Ultrasound Risk Management Policy

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## Version Control

<table>
<thead>
<tr>
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<th>Release</th>
<th>Author/Reviewer</th>
<th>Ratified by /Authorised by</th>
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<th>Changes (Please identify page no.)</th>
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<tbody>
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## Contents

1. Introduction .................................................................................................................................. 4
2. Policy Scope .................................................................................................................................. 4
3. Aim of Policy .................................................................................................................................. 4
4. Duties (Roles and Responsibilities)................................................................................................ 5
5. Definitions .................................................................................................................................... 5
6. Ultrasound Policy .......................................................................................................................... 6
   6.1 Asset Maintenance .................................................................................................................... 6
   6.2 Asset Care ............................................................................................................................... 6
   6.3 Infection Prevention and Control ............................................................................................ 7
   6.4 Recording Results .................................................................................................................... 7
   6.5 Patient Safety, Medico-Legal Requirements, Audit & Governance ....................................... 7
   6.6 Procurement ........................................................................................................................... 8
   6.7 Adverse Incident Reporting and Risk Management ............................................................ 9
7. Training and Standards ................................................................................................................. 10
8. Equality and Diversity ................................................................................................................... 10
9. Monitoring Compliance ................................................................................................................ 10
10. Consultation and Review ............................................................................................................ 11
11. Implementation of Policy ........................................................................................................... 11
12. References .................................................................................................................................... 11
13. Associated Documentation .......................................................................................................... 11
Ultrasound Risk Management Policy

1. Introduction

The Trust-wide Ultrasound Group (TUSG) exists to oversee issues related to diagnostic and therapeutic ultrasound throughout the Trust. The TUSG is made up of a wide range of healthcare professionals representing each clinical area that owns ultrasound equipment and performs their own ultrasound examinations and interventions. The Trust, through the TUSG, wants to ensure that it offers a uniform, high quality ultrasound service both within and out with the Radiology Department minimising clinical risk to patients, staff and the Trust.

2. Policy Scope

• To identify all ultrasound equipment currently in use or newly purchased, throughout the Trust and hold an up to date asset register.

• To establish what each machine is used for and, if necessary, rationalise this with any future purchases, enabling efficient use of resources.

• To advise on ultrasound procurements offering expert advice when required. This may enable bulk purchasing (if appropriate), the benefit of which may be a more competitive price for the equipment

• To establish a reasonable equipment replacement programme (5-7 years).

• To ensure that all ultrasound users have ready access to radiologists/ultrasonographers or other relevant specialised staff for advice.

• To ensure that there is a Clinical Lead User for each department owning US equipment. The Clinical Lead User will be responsible for their department’s equipment and for ensuring that this policy is complied with in full.

3. Aim of Policy

To ensure that all ultrasound examinations and ultrasound guided procedures performed within the Trust are carried out to the highest possible standard, by appropriately trained individuals, using well maintained ultrasound equipment that is fit for purpose and that results are recorded.

In addition, to ensure that:

1. All diagnostic ultrasound examinations and procedures are reported in the Radiology Information System and archived in Picture Archiving and Communication System (PACS) or their equivalents.

2. The images and/or reports of these examinations should be easily and uniformly available to all other diagnostic users for seamless patient care.

3. All ultrasound use to guide interventions is recorded for statistics and coding. Any complications arising from these should also be recorded using an appropriate system eg. RIS and PACS, or, at a minimum, within the medical notes.
4. **Duties (Roles and Responsibilities)**

It is the responsibility of each Clinical Area to nominate a Clinical Lead User. The Clinical Lead User's responsibilities are:

a. To identify all users of ultrasound equipment within their area. This should include permanent staff & rotating junior medical staff and locums.

b. To establish competence of all users.

c. To ensure that all users comply fully with this policy and the trust risk management policies.

d. To ensure that all machines are subject to regular quality assurance, regular electrical tests, have current maintenance contracts and that all faults are reported and acted upon.

e. To ensure that all equipment is comprehensively checked by the Regional Medical Physics Department, or its equivalent, on installation and thereafter on an annual basis.

f. To establish, where possible, PACS connectivity of all ultrasound equipment in order that a permanent record exists of the images of the majority of ultrasound examinations and relevant ultrasound guided procedures carried out across the Trust.

g. To facilitate the reporting of all ultrasound examinations and ultrasound guided procedures where images exist, within the Radiology Information System or its equivalent.

h. To facilitate the recording and coding of all ultrasound guided procedures where no images exist, within the Radiology Information System or the most appropriate equivalent system.

i. To attend the bi-annual TWUS meetings.

j. To nominate a housekeeper who will ensure adherence on a day to day basis with all relevant policies and report any breaches or concerns to the Clinical Lead User.

The Department's College Tutor/Educational Supervisor (who may also be the Clinical Lead User) should ensure that all trainee doctors who will be performing ultrasound examinations comply with the Trust’s Policy for Educational Supervision.

The Department’s College Tutor/Educational Supervisor should ensure that ultrasound is included in the Practical Skills Competency Self-Assessment.

The Department’s College Tutor/Educational Supervisor should ensure that each junior doctor receives the appropriate level of supervision when carrying out an ultrasound examination or guided procedure.

5. **Definitions**

**TUSG:** The Trust Wide Ultrasound Group exists to oversee issues related to diagnostic and therapeutic ultrasound throughout the Trust.

**US Clinical Lead User:** A person who will ensure that all users comply fully with this policy and the trust risk management policies in their own clinical area.
US Equipment Housekeeper: A person nominated by the Clinical Lead User who is responsible for the ultrasound equipment and its use and who will ensure adherence on a day to day basis with all relevant policies and report any breaches or concerns to the Clinical Lead User.

PACS: Using a Picture Archiving and Communications System (PACS) ensures that any images relating to an ultrasound diagnostic or therapeutic procedure are available for review by other staff who may provide any subsequent care to the patient or need to rely upon them for medico-legal purposes.

RIS: Using a Radiology Information System (RIS) or its equivalent ensures that all workload statistics and each episode of imaging is captured and integrated with the other imaging investigations for each patient.

College Tutor / Educational Supervisor: A member of the medical staff who will ensure that each junior doctor receives the appropriate level of supervision when carrying out an ultrasound examination or guided procedure.

6. Ultrasound Policy

6.1 Asset Maintenance

The Clinical Lead User should hold a list of all ultrasound equipment in their area. This should include the following information:

– Age of machine or Date of Purchase / Installation
– Manufacturer
– Model
– Transducers with serial numbers and details of replacements
– Asset register locator
– PACS connectivity
– Maintenance contract with the manufacturer. If appropriate, the annual renewal date must be specified or the total length of the contract.
– Means of procurement (purchase or lease).
– Record of quality assurance tests (internal and external)
– Record of cleaning schedule / 5 measures audits

6.2 Asset Care

The Clinical Lead User may delegate certain responsibilities pertaining to ultrasound in their area such as the general housekeeping issues related to their machine/s. Housekeeping issues include:

– Keeping the machine and it’s transducers safe when not in use

– Ensuring that all equipment is kept clean and falls within 5 measures audits for the local department / clinical area.

– Ensuring that the equipment is stocked with ultrasound gel (coupling agent) and T spray or equivalent (for effective cleaning of scan heads after each examination, according to each specific manufacturers recommendations).

– Ensuring that appropriate measures are in place for transducer disinfection, should there be a risk of cross infection or soiling.
The nominated individual will act as a point of reference for the TUSG.

The nominated individual should be trained (if necessary) to perform regular QA tests on their Department’s ultrasound equipment. They will keep a record of these tests. Advice can be sought on this from Radiology.

The nominated individual should alert the Clinical Lead User to any faults identified by any of the housekeeping or QA measures in place.

The nominated individual will be the contact point for the Regional Medical Physics Department (or its equivalent) who will also carry out regular / annual QA tests on equipment and a record of these tests will be kept.

The nominated individual will be a contact point for the machine manufacturer.

### 6.3 Infection Prevention and Control

The Clinical Lead User, Housekeeper and all other users of ultrasound machines should be familiar with the following Infection Control Policies: IC1, IC3 and IC4. These are general infection control policies and form part of general good practice by all employees.

To comply with the Trust’s Cleaning and Disinfection policy (IC15) the Clinical Lead User and/or Housekeeper should agree a cleaning regime specific to each machine held by their department with Infection Control. The regime should be followed, recorded and made available to the TUSG (Referenced to each individual manufacturer’s guidelines).

A basic regime might be daily cleaning (damp dust with a detergent solution), or cleaning before and after each use. The transducer faces should be cleaned with an appropriate cleaner such as T-Spray II.

If an ultrasound machine is used to examine a patient known to have methicillin resistant staphylococcus aureus infection or Clostridium Difficile infection, the Trust’s Infection Control Policies IC18 or 1C26 should be followed.

### 6.4 Recording Results

It is recognised that many electronic archiving systems exist within the Trust for data, records of diagnostic and therapeutic imaging and interventions. It is not the intention of this policy to cause duplication of efforts. However, there are three main principles which underpin this policy’s ethos.

### 6.5 Patient Safety, Medico-Legal Requirements, Audit & Governance

Each ultrasound scan or ultrasound guided intervention should contribute to patient care. The results/report and/or images should be accessible to the next practitioner attending the patient. Where possible this should progress from paper to an electronic format at every new opportunity.

Every patient (and the Trust) should be confident that any ultrasound scan or guided intervention will be carried out by an appropriately trained and/or qualified clinician who, in turn, has recorded that the scan or guided procedure has taken place and has reported the results and any complications.
This is a minimum requirement for both patient safety and medico-legal purposes. A system should be in place that enables the Trust to have confidence that all users of ultrasound are practise within the scope of this policy.

Furthermore, it is also important that the Trust can be confident that expensive assets are being used wisely, efficiently and safely. The appropriate recording and coding of results will also enable the Trust to recoup the appropriate tariff or funding for that exam and ensure these are ploughed back into the capital program that underpins this Ultrasound Policy.

Where an expansion in services is required, these statistics will be required to underpin any business plan and will also be used to demonstrate compliance with national guidance for ultrasound use.

The following principles should be followed:

- Every ultrasound examination and ultrasound guided procedure performed must be clinically justified.
- When appropriate, informed consent should be obtained from a patient undergoing an intimate ultrasound examination or an ultrasound guided intervention. This should be documented.
- Whenever possible, acquired images should be saved within PACS (picture archiving and communication system) or an equivalent.
- The result of each ultrasound examination and ultrasound guided procedure must be recorded in the RIS or equivalent (albeit to state that a guided procedure took place with no complications).
- In the absence of immediate access to RIS, the examination may be reported retrospectively. In the absence of RIS, a report should be written in the patient’s case notes or an equivalent electronic system.
- Each department/Clinical Lead User is responsible for establishing a means of reporting ultrasound examinations & guided procedures performed in that area. They are also responsible for embedding this practice within their area.

6.6 Procurement

The overall Trust-wide equipment replacement programme is funded from capital which in turn is managed by the Director of Estates and Risk Management.

The TUSG will review Trust-wide ultrasound equipment replacement and make recommendations for allocation of funds on an annual basis. In general the aim will be to replace existing equipment on a rolling 5 year equipment replacement programme. There must be evidence of regular use (images within PACS & reports within RMS or their equivalents). Machines that use old technology and thus pose a risk to patients & the Trust, may be replaced. All faults must be logged and reported.

Replacing Equipment

When an existing machine is due for replacement it is the responsibility of the Clinical Lead User to oversee the process. This includes arranging demonstrations of new equipment,
obtaining quotes, liaising with the Supplies Department and filling out the relevant documentation. The TUSG must be kept informed and can give advice when necessary.

Individual clinical areas wishing to purchase new ultrasound equipment, should prepare their own business case as this constitutes a service development. They must have supporting evidence for the service development. The TUSG must be made aware of the development from the outset as there may be internal solutions available that would allow financial savings for the Trust. Otherwise the TUSG can support and endorse the development.

The business case must then be submitted to the Business Case and Service Development Committee (BSDC). This process should be followed regardless of the source of funding, including Charitable Funds.

When the equipment replacement programme demonstrates that several machines need replacing in the same financial year, every effort should be made to obtain a bulk purchase from a single manufacturer with a view to securing the best deal possible. This may result in two or three departments working together on the same procurement.

### 6.7 Adverse Incident Reporting and Risk Management

Any ultrasound related adverse incident should be recorded by completing an online incident reporting form (DATIX form). Such incidents might include:

- the malfunction of the ultrasound equipment
- inappropriate use of ultrasound
- unnecessary insonation of an individual or fetus
- ultrasound equipment being used by an incompetent individual
- further tests being requested as a result of an individual practising outside their registered scope of ultrasound practice
- ultrasound equipment being used by an individual not listed as a competent user as defined by this document.
- equipment found to be faulty after use by an unregistered party.
- non-recording of results of an ultrasound examination within the patient’s medical records and/or RIS/PACS.

Once a piece of ultrasound equipment has reached the expiry date of its recommended life (5 years as per RCR) it must be risk assessed. This is an assessment of the suitability of the machine being used and the risk of using it for its intended purposes. Advice and expertise should be sought from the Radiology Department in risk assessing pieces of equipment. The risk assessment should follow the process outlined in the Trust Risk Management Strategy (RM1) and be formally documented on the approved Trust Risk Assessment documentation (RM48).

When the piece of equipment has been risk assessed, the risk and scoring must be documented on the Divisional Risk Register, as identified in RM 48 (Local Risk Management Policy/Procedure). On a half yearly basis copies of all the local Divisional Risk Registers should be forwarded to the Head of Corporate Risk. All risks scoring 8 or above will be added to the Trust Risk Register. Risks scoring 15 or above will form a prioritised Risk Register which will be presented to the Board in conjunction with the Corporate Governance Framework. The prioritised Risk Register and Governance Framework will be reviewed by the Board on a quarterly basis. This enables the Board to understand the significant risks identified within individual Divisions and Departments and make decisions based on these.
7. Training and Standards

The Ultrasound Department will provide general advice and provide assistance with training wherever possible. A formal approach should be made to the Clinical Lead Radiologist for Ultrasound.

The Royal College of Radiologists booklet “Ultrasound Training Recommendations for Medical & Surgical Specialities” (RCR, January 2005), provides ultrasound training recommendations in the following areas:

- Urology ultrasound
- Gynaecology ultrasound
- Vascular ultrasound
- Breast ultrasound
- Thoracic ultrasound
- Cranial ultrasound in infants
- Focused emergency ultrasound
- Intensive care ultrasound
- Musculoskeletal ultrasound

The standards laid out within these recommendations are high and may provide Departments with some guidance.

Other Royal Colleges such as the RCOG also have well established training regimes and standards for their members. Individual departments should ensure that their ultrasound practitioners adhere to the standards set out by their governing body.

All permanent members of staff who scan should participate in continuing medical education and professional development. Evidence of this CPD activity should be available at appraisal to inform revalidation.

The Clinical Skills Centre has a skills laboratory which contains two ultrasound machines and an ultrasound simulator. Access to a gynaecology simulator is also available within the Trust. Use of these “state of the art” facilities are encouraged.

Regular audit of the individual’s ultrasound practice should be undertaken to demonstrate the indications, performance and diagnostic quality of the service are all satisfactory.

Each department owning ultrasound equipment and performing their own scans should aim to establish a regular ultrasound discrepancy meeting.

8. Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on the grounds of any protected characteristic (Equality Act 2010).

9. Monitoring and Compliance

Monitoring compliance with this policy will be the responsibility of the Lead Clinical User for each Clinical Area.
10. Consultation and Review

This policy has been reviewed in consultation with the Trust Secretary, Membership Coordinator, Equality and Diversity Coordinator, Counter Fraud Specialist and Trust Risk Management Lead together with comments from staff who have recently been involved in updating policies. The draft has been circulated to divisional managers, service line managers, heads of service, NHSLA leads and other specialist clinical staff for comment.

In particular it has been circulated to members of the trust-wide ultrasound group that represent key clinical users in all clinical areas known to use ultrasound for diagnostic purposes or guidance for interventions. These staff also are invited to sit as members of the Trust Wide Ultrasound Group (TUSG).

11. Implementation of Policy

This policy will be circulated by the Membership Coordinator as detailed below:

The Membership Coordinator will make sure that copies of earlier versions of all polices are archived and stored in line with the Trust Records Management Policy.

When new versions are posted on the intranet, all old versions will be moved to the “archive” section of the document management system and accessed through Corporate Affairs only. The archive date is recorded within the document management system.

12. References

- NHS Information Authority – Data Quality – Policies and Procedures
- NHS Modernisation Agency (2002) Protocol Based Care NICE
- NHS Litigation Authority Risk Management Standards for Acute Trusts
- Equality Act (2010)

The Royal College of Radiologists booklet “Ultrasound Training Recommendations for Medical & Surgical Specialities” (RCR, January 2005)

13. Associated Documentations

The Trust Policies to be followed in conjunction with this policy are:

- RM1
- RM48
- RM30 Policy for Procurement, Management and Use of Medical Devices
- RM44 Local Policy: Authorised Users of Medical Devices
- RM45 Training Policy for Medical Devices
- RM04 Incident Reporting
- IC1
- IC3
- IC4
- IC18
- IC26