Homerton University Hospital NHS
NHS Foundation Trust

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North London Coroner's Service
Barnet Coroner's Court
29 Wood Street
London
EN5 4BE

28 November 2024

Dear Ms Bradford,

Re: Regulation 28 Report to Prevent Future Deaths

I write in response to the Regulation 28 Report to Prevent Future Deaths dated 11 October 2024, which you sent following the inquest touching the death of Kingsley Efosa Imafidon.

In the report, you have raised the following concerns:

1. There was no apparent liaison between the teams involved in Kingsley's care to consider any matters that may be relevant to his HbSS prior to the biopsy being carried out;

2. The Trust's Standard Operating Procedure ("SOP") for Elective Liver Biopsy does not appear to give consideration to patients with other pathologies such as HbSS;

3 There was no apparent consideration given to potential additional post-operative monitoring or requirements for a patient with HbSS;

4 The Trust's SOP refers to a document titled "*Guidelines on the use of liver biopsy in clinical practice from the British Society of Gastroenterology, the Royal College of Radiologists and the Royal College of Pathology*" (Neuberger J, Patel J, Caldwell H *et al*. Gut 2020) which provides advice on liver biopsy techniques, methods and aftercare etc. These guidelines do not appear to give consideration (and therefore guidance) in relation to the use of liver biopsy for patients with other pathologies such as HbSS.

The Trust's response to these concerns is as follows:

Concern 1

The Trust's Elective Liver Biopsy Standard Operating procedure (SOP) has been reviewed and updated in light of the concerns raised at the inquest, and the latest version was sent to Emergency Care, Medicine and Rehabilitation Services (EMRS) clinical governance meeting which was held on November 8. Within the updated SOP, Section 3 entitled 'Vetting of Referrals' has been amended to read as follows:

- *In cases where liver biopsy may be considered higher risk, in particular patients with known bleeding disorders or hyperbilirubinaemia of any aetiology, the decision to biopsy should*

be discussed in the Northeast London network liver MDT, as an alternative route for biopsy may be indicated.

- *Higher risk patients who are to undergo percutaneous biopsy should attend a pre-assessment clinic for workup prior to biopsy.*
- *Liver biopsy requests must be requested on EPR and discussed by email with radiology* [redacted] *or with the GI radiologists, Dr* [redacted] *or Dr* [redacted]

The North East London Network Liver MDT includes clinicians from other Trusts and tertiary centres, and is a forum at which specialist advice can be obtained in respect of any high risk cases. The expectation is that this will identify any need for consultation with other specialties such as haematology.

The need to adopt a MDT approach in complex cases has been disseminated across the gastroenterology department, which is the main department referring patients for biopsies. The Trust has reviewed the process of biopsy referrals, the liver biopsy pre-assessment clinic and the patient information leaflet. This has led to the creation of a template on Electronic Patient Record (EPR) for use in the pre-assessment clinic.

The Elective Liver Biopsy SOP itself is now being highlighted to clinicians at various stages. For example, when a liver biopsy is booked, the radiographic assistants who book the biopsies are now sending out a standard email which draws the referring clinician's attention to the SOP and includes a link to it. Additionally, when liver biopsy reports are sent to the referring clinician, the email attaching the report also signposts the clinicians to the SOP, with a link.

High risk patients who are due to undergo a liver biopsy will attend a pre-assessment clinic with a specialist nurse or gastroenterologist. This is another opportunity for the Trust's SOP to be considered, particularly in relation to high risk patients, and to consider whether a discussion with the *North East London Network liver MDT* or any other specialties may be required if this has not already taken place.

Concerns 2 and 3

As set out above, the Trust's Elective Liver Biopsy SOP has been updated.

The Trust is confident that the changes made to the SOP will help to ensure that appropriate consideration is given to patients with other relevant pathologies.

Discussion of complex or higher risk cases with the North East London Network Liver MDT, which is now embedded within the SOP, should highlight any particular post-operative monitoring requirements for patients with other relevant pathologies.

Concern 4

The Trust has reviewed the current guidelines entitled *Guidelines on the use of liver biopsy in clinical practice from the British Society of Gastroenterology, the Royal College of Radiologists and the Royal College of Pathology*" (Neuberger J, Patel J, Caldwell H *et al*. Gut 2020 and updated the Trust's SOP to refer to this latest guidance.

The Trust will of course review its SOP in light of any further guidance produced by The British Society of Gastroenterology, The Royal College of Radiologists and The Royal College of Pathology.

I hope that this response addresses the concerns which you have raised and explains why the Trust has chosen to take the steps it has. I thank you for bringing these issues to our attention.

Yours sincerely

[redacted]

[redacted]
Chief Executive Officer

APPENDIX 1 – Elective Liver Biopsy Standard Operating procedure dated 4 November 2024

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TYPE THE DOCUMENT TITLE

Author(s)	**[redacted] (Consultant Radiologist & Radiology Clinical lead), [redacted] (Consultant Gastroenterologist & Associate Medical Director EMRS Division),**
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Review Body	**EMRS Governance**

1. **Aim**

   This document aims to clarify the management of patients requiring liver biopsy. It defines the pre-procedure assessment and post procedure care including the criteria for nurse-led discharge.

2. **Background**

   Ultrasound guided percutaneous liver biopsies are performed by Radiology in Homerton University Hospital. Liver biopsies may be targeted at a lesion or non-targeted to obtain a diagnosis in conditions such as autoimmune hepatitis. Complications from elective percutaneous liver biopsies are rare. Studies have shown a 0.6% risk of major bleeding[1,2] and a 0.2% risk of death[2]. The 2020 British Society of Gastroenterology Guidelines on the use of liver biopsy in clinical practice, recommend post biopsy monitoring for at least 3 hours after liver biopsy, with regular clinical observations and measurement of blood pressure and pulse.[3]

3. **Vetting of referrals**

   - The clinical team must discuss requirements for liver biopsy with the patient and determine ability to consent prior to request.
   - In cases where liver biopsy may be considered higher risk, in particular patients with known bleeding disorders or hyperbilirubinaemia of any aetiology, the decision to biopsy should be discussed in the Northeast London network liver MDT, as an alternative route for biopsy may be indicated.

- Higher risk patients who are to undergo percutaneous biopsy should attend a pre-assessment clinic for workup prior to biopsy.
- Liver biopsy requests must be requested on EPR and discussed by email with radiology [redacted]@nhs.net or with the GI radiologists, Dr [redacted] or Dr [redacted].

4. **Pre-procedure assessment**

a) Blood testing must be performed by the referring clinician prior to or at referral.

- Platelet count >60
- Hb >90
- INR <1.4
- APTT 22-41 seconds

If the results are not within these parameters, a discussion with Haematology may be necessary for blood products prior to the biopsy.

b) Anticoagulation/anti-platelets:

- Low dose (75mg) aspirin does not need to be stopped
- Clopidrogrel should be stopped 7 days prior to the biopsy and restarted after 24 hours
- Ticagrelor/Prasugrel (stop 7 days prior, restart after 1 day)
- Apixaban/Rivaroxaban/Edoxaban (omit 2 days prior, restart after 3 days)
- Fondaparinux, prophylactic (omit 1 day prior, restart after 24hrs)
- Fondaparinux, therapeutic (omit 2 days prior, restart after 24hrs)
- Warfarin (omit 5 days prior, restart after 1 day)
- LMWH, prophylactic (stop 12hrs prior, restart after 1 day)
- LMWH, therapeutic (stop 1 day prior, restart after 1-3 days)
- Dabigatran (omit 2 or 4 days prior depending on renal function, restart 2-3 days

c) Ascites: It there is ascites, drainage must be performed prior to the liver biopsy.

5. **Scheduling**

- Once a date and time is allocated by the radiographic assistants ([redacted]@nhs.net), it is the referring team's responsibility to request a bed in MDU and inform the patient.
- The referring team must give the patient fasting instructions. Patients are to remain nil by mouth for 6 hours (but can have water up to 2 hours) prior to the procedure. Further information regarding stopping and restarting anticoagulation should be provided to the patient as detailed above.

6. **Post-procedure care**

- The patient is transferred within 15 minutes post procedure, from Radiology to the Medical Day Unit (MDU), or other ward where they will be observed. The patient is to be observed for a total of 4 hours, following the protocol as outlined below.

Aftercare protocol:

- strict bed rest and lie on the right side for 1 hour
- semi recumbent for the remaining 3 hours
- NBM for 3 hours and then encourage oral intake

Observation protocol (NEWS 2):

- every 15 minutes for 1 hour
- every 30 minutes for 1 hours
- every hour for the next 2 hours

The clinical team or Gastroenterology Team on bleep 247 or 108 is to be contacted if the NEWS ≥ 2 or more OR if the patient shows any features suggesting complications. This includes:.

- Systolic BP <100 or >200 mmHg
- HR >100
- Respiratory distress
- Change in conscious level
- Severe persistent abdominal pain
- Chest pain

7. **Nurse led discharge**

Once the patient meets the 4-hour observation period, they may be discharged provided they meet the nurse-led discharge criteria below.

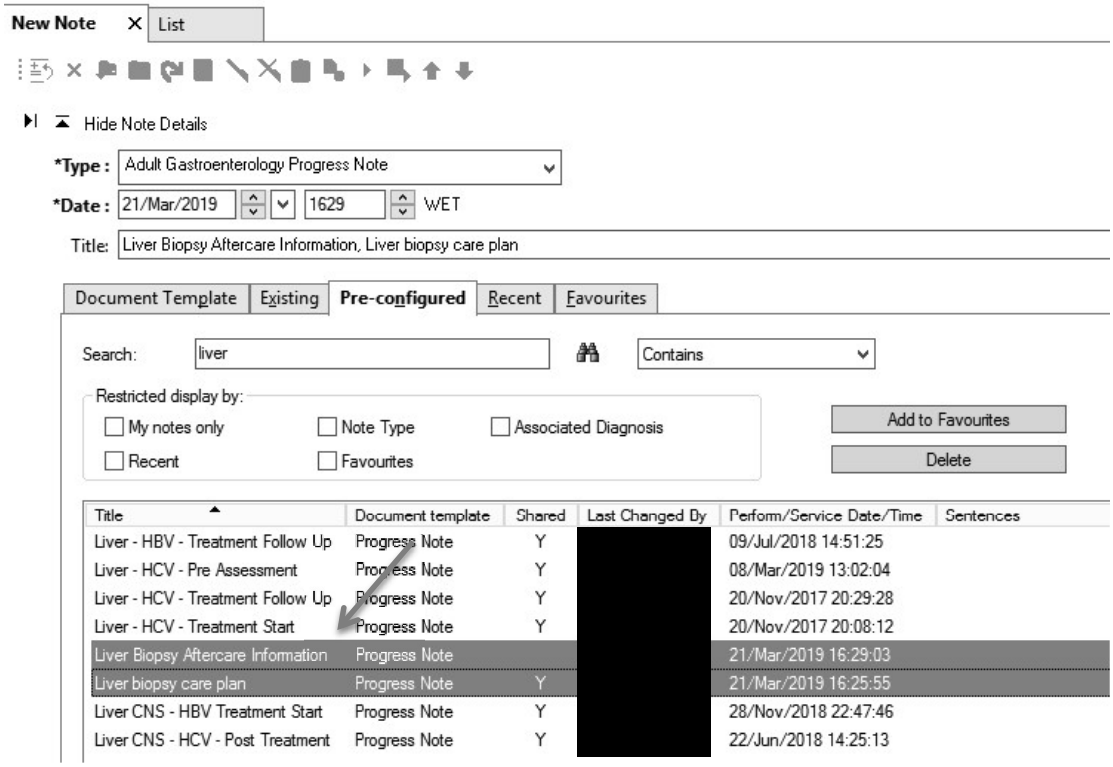
8. **Discharge checklist**

- Patient tolerating oral intake
- Patient mobilising to previous ability
- Pain score ≤ 1 and improving with simple analgesia
- NEWS score 0 or back to baseline (provided baseline ≤NEWS2)
- Wound site is clean

If they do not meet these criteria, the clinical team or Gastroenterology Team (bleep 247/108) or the on call medical doctor is to be contacted for assessment prior to discharge.

9. **Documentation**

The radiology report will include the needle type and Gauge, number of passes and drugs used during procedure as well as any immediate complications. The observation protocol and nurse led discharge checklist is on EPR as a pre-configured document template under the heading “Liver Biopsy Care Plan”. If the criteria are met, the nurse discharging the patient may then generate a discharge summary and an aftercare leaflet (see below) is to be printed and given to the patient. Verbal safety netting information is also to be provided by the discharging nurse. Follow-up will be arranged by the referring team.



10. **<u>Liver biopsy aftercare information:</u>**
    1) Please avoid vigorous or strenuous activity and heavy lifting including children for at least 1 week.
    2) You may have some discomfort at the site of the procedure or in your right shoulder. This is usually described as an ache and can be worse on breathing in. This is normal and should resolve after a few days. Over the counter pain killers such as paracetamol are recommended.
    3) You can eat and drink as normal after the period of observation in hospital.
    4) Please take all your usual medications unless advised by the doctor. If you are on blood thinning medication, you may restart it the day after unless advised by your doctor.
    5) You can go back to work as normal provided there is no heavy lifting involved.
    6) You can remove any plasters after 12 hours and bathe as normal.
    7) You should ensure that you are not alone at home for 48 hours after the biopsy.
    8) Complications from liver biopsy are rare, but if you experience severe abdominal pain, notice a sudden change in the colour of your motions (e.g. a black tar colour), extensive bruising of the abdomen, experience fainting or light-headedness, or develop a high temperature after you return home, you should present directly to the nearest emergency department (ED). These symptoms may be signs of internal bleeding or other significant complication requiring urgent attention.
    9) An outpatient appointment will be made with the requesting medical team to discuss the biopsy results when these are available.

References

1) Gilmore IT, Burroughs A, Murray-Lyon IM, et al. Indications, methods, and outcomes of percutaneous liver biopsy in England and Wales: an audit by the British Society of Gastroenterology and the Royal College of Physicians of London. *Gut 1995;36:437–441.*

2) West J and Card TR. Reduced mortality rates following elective percutaneous liver biopsies. *Gastroenterology 2020; 139:1230-1237.*

3) *Neuberger et al. Guidelines on the use of liver biopsy in clinical practice from the British Society of Gastroenterology, the Royal College of Radiologists and the Royal College of Pathology. Gut 2020;0:1-22.*

Yours faithfully

Dr [redacted]
Medical Director