NHS Blood and Transplant
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Lung Assessment and Recovery Centre (ARC)- Pilot Manual

Lung ARC to Transplant Centre SOP 6843

Caring Expert Quality

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1. *Summary of changes*

New

2. *Useful Information*

Background to Ex- vivo lung perfusion (EVLP)

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2.1 Background to Ex- vivo lung perfusion (EVLP)

EVLP of donor lungs is now established as a safe and effective approach to assess the suitability of some potential donor lungs for clinical transplantation.

Donor lungs which have certain extended selection criteria or are deemed too marginal for direct transplantation may have the potential to be used successfully after a period of more detailed objective assessment and recovery during EVLP.

Successful EVLP requires careful evaluation of donor lung eligibility for EVLP, a skilled and trained multidisciplinary team to carry out EVLP and clear objective decision making on which organs achieve success criteria for transplantation after EVLP.

Collective decision making by the lung transplant multi-disciplinary team and collective responsibility for decisions made, is an important part of a successful EVLP programme.

Patients on the lung transplant waiting list should be informed and consented about the potential for EVLP use in assessing a donor organ that they may receive.

2.2 Functions of Ex – vivo lung perfusion (EVLP)

EVLP can assist with increasing donor organ utilisation and improve access to lung transplantation for patients on the active lung transplant waiting list. There are 4 main functions of EVLP

- Provide an objective assessment of donor lung function to ensure organs are suitable for transplant
- Provide an opportunity to intervene to optimise donor lung function and re-assess suitability
- To extend preservation of the donor lungs outside the body and reset the ischaemic time
- To administer therapeutics to donor lungs that may be prophylactic or personalised treatment

2.3 Lung Assessment and Recovery Centre Pilot

Aims of the lung ARC pilot

- Test feasibility and safety of providing a national EVLP service to support increased donor lung utilisation
- To establish the logistics and governance arrangements for this new organ journey pathway
- To generate mechanisms for robust audit and data collection to be able to monitor ARC performance and impact
- To create a sense of national ownership of the ARC EVLP programme as a service provided by some for the benefit of all

3. *Glossary*

Role	Responsibility in ARC pathway
Ex- vivo Lung Perfusion (EVLP)	A medical technique that keeps donor lungs functioning outside the body to assess and improve their quality before transplantation. This technique can make marginal lungs suitable for transplant.
Recipient Centre Point of Contact (RCPoC) - Accepting Transplant Centre	Recipient Centre Point of Contact – Accepting Transplant Centre communicates between HUB, SN and Lung ARC to coordinate acceptance and transport of donated Lungs
Recipient Centre Point of Contact – ARC (RCPoC ARC)	Mobilises EVLP team and continues to support communication between Lung ARC Clinical Lead/Lung ARC EVLP Operator/RCPoC Accepting Centre and Accepting Transplant Surgeon
Accepting Transplant Centre	Accepting Transplant Centre that have accepted donor lungs for a recipient. Will need to maintain communications between Hub, Donor Hospital, ARC centre to support transplant pathway.
Accepting Transplant Surgeon	Lung Transplant Surgeon makes decision to accept lungs for transplant for a recipient. Will authorise request for Lung ARC if EVLP inclusion criteria met. Will agree this with Lung ARC lead Surgeon
Lung Assessment and Recovery Centre (ARC)	Specialist centre who will undertake EVLP of donor lungs on behalf of the Accepting Transplant Centre
Lung ARC Lead Surgeon	Leads the EVLP team at the Lung ARC. Supervises the EVLP team, liaises with Accepting Transplant Surgeon to support decision to accept for EVLP and then transplant. Undertakes or oversees the assessment of donor lungs pre-EVLP, cannulation of lungs and placing on EVLP circuit.
EVLP Operator Lung ARC	Perfusionist to set up and prime EVLP circuit, initiate perfusion and monitor perfusion indices and lung physiology
Hub Operations	Provides a communication and logistical link between the Organ Donation Services Teams, the National Organ Retrieval Service, and Transplant Centres. Hub Operations supports the organ donation and transplantation community by matching organ donors to potential recipients
Specialist Nurse (SN)	Nurse who supports potential donor families and the operational processes of organ donation.

4. *Arrival of donor lungs at Lung ARC*

Arrival of Donor Lungs at Lung ARC

Establish Lungs on EVLP

Cross Match material

Urgent Histopathology

4.1 Arrival of donor lungs at Lung ARC

See SOP6838 Lung Assessment and Recovery Centre (ARC)- Pilot Manual Donor Hospital to Lung ARC for clinical pathway prior of arrival of lungs to ARC.

On arrival at Lung ARC and once lungs correctly identified against 3 pieces of personal identifiable information (PID), donor lungs should be visually inspected by the surgeon leading the EVLP.

Start Lung ARC Passport FRM8055.

If organ damage is visualised on inspection and not documented on the Cardiothoracic Donor Information (HTA – A) form, this should be reported in line with SOP 3888- Reporting an Organ Donation or Transplantation Incident to NHSBT.
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Irreversible changes such as dense consolidation, severe contusions, lacerations or clear macroscopic emphysema should be identified before EVLP kits or perfusate bottles are opened, as these represent contraindications and EVLP should be abandoned.

Any potential technical challenges such as, short trachea or inadequate left atrial cuff for cannulation, should be identified and discussed with Accepting Transplant Surgeon so a decision can be made either to start perfusion or abandon the EVLP. These discussions should take place prior to the opening of EVLP kits or perfusate bottles.

If lungs are considered suitable for EVLP after visual inspection, the EVLP circuit can be prepared and primed by the perfusionist. While the perfusionist is preparing the circuit, surgical preparation of the lungs can start on the back table. If necessary, lungs can be stored in a designated CE marked 10 degree fridge whilst the perfusion circuit is prepared, prior to the Surgeon beginning cannulation.

After insertion of the cannulas and endotracheal tube, the lungs are placed in a saline ice slurry bowl, still inflated and covered with damp towel swabs and ice slush until the circuit is set up and perfusion is ready to start.

4.2 Establishing Lungs on EVLP

The Lung ARC will refer to local protocol to establish Lungs on EVLP. It is important to maintain communication between Lung ARC and Accepting Transplant Centre throughout the process.

Interventions in a Lung ARC will only be standard additives: antibiotics plus anti-fungals, steroids and heparin use.

4.3 Cross Match material and additional samples

All samples accompanying the donor lungs from the Donor Hospital MUST be processed by the accepting transplant centre. The Lung ARC must ensure that any samples are stored safely during the EVLP process, either on ice in the transport box (ensure adequate ice coverage and replenish if signs of melting) or in cold storage between 2-8C. All samples, including donor PID must be checked thoroughly prior to repacking them to accompany the lungs to the Accepting Transplant Centre.

Samples collected as part of the EVLP assessment are also to be processed at the Accepting Transplant Centre. It is the responsibility of the EVLP Operator to ensure samples are labelled clearly with 3 pieces of donor PID, specifying the type of sample, plus the date and time of sample collection, so it can be processed as soon as possible on arrival at the Accepting Transplant Centre.

4.4 Urgent Histopathology

If there are any findings indicating the need for urgent histopathology examination identified at the ARC, the ARC centre must inform the Accepting Transplant Centre. Due to the urgent nature of processing this sample, it may be that the ARC arranges urgent processing of this sample at the ARC, if there is capacity to do so. If histopathology sample processing is not available, then this must be urgently explored by the Accepting Transplant Centre. The logistics of this should be coordinated by the Accepting Centre RCPoC and ARC EVLP Operator.

The Accepting Transplant Centre RCPoC MUST inform the HUB at the earliest opportunity so that urgent communications can be sent to SNs and other Accepting Transplant Centres who are transplanting organs from this donor.

The Accepting Transplant Centre RCPoC has the responsibility to follow up all histopathology reports relating to histopathology, both interim and final reports. When any report is received, they must email a copy of the report to Hub Operations **odthub.operations@nhsbt.nhs.uk** and call to conform receipt, so that the findings can be disseminated to other Accepting Transplant Centres.

If the Accepting Transplant Centre stands down on the lungs, it becomes the responsibility of the ARC centre (ARC EVLP operator unless they have handed this responsibility over to the ARC RCPoC) to ensure that **interim and final** histopathology report is emailed to and received by Hub Ops **odthub.operations@nhsbt.nhs.uk**. Hub Ops will then upload to it to DonorPath and communicate to the SN and/or any other Accepting Transplant Centres. Additionally, if the lungs are being fast-tracked, this will allow any other Transplant Centres who may be considering the offer to be aware of the histopathology findings.

Note

Interim results are usually available within a few hours of receiving the sample. The final result can take up to a few weeks to return and it's important that the responsibility is clear (in the ARC or Accepting Transplant Centre) as to who will follow this up.

5. *Donor Lung Acceptance/Decline after EVLP*

Communication while lungs on EVLP

Lung Acceptance Criteria after EVLP

Lungs meet acceptance criteria after EVLP and Accepting Transplant centre proceed for transplant

Lungs meet acceptance criteria but Accepting Transplant Centre decline for their recipient.

Lungs do not meet acceptance criteria and Accepting Transplant Centre decline for their recipient. Lungs deemed untransplantable

Lung ARC lead clinician deem lung function as borderline after EVLP

Removal of lungs from EVLP and storage awaiting transport

5.1 Communication while lungs on EVLP

The Lung ARC Surgeon/EVLP Operator will establish communication pathways with the Accepting Transplant Centre including contact number. The Lung ARC will communicate with Accepting Transplant Centre when lungs have been established on EVLP and agree plan for further communication touchpoints.

Lung ARC Passport (FRM8055) must be used to capture EVLP assessment data at set timepoints. A scan of the Lung ARC Passport must be sent to Hub Operations **odthub.operations@nhsbt.nhs.uk** for upload onto DonorPath.

Once lung acceptance criteria is met, or after a maximum period of 5 hours on EVLP, the Lung ARC Surgeon must speak with the Accepting Centre Surgeon to confirm the onward plan.

5.2 Lung Acceptance Criteria after EVLP

- Lungs acceptable for transplantation on inspection and palpation
- Lung deflation test acceptable
- No pulmonary oedema build-up in the endotracheal (ET) tube
- Bronchoscopy appearance acceptable with non-recurring secretions by end of EVLP
- Left Atrium PaO2 > 40-50 kPa or deltaPaO2* of > 40 kPa at FiO2 1.0
- Stable or improving pulmonary artery pressure (<12mmHg)
- Stable or improving dynamic lung compliance
- Stable or improving peak airway pressure < 20cms H2O with adequate ventilation
- Acceptable STEEN solution loss - consumption <500mls in first hour and < 100 ml/h in subsequent hours

**perfusate LA PaO2 – perfusate PA PaO2) / FiO2*

Clinical decisions around lung acceptance criteria after EVLP will be based on a global assessment of lung(s), incorporating the above criteria and their trending direction.

The final decision to proceed to transplant the lungs will be made by the Accepting Transplant Surgeon.

If any damage has occurred to the lungs whilst at the Lung ARC, this must be discussed with the Accepting Transplant Centre and recorded on the Lung ARC Passport FRM8055. Additionally, this should be reported in line with SOP 3888- Reporting an Organ Donation or Transplantation Incident to NHSBT.
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5.3 Lungs meet acceptance criteria after EVLP and Accepting Transplant Centre proceed with plan to transplant

The final decision to proceed to transplant lungs will be made by the Accepting Transplant Surgeon

The Accepting Transplant Centre RCPoC must confirm the decision to accept with Hub Operations

- The Accepting Transplant Centre RCPoC will arrange for the transport of the donor lungs from the Lung ARC to the Accepting Transplant Centre as per their usual transport arrangements with IMT. Note the response time from booking to driver arrival is approximately 60 minutes
- IMT will also give estimated travel time to Accepting Transplant Centre. If this exceeds 5 hours, which is the agreed maximum travel time EVLP at an ARC, a further conversation must take place between the ARC Surgeon and the Accepting Transplant Surgeon to consider the risk of additional cold ischemia time.
- If the recipient is consented to the SENTINEL trial and randomised for skin flap, the Accepting Transplant Centre RCPoC must inform the SENTINEL trial team of travel times.

5.4 Lungs meet acceptance criteria but Accepting Transplant Centre decline for their recipient

If the lungs meet acceptance criteria, but the Accepting Transplant Centre decline for their recipient, the Accepting Transplant Centre RCPoC must inform Hub Operations, so the lungs can be fast-tracked as per SOP6837. Hub Operations will subsequently inform the ARC EVLP Operator of the outcome of the fast-track offer process.

5.5 Lungs don’t meet acceptance criteria and Accepting Transplant Centre decline for recipient. Lungs deemed untransplantable

If the Lung ARC Surgeon deems that the lungs do not meet acceptance criteria, this must be discussed with the Accepting Transplant Surgeon. Together they can decide if the lungs are safe to consider transplantation. If both Clinicians deem the lungs not transplantable, the Accepting Centre RCPoC must inform Hub Operations of the decline, and further offering will stand down. The lungs will not be fast-tracked, but can proceed to research offering, if research consent/authorisation is in place. If consent/authorisation for research is not in place, the Lung ARC must dispose of the lungs and complete the HTA B, returning it to NHSBT as per usual practice.

5.6 Lung ARC deems lung function as borderline after EVLP

Lung acceptance criteria after EVLP will be based on a global assessment of the lungs, incorporating the acceptance criteria and trending direction. The Lung ARC Surgeon may assess that the function of the lungs on EVLP is ‘borderline’. The Lung ARC Surgeon and Accepting Transplant Surgeon must discuss clinical considerations to aid final acceptance decision.

The final decision to proceed to transplant the lungs is made by the Accepting Transplant Surgeon. If the Accepting Transplant Centre decline for their recipient, then the Accepting Transplant Centre RCPoC must inform Hub Operations, so that the lungs can be fast tracked as per SOP6837. Hub Operations will Inform the ARC EVLP Operator of the outcome of the fast-track offering process.

5.7 Removal of lungs from EVLP and storage of lungs awaiting transport

EVLP should be stopped once the lung acceptance criteria on EVLP is achieved. The maximum time on EVLP must not exceed 5 hours. Lungs are to be packed on ice in the usual lung transport boxes, to avoid any delay to dispatching the lungs when the transportation arrives. If there is a delay to transport arrival, then Lung ARC Surgeon/ EVLP Operator can assess whether to continue to pack the lungs onto ice in the transport box or whether to store them in a cold static CE marked 10-degree fridge if they have this provision.

6. *Packing of Donor Lungs after EVLP in Lung ARC*

Packing lungs accepted for transplant after EVLP at Lung ARC

Lungs deemed non transplantable after EVLP at Lung ARC and accepted for research*Error! Bookmark not defined.*

Lungs deemed non transaplantable and not placed in research/no research consent

6.1 Packing lungs accepted for transplant after Lung ARC EVLP

The Lung ARC RCPoC or EVLP Operator MUST ensure they scan a copy of all relevant pages of the Lung ARC Passport to ARC Information Officers **(ARCInformationOfficers@nhsbt.nhs.uk).** A copy of these pages must be retained and stored at the Lung ARC as part of own record. The hard copy of the entire Lung ARC Passport must accompany the lungs to the Accepting Transplant Centre.

Lungs are to be packed as per National Standards for Organ Retrieval from Deceased Donors (MPD1043) The storage of donor lungs for transportation should be as follows:

a. Inner bag: cold Saline 2 L
b. 2nd bag: cold Saline 2 L
c. Outer bag: cold Saline 2 L

The Lung ARC must ensure the following items accompany the lungs in the organ box (in a waterproof sealed envelope):

- Paperwork
  - HTA A form
  - Hard copy of donor blood group
- Entire Lung ARC Passport FRM8055
- Crossmatch material including lymph, spleen, blood samples

Any accompanying donor samples (which may include cultures of the preservation or perfusate fluid, BAL cultures or any other relevant samples taken).

NOTE :
If the recipient is enrolled in SENTINEL Trial and randomised for skin flap, then the skin flap must also be sent alongside the lungs. The inside of the SENTINEL box must be checked to ensure there is sufficient ice, and any melted ice must be replenished before resealing for transportation alongside the lungs.

All samples accompanying the donor lungs will be processed at the Accepting Transplant Centre, ensuring any findings requiring additional action can be acted upon in a timely manner.

The EVLP Operator will take final responsibility for ensuring the correct packaging of the organ and associated samples in readiness for handover to Transport Personnel.

Seal the box with packing tape and complete the designated Lung ARC organ box label (FRM 8059) with the destination address, and stick to the outside of the organ box. The destination address must be confirmed with the Accepting Transplant Centre RCPoC by ARC EVLP Operator, prior to organ dispatch.

6.2 Lungs deemed non transplantable after EVLP at Lung ARC and accepted for research

If the donor lungs are deemed non transplantable at any point, the Lung ARC must communicate with the Accepting Transplant Centre. The Accepting Transplant Centre then has the responsibility to inform Hub Operations if they decline the lungs.

If research consent/ authorisation is place, the donor lungs will be offered as per POL 263 Allocation of Research Organs.

Hub Operations must inform the Lung ARC EVLP Operator of the outcome of the research offering. Transport will be arranged by accepting research team. If the lungs are not accepted for research, the EVLP Operator will arrange for disposal of the lungs and associated samples and complete HTA B form.

If accepted for research, the lungs must be packed as per National Standards for Organ Retrieval from Deceased Donors (MPD1043) The storage of donor lungs for transportation should be as follows:

a. Inner bag: cold Saline 2 L
b. 2nd bag: cold Saline 2 L
c. Outer bag: cold Saline 2 L

The Lung ARC must ensure the following accompany the organ in the box:

- Paperwork including (in a waterproof sealed envelope)
  - HTA A form
  - Blood Group

There is no requirement to send crossmatch material or additional samples to researchers, so these must be disposed of at the Lung ARC.

There is no requirement for Lung ARC Passport to travel to research facility locations. The Lung ARC must ensure a copy of the relevant pages of the Lung ARC Passport is scanned and emailed to ARC Information Officers (**ARCInformationOfficers@nhsbt.nhs.uk**). A hard copy of the passport must be retained and stored at the ARC as part of own record.

The ARC EVLP Operator will take final responsibility for ensuring the correct packaging of the organ and associated samples paperwork in readiness for handover to transport.

See section 9 for SENTINEL considerations

6.3 Lungs deemed non transplantable and not placed in research/no research consent

If there is no acceptance for research or no research consent/authorisation then the Lung ARC EVLP operator will arrange for disposal of the lungs and any associated cross match materials and samples. The Lung ARC EVLP Operator will complete HTA B form and returns as per current process. The Lung ARC must ensure a copy of the Lung Passport is scanned and emailed to the Hub (odthub.operations@nhsbt.nhs.uk). A hard copy of the passport must be retained and stored at the Lung ARC to maintain compliance with HTA regulations.

See section 9 for SENTINEL considerations – disposal

7. *Labelling and Handover of Donor Lungs to Transport Personnel*

Labelling the Organ Box

Handover of Donor Lungs to Transport Personnel

7.1 Labelling the Organ Box

The EVLP Operator must close the organ box but not seal it until all samples and documentation have been placed inside.

The EVLP Operator must seal the organ box utilising organ box and sealed using tamper proof sealing tape.

ARC Lungs organ box label (FRM 8059) must be completed and stuck onto the box.

The EVLP Operator MUST confirm the destination address with RCPoC at accepting centre or research centre and complete the details on the ARC Lungs organ box label accordingly.

7.2 Handover of Donor Lungs to Transport Personnel

The EVLP Operator must confirm the identity of the Transport Personnel utilising their photo ID. They must confirm with the Transport Personnel their understanding of which organ they are collecting and it's intended destination.

The transport driver will provide the EVLP Operator with three points of PID to ensure collection of the correct organ:

- ODT number
- Organ
- Destination

The ARC EVLP Operator must complete the relevant sections of FRM8052- 'ARC Organ Handover Form'. This acts as time stamp for when the organ is handed over. This form is part of the clinical record at the ARC and therefore should be retained as such.

Transport Personnel must enter their details onto the relevant section of the FRM 8059 ARC Lungs organ box label thereby documenting custody of the organ box from the Lung ARC Centre.

The EVLP Operator will inform the Accepting Transplanting Centre once the donor lungs leave the Lung ARC.

8. *Donor Lungs at Accepting Transplant Centre and data returns*

Continue to Transplantation
Lung ARC Passport

8.1 Continue to Transplantation

The Accepting Transplant Centre receive the donor lungs ensuring they correctly identify the lungs utilising 3 points of personal identifiable information (PID). A visual inspection of the lungs should be undertaken by accepting centre lead surgeon.

If organ damage is visualised on inspection and not documented on the Cardiothoracic Donor Information (HTA – A) form or ARC Lung Passport (FRM 8055), this should be reported in line with SOP 3888- Reporting an Organ Donation or Transplantation Incident to NHSBT.
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RCPoC Accepting transplant centre must send any samples for relevant testing.

8.2 Lung ARC Passport

Lung ARC passport (FRM 8055) to be completed by Accepting Transplant Centre. Data collection points are important to document at

- 4 Hours post transplant
- 24 hours post transplant
- 30 days post transplant

RCPoC Accepting Transplant Centre has responsibility to ensure scanned copy of 4 hour and 24 hour data together are to be returned on the next working day after completion to ARC Information Officers (ARCInformationOfficers@nhsbt.nhs.uk)

RCPoC Accepting Transplant Centre has responsibility to ensure scanned copy of date collated at 30 days is returned to ARC Information Officers (ARCInformationOfficers@nhsbt.nhs.uk). Entire original copy to be retained and stored at the transplant centre for own records.

9. *SENTINEL study consideration*

If the intended recipient is randomised into the SENTINEL trial a skin flap will accompany the donor lungs or arrive separately to the ARC Centre. The skin flap should remain in the SENTINEL box sealed.

Regular checks of the box must be undertaken by the EVLP Operator to ensure adequate ice coverage. If any signs of ice melting, then ice must be replenished.

A final check of the box and ice must be made just prior to transport to the Accepting Transplant Centre.

The Accepting Transplant Centre RCPoC must ensure they inform the SENTINEL plastics team of time of anticipated arrival of Lungs and SENTINEL flap at the transplant centre.

In the event of:

- Donor lungs being reoffered (due to recipient/ logistical issues) and the skin flap not required for the identified recipient or
- Lungs offered and accepted for research or
- Lungs disposed of in ARC

the skin flap must be disposed of at the Lung ARC and a HTA B form be completed. The HTA B form should note the HTA A number that accompanied the skin flap.

Training Plan: Internal NHSBT

	Trainee new to the process	Trainee trained to the previous revision.
Recommended Training Method	ODMT oncall team: • Read only Include justification if training method is different from recommended training method>	New Document
Assessment	<How assessment of competency is evidenced e.g.: • FRM511	
Cascade Plan	<Who will deliver the *Training Plan*, who will train the trainers e.g.: • Training package	

Training Plan: External NHSBT

	Trainee new to the process	Trainee trained to the previous revision.
Recommended Training Method	Lung Transplant Centres including Surgeons, clinicians, EVLP operators, perfusionists and Recipient Centre Points of Contact: • Read only • Webinars – live • Recorded webinars made available on ODT microsite This is a bespoke method as this group of professionals are external to NHSBT	First revision
Assessment	<How assessment of competency is evidenced e.g.: • ARC Champion 'assurance'	

Cascade Plan	<Who will deliver the *Training Plan*, who will train the trainers e.g.: • NHSBT will deliver train the trainer session to ARC champions to deliver locally in transplant centres	

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	5

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	<5>	
Criticality of Change Score	<4>	NA
Training Score	<20>	NA

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