# Registration process for liver indications requiring additional waiting time

# Index

## *Summary of changes*

**Patients with Hepatoblastoma Section**
- Page 5 - Updated registration process timings
- Page 5 - Updated process to ensure a phone-call and email is sent at the start of the process.

**Prioritised Paediatric Patients Section**
- Page 8 - Updated registration process timings
- Page 9 - Updated process to ensure a phone-call and email is sent at the start of the process.

**Acute on Chronic Liver Failure (ACLF) section**
- Page 11 - Updated process to ensure a phone-call and email is sent at the start of the process.
- Page 11 - Updated contents menu to reflect headers.
- Page 11 - Updated ACLF registration process timings.
- Page 12 - Updated ACLF email timings for ODT Hub: Information Services.
- Page 12 - Added reference to FRM7574 (ACLF Supplementary information)

**Neuroendocrine tumours section**
- Page 13 - Updated process to ensure a phone-call and email is sent at the start of the process.

**Unresectable Colorectal Metastases section**
- Page 15 - Updated process to ensure a phone-call and email is sent at the start of the process.

**Severe or very severe Hepatopulmonary Syndrome patients section**
- Page 17 - Updated process to ensure a phone-call and email is sent at the start of the process.

**Intrahepatic Cholangiocarcinoma section**
- Page 20 - Clarified date of agreement.
- Page 20 - Updated CRC Mets to CCA.
- Page 20 - Updated process to ensure a phone-call and email is sent at the start of the process.

# Useful Information



## 1. Policies and documents

- **POL195** – Liver Transplantation: Selection Criteria and Recipient Registration
- **SOP5844** – Hub Operations Team Manager (HOTM) Processes - Hub Operations
- **FRM4332** – Elective liver recipient registration form
- **FRM7574** – ACLF supplementary information

## 2. Definitions

- **Adult liver recipient:** aged 17 years or over at time of registration and does not fall within small adult criteria.
- **Small adult liver recipient:** aged 17 years or over at time of registration with a body weight of 40kg or less and dual-listing option specified by centre on the registration form or via submission of sequential data forms.
- **Paediatric liver recipient:** aged less than 17 years at time of registration and does not fall within large paediatric criteria.
- **Large paediatric liver recipient:** aged less than 17 years at time of registration with a body weight of 40kg or more and dual-listing option specified by centre on the registration form or via submission of sequential data forms.

## 3. Hepatoblastoma tier

- The following indications are offered through the hepatoblastoma tier
  - Patients with hepatoblastoma
  - Paediatric patients where prioritisation has been formally agreed
  - Patients with Acute on Chronic Liver Failure (ACLF)

- It has been agreed that patients should appear in the above offering sequence and additional points (as specified in the relevant sections below) are added by NHSBT to ensure the correct offering sequence.

## *Patients with Hepatoblastoma*



### 1. Introduction

Liver only patients with hepatoblastoma do not need approval from any of the other transplant centres. Note that patients with hepatoblastoma requiring liver and intestinal organs should be reviewed and agreed by the Chairs of the Multivisceral and Composite Tissues Advisory Group (MCTAG) and Liver Advisory Group (LAG) prior to registration and will require a PDV.

### 2. Registration Process

Transplant centres wishing to register a liver or liver and intestinal patient with hepatoblastoma should complete the Elective Liver Recipient Registration Form (**FRM4332**) and submit the form to NHS Blood and Transplant on ODT Online.

Transplant centres must subsequently email and phone ODT Hub: Information Services (Email: ODTRegistrationTeamManagers@nhsbt.nhs.uk, Phone: 0117 975 7523) **before** submitting the form to inform ODT Hub: Information Services that they intend to register a patient with hepatoblastoma. Confirmation from the Chairs of MCTAG and LAG should also be forwarded for liver and intestinal patients with hepatoblastoma.

Note that these emails will be actioned by both ODT Hub: Information Services during the hours of 0900 - 1700 (Monday – Sunday) and Statistics & Clinical Research during working hours (10am - 4pm Monday - Friday).

Also, note that a report is automatically produced every day showing the patients that are active on the elective transplant list with hepatoblastoma as the primary indication. Therefore, transplant centres should be aware that although the patient will appear on the active elective waiting list once the registration form is committed, they may not appear in the correct position on the hepatoblastoma tier until additional waiting time is added and there may be a delay if transplant centres do not email ODT Hub: Information Services.

ODT Hub: Information Services will check the recipient's registration to ensure that they have been correctly registered into as a hepatoblastoma recipient.

### 3. Additional Waiting Time

If it has been confirmed that the patient has hepatoblastoma, ODT Hub: Information Services will add an additional 9000 waiting time points, the waiting time will be automatically updated when the waiting time batch-job is next run:

- 00:05 – All organ waiting time is recalculated
- 10:00 – Liver and Intestinal waiting time is re-calculated
- 14:00 – Liver and Intestinal waiting time is re-calculated
- 18:00 – Liver and Intestinal waiting time is re-calculated

After the additional points have been added to the recipient the following should be emailed:

- Senior Statistician (Liver)
    - To check that registration is correct, and that points have been applied correctly
- Statistical.Enquiries@nhsbt.nhs.uk
    - To escalate if the Senior Statistician is not available
- odthuboperations.shiftmanagers@nhsbt.nhs.uk

- To inform Hub-Operations that a recipient has been added to the hepatoblastoma tier.

A representative from Statistics and Clinical Research will check and confirm the correct additional waiting time has been added.

Once confirmation has been received the recipient centre should be informed that the changes have been applied.

If waiting time has been added previously, and additional time is required, when adding the new waiting time you must include the previously added waiting time due to NTxD only allowing one set of additional waiting time points at any one time. For example, if 100 days had previously been added and an additional 50 days should be added then 150 days should be added.

If the incorrect additional waiting time is added, the lead from Statistics and Clinical Research will notify ODT Hub Information Services and confirm the correct additional waiting time. The Higher/Senior Information Office will subsequently notify the Operational Lead or Operational Manager.

If the additional waiting time added is higher than requested, the Higher/Senior Information Officer will contact the database team and request urgent amendment through both ServiceNow and a phone call.

If the additional waiting time added is lower than requested, the Higher/Senior Information Officer will correct and email the Statistical lead and Statistical Enquiries for confirmation.

The additional waiting time will be removed, as per **SOP5844**, once the transplant centre confirms the patient has received a liver transplant.

If it is confirmed that the patient doesn't have hepatoblastoma but is either a prioritised paediatric patient or has ACLF then the relevant sections should be followed.

# *Prioritised Paediatric Patients*



## 1. Introduction

Weekly teleconferences were established in April 2020 involving adult and paediatric representation from all 7 UK liver transplant centres and NHS England to discuss and maintain a national liver transplant service during COVID-19. Requests were received from all three paediatric centres to either formally or informally prioritise individual paediatric patients who are clinically deteriorating but do not meet the super-urgent criteria.

*Informal prioritisation* allows a paediatric centre with support of one or both of the other paediatric centres to seek prioritisation of a specific recipient and to receive offers of organs made to another paediatric centre for that informally prioritised recipient. It should be noted that transplant centres maintain the responsibility to ask ODT Hub Operations to offer to the transplant centre where the patient is registered when offered organs. The patients position on the transplant list will not be changed.

*Formal prioritisation* of paediatric recipients requires agreement of all three paediatric centres. If unanimously agreed, paediatric patients formally prioritised would be registered in the hepatoblastoma tier and offered livers after patients with hepatoblastoma.

Note that this is for paediatric patients aged 16 years or under.

## 2. Approval

Requests to formally prioritise paediatric patients who are clinically deteriorating will be managed and overseen by the requesting transplant centre who will provide the following with information required

- Agreed representatives from the other UK paediatric transplant centres
- Chair and Deputy Chair of the National Appeals Panel
- Head of Service Delivery - ODT Hub
- Lead Statistician for Liver Transplantation

The request should include patient identifiable data (e.g., hospital number, NHS number, date of birth, initials), age, weight and ODT recipient identification number (if applicable). Centres must include details of whether they would consider blood group incompatible offers, the liver lobes they would consider (e.g. left lateral segment or whole liver) and organs required. The process may take longer for blood group incompatible offers as this will currently need to be undertaken under a risk assessment.

It is anticipated that a decision should be made within 72 hours.

Liver only patients require approval from:

- Written approval from the Chair of LAG
- Written approval from the two other paediatric centres (Leeds/Birmingham/Kings)
    - Potentially an adult centre if the recipient is a large paediatric **and require anything over a left lateral segment**

Liver and intestinal patients require approval from:

- Written approval from the Chairs of LAG and MCTAG
- Written approval from the two other paediatric centres (Leeds/Birmingham/Kings)
    - Potentially an adult centre if the recipient is a large paediatric.

Once agreed, the registration (including amendment) process below should be followed during the hours of 0900 - 1700 (Monday – Sunday), new patient registrations and updates to existing registrations will not be processed outside of these hours, therefore, there will be a delay for all registrations submitted outside of these hours.

It has been agreed that approval for blood group incompatible offers is only required for prioritised paediatric patients aged one year or over. Centres wishing to receive blood group incompatible offers for patients aged less than one year should record blood group AB on the registration form and inform ODT Hub Information Services of the true blood group when registering an agreed patient.

Transplant centres maintain responsibility of updating the blood group to the true blood group if they would like to receive blood group compatible offers only at any point during the patients registration.

A risk assessment will be undertaken for patients aged one year or over after approvals have been granted and centres will be advised of the timescales. Please note that risk assessments can only take between 0900 – 1700 Monday-Friday, therefore, this could take 72 hours to be actioned.

## 3. Registration

Transplant centres wishing to register a prioritised paediatric patient should complete the Elective Liver Recipient Registration Form (**FRM4332**) with the following indications and submit the form to NHS Blood and Transplant on ODT Online.

Transplant centres must email and phone ODT Hub: Information Services (Email: ODTRegistrationTeamManagers@nhsbt.nhs.uk, Phone: 0117 975 7523) prior to submitting the form to inform ODT Hub: Information Services that they intend to register a prioritised paediatric patient *along with the agreement from the other centres.*

Liver only:

- 444 (hepatoblastoma) as primary indication
- True primary disease as secondary indication
- 498 (Other, please specify) as tertiary indication with "PRIORITISED PAEDIATRIC PATIENT" in the free text

Centres wishing to receive blood group incompatible offers for patients aged less than one year should record blood group AB on the registration form and inform ODT Hub Information Services of the true blood group.

Liver and intestinal:

- 444 (hepatoblastoma) as primary indication
- True primary disease as secondary indication
- 498 (Other, please specify) as tertiary indication with "PRIORITISED LIVER AND INTESTINAL PAEDIATRIC PATIENT" in the free text

Please note, liver and intestinal patients will need to be included in a PDV to specify the organs required.

Note that these emails will be actioned by both ODT Hub: Information Services during the hours of 0900 - 1700 (Monday – Sunday) and Statistics & Clinical Research during working hours (10am - 4pm Monday - Friday).

Also, note that a report is automatically produced every day showing the patients that are active on the elective transplant list with hepatoblastoma as the primary indication. Therefore, transplant centres should be aware that although the patient will appear on the active elective waiting list once the registration form is committed, they may not appear in the correct position on the hepatoblastoma tier until additional waiting time is added and there may be a delay if transplant centres do not email ODT Hub: Information Services.

ODT Hub: Information Services will check the recipient's registration to ensure that they have been correctly registered into following the above criteria.

The process above should be followed for both new patients and patients already registered on the liver transplant list.

If the recipient has had their blood group changed then an email to the following must be sent by Information Services, advising that the blood group has changed for the recipient, they must also include the original blood group. Hub Operations must both distribute crucial comms and add a note on the handover sheet stating that a prior to the organ outcome summary being generated a request must be made to Information Services to change the blood group back to the original blood group.

- Head of Service Delivery – ODT Hub
- Operational Manager – ODT Hub
- Operational Lead – ODT Hub: Information Services
- Operational Lead – ODT Hub: Operations
- ODT Hub: Operations – Shift Managers
- Senior Statistician – Liver

## 4. Additional Waiting Time

If it has been confirmed that the patient is a prioritised paediatric patient, ODT Hub: Information Services will add an additional 5000 waiting time points, the waiting time will be automatically updated when the waiting time batch-job is next run:

- 00:05 – All organ waiting time is recalculated
- 10:00 – Liver and Intestinal waiting time is re-calculated
- 14:00 – Liver and Intestinal waiting time is re-calculated
- 18:00 – Liver and Intestinal waiting time is re-calculated

After the additional points have been added to the recipient the following should be emailed:

- Senior Statistician (Liver)
  - To check that registration is correct, and that points have been applied correctly
- Statistical.Enquiries@nhsbt.nhs.uk
  - To escalate if the Senior Statistician is not available
- odthuboperations.shiftmanagers@nhsbt.nhs.uk
  - To inform Hub-Operations that a recipient has been added to the prioritised paediatric tier.

A representative from Statistics and Clinical Research will check and confirm the correct additional waiting time has been added.

Once confirmation has been received the recipient centre should be informed that the changes have been applied.

If waiting time has been added previously, and additional time is required, when adding the new waiting time you must include the previously added waiting time due to NTxD only allowing one set of additional waiting time points at any one time. For example, if 100 days had previously been added and an additional 50 days should be added then 150 days should be added.

If the incorrect additional waiting time is added, the lead from Statistics and Clinical Research will notify ODT Hub Information Services and confirm the correct additional waiting time. The Higher/Senior Information Office will subsequently notify the Operational Lead or Operational Manager.

If the additional waiting time added is higher than requested, the Higher/Senior Information Officer will contact the database team and request urgent amendment through both ServiceNow and a phone call.

If the additional waiting time added is lower than requested, the Higher/Senior Information Officer will correct and email the Senior Statistician (Liver) and Statistical Enquiries

The additional waiting time will be removed, as per **SOP5844**, once the transplant centre confirms the patient has received a liver transplant.

If it is confirmed that the patient is not a prioritised paediatric patient but is either a patient with hepatoblastoma or ACLF then the relevant sections should be followed.

## 5. Receiving blood group incompatible offers

If the recipient is over the age of 1 then approval must be given by both the OTDT Medical Director and the chair of the Liver Advisory Group, if approval is granted then the OTDT Assistant Director - Education & Governance must be made aware, then a risk assessment can be arranged with the following present (or a nominate representative):

- Quality Assurance
- Head of Service Delivery – ODT Hub
- Operational Manager – ODT Hub
- Operational Lead – ODT Hub: Information Services
- Operational Lead – ODT Hub: Operations
- Senior Statistician - Liver

# *Acute on Chronic Liver Failure (ACLF)*



## 1. Introduction

Fixed Term Working Unit was established by LAG to examine liver transplantation in critically ill patients with cirrhosis (ACLF). A report was presented at the November 2019 LAG meeting and recommended that a new tier should be added to the offering sequence after paediatric offering but before the adult elective stage. This requires an IT change which has been raised.

Feedback and concern were received from transplant centres when a transplant centre submitted a super-urgent appeal for an ACLF patient. It was agreed at the weekly centre director telecon and at LAG that, prior to the IT change, ACLF patients should be offered in the hepatoblastoma tier.

It was also agreed that a super-urgent appeal was inappropriate for ACLF patients.

Note that this is for adult patients.

**The inclusion and exclusion criteria are:**

Inclusion criteria for consideration under the ACLF process include:

- Requirement for care in ICU or HDU setting.
- Cirrhotic Chronic Liver Disease
- ACLF with 28-day survival <50%, likely grade of 3 or higher

Exclusion Criteria include:

- Age >60 years
- Active bacterial or fungal sepsis
- Multi-organ failure overwhelming or with adverse trajectory
- Excessive comorbidity
- Frailty likely to preclude rehabilitation.

## 2. Registration Process

Transplant centres wishing to register an ACLF patient must complete the Elective Liver Recipient Registration Form (**FRM4332**) with the following indications and submit the form to NHS Blood and Transplant via ODT Online.

Transplant centres must subsequently email and phone ODT Hub: Information Services (Email: ODTRegistrationTeamManagers@nhsbt.nhs.uk, Phone: 0117 975 7523) **before** submitting the form to inform ODT Hub: Information Services that they intend to register an ACLF patient. They must also email the supplementary ACLF form (FRM7574) to the following:

- ODT Hub: Information Services
- Lead statistician for Liver transplantation
- ACLFLT Working Group lead

Note that these emails will be actioned by both ODT Hub: Information Services during the hours of 0900 - 1700 (Monday – Sunday) and Statistics & Clinical Research during working hours (10am - 4pm Monday - Friday) and it should be noted that this may take up to 12 hours.

- 444 (hepatoblastoma) as primary indication
- True primary disease as secondary indication
- 498 (Other, please specify) as tertiary indication with "ACLF PATIENT" in the free text box

**Please note, ACLF registrations are processed by ODT Hub Information Services during the hours of 0900 - 1700 (Monday – Sunday), new patient registrations and updates to existing registrations will not be processed outside of these hours, therefore, there will be a delay for all registrations submitted outside of these hours.**

It has been agreed that ACLF patients should not receive split liver offers or multi-organ offers (e.g. liver/kidney offers). Transplant centres should therefore record No to whether the patient would like to receive an offer from a donor meeting splitting criteria on either the elective registration form or a new sequential update form.

Transplant centres should also remove the patient from the other organ list (please see section 3.4 in POL195 for further information).

Note that a report is automatically produced every day showing the patients that are active on the elective transplant list with hepatoblastoma as the primary indication. Therefore, transplant centres should be aware that although the patient will appear on the active elective waiting list once the registration form is committed, they may not appear in the correct position on the hepatoblastoma tier until additional waiting time is added and there may be a delay if transplant centres do not email ODT Hub: Information Services.

The process above should be followed for both new patients and patients already registered on the liver transplant list.

ODT Hub: Information Services will check the recipient's registration to ensure that they have been correctly registered into following the above criteria.

Follow-up information additional to the standard post-transplant dataset will be required from centres for recipients transplanted through the ACLF tier.

## 3. Additional Waiting Time

If it has been confirmed that the patient is an ACLF patient no waiting time points are to be added,

The following should be emailed:

- Senior Statistician (Liver)
  - To check that registration is correct, and that points appear correctly.
- Statistical.Enquiries@nhsbt.nhs.uk
  - To escalate if the Senior Statistician is not available.
- odthuboperations.shiftmanagers@nhsbt.nhs.uk
  - To inform Hub-Operations that a recipient has been added to the ACLF tier.

A representative from Statistics and Clinical Research will check and confirm the waiting time appears correctly.

Once confirmation has been received the recipient centre should be informed that the changes have been applied.

it is confirmed that the patient is not an ACLF patient but is either a patient with hepatoblastoma or a prioritised paediatric patient, then the relevant section should be followed.

## *Neuroendocrine tumours*



### 1. Introduction

Appendix B of **POL195** (Liver Transplantation: Selection Criteria and Recipient Registration) details the inclusion and exclusion criteria for the neuroendocrine tumour (NET) service evaluation.

### 2. Approval

The National NET Board will review all suitable patients referred and determine suitability for the liver transplant pathway. Once agreed, these patients **do not** require approval from the National Appeals Panel or LAG Chair.

### 3. Registration

Transplant centres wishing to register a NET patient should complete the Elective Liver Recipient Registration Form (**FRM4332**) with the following information and submit the form to NHS Blood and Transplant on ODT Online.

Transplant centres must email ODT Hub: Information Services (ODTRegistrationTeamManagers@nhsbt.nhs.uk) **before** submitting the form to inform ODT Hub: Information Services that they intend to register a NET patient *along with the agreement from the national NET Board.*

Note that these emails will be actioned by both ODT Hub: Information Services and Statistics & Clinical Research during working hours (10am - 4pm Monday - Friday).

- 498 (other please specify) as primary indication with "NEUROENDOCRINE TUMOUR (NET) PATIENT" in the free text
- Variant syndrome=Yes
- Other variant syndrome=Yes
- Date of agreement to be date agreed by National NET Board

UKELD does not need to be examined as other variant syndrome are offered through the variant syndrome pathway regardless of UKELD.

Also, note that a report is automatically produced every day showing the patients that are active on the elective transplant list with one of the new cancer indications as the primary indication. Therefore, transplant centres should be aware that although the patient will appear on the active elective waiting list once the registration form is committed, they may not appear in the correct position on the variant syndrome until additional waiting time is added and there may be a delay if transplant centres do not email ODT Hub: Information Services.

ODT Hub: Information Services will then contact Statistical Enquiries (statistical.enquiries@nhsbt.nhs.uk) and the Lead Statistician for Liver Transplantation to confirm the patient registration.

## 4. Additional Waiting Time

It has been agreed that NET patients should receive a named patient offer within 6 months of listing. Therefore once confirmed, a Lead from Statistics & Clinical Research will email ODT Hub: Information Services to confirm, based on recipient blood group and weight the additional waiting days that should be added.

Additional time is calculated in Additional time for HPS and new service evaluations.sas which is stored in F:\Stats & Audit\Shared\Liver\Allocation\Additional time.

**Running instructions:**

- Open the SAS program
- Enter the recip_id identified in the daily batchjob or email (if centre emails)
- Enter 1 for net, crc, cca, shps or vshps as appropriate (leave the four as 0)
- Run the whole program
- Open wtime3a dataset and if extra variable is greater than 0 email ODTRegistrationTeamManagers@nhsbt.nhs.uk asking for the additional waiting time specified in extra to be added for the specific recip_id e.g. “please can we add AAAA extra additional waiting days for recip_id ZZZZZ (registration_id XXXXX).”

ODT Hub: Information Services will confirm receipt of the email and add the additional waiting time. The waiting time will be automatically updated when the waiting time batch-job is next run:

- 00:05 – All organ waiting time is recalculated
- 10:00 – Liver and Intestinal waiting time is re-calculated
- 14:00 – Liver and Intestinal waiting time is re-calculated
- 18:00 – Liver and Intestinal waiting time is re-calculated

After the additional points have been added to the recipient the following should be emailed:

- Senior Statistician (Liver)
  - To check that registration is correct, and that points have been applied correctly
- Statistical.Enquiries@nhsbt.nhs.uk
  - To escalate if the Senior Statistician is not available
- odthuboperations.shiftmanagers@nhsbt.nhs.uk
  - To inform Hub-Operations that a recipient has been added to the Neuroendocrine tumours tier.

A representative from Statistics and Clinical Research will check and confirm the correct additional waiting time has been added.

Once confirmation has been received the recipient centre should be informed that the changes have been applied.

If waiting time has been added previously, and additional time is required, when adding the new waiting time you must include the previously added waiting time due to NTxD only allowing one set of additional waiting time points at any one time. For example, if 100 days had previously been added and an additional 50 days should be added then 150 days should be added.

If the incorrect additional waiting time is added, the lead from Statistics and Clinical Research will notify ODT Hub Information Services and confirm the correct additional waiting time. The Higher/Senior Information Office will subsequently notify the Operational Lead or Operational Manager.

If the additional waiting time added is higher than requested, the Higher/Senior Information Officer will contact the database team and request urgent amendment through both service now and a phone call.

If the additional waiting time added is lower than requested, the Higher/Senior Information Officer will correct and email the Statistical lead for confirmation.

The additional waiting time will be removed, as per **SOP5844**, once the transplant centre confirms the patient has received a liver transplant.

## *Unresectable Colorectal Metastases*



### 1. Introduction

Appendix C of POL195 (Liver Transplantation: Selection Criteria and Recipient Registration) details the inclusion and exclusion criteria for the Colorectal (CRC) metastases service evaluation.

### 2. Approval

Individual transplant centres will review all suitable patients referred and determine suitability for the liver transplant pathway. These patients **do not** require approval from the National Appeals Panel or LAG Chair.

### 3. Registration

Transplant centres wishing to register a CRC Mets patient should complete the Elective Liver Recipient Registration Form (**FRM4332**) with the following information and submit the form to NHS Blood and Transplant on ODT Online.

Transplant centres must email ODT Hub: Information Services (ODTRegistrationTeamManagers@nhsbt.nhs.uk) **before** the form to inform ODT Hub: Information Services that they have registered a CRC Mets patient.

Note that these emails will be actioned by both ODT Hub: Information Services and Statistics & Clinical Research during working hours (10am - 4pm Monday - Friday).

- 498 (other please specify) as primary indication with "COLORECTAL (CRC) METASTASES PATIENT" in the free text
- Variant syndrome=Yes
- Other variant syndrome=Yes
- Date of agreement to be date registered

UKELD does not need to be examined as other variant syndrome are offered through the variant syndrome pathway regardless of UKELD

Also, note that a report is automatically produced every day showing the patients that are active on the elective transplant list with one of the new cancer indications as the primary indication. Therefore, transplant centres should be aware that although the patient will appear on the active elective waiting list once the registration form is committed, they may not appear in the correct position on the variant syndrome until additional waiting time is added and there may be a delay if transplant centres do not email ODT Hub: Information Services.

ODT Hub: Information Services will then contact Statistical Enquiries (statistical.enquiries@nhsbt.nhs.uk) and the Lead Statistician for Liver Transplantation to confirm the patient registration.

## 4. Additional Waiting Time

It has been agreed that CRC Mets patients should receive a named patient offer within 3 months of listing. Therefore once confirmed, a Lead from Statistics & Clinical Research will email ODT Hub: Information Services to confirm, based on recipient blood group and weight the additional waiting days that should be added.
Additional time is calculated in Additional time for HPS and new service evaluations.sas which is stored in F:\Stats & Audit\Shared\Liver\Allocation\Additional time.

**Running instructions:**

- Open the SAS program
- Enter the recip_id identified in the daily batchjob or email (if centre emails)
- Enter 1 for net, crc, cca, shps or vshps as appropriate (leave the four as 0)
- Run the whole program
- Open wtime3a dataset and if extra variable is greater than 0 email ODTRegistrationTeamManagers@nhsbt.nhs.uk asking for the additional waiting time specified in extra to be added for the specific recip_id e.g. “please can we add AAAA extra additional waiting days for recip_id ZZZZZ (registration_id XXXXX).”

ODT Hub: Information Services will confirm receipt of the email and add the additional waiting time. The waiting time will be automatically updated when the waiting time batch-job is next run:

- 00:05 – All organ waiting time is recalculated
- 10:00 – Liver and Intestinal waiting time is re-calculated
- 14:00 – Liver and Intestinal waiting time is re-calculated
- 18:00 – Liver and Intestinal waiting time is re-calculated

After the additional points have been added to the recipient the following should be emailed:

- Senior Statistician (Liver)
  - To check that registration is correct, and that points have been applied correctly
- Statistical.Enquiries@nhsbt.nhs.uk
  - To escalate if the Senior Statistician is not available
- odthuboperations.shiftmanagers@nhsbt.nhs.uk
  - To inform Hub-Operations that a recipient has been added to the Unresectable Colorectal Metastases tier.

A representative from Statistics and Clinical Research will check and confirm the correct additional waiting time has been added.

Once confirmation has been received the recipient centre should be informed that the changes have been applied.

If waiting time has been added previously, and additional time is required, when adding the new waiting time you must include the previously added waiting time due to NTxD only allowing one set of additional waiting time points at any one time. For example, if 100 days had previously been added and an additional 50 days should be added then 150 days should be added.

If the incorrect additional waiting time is added, the lead from Statistics and Clinical Research will notify ODT Hub Information Services and confirm the correct additional waiting time. The Higher/Senior Information Office will subsequently notify the Operational Lead or Operational Manager.

If the additional waiting time added is higher than requested, the Higher/Senior Information Officer will contact the database team and request urgent amendment through both service now and a phone call.

If the additional waiting time added is lower than requested, the Higher/Senior Information Officer will correct and email the Statistical lead for confirmation.

The additional waiting time will be removed, as per **SOP5844**, once the transplant centre confirms the patient has received a liver transplant.

## *Severe or very severe Hepatopulmonary Syndrome patients*



### 1. Introduction

LAG(20)40 details the findings and recommendations of the Hepatopulmonary syndrome waiting list prioritisation Fixed term working unit. The FTWU recommend that ideally all severe-very severe HPS patients (PaO2 on air <8 kPa) are transplanted within 1-year of listing. The FTWU also recommended that ideally all very severe HPS patients (PaO2 on air <7 kPa) are transplanted within 3 months of listing.

### 2. Approval

Requests to prioritise patients with severe or very severe hepatopulmonary syndrome patients who are clinically deteriorating will be managed and overseen by the requesting transplant centre who will provide the following with information required:

- Chair and Deputy Chair of the National Appeals Panel
- Head of Service Delivery - ODT Hub
- Lead Statistician for Liver Transplantation

It is anticipated that a decision should be made within 24 hours.

Please note that this includes patients not currently on the list as well as patients on the list (regardless of pathway).

Once agreed, the registration (including amendment) process below should be followed within working hours Monday to Friday.

### 3. Registration

Transplant centres wishing to register a patient with either severe or very severe HPS **who is not currently on the list** should complete the Elective Liver Recipient Registration Form (FRM4332) with the following information and submit the form to NHS Blood and Transplant on ODT Online.

- Variant syndrome=Yes
- Hepatopulmonary syndrome=Yes

Transplant centres **wishing to move a currently registered patient with either severe or very severe HPS from the CLD/HCC pathway** should update the status to 23 (suspended pending transition) and then complete a new Elective Liver Recipient Registration Form (FRM4332) with the following information and submit the form to NHS Blood and Transplant on ODT Online.

- Variant syndrome=Yes
- Hepatopulmonary syndrome=Yes

Transplant centres should must email ODT Hub: Information Services (ODTRegistrationTeamManagers@nhsbt.nhs.uk) **before** submitting the form to inform ODT Hub: Information Services that they intend to register a patient along with the agreement from the LAG Chair.

Transplant centres must also email ODT Hub: Information Services (ODTRegistrationTeamManagers@nhsbt.nhs.uk) if they have a patient **currently registered on the Variant syndrome pathway with HPS who is deteriorating to severe or very severe**.

Note that these emails will be actioned by both ODT Hub: Information Services and Statistics & Clinical Research during working hours (10am - 4pm Monday - Friday).

ODT Hub: Information Services will then contact Statistical Enquiries (statistical.enquiries@nhsbt.nhs.uk) and the Lead Statistician for Liver Transplantation to confirm either the patient registration or update.

The agreed offering pathway for patients with non-severe HPS is dependent on UKELD with patients with a UKELD of 49 or above offered through the Chronic Liver Disease pathway and not the variant syndrome pathway. The Lead Statistician for Liver Transplantation will review the patients actual UKELD and a dummy sequential update may need to be submitted with a UKELD less than 49 recorded so that patients with severe or very severe HPS are offered through the variant syndrome pathway.

If UKELD≥49

- Obtain the relevant registration_id from liver_reg_elective or recipient_status_history for the recip_id required.
- Obtain the data from liver_reg_investigation for the registration_id required.
- Extract the data into Excel
- Take a copy of the actual data and keep the latest data row
- Ensure investigation_type=2
- Change the investigation_date to date/time examined
- Null assessment_id and created_date (this will automatically be created when uploaded)
- Change the sodium value in the UKELD calculator to obtain a UKELD of 48 or less.
- Update the Excel document and save in year specific (e.g. 2023) folder in J:\DataServices_Stats\Data Error\Attachments
- Raise a database amendment request asking for it to be done asap as it affects offering pathway in Service Now
- Email database team to inform them that a new database amendment request has been submitted.

(See J:\DataServices_Stats\Data Error\Attachments\2022 for examples)

## 4. Additional Waiting Time

It has been agreed that patients with severe and very severe HPS should receive a named patient offer within 12 and 3 months of listing respectively.

Therefore once confirmed, a Lead from Statistics & Clinical Research will email ODT Hub: Information Services to confirm, based on recipient blood group and weight the additional waiting days that should be added.

Additional time is calculated in Additional time for HPS and new service evaluations.sas which is stored in F:\Stats & Audit\Shared\Liver\Allocation\Additional time.

**Running instructions:**

- Open the SAS program
- Enter the recip_id identified in the daily batchjob or email (if centre emails)
- Enter 1 for net, crc, cca, shps or vshps as appropriate (leave the four as 0)
- Run the whole program
- Open wtime3a dataset and if extra variable is greater than 0 email ODTRegistrationTeamManagers@nhsbt.nhs.uk asking for the additional waiting time specified in extra to be added for the specific recip_id e.g. “please can we add AAAA extra additional waiting days for recip_id ZZZZZ (registration_id XXXXX).”

Please note that patients already on the list will either be given additional waiting time or continue with their accrued waiting time (whichever higher) but not both.

ODT Hub: Information Services will confirm receipt of the email and add the additional waiting time. The waiting time will be automatically updated when the waiting time batch-job is next run:

- 00:05 – All organ waiting time is recalculated
- 10:00 – Liver and Intestinal waiting time is re-calculated
- 14:00 – Liver and Intestinal waiting time is re-calculated
- 18:00 – Liver and Intestinal waiting time is re-calculated

After the additional points have been added to the recipient the following should be emailed:

- Senior Statistician (Liver)
  - To check that registration is correct, and that points have been applied correctly
- Statistical.Enquiries@nhsbt.nhs.uk
  - To escalate if the Senior Statistician is not available
- odthuboperations.shiftmanagers@nhsbt.nhs.uk
  - To inform Hub-Operations that a recipient has been added to Severe or very severe Hepatopulmonary Syndrome patients tier.

A representative from Statistics and Clinical Research will check and confirm the correct additional waiting time has been added.

Once confirmation has been received the recipient centre should be informed that the changes have been applied.

If waiting time has been added previously, and additional time is required, when adding the new waiting time you must include the previously added waiting time due to NTxD only allowing one set of additional waiting time points at any one time. For example, if 100 days had previously been added and an additional 50 days should be added then 150 days should be added.

If the incorrect additional waiting time is added, the lead from Statistics and Clinical Research will notify ODT Hub Information Services and confirm the correct additional waiting time. The Higher/Senior Information Office will subsequently notify the Operational Lead or Operational Manager.

If the additional waiting time added is higher than requested, the Higher/Senior Information Officer will contact the database team and request urgent amendment through both service now and a phone call.

If the additional waiting time added is lower than requested, the Higher/Senior Information Officer will correct and email the Statistical lead for confirmation.

The additional waiting time will be removed, as per **SOP5844**, once the transplant centre confirms the patient has received a liver transplant.

# *Intrahepatic Cholangiocarcinoma*



## 1. Introduction

Appendix D of POL195 (Liver Transplantation: Selection Criteria and Recipient Registration) details the inclusion and exclusion criteria for the intrahepatic Cholangiocarcinoma (CCA) service evaluation.

## 2. Approval

Individual transplant centres will review all suitable patients referred and determine suitability for the liver transplant pathway. These patients **do not** require approval from the National Appeals Panel or LAG Chair.

## 3. Registration

Transplant centres wishing to register a CCA patient should complete the Elective Liver Recipient Registration Form (**FRM4332**) with the following information and submit the form to NHS Blood and Transplant on ODT Online.

Transplant centres must email ODT Hub: Information Services (ODTRegistrationTeamManagers@nhsbt.nhs.uk) **before** submitting the form to inform ODT Hub: Information Services that they intend to register a CCA patient.

- 498 (other please specify) as primary indication with "CHOLANGICARCINOMA (CCA) PATIENT" in the free text
- Variant syndrome=Yes
- Other variant syndrome=Yes (note that all the individual variant syndrome questions should be answered on the form).
- Date of agreement must be the date registered for CCA.

Note that these emails will be actioned by both ODT Hub: Information Services and Statistics & Clinical Research during working hours (10am - 4pm Monday - Friday).

Also, note that a report is automatically produced every day showing the patients that are active on the elective transplant list with one of the new cancer indications as the primary indication. Therefore, transplant centres should be aware that although the patient will appear on the active elective waiting list once the registration form is committed, they may not appear in the correct position on the variant syndrome until additional waiting time is added and there may be a delay if transplant centres do not email ODT Hub: Information Services.

ODT Hub: Information Services will then contact Statistical Enquiries (statistical.enquiries@nhsbt.nhs.uk) and the Lead Statistician for Liver Transplantation to confirm the patient registration.

## 4. Additional Waiting Time

It has been agreed that CCA patients should receive a named patient offer within 3 months of listing. Therefore once confirmed, a Lead from Statistics & Clinical-Research will email ODT Hub: Information Services to confirm, based on recipient blood group and weight the additional waiting days that should be added.

Additional time is calculated in Additional time for HPS and new service evaluations.sas which is stored in F:\Stats & Audit\Shared\Liver\Allocation\Additional time.

**Running instructions:**

- Open the SAS program
- Enter the recip_id identified in the daily batchjob or email (if centre emails)
- Enter 1 for net, crc, cca, shps or vshps as appropriate (leave the four as 0)
- Run the whole program
- Open wtime3a dataset and if extra variable is greater than 0 email ODTRegistrationTeamManagers@nhsbt.nhs.uk asking for the additional waiting time specified in extra to be added for the specific recip_id e.g. “please can we add AAAA extra additional waiting days for recip_id ZZZZZ (registration_id XXXXX).”

ODT Hub: Information Services will confirm receipt of the email and add the additional waiting time. The waiting time will be automatically updated when the waiting time batch-job is next run:

- 00:05 – All organ waiting time is recalculated
- 10:00 – Liver and Intestinal waiting time is re-calculated
- 14:00 – Liver and Intestinal waiting time is re-calculated
- 18:00 – Liver and Intestinal waiting time is re-calculated

After the additional points have been added to the recipient the following should be emailed:

- Senior Statistician (Liver)
  - To check that registration is correct, and that points have been applied correctly
- Statistical.Enquiries@nhsbt.nhs.uk
  - To escalate if the Senior Statistician is not available
- odthuboperations.shiftmanagers@nhsbt.nhs.uk
  - To inform Hub-Operations that a recipient has been added to the Intrahepatic Cholangiocarcinoma tier.

A representative from Statistics and Clinical Research will check and confirm the correct additional waiting time has been added.

Once confirmation has been received the recipient centre should be informed that the changes have been applied.

If waiting time has been added previously, and additional time is required, when adding the new waiting time you must include the previously added waiting time due to NTxD only allowing one set of additional waiting time points at any one time. For example, if 100 days had previously been added and an additional 50 days should be added then 150 days should be added.

If the incorrect additional waiting time is added, the lead from Statistics and Clinical Research will notify ODT Hub Information Services and confirm the correct additional waiting time. The Higher/Senior Information Office will subsequently notify the Operational Lead or Operational Manager.

If the additional waiting time added is higher than requested, the Higher/Senior Information Officer will contact the database team and request urgent amendment through both service now and a phone call.

If the additional waiting time added is lower than requested, the Higher/Senior Information Officer will correct and email the Statistical lead for confirmation.

The additional waiting time will be removed, as per **SOP5844**, once the transplant centre confirms the patient has received a liver transplant.

## 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.:<br>• Formal training package | <Training methods for each role/department identified e.g.:<br>• Formal training package |
| **Assessment** | <How assessment of competency is evidenced e.g.:<br>• FRM511 | <How assessment of competency is evidenced e.g.:<br>• FRM511 |
| **Cascade Plan** | <Who will deliver the *Training Plan*, who will train the trainers e.g.:<br>• Author trains department managers or key trainers, who then cascade training to their department.<br>• Author allows trainers to approve their own training, who then cascade training.<br>• Author authorises self-directed training> | < Who will deliver the *Training Plan*, who will train the trainers e.g.:<br>• Author trains department managers or key trainers, who then cascade training to their department.<br>• Author allows trainers to approve their own training, who then cascade training.<br>• Author authorises self-directed training> |

**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**:<br>(i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align)<br>(ii) result in the discard of a small number of replaceable products and/or<br>(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)<br>(ii) result in the discard of a medium number of replaceable products and/or<br>(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:<br>(i) directly impact product quality, patient/donor safety<br>(ii) result in the discard of a large number of replaceable products<br>(iii) result in the discard of an irreplaceable product and/or<br>(iv) result in a delay to patient treatment. |
| 5. Very High | A process whose failure, in full or in part, is **certain** to:<br>(i) directly impact product quality, patient/donor safety<br>(ii) result in the discard of a large number of replaceable products<br>(iii) result in the discard of an irreplaceable product and/or<br>(iv) result in a delay to patient treatment. |
| **Process Criticality Score** | 4 |

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.<br><br>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.<br><br>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.<br><br>E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks |
| 4. High | A new process of moderate complexity, OR<br><br>An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed.<br><br>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<br><br>An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed.<br><br>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** | 3 |

## Training Plan Risk Matrix:

| Criticality of Change | Process Criticality: 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** | 4 | |
| **Criticality of Change Score** | 3 | 3 |
| **Training Score** | 12 | 12 |

## 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 |