identified recipient.
- Decline for both direct and ARC (no response to Hub Operations results in decline)

6.3 Kidney accepted by ARC with no recipient

If there is more than one kidney ARC rostered on as active, Hub Operations will allocate the kidney to the ARC closest to the current location of the kidney. Hub Operations will inform the ARC if the kidney has been allocated to them.

From this point, the coordinator at the ARC must lead communications between Hub Operations and the donor hospital throughout the rest of the donation process.

7. Retrieval

7.1 National Organ Retrieval Service (NORS) mobilisation
7.2 ARC Mobilisation
7.3 Theatre Communication
7.4 Kidney packing

7.1 National Organ Retrieval Service (NORS) mobilisation

Hub Operations will mobilise NORS retrieval team as per SOP4574 – *Logistics & NORS Mobilisation*.
No additional kit is required for the NORS retrieval team when the kidney ARC is involved.

7.2 ARC Mobilisation

Once Hub Operations allocates the kidney to the ARC for assessment, local process should be followed within the ARC to ensure the ARC team is mustered and available to receive the kidney.

7.3 Theatre Communication

Any urgent communication during retrieval will be communicated to the Lead ARC Surgeon (or ARC designated individual) either directly from the SN or via Hub Operations.

Once the anatomy is documented on TransplantPath, Hub Operations will confirm the final kidney allocation with the ARC, e.g. the destination of the left or right kidney, and inform them if there is damage for the Lead ARC Surgeon to review on TransplantPath.

7.4 Kidney packing

The kidney and associated cross match material, vessels and paperwork will to be packed on ice as instructed in SOP5499 *Theatre Manual for Deceased Organ Donors for Theatre*, and MPD1043 *National Standards for Organ Retrieval from Deceased Donors.*
(Policies and guidance - ODT Clinical - NHS Blood and Transplant)

8. Arrival of Kidney at Kidney ARC

Once the donor kidney arrives at the Kidney ARC, the kidney and associated samples become the responsibility of the Kidney ARC.

Refer to SOP6889 *Kidney Assessment and Recovery Centre (ARC)- Pilot Manual-Kidney ARC to Transplant Centre* from this point onwards.
(Assessment and Recovery Centres programme - ODT Clinical - NHS Blood and Transplant).

Training Plan for Documents:

Type of Change	< Brand New Process >	
Stakeholders who require training	**Trainee new to the process**	**Trainee trained to the previous revision.**
	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 from the donor hospital to the ARC >	

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.: • Email confirmation from kidney centre director to NHSBT ARC programme team	<How assessment of competency is evidenced e.g.: • n/a
Cascade Plan	<Who will deliver the *Training Plan*, who will train the trainers e.g.: • <SOP and slide set to be provided to Kidney ARC champion network by ARCs team >	< Who will deliver the *Training Plan*, who will train the trainers e.g.: • 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