Head and Neck Ultrasound Guided Superficial Core Biopsy

Standard Operating Procedure
UHL Radiology (LocSSIPs)

Change Description	Reason for Change
☐ Change in format	☒ Trust requirement

APPROVERS	POSITION	NAME
Person Responsible for Procedure:	Consultant Radiologist Consultant Radiographer (Head & Neck Imaging)	Dr R Vaidhyanath Amy Barnes
SOP Owner:	Consultant Radiographer (Head & Neck Imaging)	Amy Barnes
Sub-group Lead:	Consultant Radiologist	Aejaz Syed

Appendices in this document:

Appendix 1: UHL Safer Surgery Head and Neck Imaging Ultrasound Checklist

Appendix 2: Patient Information Leaflet for Having a sample of abnormal tissue taken for examination (ultrasound guided soft tissue biopsy)

Appendix 3: Management of patient's referred for ultrasound guided core biopsy Routine referrals booking pathway

Appendix 4: Management of patients referred for ultrasound guided core biopsy 2WW / urgent referrals booking pathway

Appendix 5: Anticoagulation Management Guidelines for Patients Having Elective Superficial Ultrasound Guided Core Biopsy

Appendix 6: Patient Group Directive (PGD) Lidocaine (Protocol No: IMA-12)

Appendix 7: (FNA) Fine Needle Aspiration Biopsy Risk Management Assessment Form

Introduction and Background:

This Local Safety Standards for Invasive Procedures (LocSSIP) has been developed in line with NHS England, National Safety Standards for Invasive Procedures, with the purpose to deliver safer care for patients

undergoing invasive procedures and to promote continuous Quality Improvement (QI).

Head and neck tumours are frequently encountered clinically; ultrasound guided Core Biopsy is easily accessible, inexpensive diagnostic procedures that can effectively narrow the differential diagnoses if not reach a confirmed diagnosis. Thus, ultimately reduces the number of patients needing more invasive tests such as open / excision biopsy under general anaesthetic. It is well established in literature that CB, by suitably trained operators, can be safely and easily performed for superficial lymph nodes, salivary gland tumours and thyroid nodules.

This procedure can take place on the three main UHL sites. Leicester Royal Infirmary (LRI), Glenfield Hospital (GH) and Leicester General Hospital (LGH). In the event that such a procedure is carried out at another hospital in University Hospitals of Leicester (UHL), this LocSIPP will be referred to.

Indications include referrals for;

- Clinical suspicion of Lymphoma, anaplastic and thyroid carcinoma
- Non-diagnostic or equivocal fine needle aspiration,
- Diagnosis of metastatic disease
- Diagnosis of nodal Tuberculosis
- Further subtyping such as p16 status
- Clinical Trials
- Other justified request

Contraindications include;

- Where patients are on anticoagulation refer to anticoagulation management guidelines **(appendix 5)**
- Patients on anticoagulation / antiplatelet medication should be discussed and management appropriately by the referring Clinician.
- Patients on anticoagulation / antiplatelet medication from Primary care should be referred to an appropriate secondary care clinician / MDT prior to commencing
- Any negotiating circumstances for interventional procedure are discussed at MDT meetings and actions are pre-empted at that point.

Practitioners must have current Registered status with health & care professions council or equivalent to perform this procedure in training or independently. Patient Group Direction (PGD) included in **(appendix 6)**

Never Events:

Possible never events with appropriate prevention and measures as described in this document may include but is not limited to:

- Incorrect patient.

Prevention:
Using patient identification see UHL Patient Identification Band Policy

- Incorrect biopsy site

Prevention:
Full ultrasound examination to take place prior to biopsy.
All previous imaging to be reviewed.
Safe site checklist
Mark biopsy site if appropriate

- Sharps Injury

Refer to UHL Sharps Safety Policy B8/2013

List management and scheduling:

Core Biopsy (CB) can be referred via many routes including;

- GP
- Secondary care referrals
- Multi-disciplinary team meetings
- Ward / Clinics

Minimum dataset required for scheduling a patient onto a suitable ultrasound list;

- Justified & signed clinical request including;

- Patient name.
- Identification numbers, i.e. NHS number with or without hospital number.
- Date of birth.
- Gender.
- Planned procedure.
- Site and side of procedure if relevant.
- Source of patient, e.g. ward or admissions lounge.

Further information that can be provided when relevant may include;

- Anticoagulation profile
- Significant comorbidities.
- Allergies, e.g. to latex or iodine.
- Infection risk.

- Referring clinicians requesting core biopsy should provide details of anticoagulation medication or contraindications clearly on the request form.
- Booking staff should follow the anticoagulation flowchart; routine / 2WW **(appendix 3 & 4)**
- All requests should be vetted by an appropriate professional
- Patients on a dedicated Consultant Radiologist / Advanced Practitioner/ Consultant Radiographer list are potential candidates for core biopsy without prior arrangement. Patient suitability for the procedure can be ascertained at the time of ultrasound examination by a suitably trained ***operator.***
- Patients can be referred directly for core biopsy in One Stop Clinic or equivalent. Patient suitability for the procedure can be ascertained at the time of ultrasound examination by a suitably trained ***operator***.
- In-patients will be booked onto an appropriate ultrasound list after discussion with the Radiologist / SPR / Advanced Practitioner / Consultant Radiographer
- Patients that do not attend their appointments will have the request returned to the referrer; management for further biopsy is the responsibility of the referring team.
- List schedules are managed by the ***operator*** and will be communicated to the procedure team, this must take into account expected workload.
- Non-medical professional / Radiology trainees should liaise with ***Senior Operator*** namely Consultant Head & Neck Radiologist

Patient preparation:

Ideally patients will have the procedures explained by the referring team.

No pre procedural arrangements (included fasting/hydration)

Patient Information Leaflet (PIL) available on YourHealth: Having a sample of abnormal tissue taken for examination (ultrasound guided soft tissue biopsy)

A full and thorough explanation is provided to the patient prior to procedure.

Pre-procedural investigations and work-up required;

- Anticoagulation / antiplatelet profile / INR if appropriate, refer to Anticoagulation Management Guideline **(appendix 5)**
- Review previous imaging
- Full ultrasound examination of the neck immediately prior to procedure.

Patients with special requirements such as:

- Diabetes – Procedure may continue, directed by the ***operator***
- Use of anti-platelet agents – refer to Anticoagulation Management Guideline **(appendix 5)**
- Use of anticoagulants - refer to Anticoagulation Management Guideline **(appendix 5)**

Consent process

- Procedure to be fully explained at the time of ultrasound examination by the ***operator***
- Verbal consent ticked on the UHL Safer Surgery Head and Neck Imaging Ultrasound Checklist **(appendix 1)** by the ***procedure team.***
- UHL Safer Surgery Head and Neck Imaging Ultrasound Checklist completed in full and scanned onto CRIS **(appendix 1)**
- Procedure team to 'STOP THE LINE' at any point.
- Superficial percutaneous Core Biopsy is a low risk procedure; refer to risk assessment in **appendix 7.** Patients should be made aware of rare but possible bleeding/haematoma/infection/non diagnostic result.
- Shared Decision Making (SDM) will be considered as per GMC (Decision making and consent (gmc-uk.org))

- If verbal consent cannot be obtained patient will be referred back to the referring Clinician. If this is Primary care an appropriate secondary care referral should be made.

Staff members and patients should follow current personal protective equipment/covid-19 guidance as appropriate.
It is generally recommended:

- Patients are screened for COVID-19 symptoms prior to procedure
- Patients wear surgical masks if appropriate
- Staff wear gloves, apron masks as appropriate

Patients with individual needs such as disabilities or those requiring translation/interpretation should be communicated by the referrer. Needs that where not known prior to the appointment that cannot be met on the day should be manged with the referring team and an appointment re-arranged at the earliest convenience.

Out-patients are not admitted for this procedure

Where the procedure is performed on an In-patient, the patient should be wearing an ID band and verification of patient details should be performed in accordance with UHL Patient Identification Band Policy:

- Details on the Patient Identification band should be verified by the patient asking them to confirm their full name and date of birth
- Never read the patient details out and allowing them to passively agree

Workforce :

Minimum safe ***procedure team*** consist of the ***operator***; Radiologist /Radiology Trainee / Consultant Radiographer / Advanced Practitioner and a suitably trained ***operator's assistant;*** Band 2/3 RDA. This will also

apply to out of hours working.

Refer to UHL Chaperone policy.

All members of the procedural team should maintain training; highlight any additional needs to management and practice within the limits of their proven and agreed competence.

Escalation procedure to be followed if the clinical situation overwhelms the available resources.

- 2222 in case of cardiac arrest. Crash trolley in Angiography or nearest area
- Medical / nursing support from Angiography department or nearest department
- ***Senior operator*** for procedural difficulties.
- In the absence of available assistance procedure should be postponed.

Trainees will be supported directly and indirectly, in accordance with their phase in training and competencies.

Clinical practice and technology relating to invasive procedures are subject to constant development and change. All members of the workforce must receive regular updates and continuous professional development.

If minimum staffing requirements cannot be met procedure will not take place.

Ward checklist, and ward to procedure room handover:

Patients referred during an in-patient stay will be arranged by the ***operator.***

Patient should be identified according to UHL Patient Identification Policy.

Ultrasound examination performed to confirm suitability.

Explanation of the ultrasound findings and procedure outcome will be written in patient notes.

Patient will be transported from and back to the ward via the portering system, it is the responsibility of the ward to provide an escort if necessary.

Procedural Verification of Site Marking:

Site of procedure is decided on at the time of the procedure by ultrasound examination. Any delay in procedure should result in a full ultrasound examination before commencing procedure.

Details of the Biopsy target will be documented in the Radiology report, pathology request and patients notes (if appropriate).

Surgical site marking - when appropriate but most often the scan and biopsy are done at the same time without change in operator /team. Lesion is visualised on ultrasound.

Team Safety Briefing:

The Team Safety Briefing must occur at the start of any elective, unscheduled, emergency procedure session or at the beginning of the Core Biopsy (CB) procedure.

1) Team Safety briefing to take part in the ultrasound room at the beginning of the Core Biopsy procedure. **Operator** and **operator's assistant** to be present, as a minimum.
2) Time allocated to the procedure should include the safety briefing.
3) Patient's details including name, date of birth an address should be confirmed prior to ultrasound examination.
4) UHL Safer Surgery Head and Neck Imaging Ultrasound Checklist should be completed fully and saved as a document on the CRIS examination.
5) Team members are encouraged to ask questions, seek clarification or raise concerns about any aspect of patient care or the planned procedure.

Sign In:

All patients undergoing invasive procedures under general, regional or local anaesthesia, or under sedation, must undergo safety checks on arrival at the procedure area:
The Sign In.

Along with the time out and sign out, this is based on the checks in the WHO Surgical Safety Checklist and forms part of the Five Steps to Safer Surgery. Noise and interruptions should be minimised during the sign in.

Participation of the patient (carer/guardian) in the sign in should be encouraged when possible
The checks performed during the sign in should include when relevant, but are not limited to:

- Patient name checked.
- Surgical site marking if applicable.
- Anaesthetic safety checks: machine, monitoring, medications.
- Allergies.
- Anti-coagulation
- Aspiration risk.

- Potential airway problems.
- Arrangements in case of blood loss.

The UHL Safer Surgery Head and Neck Imaging Ultrasound Checklist should be complete prior to procedure
The minimum workforce should be present during Sign In.

Time Out:

The Time Out should not be performed until any omissions, discrepancies or uncertainties identified in the sign in have been fully resolved.

A Time Out must be conducted immediately before skin incision or the start of the procedure. It should include when relevant, but is not limited to, checks of:

- Patient's name and identity band against the consent form.
- The results of any relevant tests that must be present and available
- The procedure to be performed.
- Verification of surgical site marking.
- Any specific equipment requirements or special investigations.
- Any critical or unexpected steps.
- Confirmation of sterility of instruments and equipment.
- Any equipment issues or concerns.
- Patient allergies.

Performing the procedure:

Ultrasound scan of appropriate area

Set up procedure trolley; It should include when relevant, but is not limited to

- Probe cover
- Chlorprep
- sterile carepack
- 1% lidocaine
- 25g needle
- 2ml syringe
- Scalpel
- Core biopsy needle (Temno Evolution or equivalent)
- Gauze

- sterile dressing

- Prep skin & probe with Chlorprep
- Subcutaneous injection of up to 2ml lidocaine
- Make a small dermal incision with scalpel for needle to pass (if necessary).
- Perform core biopsy under ultrasound guidance
- Prep skin & probe with Chlorprep between passes
- Use sterile dressing over biopsy site
- Place tissue cores into named histology / microbiology sample pot as appropriate
- Complete appropriate paperwork checking correct patient details, history and procedure information
- Send sample to pathology as appropriate
- Complete sample tracking form, signed (delivered by & received by)
- Scan tracking form as a document on CRIS examination
- Use 2WW orange bag / bio hazard bags as appropriate
- Contact Pathology directly with any urgent information as appropriate

Monitoring:

The ***operator*** is responsible for assessing the patient throughout examination.

Consent to continue between each pass should be sought.

The procedure should be abandoned if the patient or any ***procedure team*** member deems it unsafe or the patient can no longer tolerate the procedure.

Prosthesis verification:

Not Applicable.

Prevention of retained Foreign Objects:

All items are accounted for and that no item is unintentionally retained at the surgical site, in a body cavity, on the surface of the body, or in the patient's clothing or bedding.

All items used in the procedure should be accounted for and disposed of appropriately

Radiography:

Review appropriate previous imaging including;

Computed Tomography (CT)
Magnetic Resonance Imaging (MRI)
Radionuclide imaging (PET/SPECT CT)

Sign Out:

All patients undergoing invasive procedures under general, regional or local anaesthesia, or under sedation, must undergo safety checks at the end of the procedure but before the handover to the post-procedure care team:
The Sign Out.

Sign out checks should be conducted at the end of the procedure and before the patient is awoken from general anaesthesia or, when general anaesthesia is not used, before the patient leaves the procedure room. These checks should include when relevant, but are not limited to:

- Confirmation of the procedure performed, to include site and side if appropriate.
- Confirmation that instruments, sharps and swab counts are complete (or not applicable).
- Confirmation that any specimens have been labelled correctly, to include the patient's name and site or side when relevant.
- Discussion of post-procedural care, to include any patient-specific concerns.
- Equipment problems for inclusion in the debriefing.

Handover:

If appropriate relevant procedural information communicated via patient notes / direct communication with referring team
Otherwise a Radiology report will be approved post procedure with all necessary communication, It should include when relevant, but is not limited to;

Procedure performed with details of equipment used
Relevant findings
Details of procedure complications
Advice and guidance if appropriate

Team Debrief:

A debriefing should be performed at the end of the procedure sessions.

The total time set aside for the procedure or list of procedures should include the time taken to conduct the debriefing.

Every member of the ***procedural team*** should take part in the debriefing. Any team member may lead the debriefing, but the ***operator*** must be present.

For each patient, the discussion should include, but is not limited to:
- Things that went well.
- Any problems with equipment or other issues that occurred.
- Any areas for improvement.

Records of debriefings should include an action log that can be used to communicate examples of good practice and any problems or errors that occurred. Each procedural team should have an identified member who is responsible for feeding this information into local governance processes.

If a significant issue about the care of a patient arises during the debriefing, a clear and contemporaneous note of this should be made in the patient's records and a DATIX should be completed in the first instance.

Post-procedural aftercare:

Patient monitored post procedure as appropriate. Patient can be moved to waiting area during this period. Care should be escalated as appropriate.

Discharge:

Core Biopsy (CB) in the neck is performed as an out-patient procedure.

See above for post procedural after care.

In-patients will be transferred back to the ward with details of the procedure in the hand held notes (if available).

All procedure details are documented on the Radiology report.

Referring clinician is responsible for acting upon results and for communication with patient regarding follow-up

Governance and Audit:

A safety incident is rare, however will be reported on DATIX. Datix incidents will be reviewed and appropriate action taken.

Where the procedure is a performed by a Trainee / Advanced practitioner local Governance procedures should be followed to ensure there is a mechanism to capture and promote learning.

It is good practice for all ***operators*** to audit their own work and present it in an appropriate forum.

To submit monthly Safe Surgery Audit and WHOBARS assessment as Per Safe Surgery Quality Assurance & Accreditation programme.

Training:

All operators are obliged to read and comply with this local procedure.

All trainees should be trained according to a set criteria and standard such as the Royal College of Radiologist training programme.

All trainees / operators should be employed and have a current contract of employment with University Hospitals of Leicester

Documentation:

Radiology CRIS report to include:

- Details of procedure including needle gauge
- Local anaesthetic; LOT and expiry date
- Complications, if any
- Scanned copy of UHL Safer Surgery Head and Neck Imaging Ultrasound Checklist (appendix 1)

If the procedure is performed as an In-patient, details of the procedure performed and any necessary communication regarding post procedural care to be documented in the notes as appropriate.

References to other standards, alerts and procedures:

National Safety Standards for Invasive Procedures, NHS England 2015:
https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/09/natssips-safety-standards.pdf

Standard infection control precaution: national hand hygiene and personal protective equipment, NHS England and NHS Improvement 2019
https://improvement.nhs.uk/resources/national-hand-hygiene-and-personal-protective-equipment-policy/

Guidance on Implementing safety checklist for procedures, second edition
https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr191_checklists-radiological-procedures.pdf

INsite Infection Prevention
INsite - Infection Prevention (xuhl-tr.nhs.uk)

Diagnostic Ultrasound Examinations SOP 706

UHL Policy for Hand Hygiene B32/2003
UHL Guidelines for Decontamination of Ultrasound Probes B33/2016
UHL Policy for Cleaning and Decontamination/Infection Control B5/2006
UHL Personal Protective Equipment at Work Policy B9/2004
UHL Latex Allergy in Patients and Staff Policy B29/2005
UHL Policy for Consent to Examination or Treatment A16/2002
UHL Policy for Documenting in Patient Health Records (all Media) B30/2006
UHL Information Governance Policy B4/2004
UHL Chaperone Policy B39/2008
UHL Patient Identification Band Policy B43/2007
UHL Procedure for patient identification (IRMER procedure) SOP501 May/2018
UHL Hospital Linen Infection Prevention Principles B14/2012
UHL Preventing transmission Of Infection Including Isolation Guidelines B65/2006
UHL Delegated Consent Policy B10/2013
UHL Guideline: Anticoagulant Bridging Therapy for Elective Surgery and Procedures B30/2016
UHL Patient Group Directions Policy (for supply of medicines to patients) B43/2005
UHL Sharps Safety Policy B8/2013
UHL Patient Identification Band Policy B43/2007
Shared decision making for doctors: Decision making and consent (gmc-uk.org)
COVID and PPE: UHL PPE for Transmission Based Precautions - A Visual Guide
COVID and PPE: UHL PPE for Aerosol Generating Procedures (AGPs) - A Visual Guide

Glossary

Procedure, to include surgical operations, invasive cardiological procedures, endoscopy, interventional radiology, thoracic procedures and biopsies.

Procedure area, to include the operating theatres, cardiac catheter laboratories, endoscopy suites, labour ward and radiology department.

Procedure room, to include the individual procedural venue, e.g. operating theatre, delivery room and endoscopy room.

Procedure team, to include all those involved in the performance of the procedures, including doctors, nurses, midwives, operating department practitioners (ODPs), healthcare assistants (HCAs), technicians, scientists and any others directly involved in the performance of the procedure.

Operator, to include the surgeon, endoscopist, cardiologist, obstetrician, midwife, radiologist or other healthcare professional or practitioner performing the invasive procedure.

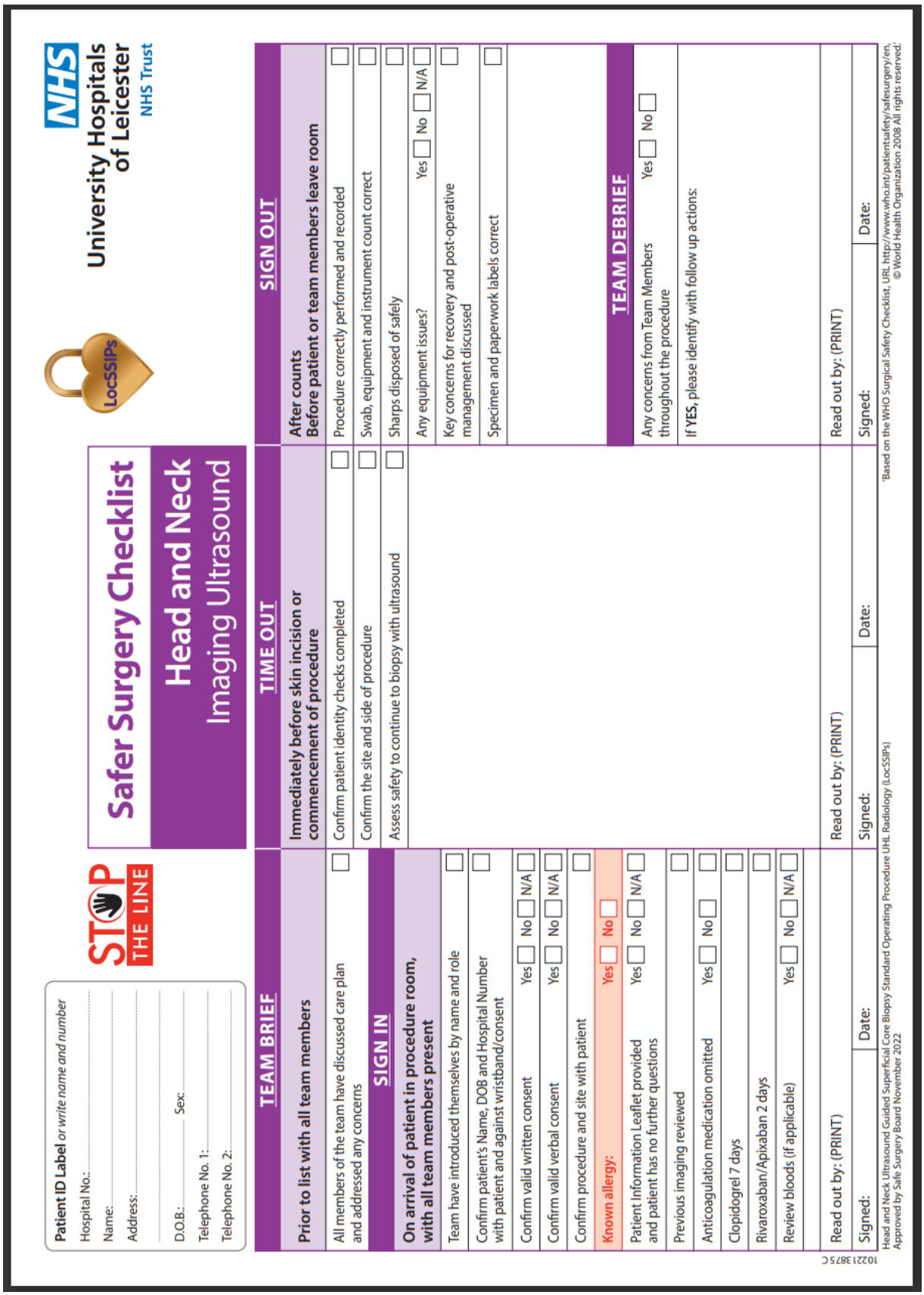
Senior operator, to imply the clinician with overall responsibility for the procedure.

Operator team or clinical team, to include the surgical or other team planning, scheduling and delivering care for the patient undergoing an invasive procedure.

Operator's assistant, to include any healthcare professional acting as first assistant to the operator.

END

Appendix 1: UHL Safer Surgery Head and Neck Imaging Ultrasound Checklist



Safer Surgery Checklist

Head and Neck Imaging Ultrasound

University Hospitals of Leicester NHS Trust

LocSSIPs

STOP THE LINE

Patient ID Label *or write name and number*

Hospital No.:

Name:

Address:

D.O.B.: Sex:

Telephone No. 1:

Telephone No. 2:

TEAM BRIEF

Prior to list with all team members

All members of the team have discussed care plan and addressed any concerns ☐

SIGN IN

On arrival of patient in procedure room, with all team members present

Team have introduced themselves by name and role ☐

Confirm patient's Name, DOB and Hospital Number with patient and against wristband/consent ☐

Confirm valid written consent Yes ☐ No ☐ N/A ☐

Confirm valid verbal consent Yes ☐ No ☐ N/A ☐

Confirm procedure and site with patient ☐

Known allergy: Yes ☐ No ☐

Patient Information Leaflet provided and patient has no further questions Yes ☐ No ☐ N/A ☐

Previous imaging reviewed ☐

Anticoagulation medication omitted Yes ☐ No ☐

Clopidogrel 7 days ☐

Rivaroxaban/Apixaban 2 days ☐

Review bloods (if applicable) Yes ☐ No ☐ N/A ☐

Read out by: (PRINT)

Signed: Date:

TIME OUT

Immediately before skin incision or commencement of procedure

Confirm patient identity checks completed ☐

Confirm the site and side of procedure ☐

Assess safety to continue to biopsy with ultrasound ☐

Read out by: (PRINT)

Signed: Date:

SIGN OUT

After counts Before patient or team members leave room

Procedure correctly performed and recorded ☐

Swab, equipment and instrument count correct ☐

Sharps disposed of safely ☐

Any equipment issues? Yes ☐ No ☐ N/A ☐

Key concerns for recovery and post-operative management discussed ☐

Specimen and paperwork labels correct ☐

TEAM DEBRIEF

Any concerns from Team Members throughout the procedure Yes ☐ No ☐

If **YES**, please identify with follow up actions:

Read out by: (PRINT)

Signed: Date:

'Based on the WHO Surgical Safety Checklist, URL http://www.who.int/patientsafety/safesurgery/en, © World Health Organization 2008 All rights reserved.'

Head and Neck Ultrasound Guided Superficial Core Biopsy Standard Operating Procedure UHL Radiology (LocSSIPs)
Approved by Safe Surgery Board November 2022

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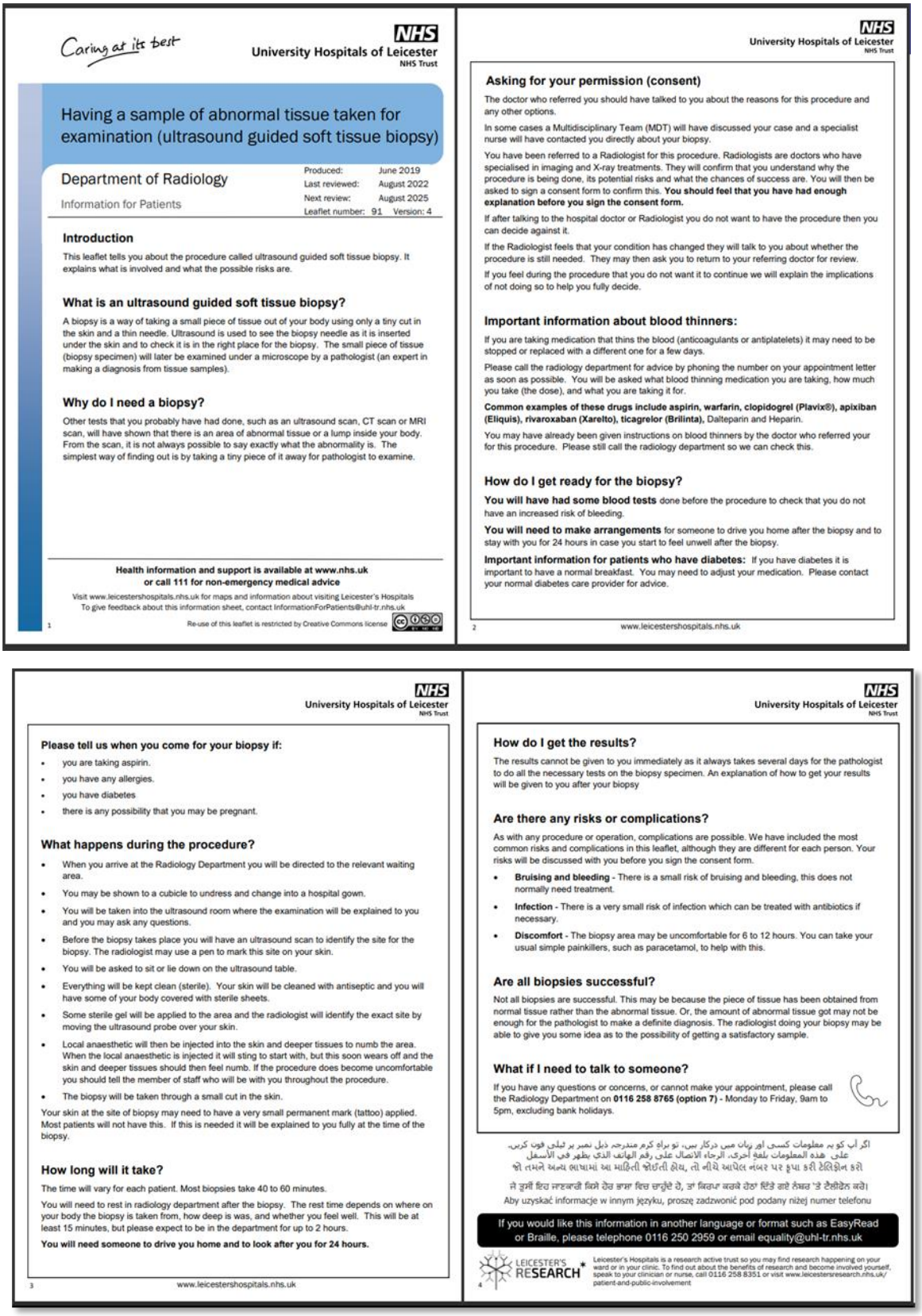
Appendix 2: Patient Information Leaflet for Having a sample of abnormal tissue taken for examination (ultrasound guided soft tissue biopsy) Available at: Having a sample of abnormal tissue taken for examination (ultrasound guided soft tissue biopsy) (leicestershospitals.nhs.uk)



Caring at its best

NHS University Hospitals of Leicester NHS Trust

Having a sample of abnormal tissue taken for examination (ultrasound guided soft tissue biopsy)

Department of Radiology

Information for Patients

Produced: June 2019
Last reviewed: August 2022
Next review: August 2025
Leaflet number: 91 Version: 4

Introduction

This leaflet tells you about the procedure called ultrasound guided soft tissue biopsy. It explains what is involved and what the possible risks are.

What is an ultrasound guided soft tissue biopsy?

A biopsy is a way of taking a small piece of tissue out of your body using only a tiny cut in the skin and a thin needle. Ultrasound is used to see the biopsy needle as it is inserted under the skin and to check it is in the right place for the biopsy. The small piece of tissue (biopsy specimen) will later be examined under a microscope by a pathologist (an expert in making a diagnosis from tissue samples).

Why do I need a biopsy?

Other tests that you probably have had done, such as an ultrasound scan, CT scan or MRI scan, will have shown that there is an area of abnormal tissue or a lump inside your body. From the scan, it is not always possible to say exactly what the abnormality is. The simplest way of finding out is by taking a tiny piece of it away for pathologist to examine.

Health information and support is available at www.nhs.uk or call 111 for non-emergency medical advice

Visit www.leicestershospitals.nhs.uk for maps and information about visiting Leicester's Hospitals
To give feedback about this information sheet, contact InformationForPatients@uhl-tr.nhs.uk

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Asking for your permission (consent)

The doctor who referred you should have talked to you about the reasons for this procedure and any other options.

In some cases a Multidisciplinary Team (MDT) will have discussed your case and a specialist nurse will have contacted you directly about your biopsy.

You have been referred to a Radiologist for this procedure. Radiologists are doctors who have specialised in imaging and X-ray treatments. They will confirm that you understand why the procedure is being done, its potential risks and what the chances of success are. You will then be asked to sign a consent form to confirm this. **You should feel that you have had enough explanation before you sign the consent form.**

If after talking to the hospital doctor or Radiologist you do not want to have the procedure then you can decide against it.

If the Radiologist feels that your condition has changed they will talk to you about whether the procedure is still needed. They may then ask you to return to your referring doctor for review.

If you feel during the procedure that you do not want it to continue we will explain the implications of not doing so to help you fully decide.

Important information about blood thinners:

If you are taking medication that thins the blood (anticoagulants or antiplatelets) it may need to be stopped or replaced with a different one for a few days.

Please call the radiology department for advice by phoning the number on your appointment letter as soon as possible. You will be asked what blood thinning medication you are taking, how much you take (the dose), and what you are taking it for.

Common examples of these drugs include aspirin, warfarin, clopidogrel (Plavix®), apixiban (Eliquis), rivaroxaban (Xarelto), ticagrelor (Brilinta), Dalteparin and Heparin.

You may have already been given instructions on blood thinners by the doctor who referred your for this procedure. Please still call the radiology department so we can check this.

How do I get ready for the biopsy?

You will have had some blood tests done before the procedure to check that you do not have an increased risk of bleeding.

You will need to make arrangements for someone to drive you home after the biopsy and to stay with you for 24 hours in case you start to feel unwell after the biopsy.

Important information for patients who have diabetes: If you have diabetes it is important to have a normal breakfast. You may need to adjust your medication. Please contact your normal diabetes care provider for advice.

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Please tell us when you come for your biopsy if:

- you are taking aspirin.
- you have any allergies.
- you have diabetes
- there is any possibility that you may be pregnant.

What happens during the procedure?

- When you arrive at the Radiology Department you will be directed to the relevant waiting area.
- You may be shown to a cubicle to undress and change into a hospital gown.
- You will be taken into the ultrasound room where the examination will be explained to you and you may ask any questions.
- Before the biopsy takes place you will have an ultrasound scan to identify the site for the biopsy. The radiologist may use a pen to mark this site on your skin.
- You will be asked to sit or lie down on the ultrasound table.
- Everything will be kept clean (sterile). Your skin will be cleaned with antiseptic and you will have some of your body covered with sterile sheets.
- Some sterile gel will be applied to the area and the radiologist will identify the exact site by moving the ultrasound probe over your skin.
- Local anaesthetic will then be injected into the skin and deeper tissues to numb the area. When the local anaesthetic is injected it will sting to start with, but this soon wears off and the skin and deeper tissues should then feel numb. If the procedure does become uncomfortable you should tell the member of staff who will be with you throughout the procedure.
- The biopsy will be taken through a small cut in the skin.

Your skin at the site of biopsy may need to have a very small permanent mark (tattoo) applied. Most patients will not have this. If this is needed it will be explained to you fully at the time of the biopsy.

How long will it take?

The time will vary for each patient. Most biopsies take 40 to 60 minutes.

You will need to rest in radiology department after the biopsy. The rest time depends on where on your body the biopsy is taken from, how deep is was, and whether you feel well. This will be at least 15 minutes, but please expect to be in the department for up to 2 hours.

You will need someone to drive you home and to look after you for 24 hours.

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How do I get the results?

The results cannot be given to you immediately as it always takes several days for the pathologist to do all the necessary tests on the biopsy specimen. An explanation of how to get your results will be given to you after your biopsy

Are there any risks or complications?

As with any procedure or operation, complications are possible. We have included the most common risks and complications in this leaflet, although they are different for each person. Your risks will be discussed with you before you sign the consent form.

- **Bruising and bleeding** - There is a small risk of bruising and bleeding, this does not normally need treatment.
- **Infection** - There is a very small risk of infection which can be treated with antibiotics if necessary.
- **Discomfort** - The biopsy area may be uncomfortable for 6 to 12 hours. You can take your usual simple painkillers, such as paracetamol, to help with this.

Are all biopsies successful?

Not all biopsies are successful. This may be because the piece of tissue has been obtained from normal tissue rather than the abnormal tissue. Or, the amount of abnormal tissue got may not be enough for the pathologist to make a definite diagnosis. The radiologist doing your biopsy may be able to give you some idea as to the possibility of getting a satisfactory sample.

What if I need to talk to someone?

If you have any questions or concerns, or cannot make your appointment, please call the Radiology Department on **0116 258 8765 (option 7)** - Monday to Friday, 9am to 5pm, excluding bank holidays.

اگر آپ کو یہ معلومات کسی اور زبان میں درکار ہیں، تو براہ کرم مندرجہ ذیل نمبر پر ٹیلی فون کریں۔
على هذه المعلومات بلغة أخرى، الرجاء الاتصال على رقم الهاتف الذي يظهر في الأسفل
જો તમને અન્ય ભાષામાં આ માહિતી જોઈતી હોય, તો નીચે આપેલ નંબર પર ફોન કરી ટેલિફોન કરો
ਜੇ ਤੁਸੀਂ ਇਹ ਜਾਣਕਾਰੀ ਕਿਸੇ ਹੋਰ ਭਾਸ਼ਾ ਵਿਚ ਚਾਹੁੰਦੇ ਹੋ, ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਹੇਠਾਂ ਦਿੱਤੇ ਗਏ ਨੰਬਰ 'ਤੇ ਟੈਲੀਫੋਨ ਕਰੋ।
Aby uzyskać informacje w innym języku, proszę zadzwonić pod podany niżej numer telefonu

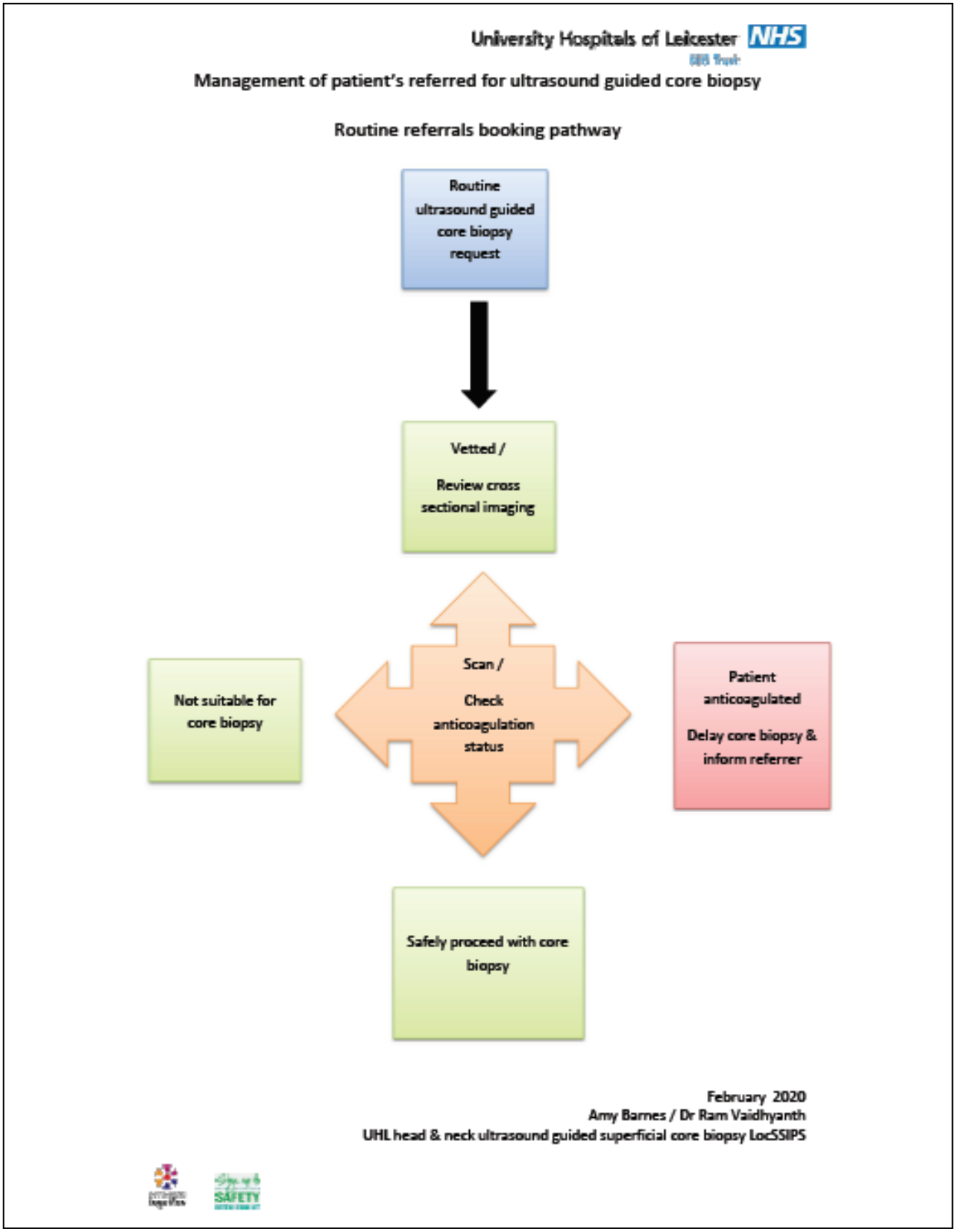
If you would like this information in another language or format such as EasyRead or Braille, please telephone 0116 250 2959 or email equality@uhl-tr.nhs.uk

LEICESTER'S RESEARCH

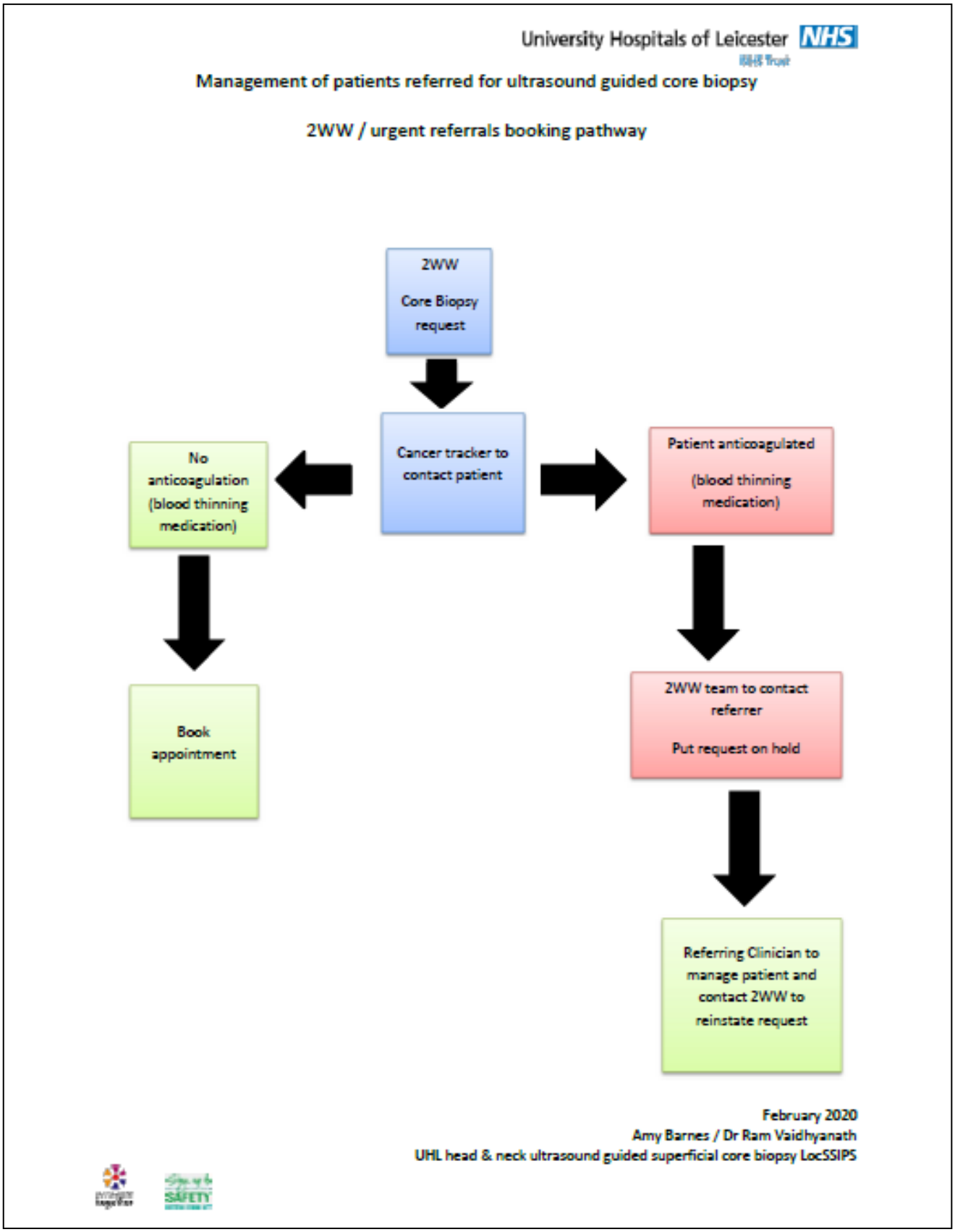
Leicester's Hospitals is a research active trust so you may find research happening on your ward or in your clinic. To find out about the benefits of research and become involved yourself, speak to your clinician or nurse, call 0116 258 8351 or visit www.leicestersresearch.nhs.uk/patient-and-public-involvement

4

Appendix 3: Management of patient's referred for ultrasound guided core biopsy Routine referrals booking pathway



Appendix 4: Management of patients referred for ultrasound guided core biopsy 2WW / urgent referrals booking pathway



Appendix 5: Anticoagulation Management Guidelines for Patients Having Elective Superficial Ultrasound Guided Core Biopsy

University Hospitals of Leicester NHS
NHS Trust

Anticoagulation Management Guidelines for Patients Having Elective Superficial Ultrasound Guided Core Biopsy

Anticoagulant / Antiplatelet Medication	Discontinue Yes* / No	Timing of LAST dose BEFORE procedure if discontinuing	Timing of FIRST dose AFTER day of procedure*
• aspirin, any dose	No		
• clopidogrel	Yes	-7 days	Day + 1
• warfarin RECOMMEND INR <2.0	Possible to continue	CHECK INR WITHIN 1 WEEK	Day 0 (evening)
• Subcutaneous heparin 1. prophylactic 2. therapeutic	 No Possible to continue	 >24 hours	 Day + 1
• dabigatran	No		
• rivaroxaban / apixaban	Yes	-2 day	Day + 1

COMMENTS

NOTE *

- The referring Clinician will be responsible for appropriate patient management and clinical care, this may involve continuation / bridging of anticoagulation medication
- The referring team must give instruction to the patient

Better care together

Sign up to Safety Learn Learn Act

February 2020 UHL head & neck ultrasound guided superficial core biopsy LocSSIPS

Appendix 6: Patient Group Directive (PGD) Lidocaine (Protocol No: IMA-12)

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST CLINICAL SUPPORT DIVISION PHARMACY SERVICE	Issue Date:	Dec 2022
	Review Date:	Dec 2024
	Protocol No:	IMA-12
PATIENT GROUP DIRECTION	Version:	8.0

Supply and administration of: **LIDOCAINE 1% Injection**

Master copy held by:	Available on INSite
Department/CMG(s):	Imaging, CSI

- This PGD is to be read, agreed to and signed by all health professional staff it applies to.
- One copy is given to the health professional and the original being kept by the manager.

1. Clinical Condition

Define situation/condition	Vascular Access Service Local anaesthesia prior to insertion and removal of Vascular Access Devices (VADs). Breast Care Centre Investigations in a breast clinic in the Breast Care Centre for screening or symptomatic services. Head and Neck Ultrasound Service Local anaesthesia prior to core biopsy/fine needle aspiration of neck lumps.
Criteria for inclusion	Vascular Access Service Local anaesthesia to the skin prior to insertion and removal of VADs in adult patients. Breast Care Centre Local anaesthesia to the breast in an adult patient prior to breast biopsy sampling and breast lesion localisation. Head and Neck Ultrasound Service Local anaesthesia to the neck in an adult patient prior to neck lump biopsy.
Criteria for exclusion	Known hypersensitivity to anaesthetics of the amide type.
Action if excluded	Refer to Lead Radiologist.
Action if patient declines	If patients do not wish to receive medication under a group protocol, then a referral should be made to the supervising Radiologist.

Page 1 of 4

Issue date: Dec 2022 PGD IMA-12 Version 8.0

2. Characteristics of staff

Qualifications required	Vascular Access Service Qualified Nurses whose role is to perform the insertion and removal of VADs are authorised to administer Lidocaine (lignocaine) 1%. Qualified nurses must have undertaken training in the insertion and removal of VADs. Breast Care Centre Only Radiographers authorised to administer Lidocaine (lignocaine) 1% who when requested to perform a breast biopsy sampling or breast lesion localisation will have completed an assessment of competence. The Radiographer must have undertaken training in breast biopsy sampling and breast lesion localisation via either an approved external course or following a local departmental training programme. Head and Neck Ultrasound Service Qualified Radiographer/Sonographer who has completed Level 2 training (RCR recommendations) and have undertaken assessment of competency by a Consultant Head and Neck Radiologist, are authorised to administer Lidocaine (lignocaine)1% prior to core biopsy / fine needle aspiration
Additional requirements	Additional training requirements-as above
Continued training requirements	The Nurse Practitioner or Radiographer will be responsible for ensuring their practice is up to date and will be provided with an opportunity for update or re-training by their manager.

3. Description of treatment

Name of medicine and Pharmaceutical form	**Lidocaine 1% injection** (10mg in 1ml)
POM/P/GSL	POM (Prescription only medicine)
Dose(s)	Vascular Access Service • Normally, 1 - 2ml lidocaine 1% injection (10 -20mg) is administered subcutaneously into the skin prior to insertion or removal of VADs. Occasionally up to 5ml (50mg) may be administered if the procedure is difficult or a second procedure is required. Breast Care Centre • Normally, 2ml lidocaine 1% injection (20mg) is administered subcutaneously into the breast prior to breast biopsy sampling or breast lesion localisation per site. • Occasionally up to 5ml (50mg) may be administered if the lesion is deep, the patient experiences discomfort or a 2nd biopsy is required per site Head and Neck Ultrasound Service • Normally 2ml Lidocaine1% injection (20mg) is administered subcutaneously into the neck prior to core biopsy or fine needle aspiration of neck lumps.
Route	Subcutaneous infiltration.
Frequency	Once, or if required, twice during the examination.
Total dose/number	Not applicable.

Precautions	• Not for intravenous injection. • Use with caution in patients with complete heart block, myasthenia gravis, epilepsy, known severe liver or renal disease, bradycardia, severe respiratory depression, congestive heart failure, heart block, cardiac arrhythmias or hypovolaemia. • Avoid in pregnancy unless benefits outweigh risks (i.e. if there is a suspicion of cancer) *Consult SPCs for complete list of Precautions. SPCs available through Medicines Information (6491) or on e-MC website (http://www.medicines.org.uk)*
Adverse effects	Rarely, allergic reactions Other adverse effects are usually the result of inadvertent IV injection and include: • *Commonly*: Hypotension, nausea, paraesthesia, dizziness, bradycardia. • *Uncommonly*: CNS excitation/depression, e.g., tremor and blurred vision. *Consult SPCs for complete list of Adverse effects. SPCs available through Medicines Information (6491) or on e-MC website (http://www.medicines.org.uk)*
Action to be taken if adverse effects reported	• Resuscitation team to be called in the event of cardiac or respiratory arrest (dial 2222). • Refer to supervising Radiologist immediately. • Datix form to be completed • Severe or unusual adverse drug reactions must be documented on a 'Report on Suspected Adverse Reactions' form (yellow form). • Post procedure – patient to contact GP.
Follow up treatment	None
Written/Verbal advice for patient/carer before/after treatment	• Written/verbal consent for procedure has been obtained. • Advise that infiltration may be uncomfortable. • Advice on post procedure care to be given verbally by the practitioner performing the procedure.
Supply and storage	• The medication will be kept as stock in the Vascular Access Suite, Breast Care Centre, Interventional Radiology Department and in the ENT OP clinic. • Store below 25^0C
Documentation	• The administration of lidocaine (lignocaine) 1% will be recorded in the Anaesthetic/Procedure Book (Vascular Access Service), screening or symptomatic records (Breast Care Centre) or on the Radiology Information System (CRIS). • Drug, volume, date of expiry, batch number and signature will be recorded.

References:

1. HSC 2000/026: Patient Group Directions, Department of Health, August 2000
2. Summary of Product Characteristics (SPC) – Lidocaine Hydrochloride Injection BP 1%, Advanz Pharma. Accessed via medicines.org.uk, text last revised March 2021

Authorising Personnel

To include signatures of:

- UHL Medical Director or Head of Service/Clinical Director
- UHL Director of Nursing or Senior CBU Nurse
- Chief Pharmacist - Chair of the Medicines Management Group (or designated representative) who approves the PGD on behalf of the Trust

and optionally:

- CMG Lead Pharmacist
- Consultant(s) whose patients will receive treatment under this PGD
- CMG Clinical Governance Manager
- Other authorised senior CMG /Department representative(s) with a PGD responsibility

Signature	Name and position
	**Dr Prashanth Patel** **Clinical Director, CSI**
	**Lisa Lane** **Head of Nursing, CSI**
	**Mohammed Karolia** **Deputy Chief Pharmacist Medicines Optimisation**

Appendix 7: (FNA) Fine Needle Aspiration Biopsy Risk Management Assessment Form

UHL RISK MANAGEMENT ASSESSMENT FORM			Local Ref. No.
CMG/Corporate Directorate / service	CSI/ Imaging	Objective	Performing ultrasound guided fine needle aspiration biopsy with non-safer sharp needles.
Date of Assessment	20.1.2022	Assurance Source *(How was this risk identified)*	introduction of safer sharp devices, to be used where practicable to do so

Risk Description: (Risks must be described using the **If (cause)... then (event)... leading to (effect)** approach)

If (cause)... patients require ultrasound guided fine needle aspiration biopsy it is perfomed with capillary action, this is performed by twisting the needle hub between the forefinger and thumb with simultaneous forward and back motion within the target lesion

Then (event)... if safe sharp needles are used this capillary action can not be performed adequately

Leading to (effect)...
Inadequate cytology sample

Harm (Patient/Non Patients):
- Non diagnostic biopsy
- Increased time to diagnosis
- Risk of complications increases with number of biopsies performed

Reputation:
- Low sample adequacy would fall below expected rate
- Risk to patient & referring team confidence in diagnostic ability
- Risk to service and Trust reputation

Service Disruption:
- Increased number of appointments in radiology and multidicerplinary departments leading to increased capacity issues

Financial Loss:
- Uneceesary apppointments for repeat biopsies
- Cost to perform biopsy
- Pathology time to assess & report

Controls: (List current controls in place under each of the relevant sub headings)

Preventive:
- Sharp safety
- Infection prevention mandatory training complient
- Adequate training and supervision/ robust sign off procedure for performing FNA independently
- Appropriate personal protective equipment
- Adequately stocked and available equipment
- Appropriately sized sharp bins
- Trained Radiology Department Assisstants

Detective:
- Sharp injury
- Datix

Corrective:
- Refresher training
- Risk assess competencies

NB: Paper copies of this document may not be most recent version. The definitive version is held on INsite Documents

Current Risk Rating: (The current risk rating should take in to account the controls currently in place)

Note: Risk should be evaluated for the worst credible case rather than worst conceivable risk

Risk categories: select highest risk subtype score to enter on to Datix risk register – NOTE - Delete risk categories if not applicable to the risk being assessed	Consequence (C)	x	Likelihood (of risk event occurring) – *enter one score for likelihood only* (L)	=	Current Risk Rating
Harm	3	x	2	=	6
Reputation	2	x		=	4
Service Disruption	2	x		=	4
Financial Loss	1	x		=	2

Action Plan: (List what actions have been agreed to treat the risk) *(Copy & paste to add more rows)*

Action Plan	Assigned to	Start date	Due date	Completed date	Cost £
Comply with mandatory training					
Comply with appropriate guidelines					

Target Risk Rating: (The target risk rating should take in to account all actions, above)

Note: Risk should be evaluated for the worst credible case rather than worst conceivable risk

Risk categories: Assess against the same risk categories as per the current risk rating	Consequence (C)	x	Likelihood (of risk event occurring) – *enter one score for likelihood only* (L)	=	Target Risk Rating
Harm		x		=	
Reputation		x		=	
Service Disruption		x		=	
Financial Loss		x		=	

Risk Assessment Approval: (All risk assessments must be approved prior to being entered on to Datix)

Risk Assessor name	Amy Barnes	Line Manager name	Lewis cade	Date approved by Line Manager	26.1.22

NOTE: This Risk Assessment form must be approved by the CMG / corporate directorate Management Team prior to beng ntered on to the Datix risk register. If there is no signature the risk will be suspended on Datix.

Approved by CMG / Director: name		Signature		Date	

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Scoring Guidance: Risk should be evaluated for the worst credible case rather than worst conceivable risk

Consequence score (impact of the event occurring) and example of descriptors					
Risk Sub-type	1	2	3	4	5
	Insignificant	**Minor**	**Moderate**	**Major**	**Extreme**
HARM (PATIENT / NON-PATIENT) (Consequence on the safety of patients/staff/others including physical/ psychological harm)	**No harm.** *e.g.:* *Discomfort.* *No time off work.*	**Minor harm – first aid treatment.** *e.g.:* *Small laceration, sprain.* *Grade 1 pressure ulcer.* *Increase in LoS by 1-3 days.* *Temporary stress / anxiety.* *Intolerance to medication.* *Requiring time off work for <7 days.*	**Moderate harm – semi permanent /medical treatment required up to 1 year.** *e.g.:* *Fracture / dislocation / concussion.* *Sustained stress / anxiety / depression / emotional exhaustion.* *Grade 2 or3 pressure ulcer.* *Healthcare associated infection.* *Increase in LoS by 4 – 15 days.* *Noticeable adverse reaction to medication.* *Requiring time off work for 7 - 14 days (RIDDOR/agency reportable).*	**Severe permanent/long-term harm caused by an event.** *e.g.:* *Loss of a limb.* *Disability.* *Long-term mental illness.* *Grade 4 pressure ulcer.* *Long-term HCAI.* *Retained instruments after surgery.* *Increase in LoS by >15 days.* *Severe allergic reaction to medication.* *Requiring time off work for >14 days (RIDDOR/agency reportable).*	**Fatalities/ permanent harm or irreversible health effects caused by an event.**
REPUTATION (loss of public confidence / breach of statutory duty / enforcement action)	Minimal reduction in public, commissioner and regulator confidence Minor non-compliance with CQC	Minor, short term reduction in public, commissioner and regulator confidence. Single breech of regulatory duty Local media coverage >1 (<3) day	Significant, medium term reduction in public, commissioner and regulator confidence. Single breach of regulatory duty with Improvement Notice Local media coverage >3 days	Widespread reduction in public, commissioner and regulator confidence. Multiple breeches in regulatory duty with subsequent Improvement notices and enforcement action National media coverage >1 (<3) day	Widespread loss of public, commissioner and regulator confidence. Multiple breeches in regulatory duty with subsequent Special Administration or Suspension of CQC Registration / prosecution National media coverage >3 days
SERVICE DISRUPTION	Negligible disruption – service continues without impact	Temporary service restriction (delays) of <1 day	Temporary disruption to one or more Services (delays) of >1 day	Prolonged disruption to one or more critical services (delays) of >1 week	Closure of services / hospital

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FINANCIAL LOSS	0 - £50K annual impact	£50k - £100K annual impact	£100k – £1m annual impact	£1m - £5m annual impact	Annual loss > £5 million impact

How to assess likelihood: The likelihood is a reflection of how likely it is the risk event described will occur with the current controls in place.

Likelihood score	1	2	3	4	5
Descriptor	**Extremely unlikely**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
Qualitatively:	Will probably never happen/recur. Unlikely to happen except in very rare circumstances.	Do not expect it to happen/recur. Unlikely to happen except in specific circumstances.	Might happen or recur occasionally. Likely to happen in a relatively small number of circumstances.	Will happen/recur but it is not a persisting issue. Likely to happen in many but not the majority of circumstances.	Will happen/recur frequently. More likely to happen than not.
Probability:	Less than 1 chance in 1,000 (< 0.1% probability).	Between 1 chance in 1,000 & 1 in 100 (0.1 - 1% probability).	Between 1 chance in 100 & 1 in 10 (1- 10% probability).	Between 1 chance in 10 & 1 in 2 (10 - 50% probability).	Greater than 1 chance in 2 (>50% probability).

Risk score: The risk score is calculated by multiplying the consequence score by the likelihood score.

	← Consequence →				
Likelihood	**1**	**2**	**3**	**4**	**5**
↓	**Insignificant**	**Minor**	**Moderate**	**Major**	**Extreme**
1 Extremely unlikely	1	2	3	4	5
2 Unlikely	2	4	6	8	10
3 Possible	3	6	9	12	15
4 Likely	4	8	12	16	20
5 Almost certain	5	10	15	20	25

RISK RATING (SCORE)	SUGGESTED ACTION REVIEW PERIODS
Low (1 – 4)	Acceptable risk requiring no immediate action. Review annually. Note: Anything with an impact of 5 and above should be discussed at the CMG Board with a view to entering on the risk register.
Moderate (8 – 12)	Review at least quarterly. Place on risk register.
High (15 – 20)	Review at least monthly. Place on risk register.
Extreme (25)	Review weekly. Place on risk register.