NHS Blood and Transplant
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Liver Assessment and Recovery Centre (ARC) – Pilot Manual.

Liver ARC to Accepting Transplant Centre

Index

1. Summary of changes

Updated to reflect the change that all microbiology samples must be processed in the ARC. There is additional responsibility to ARC team to track and share these results as soon as they are available to Hub Operations and the liver transplanting centre

Additional rewording to the section 8.1 Ex- Situ Machine Perfusion (ESMP) form return as responsibility is split between ARC and transplanting centre

2. Introduction

Liver perfusion at an Assessment and Recovery Centre (ARC) is the process whereby a donor liver is transported to a dedicated facility separate from the accepting transplant centre. At the ARC, the liver will undergo ex-vivo machine perfusion which allows the liver to be maintained under controlled physiological or hypothermic conditions to allow functional assessment, preservation, and potential reconditioning prior to transplantation.

The Liver Assessment and Recovery Centre Pilot aims to:

- Test the feasibility and safety of providing a national liver machine perfusion service to support increased donor liver 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

3. Glossary

Term	Definition
Liver Assessment and Recovery Centre (ARC)	Specialist centre who will undertake liver machine perfusion on behalf of the accepting transplant centre.
Normothermic Machine perfusion (NMP)	An ex-vivo organ preservation method where a donor liver is continuously perfused at normal physiological temperature with oxygenated perfusate, enabling ongoing metabolism, bile production, and functional assessment prior to implantation.
Hypothermic Oxygenated Perfusion (HOPE)	An ex-vivo liver preservation method in which the organ is continuously perfused at hypothermic temperature with an oxygenated perfusate, aiming to support mitochondrial function, reduce reperfusion injury, and improve post-transplant outcomes.
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
Donor after Brainstem Death (DBD)	Deceased donor who donates organs following confirmation of death by neurological criteria
Donor after Circulatory Death (DCD)	Deceased donor who donates organs following confirmation of death by circulatory criteria

4. Roles and Responsibilities

Role	Responsibility in ARC pathway
Transplant Coordinator - accepting transplant centre	Transplant Coordinator – accepting transplant centre communicates between Hub Operations, SN and Liver ARC to coordinate acceptance and transport of donated liver
Transplant Coordinator – ARC	Mobilises ARC perfusion team and continues to support communication between liver ARC Clinical Lead/Liver ARC perfusionist/Transplant centre - accepting centre and accepting transplant surgeon
Accepting Transplant Centre	Accepting transplant centre that have accepted donor liver for a recipient. Will need to maintain communications between Hub Operations and the ARC centre to support the transplant pathway.
Accepting Transplant Surgeon	Liver Transplant Surgeon makes decision to accept liver for transplant for their recipient.
Liver ARC Lead Surgeon	Leads the liver perfusion team at the Liver ARC. Liaises with accepting transplant surgeon to support decision to transplant. Undertakes or oversees the assessment of donor liver pre-perfusion, cannulation of liver and placing on NMP (and HOPE if indicated) circuit.
Liver ARC Organ Preservation Practitioner	Organ Preservation Practitioner to set up and prime HOPE and NMP circuit, initiate perfusion and monitor perfusion indices and liver physiology.
Hub Operations	Hub Operations provides a link in the transplant process 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 and allocating organ donors.
Specialist Nurse (SN)	Nurse who supports potential donor families and the operational processes of organ donation.
NMP escort	Competent individual from the liver ARC who will escort the liver on NMP from the ARC to the Accepting Transplant Centre

5. Arrival of donor liver at Liver ARC

5.1 Arrival of liver at Liver ARC

Refer to SOP 6885 *Liver Assessment and Recovery Centre (ARC) – Pilot Manual - Donor Hospital to Liver ARC* for a description of the clinical pathway prior to arrival of liver at the ARC.

On arrival at ARC the liver must be correctly identified against 3 pieces of **donor** personal identifiable information (PID), and the liver should be visually inspected by the Lead Surgeon.

Start FRM8122 *Liver ARC Passport*.

If organ damage is noted on inspection and not documented on the Liver Donor Information (HTA – A FRM 4147) 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 can be uploaded to TransplantPath directly or emailed to Hub Operations (ODThub.operations@nhsbt.nhs.uk) for upload if this is required.

If liver is considered suitable for perfusion after visual inspection the circuit can be prepared and primed by the OPP.

5.2 Ex vivo machine perfusion of liver

There is a requirement to undertake HOPE and then NMP or NMP alone as per below:

Type of donor and method of retrieval	Perfusion strategy
Super rapid recovery DCD (without NRP)	HOPE followed by NMP
DCD with NRP	NMP alone
DBD	NMP alone

Machine perfusion of liver is undertaken as per ARC local perfusion protocols. The liver and associated samples must always be clearly labelled utilising the FRM 8154 *ARC Liver Transport label* with 3 pieces of **donor** Personal Identifiable Data (PID) – Donor ODT number, donor date of birth, donor hospital.

The following points must be actioned to maintain traceability, sterility and accurate identification of the liver 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.
- Ensure clear identification of the liver on OrganOx using ARC labels provided including 3 **donor** PID.
- ARC labelled liver ice box must be used to keep all documentation (donor blood group, HTA-A) as well as donor lymph, spleen, blood, vessels and biopsy. (Microbiology samples including

cold storage fluid and the NMP circuit cultures will be processed at ARC following local processes).

- When at the ARC, the liver should be monitored by the designated members of the ARC team. This should be a different team to any other organ perfusion being undertaken at the same time.

If new organ damage is caused and or visualised at any point during the machine perfusion processes this must be documented on the Liver ARC Passport FRM8122, and reported in line with SOP3888- *Reporting an Organ Donation or Transplantation Incident* to the NHSBT Patient Safety Team.
Tell us about an incident - ODT Clinical - NHS Blood and Transplant
Images of any damage can be uploaded to TransplantPath directly or emailed to Hub Operations (odthub.operations@nhsbt.nhs.uk) for upload if this is required. If uploading direct ensure telephone call to Hub Operations to confirm update (01179 757580).

5.3 Cross match material and vessels
All cross match material (lymph, spleen and blood) and vessels accompanying the liver from the donor hospital must be stored safely in the ARC on melting water ice in a liver organ box. The ARC OPP must regularly check the box and replenish ice if there are signs of melting.
The organ box must be labelled clearly with *ARC liver transport label* (FRM8154) ensuring donor PID is visible externally on the box. This must be cross checked with any accompanying samples, and placed in the box. When preparing for transport this will be a source to cross check the donor PID to ensure the correct organ box and samples travel to the accepting transplant centre with liver on NMP.

5.4 ARC routine sampling protocol- biopsy and microbiology

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

The ARC must ensure that all microbiology sample results processed for the ARC are tracked, reviewed, and appropriately communicated as soon as results are recieved.

ARC centres must identify person/s in their centre who are responsible for follow up and communication of microbiology results.

Record details of all samples taken on the Liver ARC Passport FRM8122.

Sample to be taken	Taking of the sample	Storage of sample	Area to process	Area responsible for result reporting and sharing
Routine Biopsy (section 5.4.1)	1 core biopsy from the left lateral segment	Formalin specimen container in ice box	Accepting transplant centre	Accepting transplant centre
Abdominal Transport fluid microbiology (section 5.4.2)	Sterile pot/s 30-40mls (minimum 20ml)	Process as soon as possible (maximum 18 hours if refrigerated)	ARC	ARC
Pre-machine perfusion microbiology (section 5.4.2)	Blood culture bottle (minimum 10ml per bottle) taken from NMP circuit	Process within 4 hours of sampling	ARC	ARC
After 1-hour NMP microbiology (section 5.4.2)	Blood culture bottle (minimum 10ml per bottle) taken from NMP circuit	Process within 4 hours of sampling	ARC	ARC
End of NMP microbiology (section 5.4.2)	Blood culture bottle (minimum 10ml per bottle) taken from NMP circuit	Process within 4 hours of sampling	Accepting transplant centre/ARC	Accepting transplant centre/ARC

Samples that accompany the liver 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 ARC liver biopsy
A biopsy of the liver pre NMP is required for service evaluation purposes.
1 core biopsy from the left lateral segment of the liver prior to HOPE (if being used) or prior to NMP should be taken. This must be labelled clearly with 3 pieces of donor PID, alongside the date/time taken. The biopsy is to be placed in formalin and stored in the large liver box on melting water ice, alongside any other samples for transport to the accepting transplant centre, who will be responsible for processing the samples. This must be recorded in the Liver ARC Passport FRM8122.

Commented [JH1]: The biopsy must be placed in aformalin and the pot labelled clearly with 3 identifiers of donor PID alongside the date and time taken. This should then be stored in the large liver……..

5.4.2 ARC Microbiology samples
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.

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

5.4.2.1 Abdominal transport fluid
As per UK Standards for Microbiology Investigations Abdominal organ transport fluid testing/ Investigations (Document library) B 62 - Abdominal organ transport fluid testing, abdominal transport fluid samples must be taken when the liver is unpacked at the ARC. This must be collected in sterile pots 30-40mls (minimum 20ml). This should be sent for urgent processing as soon as possible but **must be processed within 18 hours** of collection if the sample is refrigerated.

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.
Policies and guidance - ODT Clinical - NHS Blood and Transplant/ Additional Policy and Guidance.

5.4.2.2 Blood culture from NMP circuit
As per UK Standards for Microbiology Investigations Sepsis and systemic or disseminated Infections (Document library) S 12 - Sepsis and systemic or disseminated infections**,** blood culture samples should be sent for urgent processing, as soon as possible after collection and ideally within a **maximum of 4 hours** from sample collection. These samples must be clearly labelled with 3 pieces of donor PID, date/time of collection, and type of sample.

Blood culture samples of the NMP circuit fluid must be taken and placed in blood culture bottles at the following time points:

1) Pre-machine perfusion
2) After 1 hour on NMP
3) End of NMP (this may be at the Transplant Centre or more rarely at the ARC)

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 uploading results to TransplantPath and verbally communicating to the Hub Operations and the Accepting Liver Centre as soon as they are available.

5.4.3 Additional samples
Any additional clinical samples required as part of the NMP assessment must be processed at the accepting transplant centre unless this is a microbiology sample in which case the ARC must process. 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 liver ice box. Any additional samples must be clearly identified on the Liver Passport.

5.4.4 Liver stand down at ARC or Accepting Transplant Centre and samples are in process
If liver is stood down for transplant at ARC or accepting transplant centre and samples are in process they must 1) Continue with the processing of microbiology testing of abdominal transport fluid as this could have implications for other recipients 2) stand down all other processing 3) if unable to stand down the processing then the centre who has processed the sample (ARC or Accepting Transplant Centre) must ensure follow up all results and ensure they are uploaded to TransplantPath and verbally communicated to Hub Operations.

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* should be followed. In the Liver ARC, responsibilities are different depending on the pathway in which the liver has been accepted. Roles and responsibilities for processing urgent histopathology samples and the communication of results is outlined below:

Liver accepted by Transplant Centre via an ARC

- If a lesion is unexpectedly identified at the ARC prior to or during perfusion it will be the responsibility of the ARC to inform the Accepting Transplant Centre as soon as possible. The Accepting Transplant Centre Transplant Coordinator must inform Hub Operations of the need for urgent histopathology, so that the SN and other Transplanting Centres can be urgently informed.
- The Accepting Centre Transplant Coordinator must identify where the lesion can be processed and reported on as quickly as possible, this could be at the ARC site if they are able to do so or can be sent as a matter of urgency to the Accepting Transplant Centre to process.
- If neither site can process the sample, this must be escalated to Organ Donation Management Team on call (07623 512 222*)*

OR

ARC accept without recipient (as 8th centre)

- ARC Transplant Coordinator will have the responsibility to inform the Hub Operations of the need for urgent histopathology so that so that other Transplanting Centres can be urgently informed.
- The sample can be processed at the ARC site if possible.
- If ARC site cannot process the sample escalate to Organ Donation Management Team on call (07623 512 222)

The ARC or the Accepting Transplant Centre must ensure timely communication with relevant parties, in line with SOP5735 – *New Findings Made at Transplant Centres Requiring Histopathology Assessment.*

It is important to follow-up interim **AND** final results of any urgent histopathology samples processed at either the ARC or the Accepting Transplant Centre. The below table outlines the roles and responsibilities for this process.

Liver ARC acceptance pathway	Site urgent lesion biopsy processed	Responsibility for informing Hub Operations	Responsibility for results (interim and final) and communicating
Accepting Transplant Centre via ARC	ARC	Accepting Centre Transplant Coordinator	ARC Transplant Coordinator
Accepting Transplant Centre via ARC	Accepting Transplant Centre	Accepting Centre Transplant Coordinator	ARC Transplant Coordinator
ARC without recipient (as '8th centre')	ARC	ARC Transplant Coordinator	ARC Transplant Coordinator

Note

Interim histopathology results are usually available within a few hours of the sample being received by the laboratory. The final result can take up to two weeks to return therefore, it is important that all results are communicated to Hub Operations as soon as possible.

Whether urgent histopathology is processed at an accepting transplant centre or a Liver ARC, the transplant coordinator at the respective venue needs to ensure the final report is shared with Hub Operations as it becomes available.

6. Liver acceptance/decline/offering during NMP

6.1 Non-viability criteria of liver on NMP

ARC team must continually monitor liver throughout the perfusion, record details in Liver ARC Passport FRM8122. After a maximum 6 hours if any of the below criteria are met then the ARC surgeon can deem the liver untransplantable. This assessment is based on global assessment of the liver on NMP.

Criteria used to determine non-viability at 4-6 hours of NMP	
Parameter	**Criteria**
Hepatocellular	
Lactate	> 4mmol
Glucose	Up trending
ALT or AST	> 6000 IU/L at 4 hours
Bile	
pH	<7.5
Pefusate: bile Glucose ratio	>0.67
Perfusion time	
>30 hours on NMP	

If the liver is deemed untransplantable by ARC Lead Surgeon, the following steps must be followed, depending on the pathway in which the liver has entered the ARC.

- Accepted to transplant centre via ARC pathway
    - Speak with the accepting transplant centre to inform them of plan to stand down.
    - The accepting transplant centre transplant coordinator must inform Hub Operations of the decision to stand down for transplantation
    - Hub Operations will proceed to research offering should there be research consent / authorisation
    - The ARC centre will package the liver in line with POL278 *OTDT Manual 12: Recipient Centre National Operating Procedures in Deceased and Living Donation and Transplantation* if has been accepted for research or dispose of the liver ensuring HTA-B form (FRM6295) is completed.

Or

- ARC accepting without recipient (as 8th centre)
    - ARC Transplant Coordinator must inform Hub Operations of the plan to stand down
    - Hub Operations will proceed to offering down the research offering pathway, should there be donor research consent / authorisation

- The ARC centre will package the liver in line with POL278 *OTDT Manual 12: Recipient Centre National Operating Procedures in Deceased and Living Donation and Transplantation* if has been accepted for research or dispose of the liver ensuring HTA-B form (FRM6295) is completed.

If the liver is assessed as suitable for transplantation by the ARC lead surgeon, then liver is to remain on NMP and section 6.3 OR 6.4 depending on if the liver is already placed to a centre or needs to be offered on along fast track.

6.2 Acceptance/decline liver accepted to transplant centre via ARC centre
If liver has been accepted by a Transplant Centre via an ARC, the ARC Lead Surgeon should maintain communication with the accepting transplant centre lead surgeon. The transplant coordinators at both sites should also have established communication routes between each other.

Ongoing monitoring of the liver on NMP including hourly perfusion data must be recorded in the Liver ARC Passport FRM8122.

For the final decision regarding transplant, the ARC (Surgeon or OPP) must ensure the completed perfusion data is visible to accepting transplant centre via TransplantPath by uploading the perfusion data section as instructed in the Liver ARC Passport FRM8122. Follow instructions in INF1833 *TransplantPath users: Uploading Files, Images and Video* and ensure that a call is made to Hub Operations once upload is complete to alert them. Only 1 upload of the Liver ARC Passport FRM8122 to TransplantPath is required for
the final decision transplant.

If the ARC is unable to upload to TransplantPath themselves, images of the perfusion data can be emailed to Hub Operations odthub.operations@nhsbt.nhs.uk**.** Ensure that a phone call is made to Hub Operations to confirm their receipt and requirement for them to upload to TransplantPath as a matter of urgency.

There can be three outcomes at this point:

1) Final decision remains to send the liver to the accepting transplant centre, move to section 7.

2) Accepting transplant centre declines the liver, but the ARC Surgeon considers the liver to be transplantable, then the accepting transplant centre must inform Hub Operations and instruct them to proceed to fast track offering as described in section 6.3.

3) Accepting transplant centre declines the liver and the ARC surgeon agrees the liver is not viable for transplant as described in section 6.1, then liver offering can stand down. The accepting transplant centre transplant coordinator must inform Hub Operations of the final decision, so that Hub Operations can proceed to research offering (if research consent/authorisation is in place). Follow steps in section 6.1 around facilitating liver for research or disposal.

6.3 ARC accept without recipient (as 8th centre)
If the ARC accepts a liver to machine perfuse it without an intended recipient being identified, then an offer will need to be sent from the ARC to all Centres via fast track, for final placement of the liver.

The timing of this offer will be subject to assessment on the NMP however its likely to be between 2-6 hours on NMP.

Note

If the ARC Lead Clinician does not consider the liver to be transplantable after assessment for 6 hours on NMP based on the 'Non-viability criteria' (see section 6.1), then the liver must not be offered out via fast track and can stand down.

Once the ARC Lead Surgeon deems the liver suitable for reoffer and transplant, the following must occur:

- Liver to remain on NMP
- Perfusion data from the Liver ARC Passport FRM8122 must be uploaded to TransplantPath. This must be followed up with a phone call to Hub Operations to alert them to the upload. If the ARC centre unable to upload directly to TransplantPath (local centre to agree who is responsible) must scan a copy of the relevant pages in the Liver ARC Passport FRM8122 and email odthub.operations@nhsbt.nhs.uk followed up with a call to confirm receipt.
- Transplant Coordinator at the ARC must call Hub Operations to send the fast track offer to all Centres
- Centres will be allowed 45 mins to review offer and respond to Hub Operations
- Transplant centres must respond to Hub Operations with a fast track decision, and no response will mean no interest
- The ARC Surgeon must be available to take clinical calls about the liver

Hub Operations will allocate the liver according to POL196 *Deceased Donor Liver Distribution and Allocation and* inform the centre who has been allocated the liver. The ARC as a centre itself, may express an interest as part of the fast-track offering process, but they will be placed at the bottom of the fast-track allocation sequence. Any queries regarding allocation at the time can be escalated to Hub Operations.

Note

For any travel time from ARC to transplant centre > 5 hours by road there must be a MS Teams call (arranged by Hub Operations) to discuss and agree feasibility of an extended journey and the wider impact. This call must include the Accepting Centre Transplant Coordinator/Surgeon, ARC Surgeon, ARC Escort, Hub Operations Shift Manager, IMT representative and ODMT on call (if required). Examples of factors to review include (but are not limited to):

- Availability of escort from ARC, including impact on future work requirements
- Availability of IMT vehicles and drivers in view of national activity
- Anticipated total duration of NMP
- Flights cannot be utilised for this journey

If the liver has been accepted, proceed to section 7

If there is no acceptance of the liver, then Hub Operations must offer for research (if research consent/authorisation is in place). ARC livers will not be transported on NMP to a research facility, so the liver must be removed from NMP and stored on melting water ice while the research offer is ongoing. If there is no research placement, then the ARC must dispose of the liver and complete HTA-B paperwork.

6.4 Liver deemed not for transplant – management of samples and vessels
If the liver is stood down for transplant at any point in the ARC, then the ARC has the responsibility to ensure all samples accompanying the liver; those received from donor hospital and any samples generated in the ARC, are disposed of in line with local processes.

Vessels can only be stored for use if there is a HTA license in place to store and bank tissues. Where vessels have been stored under HTA licensing, the ARC must ensure vessels are disposed of in line with local processes should the maximum storage time frame be reached.

6.5 Liver on OrganOx *metra* >24hours
The OrganOx *metra* IFU, states the device is intended to be used to sustain donor livers destined for transplantation in a functioning state for up to 24 hours. Therefore, the aim for livers in the ARC pilot will be to limit NMP to this 24 hour window.

If Liver ARC NMP time on the OrganOx m*etra* exceeds 24 hours (e.g., extended transport, logistical delays, recipient change), a dynamic risk assessment must be completed and documented. This assessment must outline the risks of using the OrganOx *metra* outside its IFU include a clear risk–benefit evaluation for proceeding with transplantation.
The Accepting Transplant Centre's Consultant Surgeon must record this assessment in local documentation. If the ARC Lead Surgeon participates in the decision, this must also be documented and stored within ARC records.

If decision is made to stand down the liver at this point, responsibility for communication is described below:

- Accepted to transplant centre via ARC pathway
  - Accepting Centre Transplant Coordinator must inform Hub Operations of the decision to stand down for transplantation
  - Hub Operations will proceed to research offering should there be research consent/authorisation in place
  - Hub Operations will advise of placement for research and the centre where the liver is at the time of stand down (ARC or Transplant Centre) must package liver and support transport arrangements as advised
  - If no research placement ARC or Transplant Centre must dispose of the liver ensuring HTA-B (FRM6295) form is completed.

Or

- ARC accepting without a recipient
  - The ARC Transplant Coordinator must inform Hub Operations of the plan to 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 ARC must package liver and support transport arrangements as advised
  - If no research placement ARC must dispose of the liver ensuring HTA-B form (FRM6295) is completed

NOTE
For the Liver ARC pilot, the liver must not be perfused beyond **30 hours**. If this time is exceeded, then the liver must be stood down for transplant.

7. Liver transport

7.1 Arranging transport

The Accepting Transplant Centre Transplant Coordinator must arrange the transport to manoeuvre the liver from the ARC to the Accepting Transplant Centre with IMT (0151 480 5152), ensuring that IMT are made aware that the liver is travelling on OrganOx *metra* with escort, and must confirm:

- The vehicle provided must have inverter compatible with OrganOx *metra*
- Straps for securing the OrganOx Metra
- Van has ramp onboard

The vehicle and driver should be available within 60 minutes of being contacted, and IMT will advise if this time is longer.

The Accepting Transplant Centre Transplant Coordinator must keep the ARC OPP informed of anticipated timings or any delays either direct or via the ARC Transplant Coordinator.

7.2 Preparing for transport on OrganOx *Metra*

The liver will travel to the Accepting Transplant Centre on the OrganOx *metra* device. One competent member of staff will accompany the liver on the device to the Transplant Centre.

The ARC Escort must be familiar with the device. The ARC Escort is not expected to perform any intervention on the liver or device during transport except monitor for alarms and record these in the Liver ARC Passport FRM8122.

The OrganOx *metra* should remain on it's own trolley throughout transit. Local manual handling risk assessment and procedures must be followed to ensure safe manual handling of the OrganOx *metra* device. There should be no requirement to perform a physical lift of the device. Consult OrganOx *metra* instructions for use (IFU Metra.) section 1 for further information about safe maunal handling.

The allocated IMT van must have a ramp fitted to allow safe movement of the device into and out of the van. If this is not available, the ARC Lead Surgeon and ARC Escort must undertake a local dynamic manual handling risk assessment to consider the options for continuing with transport, also considering the manual handling implications of the device at the Accepting Transplant Centre.

The following steps must be undertaken to prepare the OrganOx *metra* for transport and minimise the risk of an alarm, failure of device and suboptimal performance of the device in transport. FRM8143 *ARC Liver Transport Checklist – OrganOx metra (NMP)* must be completed prior to, during and after handover by escort. This form is to be retained by the ARC Escort and stored at the ARC after completion. FRM8143 is to be used in conjunction with the below checks for readiness for travel alongside OrganOx *metra* IFU Metra

If any of the following steps are not able to be completed, the ARC Escort must escalate to the Lead ARC Clinician to determine whether to proceed to transport, to wait until all steps can be

fulfilled, or to stand down. Of note, OrganOx have a 24 hour helpline that can that can also be utilised should this be required (+44) 800 085 444.

7.2.1 Step 1. Organ identification check

- Ensure ARC Liver label FRM8154 is attached to *metra* with clear 3 pieces of donor PID to identify the organ for transport.
- Ensure liver ice box is filled with fresh melting water ice and packed with any related vessels, lymph, spleen, bloods,biopsy and additional samples. The liver ice box must also include the HTA-A form (FRM4147) and a hard copy of the donor blood group (in waterproof envelope). This liver ice box must be sealed with organ box packing tape, and confirm completed ARC liver transport label (FRM 8143) stuck onto the box.

NOTE

No microbiology samples should travel with the liver to the accepting centre. These are all to be processed in the ARC

7.2.2 Step 2. OrganOx *metra* checks

- Top up water reservoir to maximum level
- Ensure that the drainage tube to the “ascites” pump does not have an airlock, which commonly happens immediately beneath the liver bowl, or escaped blood will not be recirculated.
- Fully de-air the portal reservoir prior to placing hard case on the OrganOx Metra.
- Ensure OrganOx *metra* battery is fully charged (minimum >90%)- if not then consider delay transport until this is reached.
- Check final blood gas including glucose and set dial, attaching feed if ≤10mmol/L – it will alarm 4h after this test. Setting the glucose should be the last thing done before disconnecting the OrganOx *metra* from the mains.

  Optional: If planning to remotely monitor, connect phone to OrganOx *metra* wifi. Refer to section 10 in the OrganOx *metra* IFU Metra

7.2.3 Step 3. Sterility & Organ security

- Liver bowl and liver bowl lid must be secure

7.2.4 Step 4. Equipment and Setup for transport

- Place hard cover on and secure with 4 locks
- Confirm OrganOx *metra* is charged >90% - if it is below this consider taking time to charge to this level before transport
- Prior to power disconnection, check the following with IMT driver:
  - IMT driver is onsite and where the van is parked
  - Check the driver knows the destination address.
  - Fastest and most direct route is planned
  - Van supplied has working inverter sufficient for OrganOx *metra* and is turned on
  - Confirm van has a ramp
- Steps to disconnect the OrganOx *metra* from the mains power supply
  - ensure the green main power switch is ‘off’

- Remove plug from socket and safely secure cable to the OrganOx *metra* for use in transport

7.2.5 Step 5. Transfer to and into IMT vehicle

- Ramp to be used to manouvre OrganOx *metra* into dedicated space in van
- Position OrganOx metra:
  - with the plug end as close to the power supply as possible
  - Graphic user interface (GUI) visible to escort if able. Although escort is not obliged to be able to see GUI at all times. This can be monitored via phone as above or not at all.
- Allow space around the OrganOx *metra* for effective cooling. The vents are located in the base of the unit.
- Secure OrganOx *metra* inside vehicle using rachet straps (supplied by IMT) around the handles as instructed in section 1 OrganOx *metra* IFU Metra. The rachet straps must be secure to anchor points in the vehicle as close to the vehicle base as possible. (minimum 3 points)

The straps MUST NOT go across the top of the OrganOx metra

- Steps to plug OrganOx *metra* into van power supply
  - Ensure green main power switch on OrganOx *metra* is in 'off' position
  - Plug into power supply
  - Turn green main power supply switch to 'on'
  - Confirm the device is charging by checking that the 'mains plug' icon is illuminated. If the battery indicator LED is lit then this is not charging. You cannot leave until the mains plug icon is illuminated. See section 1 in OrganOx *metra* IFU Metra.

7.2.6 Step 6. Communication check

- Receiving centre informed of departure and estimated time of arrival
- Confirm escalation contacts available

7.3 Transport liver on OrganOx *metra* to Accepting Transplant Centre

The ARC Escort is not expected to perform any intervention on the liver during transport. If there is an audible alarm or on checking the mobile app an alarm is noted the Escort must log this in the Liver ARC Passport FRM8122.

Common alarms may sound during transport.

Alarm	Error code	Action
Insufficient water in the reservoir		**Not critical during transport – continue to Accepting Transplant Centre**. Nothing needs to be done in transit providing this was not alarming before setting off. This should be prevented before departure by topping up the reservoir.

More than 4 hours since the last glucose measurement		**Not critical during transport – continue to Accepting Transplant Centre.** The glucose should have been checked before departure and the value updated on the OrganOx *metra* – silence if you can and continue journey
No power		**Critical during transport - escalate**. Driver should stop at the next convenient and safe location. Escort check OrganOx *metra* is plugged in and inverter switch 'on'. If power cannot be restored escalate to ARC Lead Clinician and OrganOx 24 hours helpline if needed. *If power cannot be restored the organ is lost, inform* Accepting Transplant Centre *and return to base.*

If Escort has any concerns, contact ARC Lead Clinician or the 24 hour helpline OrganOx (0800 085 444) for support.

7.4 Handover at Accepting Transplant Centre (step 7 on FRM 8143)
Escort must keep the Accepting Transplant Centre updated with arrival times along the journey. On arrival to Accepting Transplant Centre, a member of staff should meet the Escort at the vehicle to support with safe movement of the OrganOx *metra* and liver box to the theatre suite.

When unplugging the OrganOx *metra* from the vehicle power supply, the green main power switch is in the 'off' position.

When plugging the OrganOx *metra* device in at the hospital, ensure the green main power switch is off, plug device in to power supply and then turn the green main power switch to 'on'.

Once the Escort and Accepting Transplant Centre staff are satisfied that the OrganOx *metra* is safely stored and charging, and the liver ice box has been delivered to the theatre suite, then handover can commence. This must include:

- Confirm liver identification (3 pieces of donor PID) on OrganOx *metra* and accompanying liver ice box.
- Check and confirm all samples and documentation are present in liver ice box.
    - The Accepting Transplant Centre will have the responsibility to process all samples received which will include a pre NMP liver biopsy.
    - The Accepting Transplant Centre must enquire at this stage if any samples are not labelled clearly
- The ARC Escort must provide a perfusion summary including any additional information that wasn't available to the Accepting Transplant Centre at time of organ acceptance at the ARC.
- The ARC Escort must provide a summary of any events recorded in transit as recorded on FRM 8122
- The ARC Escort and Accepting Transplant Centre to sign FRM8143 as evidence of handover. This is to be retained by the ARC Escort and stored at the ARC with other relevant ARC perfusion documentation
- The Liver ARC Passport FRM8122 must be completed up to the point of handover by the ARC Escort to the Accepting Transplant Centre. The original hard copy of the Liver ARC Passport

FRM8122 to retained by Accepting Transplant Centre. A copy of this form must be made for the ARC Escort to take back to and retain at the ARC.

Once handover is complete, the liver and all associated materials pass to the responsibility of the Accepting Transplant Centre

7.5 Return of ARC escort and OrganOx *metra* to ARC
IMT will provide transport for the ARC escort and OrganOx *metra* to return to the ARC.

Note
The ARC cannot accept livers for ARC perfusion until their OrganOx *metra* is returned therefore it is important that this is done at the earliest possible time.

7.5.1 OrganOx *metra* returning with Escort
The Accepting Transplant Centre will be able to advise the ARC Escort of the anticipated time for deinstrumentation of liver from OrganOx *metra* in their unit. The ARC Escort should arrange their own travel back to the ARC with the OrganOx m*etra*. The ARC Escort must be clear that they are travelling back to the ARC with OrganOx m*etra*. IMT should be able to supply transport within 60 minutes of booking.

The Accepting Transplant Centre must support the ARC Escort to ensure OrganOx *metra* is cleaned as per Section 1 OrganOx *metra* IFU Metra. The Accepting Transplant Centre must support the ARC Escort and IMT to safely manoeuvre the OrganOx *metra* to and into the van. Steps outlined in section 7.2.4 must be followed for unplugging the OrganOx *metra* device from the mains power supply. OrganOx *metra* must be secured with rachet straps in the van as per section 7.2.5 There is no requirement for the OrganOx *metra* device to be plugged in to the van supply during the travel back to the ARC.

7.5.2 Escort retuning to ARC without OrganOx *metra*
If it the liver will require >1 hour or more continued perfusion at Accepting Transplant Centre the ARC Escort can travel back to base without the OrganOx *metra*. With support of Accepting Centre Transplant Coordinator the ARC Escort must arrange transport and must be clear this is without the OrganOx *metra* as this can affect what vehicle IMT supply. IMT should be able to supply transport within 60 minutes of booking.

7.5.3 OrganOx *metra* returning to ARC alone
If the OrganOx *metra* has been left at the Accepting Transplant Centre due to the timing of the planned deinstrumentation, then the Accepting Transplant Centre must arrange for transport of the OrganOx *metra* back to the ARC as soon as they know what time the device will be available to transport. IMT should be able to supply transport within 60 minutes of booking.

The Accepting Transplant Centre must ensure the OrganOx *metra* has had all consumables removed and the device is cleaned as per instruction in Section 1 OrganOx *metra* IFU Metra. Any damage to the device during its time in the Accepting Transplant Centre MUST be communicated to the ARC Lead Clinician as a matter of urgency. OrganOx *metra* should remain plugged into a power supply whilst at the Accepting Transplant Centre.

The Accepting Transplant Centre must support IMT to safely manoeuvre the OrganOx *metra* to and into IMT van. Steps outlined in section 7.2.4 must be followed for unplugging the Organ Ox *metra* device from the mains power supply. OrganOx *metra* must be secured with rachet straps in the van as per section 7.2.5 There is no requirement for the OrganOx m*etra* device to be plugged in to the van supply during the travel back to the ARC.

The Accepting Transplant Centre must communicate with the ARC Transplant Coordinator to confirm timings of return of OrganOx Metra. The ARC Transplant Coordinator can contact IMT for an update on timings to ensure staff are available to receive and unload the OrganOx *metra* and return it to the ARC theatre suite.

7.5.4 Liver ice box return

Address for liver ice box should be on the box. Accepting Transplant Centre must ensure it is cleaned and returned to its place of origin as per local process.

8.0 Follow-up and data returns

8.1 Ex-Situ Machine Perfusion(ESMP) form completion

All livers that undergo machine perfusion must be reported via the ESMP form.

- ARC must complete form 1
- Accepting Transplant Centre must complete form 2

8.2 Liver ARC Passport FRM8122 – Liver transplanted

A copy of FRM 8122 is to be made at the Accepting Transplant Centre by the ARC Escort at handover. The original Liver ARC Passport FRM8122 is to remain with the ARC Escort and should be completed upon return to the ARC. Once Liver ARC Passport FRM8122 completed, a copy must be emailed to ARC Information Officers (ARCInformationOfficers@nhsbt.nhs.uk) within 2 working days of completion. The responsibility of who emails this is subject to ARC local processes. The ARC must retain a copy of the completed form for their own requirements.

8.3 Routine recipient follow-up

Transplanting Centre should follow usual process for recipient follow-up information by completing FRM4309 - *Liver Follow Up,* FRM4148 - *UK Liver Transplant 3 Month Follow Up and* FRM4149 - *UK Liver Transplant Audit Annual Follow Up* at their respective time points .

8.4 Liver ARC Passport FRM8122 – Liver stand down

If the liver stands down at the ARC then it is the responsibility of ARC to complete Liver ARC Passport FRM8122 as fully as possible. A copy of this must be emailed to ARC Information Officers (ARCInformationOfficers@nhsbt.nhs.uk) within 2 working days of completion. The responsibility of who emails this is subject to ARC local processes. The ARC must retain a copy of the completed form for their own record. The ARC must ensure completed HTA-B form is returned to NHSBT.

8.5 Liver ARC microbiology results

The liver ARC must have a local process in place to ensure results of all microbiology tests are tracked and reported timely. The ARC must ensure results are uploaded to TransplantPath and communicated verbally to Hub Operations and accepting transplant centre as soon as they are available.

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

Positive abdominal organ transport fluid must be communicated on FRM FRM5964 – *Transport Fluid Alert Form* in line with MPD1338/2 – *Positive Transport Fluid*.

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 uploading results to TransplantPath and verbally communicating to the Hub Operations and the Accepting Liver Centre as soon as they are available.

Training Plan for Documents:

Type of Change	< Version2 >	
Stakeholders who require training	**Trainee new to the process**	**Trainee trained to the previous revision.**
	External to NHSBT document - Liver ARC pilot centres and liver 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 liver 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.: • Read receipt from champion network of dissemination of information	<n/a
Cascade Plan	<no formal training. Read receipt from 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