Name of Policy: Ultrasound Risk Management Policy

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This policy supersedes all previous issues.
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Gateshead Health NHS Foundation Trust

Ultrasound Risk Management Policy

1. Introduction

The Trust-wide Ultrasound Group (TUSG) has been established to oversee issues related to diagnostic ultrasound throughout the Trust. TUSG is made up of a wide range of healthcare professionals representing each department that owns ultrasound equipment and performs their own ultrasound examinations. The Trust, through 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. Scope of Service

- To identify all ultrasound equipment currently in use or newly purchased, throughout the Trust.
- To identify all users of ultrasound equipment
- To establish what each machine is used for and, if necessary, rationalise this with any future purchases, enabling efficient use of resources.
- To ensure that all machines are subject to quality assurance and electrical tests and have current maintenance contracts.
- To ensure that all equipment is comprehensively checked by the Regional Medical Physics Department, on installation and thereafter on an annual basis.
- To establish competence of all users
- To establish PACS connectivity of all ultrasound equipment where possible in so doing a permanent record of the images of the majority of ultrasound examinations and ultrasound guided procedures carried out across the Trust will exist.
- Facilitate the reporting of all ultrasound examinations and ultrasound guided procedures within the Radiology Information System.
- TSUG is to be involved in all future ultrasound procurements offering expert advice when required. This will 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 establish password protection of all ultrasound equipment to prevent unauthorised use.
- To ensure that all users have ready access to radiologists/ultrasoundographers or other relevant specialised staff for advice.
- To ensure that there is a Clinical Lead User for each department who will be responsible for the equipment and implementing the Trust-wide Use of Ultrasound policy.
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. In addition, all examinations and procedures are to archived/reported in the Radiology Information System and Picture Archiving and Communication System.

4. Roles and Responsibilities

It is the responsibility of each Department to nominate a Clinical Lead User who will take responsibility for ensuring that all those who use the ultrasound equipment comply fully with the Trust Risk management Policies RM30, RM 44 and RM 45.

The Clinical Lead User should keep a list of registered users. This should include permanent staff members and, where relevant, the names of rotating junior medical staff or locum staff who intend to perform ultrasound examinations. They should be made aware of this policy on induction to the Trust.

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.

The Clinical Lead User is expected to complete the Self Compliance Tool, (see appendix 9), on an annual basis and return this information to both the chair of the TUSG and the Trust Clinical Risk Manager.

5. Care, Maintenance and Infection Control

Each Department should hold a current list of it’s ultrasound machines. The information to be on this list should include: age, manufacturer, model, transducers, serial numbers, asset register locator, PACS connectivity and whether there is an ongoing maintenance contract with the manufacturer. If a maintenance contract exists the annual renewal date must be specified. The TUSG should hold a copy of this.

- Each Department should nominate an individual to be responsible for the general house keeping issues related to their machine/s: This may be the Clinical Lead User or another individual (Housekeeper).
Housekeeping issues include keeping the machine and its transducers in a safe place when not in use, ensuring that they are kept clean, ensuring that the equipment is stocked with ultrasound gel (coupling agent) and T spray (for cleaning scan heads after each examination).

- The nominated individual will act as a point of reference for the TUSG.
- The nominated individual will be trained (if necessary) by Radiology staff to perform regular QA tests on their Department's ultrasound equipment. They will keep a record of these tests.
- The nominated individual will be the contact point for the Regional Medical Physics Department who will also carry out regular QA tests on equipment and a record of these tests will be kept.
- The nominated individual will be the contact point for the machine manufacturer.
- 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. A basic regime might be daily cleaning (damp dust with a detergent solution), or cleaning before and after each use.
- 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. Recording Results

- Every ultrasound examination and ultrasound guided procedure performed Trust-wide must be clinically justified.
- Whenever possible, acquired images should be saved within PACS (picture archiving and communication system).
- The result of each ultrasound examination and ultrasound guided procedure must be recorded in RIS (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.

7. 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.
- Individual departments wishing to purchase new ultrasound equipment, should prepare their own business case. This should be presented to the TUSG in the first instance. With the endorsement of the TUSG, the business case can be submitted to the Business Case and Service Development Committee.

- The department should state which machine they wish to replace and provide a specification for the machine they wish to acquire.

- Demonstrations of new equipment should be arranged by individual departments. The TUSG will readily give advice when necessary

- The TUSG will endeavour to make bulk purchases from a single manufacturer to obtain the best deal possible.

8. Standards/Training

- The Ultrasound Department will provide general advice and provide assistance with training wherever possible.
- 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.
- All permanent members of staff who scan should participate in continuing medical education and professional development.
- 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.
- The TUSG will audit a Department’s adherence to the overall ultrasound operational policy.

9. 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
- ultrasound equipment being used by an individual not listed as a competent user as defined by this document.
- Non-recording of results of an ultrasound examination within the patient’s medical records and/or RMS.

Once a piece of ultrasound equipment has reached the expiry date of it’s 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 it’s 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.

The Trust Risk Management Policies to be followed in conjunction with this policy are:
- 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
Appendix 1

Accident & Emergency

Focused assessment with sonography in trauma (FAST), extended FAST scan (to look for pleural fluid) and assessment for abdominal aortic aneurysms takes place in A&E. These scans cannot be anticipated and therefore cannot be booked in on DICOM worklist in advance.

The stored images, therefore, should be downloaded into PACS retrospectively as their review may be useful for follow up imaging and/or medicolegal purposes. Downloading can be performed at a convenient time by a nominated individual. The regularity with which this is carried out depends upon the number of scans that take place on a daily/weekly basis.

With regard to the reporting of scans, it is not expedient to report them in RIS in an emergency situation. At this time, a hand written report will suffice. Full reports should be entered into RIS retrospectively, using the paper sheets completed at the time of the scan. This can be undertaken by secretarial staff transcribing the handwritten report. Short codes can be created to facilitate this.

For the future, focused echocardiograms and ultrasound guided central line insertion will take place in A&E. The results of these scans should be recorded as described above. It is acknowledged that video and cine-loops may be difficult to archive and local arrangements may be necessary.

It should be noted that to be medicolegally acceptable all images, thermal or otherwise, should display the patient’s name, DOB and the correct date and time wherever possible.
Appendix 2

Critical Care

The Critical Care Department (CCD) use ultrasound to guide insertion of central venous catheters (CVC). In general no images are acquired and therefore there is no requirement for PACS.

An ultrasound guided procedure however has taken place and should be reported in the patient’s medical records and ideally in RIS. The report can be entered into RIS retrospectively by a nominated individual (secretarial staff) on a weekly/twice weekly basis depending on numbers. To facilitate this, a record of all patients who have had an ultrasound guided line inserted should be kept and a report short code can be created in RIS. For example: “CVC inserted under ultrasound guidance with no immediate complications”

The CCD may decide how much detail they wish to add onto the RIS. For instance the site and type of line inserted, number of attempts, etc.

If complications were to arise following a guided line insertion the details should be entered into the patient’s notes and RIS. The relevant clinician may choose to do this themselves or use dictation with secretarial support entering the details into RIS.

This principle should be followed for other types of imaging or ultrasound guided procedures carried out by CCD staff i.e. US guided nerve blocks, limited echocardiography, chest drainages, etc.

If diagnostic scans are carried out, these should follow the guidance and standards set out for diagnostic radiology. It should be noted that to be medico-legally acceptable all images, thermal or otherwise, should display the patient’s name DOB and the correct date and time wherever possible.
Appendix 3

Womens Health

Many of the ultrasound examinations and the ultrasound guided procedures that take place within this department can be anticipated. Therefore, examinations can be booked into PACS and RIS in advance. This enables the creation of a DICOM worklist which generates accurate information from which patient files are created within PACS. These include booked lists of dating scans, anomaly scans, growth scans, biophysical profile assessments, EPAU scans, scans generated from termination clinics and the majority of scans performed within the IVF Unit (follicle tracking, egg collections, etc.). Once such scans have taken place, they should be reported within RIS using the RIS Obstetric Reporting package as required.

Those scans that cannot be anticipated within this department are the scans carried out on an on-call basis, (presentation scans, placental localisation, viability). The result of such a scan should be written in the patient’s notes and entered into RIS retrospectively. The stored images can be downloaded in PACS by a nominated individual on a regular basis depending upon the frequency of such examinations.

If using a non-DICOM compliant machine, thermal images should be printed and stored in the patient’s notes. This is currently highly likely as both machines in Maternity are not DICOM compliant (Toshiba Nemio and Aloka SSD 1000).

It should be noted that to be medicolegally acceptable all images, thermal or otherwise, should display the patient’s name, DOB and the correct date and time wherever possible.
Appendix 4

Endoscopy/Urology

Transrectal ultrasound of the prostate gland and ultrasound guided prostatic biopsy take place in this location.

The scans carried out in this area can be anticipated, Therefore they can be entered onto a DICOM worklist and archived on PACS. Similarly, the examinations can be reported into RIS. This can be performed on a contemporaneous basis by the clinician concerned. Alternatively, the clinician may opt to dictate their reports which can be entered into RIS by their own secretarial staff.

Bladder volume are scans carried out in the Urology Clinic by a Nurse Specialist. These scans are performed on every patient who attends this clinic and the result of the scan is recorded in the patient’s medical records. With the agreement of the TUSG, these examinations are exempt from being entered into PACS and RIS.

It should be noted that to be medicolegally acceptable all images, thermal or otherwise, should display the patient’s name, DOB and the correct date and time wherever possible.
Appendix 5

Vascular Surgery

The Department of Vascular Surgery carry out scans for abdominal aortic aneurysm screening. These are carried out in the community (Healthcare Centres & GP Practices). The machine currently in use archives to CD only, but in future may be replaced by a fully DICOM compliant system.

This work can be anticipated and as such can be booked on DICOM worklist in advance. When the examinations are carried out the images are stored on the ultrasound machine’s hard drive. These images should be downloaded into PACS retrospectively. This task can be performed at a convenient time by a nominated individual.

Handwritten reports are issued contemporaneously on these scans. The handwritten report should be entered into RIS retrospectively.

It should be noted that to be medicolegally acceptable all images, thermal or otherwise, should display the patient’s name, DOB and the correct date and time wherever possible.
Appendix 6

Echo-Cardiography

The scans performed in this department are archived according to local policy as they are largely moving clips and cannot be currently stored to PACS.

The reports are also in a different format to a standard text report and are archived according to local departmental policy.

In all other respects, the guidelines outlined in this policy should be achievable for the equipment owned by Cardiology. However, thought should be given to using the RIS for data generation such as numbers of scans performed, etc. if computerised systems do not currently exist to record this.

This Department’s expert opinion may be sought by the TUSG for areas of focused practice outwith Echocardiography e.g ICU and A&E where some staff have taken a focussed echo course or module.

It should be noted that to be medicolegally acceptable all images, thermal or otherwise, should display the patient’s name, DOB and the correct date and time wherever possible.
Appendix 7

Gynae-Oncology

UKTOCS is currently exempt from PACS as it is not DICOM compliant. The images are stored onto CD roms and thermal paper.

The reports are transcribed from paper proformas onto the specific computer system used by the national ovarian screening programme. It would therefore be inappropriate to include this under this policy. It is therefore inappropriate to use the RIS system. In addition this national trial will be closing in 2008.

Any examinations carried out on this equipment by either a sonographer or a member of the medical staff for diagnostic purposes and not as part of the trial, should be reported in RIS. Thermal images of the examination should be stored with the patient’s medical records. The patient’s name and the date and time of the examination should be on the images.
Appendix 8

Breast Unit

All breast ultrasound examinations carried on symptomatic patients rather than those from the screening programme should be reported in RIS and images stored in PACS.

It should be noted that to be medicolegally acceptable all images, thermal or otherwise, should display the patient’s name DOB and the correct date and time wherever possible.
Appendix 9

**Self Compliance Tool**

Can you identify all ultrasound equipment currently in use in your department? Please list machines (make, model, age and locations).

Can you identify all users of ultrasound equipment in your department:
- Consultants, junior doctors, non-medical staff?
- NB. There should be a scheme of work in place for non-medical staff to govern the delegation of ultrasound skills and responsibilities for reporting.

What are the ultrasound qualifications of your users?
- If no formal qualifications, what training have they had?

What is each machine in your department used for?
- How many sessions or percentage of time is it in use?
- How many scans are performed per session on each machine?

Is each machine subject to regular quality assurance (QA)?
- How frequently? Who does the tests? Where are the results kept?
- Does each machine have annual electrical tests?
- Does each machine have a current maintenance contract?
- Please specify the date of renewal for the maintenance contract.

Is all equipment comprehensively checked by the Regional Medical Physics Department on installation and thereafter on an annual basis?
- When was it last done? Where do you keep the records?

Which of your departments' machines currently have the potential for full PACS connectivity? i.e they should have DICOM send, DICOM print and DICOM worklist.
- Is password protection possible on your current ultrasound equipment?

Does your department currently keep a permanent record of the images of each ultrasound examination and guided procedure carried out?

Does your department report all ultrasound examinations and ultrasound guided procedures?
- How is this currently achieved:
  - Within the notes?
  - Within your own computer system?
  - Within the Radiology Information System (RIS)?

Who is your nominated Clinical Lead User – they will be responsible for the equipment and implementing the Trust-wide Use of Ultrasound Policy?

If not the same person, who will ensure compliance with the policy on a day to day basis? This may be a member of the nursing staff, a midwife or other non-medical person.