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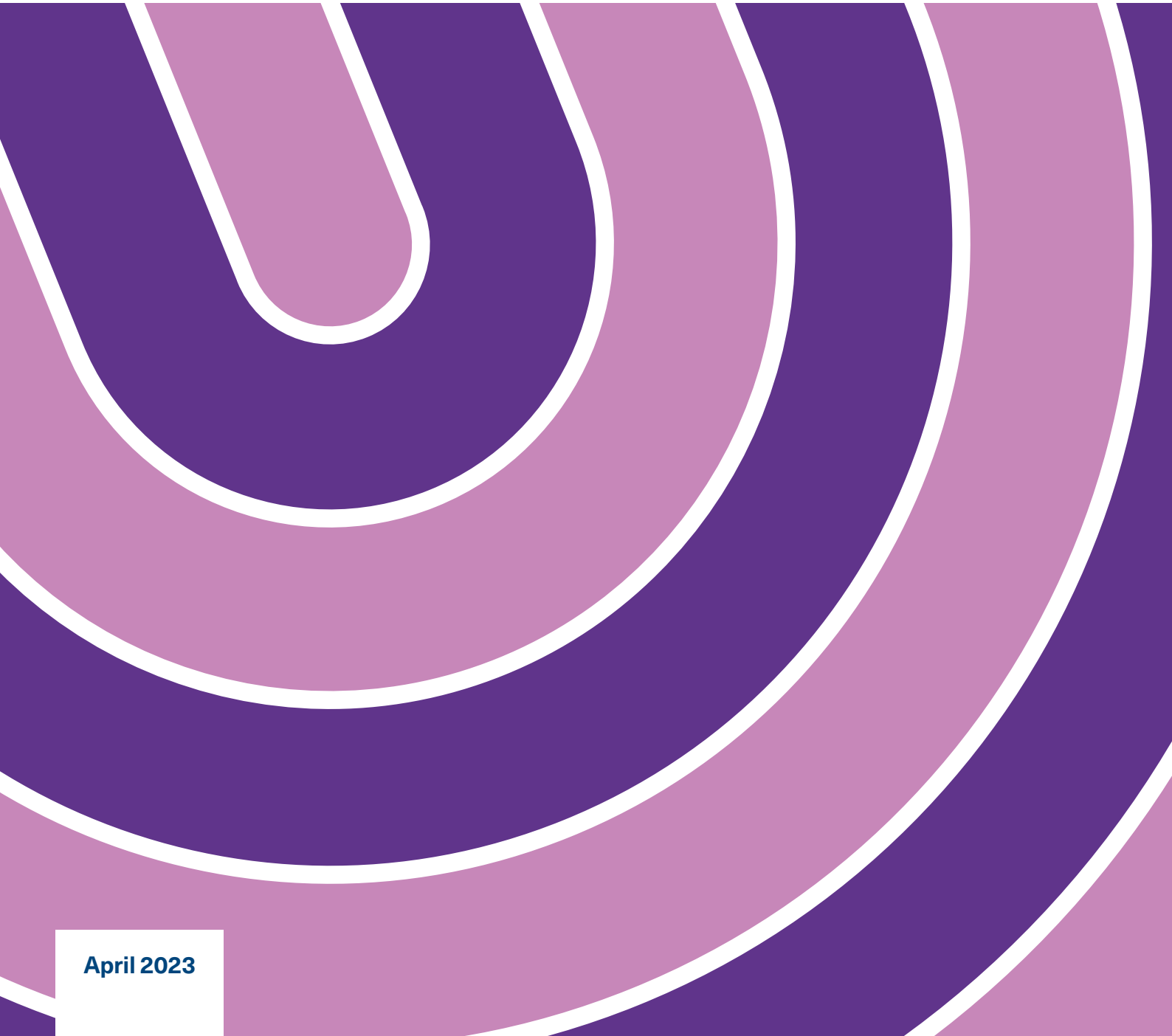
BMUS

Clinical Radiology
The Royal College of Radiologists

Recommendations for specialists practising ultrasound independently of radiology departments

Safety, governance and education

A joint collaboration by the British Medical Ultrasound Society and The Royal College of Radiologists



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1 Introduction

Clinical ultrasound is being embraced by many health professionals other than radiologists or sonographers working in traditional departments of radiology. This is testament to the flexibility and versatility of the modality and technology in aiding and expediting patient care and management.

Where the use of point of care ultrasound (POCUS) is becoming increasingly routine, clinicians can be helped by guidance on how they can ensure their own practice can be demonstrated as safe and the rapidly developing range of applications do not outpace the existing governance and safeguards for good clinical care. It is thus important to have a generic framework of standards that engenders best practice among all users of ultrasound. It is essential that there is also good collaboration between all departments, in particular radiology departments, information technology leads and clinicians who undertake ultrasound.

This guide offers a framework for good clinical ultrasound practice, primarily aimed at ultrasound practitioners not working under the umbrella of a radiology department. Good governance is essential for the safety of the patient and protection of the practitioner. This document is intended to be used as a checklist for novice users, a reference source for experienced users and a good-practice guide for radiology departments collaborating with POCUS users.

It is important to emphasise that the scope of practice for each individual should be commensurate with their level of training and that these users should also maintain training standards in ultrasound as relevant to their clinical practice.

2 Governance of ultrasound equipment

POCUS imaging scanners cover a wide variety of equipment that can range from cart-based scanners, to portable laptop scanners, to handheld scanners. This ultrasound equipment has two principal components:

- The transducer
- The associated beam-forming, data processing and image-display components.

The coupling of these two components is at present done in two ways.

- For cart-based scanners and laptop scanners this is done through traditional multiplexed cables and ports.
- For transducers connected to mobile and tablet devices this is done with USB cables or wirelessly. When the transducer is under the control of mobile and tablet-based devices, the use of application-based software increases the variety of scanner architecture that is used to form and display the ultrasound image.

Unlike traditional primary diagnostic cart-based ultrasound scanners, POCUS scanners can be relatively inexpensive. Often their cost falls below that required for a formal finance application to justify purchase.

The combination of low cost, plurality of clinical applications and ease of use of POCUS equipment has resulted in a rapid increase in the number of POCUS devices. This has clear clinical benefits, but it also poses clinical risks if there is not good governance of their use. Paramount to this is the involvement of a medical physicist who should be consulted, and where appropriate a commensurate service contract should be in place to include maintenance and quality assurance (QA) of these scanners. Ideally, all ultrasound equipment maintenance should be centralised and under the responsibility of a clinical engineering team.

To provide a structure under which good equipment governance can be achieved, the following are proposed.

- Include a governance policy for POCUS equipment where the main elements of good governance are based around administrative controls.
    a. Appoint a lead who will:
        i. Oversee the purchase of POCUS equipment and maintain an up-to-date asset register
        ii. Ensure a list of authorised users is maintained
        iii. Establish training records for authorised users
        iv. Maintain a list of standard operating procedures for clinical scans
        v. Ensure that the use of personal mobile or tablet devices is avoided where possible – when personal devices have to be used to perform the scan, the appointed lead must be aware and local governance procedures must be followed
        vi. Ensure that national requirements for data security and image storage are fulfilled (see section 3f ‘Image storage and data protection’)
        vii. Ensure that appropriate clinical presets are available on the scanner
        viii. Ensure that regular QA checks are performed.

b. Ensure that there are procedures for:
   i. Acceptance testing of POCUS equipment (see Appendix 1)
   ii. Regular checks of image-quality performance of POCUS equipment
   iii. Regular QA checks of POCUS equipment
   iv. Day-to-day care of the equipment and fault reporting[1]
   v. Ensuring clinical presets follow national and international guidelines on scanner output, in particular for lung, neonatal/obstetric and ophthalmic applications
   vi. Collaborating with medical ultrasound physicists where appropriate.

- All clinical users must have a good understanding of the operation of POCUS scanners and how this relates to both image quality and safety. In particular, the following areas should form part of an educational ultrasound training programme.
  a. An understanding of the operation of devices:
     i. Availability and use of time gain compensation control
     ii. Availability and use of Doppler modes
     iii. Availability of M-mode
     iv. Availability of focus control where available (note: on some systems this automatically changes when altering the depth)
     v. Availability of beam steering in colour Doppler mode
     vi. Awareness of the use of image processing and artificial intelligence (AI) algorithms in the image formation process; AI is likely to play an increasing role in the work of all ultrasound users and they must be aware of its impact on their decision-making
     vii. An understanding of safety guidelines and the safety indices displayed on a scanner (see Appendix 1)
     viii. An awareness of current safety limits (see Appendix 2).

Equipment hygiene and use of ultrasound gel

Ultrasound equipment, including particularly the transducer and ultrasound coupling gel, is a known source of bacterial cross-infection between patients.[2] Therefore, after every procedure, practitioners must take appropriate care to clean equipment, change personal protective equipment and observe good hand hygiene. General guidance is found in the Society of Radiographers (SoR) and British Medical Ultrasound Society (BMUS) *Guidelines for Professional Ultrasound Practice*, updated annually. www.bmus.org/media/resources/files/SoR_and_BMUS_guidelines_2022_7th_Ed.docx.pdf.

Recommended methods for cleaning transducers, including hand-held devices, vary depending on manufacturer and transducer composition. Practitioners should seek guidance directly from the manufacturer if it is not supplied with the device at the time of purchase. Simple information on transducer decontamination and a best-practice summary can be downloaded in poster form at www.bmus.org/policies-statements-guidelines/professional-guidance/guidance-pages/ultrasound-transducer-decontamination/.

POCUS users must be aware of when and how to use sterile and non-sterile ultrasound gel. In 2021, the UK Health Security Agency provided guidance, including a decision tree, on safe use of appropriate ultrasound gel in a range of high-risk and low-risk healthcare

settings. Details on gel type, shelf life, storage and removal from skin surfaces are included. This guidance is of particular relevance to three groups of POCUS users:

- Those performing interventional procedures
- Those who may be caring for vulnerable patients such as in intensive care units, neonatal units or cancer wards
- Those practising ultrasound infrequently, such as in remote clinics, whereby the safe shelf life of gel may be exceeded.

Full details can be accessed at www.gov.uk/government/publications/ultrasound-gel-good-infection-prevention-practice.

3 Governance in the use of ultrasound

As in all areas of healthcare, good clinical governance in ultrasound helps to maintain quality of service and has multiple benefits. It is the framework through which organisations can continually monitor and improve services. Clinical governance includes QA, quality improvement, and risk and incident management. Primarily, it helps to ensure a high standard of care to the patient, thus safeguarding the patient and optimising the benefits of the procedure/examination performed. Clinical governance aids standardisation of best practice across providers, thus ensuring the highest standards of care provided. Furthermore, it facilitates detection of suboptimal care so that timely methods may be implemented to recover and improve.

Robust clinical governance procedures help to protect the practitioner by ensuring optimum and evidence-based care pathways are followed. Practitioners are accountable for their actions, and, in a UK court of law, it is expected that any ultrasound scan or ultrasound-guided procedure must be performed in a safe, competent manner and to a minimum standard, regardless of the experience or professional background of the person carrying out the POCUS scan.

a. Education and training

Ultrasound imaging carries no radiation burden and, in trained hands, looks very easy to do. These factors can be significant drivers for misuse of this most versatile modality.[3,4] All ultrasound users and their employers should not underestimate the cost of misdiagnosis to both patient and healthcare organisation if the user has failed to seek and complete appropriate training and assessment. Traditionally, radiologists have placed themselves at the forefront of training others,[5] but in view of the explosion of ultrasound applications, it is acknowledged that POCUS users must take responsibility for their own clinical education by following an established training curriculum from established POCUS groups and courses. Such courses seek to ensure that training is at the appropriate level and fit for purpose. It should be stressed that accreditation and quality control from certified bodies appropriate for the individuals' specialty are essential. These often follow a general framework of a theoretical phase including ultrasound physics and governance, an experiential phase documenting logbook experience with a supervisor and an assessment phase with formal assessment by an experienced practitioner. Beyond this, an attempt must be made to demonstrate maintenance of skills via continuing professional development (CPD).

Skills associated with ultrasound imaging

The professional values, knowledge, skills and behaviours associated with being an effective user of ultrasound are multiple and complex.[6,7] The psychomotor skills required for safe, competent scanning are often developed over a long learning curve,[8] including much practical training. In addition to acquiring the necessary spatial awareness, further skills such as the ability to interpret and record findings and arrange safe onward management for the patient, be it discharge, further tests or intervention, also need to be learned before the practitioner is deemed fit to practise in an unsupervised capacity. Therefore, a multilayered approach to learning is required and will comprise both clinical and theoretical components regardless of the trainee's background or their intended use of ultrasound.

Clinical training

Supervised clinical practice is essential during the training period. The trainee must be supported by an experienced named mentor throughout training and must always be supervised by a qualified individual until they have proven competence. It is acknowledged that supervision may be a combination of direct, remote and retrospective supervision and image review.

Practical training elements may comprise both 'real-life' clinical settings with patients and classroom settings using volunteers, simulators and phantoms. Currently, there are many high-quality sophisticated ultrasound simulators available that mimic human tissue and pathologies. In addition, low-budget home-made phantoms aid orientation and psychomotor skill development in novices. These training aids expedite learning, ease the training burden on busy departments and allow individuals to hone their skills in a safe, unpressured environment.[9–11] It is recommended therefore that trainees, where possible, access phantoms and simulators early on in their training programme.

Progress

Further core aspects of clinical training include as a minimum:

- Patient care
- Patient and staff communication
- Timeliness of examination and complementary imaging
- Equipment controls
- Equipment care, QA and fault recognition
- Image acquisition and interpretation involving normal, abnormal and equivocal conditions
- Storage of images
- Report writing
- Onward recommendations and management.

The trainee's ability in these areas must be monitored and reviewed regularly for progress, with comments recorded for retrospective analysis by their trainers. Progress sheets should be simple and consistent and should include comments from direct observational assessments. Input from the trainer and trainee are essential.

In some settings, logbooks containing case numbers may be suitable methods for evidencing progress. However, it is unwise to stipulate minimum numbers of normal and abnormal cases a trainee should collate since the speed of reaching safe practice and competence is highly variable between individuals.[12,13] Regular, timely progress reports from the named mentor and supplemented by supervising individuals within the team will ensure the trainee remains focused, supported and self-aware.

In the event of discontinuity of mentorship, either because the trainee is rotated to a new placement or because the mentor has withdrawn, a new mentor must be found and new agreements established.

A robust summative assessment of competence must take place before the individual is deemed fit to practise unsupervised. After reaching competence, a short preceptorship period is recommended to ease the sharp transition between trainee and newly qualified novice practitioner.

Suboptimal performance

The training period for the trainee and the number of attempts allowed for passing a summative assessment must be agreed in advance. For those not reaching the expected milestones in the agreed time frame, and in the absence of extenuating circumstances, a clear action plan should be devised, providing evidence of practice to date, feedback given, progress targets missed and a new and final deadline offered.

b. Education and training: finding specific pathways

Many UK medical colleges and professional societies already have well-established, high-quality ultrasound training programmes, which are tailored to the clinicians' needs and are fit for purpose. Furthermore, some clinical departments will have developed a long history of ultrasound training and have reached a critical mass of experienced ultrasound practitioners who are now in a position to cascade training to others. Where possible, we recommend that individuals seek the right accredited programme dependent on their specific professional background and/or clinical specialty by initially contacting their respective senior clinical colleague or medical college for advice. It is important to emphasise that ultrasound courses are growing rapidly in number, are unregulated, may be transient and may not necessarily be of the right standard. Therefore, practitioners seeking training should identify robust courses that, as a minimum:

- Are recommended by their professional organisation/college
- Include physics, instrumentation and safety elements
- Cover theoretical elements including evidence-based practice, complementary imaging and diagnostics, recording and storing data, medicolegal implications and governance
- Have a clinical/practical element including patient care, image acquisition, interpretation and disease appearances
- Include both formative and summative assessments of competence
- Encourage audit and CPD after successful completion of training.

Accredited ultrasound courses

A number of UK universities offer routes into ultrasound, mostly at postgraduate level. These range from short, focused courses to modular programmes designed to lead to a full Master's qualification. The accrediting body for such courses is the Consortium for the Accreditation of Sonographic Education (CASE), which comprises seven member organisations with a key stake in ultrasound training. Details of CASE composition and activity can be found at www.case-uk.org.

Practitioners, regardless of healthcare background, are eligible to enrol on a CASE-accredited university course provided they meet the entry requirements. In the absence of an established, profession-specific course, individuals using or hoping to use ultrasound within their clinical practice are encouraged to explore the CASE course directory and seek guidance from university course leaders. Information regarding POCUS training opportunities can also be found at www.bmus.org/education-and-cpd/cpd-resources/specialty-pages/npocus.

Free learning resources

To supplement learning, an educational resource, *e-Learning for Healthcare*, has been produced by NHS England in collaboration with the NHS and professional bodies, including The Royal College of Radiologists, The Royal College of Emergency Medicine and College of Radiographers.

e-Learning for Healthcare is available online and is free to NHS staff once registered at www.e-lfh.org.uk, and e-learning sessions under the following titles may be of particular use to those seeking supplementary ultrasound education: Clinical Imaging, Radiology R-ITI, Emergency Medicine, ICE-BLU, FAMUS and ISUOG lecture libraries.

c. Continuing professional development (CPD)

A commitment to lifelong learning and CPD is required of all healthcare professionals in order to remain up to date, develop throughout their careers and deliver the highest service standard by providing evidence-based best practice. CPD helps to improve safety and quality of care for patients. Ultrasound users must engage with CPD to maintain and improve their sonographic practice, including for the following reasons:

- Variable imaging appearances of disease processes
- Advances in image resolution and equipment technology
- Educational developments and new initiatives
- Changes to national and international guidance and recommendations.

Quality CPD

CPD emphasis is moving towards a more holistic system, focused on quality of CPD rather than quantity. Professional and personal development requires analysis and evaluation of events through reflection. The RCR and BMUS endorse this model and encourage individuals to recognise and engage with CPD events regularly and keep a simple record of the impact or outcome of the event on their practice. Individuals should undertake a mix of CPD activities, including work-based activities, formal study and self-directed learning, as well as attending relevant courses and educational/scientific meetings.

The following table, although not exclusive, may be used as a framework to aid practitioners' understanding of CPD and CPD activities.

CPD type	Example	Possible activities
Clinical practice		
Maintain existing skills	▪ Detection rate for a specific condition (eg, proximal leg DVT) ▪ Understand 'rule-in' techniques (eg, FAST) ▪ Ultrasound-guided suprapubic bladder catheterisation ▪ Ultrasound-guided musculoskeletal steroid injections ▪ Fetal measurements, uterine and fetal Doppler assessments	▪ Work with others ▪ Self-audit ▪ Peer review ▪ Access e-learning material ▪ Identify best practice by reading contemporary research papers and current national guidance
Upskill in an additional or advanced ultrasound application	▪ Cardiac measurements ▪ Calf vein assessment ▪ Ultrasound assessment for cholecystitis/ appendicitis ▪ Nerve blocks ▪ Fetal cardiac screening ▪ Vascular access	▪ Shadow a more experienced colleague or staff from other professions ▪ Attend a webinar/study day ▪ Enrol for formal study ▪ Identify best practice by reading contemporary research papers and current national guidance
Encounter unusual, equivocal or challenging imaging appearances	▪ Tumour-mimicking conditions ▪ Old venous thrombus on new ▪ Malformations and variants	▪ Seek second opinion ▪ Follow up further imaging ▪ Discuss at multidisciplinary team (MDT) or discrepancy/ learning meetings ▪ Read contemporary research papers ▪ Submit a case report for publication

CPD type	Example	Possible activities
Patient communication	▪ Explaining the limitations and/or uncertainty of ultrasound ▪ Gaining consent for a procedure ▪ Giving upsetting news ▪ Receiving a written complaint or note of gratitude from a patient	▪ Shadow a more experienced colleague or staff from other professions ▪ Access e-learning material ▪ Reflect on patients' and relatives' responses and perform a feedback audit/exercise
Report writing	▪ Clarity, safety and precision of reports produced	▪ Shadow a more experienced colleague or staff from other professions ▪ Peer review ▪ Discuss at MDT meeting ▪ Discuss at discrepancy meeting ▪ Audit performance using GAP tool or similar
Technology		
Upgrading ultrasound machine	▪ Replace or add an ultrasound device	▪ Engage with applications specialist ▪ Seek advice from medical physics ▪ Watch instruction videos
Changes to ultrasound transducers	▪ New biopsy guide/new software package	▪ Engage with applications specialist ▪ Seek advice from medical physics ▪ Watch instruction videos ▪ Access available literature ▪ Network with experienced staff at other sites

CPD type	Example	Possible activities
Learning new image storage and reporting method	▪ Train to access and use picture archiving and communication system (PACS) or cloud-type platforms	▪ Engage with trainer ▪ Watch instruction videos ▪ Access available literature ▪ Network with experienced staff at other sites
National/international guidance		
Change in practice	▪ Publication of new guidance or recommendation ▪ National or international recommendation update or amendment ▪ Change in government policy	▪ Review new guidance and compare with old ▪ Discuss with relevant peers and key stakeholders ▪ Consider implications for amending practice ▪ Consider impact on patients and associated services ▪ Consider review after suitable time interval

d. Audit

Regular audit of an individual's practice should be undertaken to demonstrate that indications, performance and diagnostic quality of the ultrasound service are satisfactory and in keeping with recommended national standards. Clinical audit templates and 'recipes' are available from the RCR, BMUS (the BMUS Recommended Audit Tool is at www.bmus.org/policies-statements-guidelines/professional-guidance/guidance-pages/bmus-recommended-audit-tool) and also in the *Best Practice in Clinical Audit* document produced by the Healthcare Quality Improvement Partnerships (HQIP) and available at www.hqip.org.uk/resource/best-practice-in-clinical-audit/#.Ybhok73P02w.

In order to facilitate the learning experience from 'misses', incorrect interpretation or any significant related incidents, attendance at regular discrepancy and case conference meetings is encouraged, within either the individuals' own specialty or the radiology department. It is also helpful to share teaching cases and examples of best practice at these meetings, and the RCR radiology events and learning meetings (REALM) are a good example of how to approach this at a departmental level. A pathway to handle and learn from significant incidents should also be in place. It is not advisable for individuals to practise ultrasound in isolation and undertake no external audit.

e. Record-keeping

The documentation of POCUS scans in patients' records, ideally with images where appropriate, is essential and should be saved in an accessible but password-protected permanent repository such as a PACS or cloud-based platform. The lack of this permanent record may cause harm through inability to review examinations, repeat unnecessary imaging and inappropriate interval follow-up scanning. It is also important to emphasise that consultation with a radiologist or person of appropriate expertise is advised in indeterminate cases to ensure that the most appropriate imaging or tests are performed within an appropriate time frame.

As a minimum, therefore, practitioners performing these scans must have a means of documenting the event, recording findings and archiving images for medicolegal purposes.

The expected standard for best practice is that all POCUS imaging is recorded permanently and is accessible to all involved with the patient's care. It is appreciated that some POCUS examinations, such as ultrasound-guided procedures, do not require saving images. Furthermore, storage of large cine loops may be problematic, but a permanent report indicating that the procedure took place must be recorded in the patient's notes and be readily accessible to other healthcare professionals.

It is recommended that POCUS reports must include at least: time, date, location, practitioner name and grade, reason for the examination, clinical area (such as pelvis, lung, shoulder or FAST), outcome, complications if any and subsequent action or recommendation if appropriate. A recommended simple report template is available at www.bmus.org/static/uploads/resources/Best_practice_PoCUS_governance_statement_combined.pdf.

f. Image storage and data protection

Even before a POCUS machine is put into routine use a careful assessment is required to ensure that GDPR (EU 2016/679),[14] DPA (2018) legislation[15] and NHS Digital requirements[16,17] are adhered to (https://digital.nhs.uk).

The general principle is to ensure that data are protected from being stolen, misused or lost. The main leads in the organisation will be the information governance department.

Image quality, patient demographics and data retention

A clinical decision should be made on the storage of images, and national guidance should be followed where applicable. If images and cine loops are to be saved, they should be archived to a centralised system appropriate for the clinical practice of the user. These systems may include PACS in a hospital-based setting or a secure cloud-based platform for other locations. Some manufacturers now offer data storage solutions, but in the absence of access to PACS or cloud, password-protected portable hard drives stored in a lockable cupboard are acceptable. It is important to ensure that data demographics are correct and images and cine loops are saved at an appropriate compression level, as loop storage requirements are far greater than for single images. As single images are very small in size, the best choice would be to send them with lossless compression. This should be discussed with the PACS or governance manager and the ultrasound supplier.

Storage must include accurate patient demographics, and a digital imaging and communications in medicine (DICOM) work list should be used, where feasible. This would ideally be generated by booking the patient into a radiology information system (RIS)

or patient admission system (PAS). To ensure that a work list is readily available on the POCUS device when scanning, it is recommended that the scanner is Wi-Fi enabled. It is acknowledged that in urgent cases this may not be possible and thus protocols should be in place to ensure accurate patient data are added and images stored correctly in these cases.

The retention of studies stored on the PACS should be managed centrally, but a protocol to ensure that data are deleted from the POCUS hard drive at regular intervals should be in place as it is part of NHS Digital requirements in accordance with duration of record storage.[18]

Data security

Before purchasing a POCUS machine, the following should be assessed along with the imaging performance of the scanner.

- Operating system: With ransomware becoming more prevalent,[17] it is recommended that operating systems are supported and are patched for security flaws.[16] Discuss with the supplier how long the operating system is going to be supported, and what their policies are on patching and software/operating upgrades.
- Controlled access to patient data on the POCUS machine via user passwords and encryption of the patient data. It is also important that there is an emergency mode that allows scans to be performed without entering patient data, though this must be added after.
- The scanner should be set for Wi-Fi (with appropriate data security), where possible, to make access to a PACS or image storage device easier.
- For some POCUS machines the ability to send studies to an IT system outside the control of the practice/department may be required. When starting a new service, a data protection impact assessment (DPIA) should be completed.[19,20] The local information governance team will be able to provide advice. This is essential for compliance with GDPR when the POCUS device sends studies outside the organisation .
- There are a number of POCUS machines that have wireless connection with an app on a smartphone or tablet. This should ideally be a device owned by the organisation, but in any event a DPIA is required. If a personal device is used, patient data must be removed if the personal device is either scrapped or if ownership of the device is transferred to a third party.

g. Support from imaging specialists

It is recommended that POCUS colleagues engage with ultrasound providers and radiology departments to establish cooperation and collaboration among users of ultrasound from different specialties to ensure that the best possible service is provided to patients. The level of clinical and training support available may vary between radiology departments, but it is envisaged that at least a report and record of the POCUS study, ideally with stored images, would be readily available and could be integrated into the patient's electronic records.

4 Summary of standards and key points for POCUS users

Standard	Key points
Governance of ultrasound equipment	▪ Appoint a lead (if not yourself) to oversee purchasing, maintenance and regular QA ▪ Understand the importance of regular equipment QA and your responsibility for care of the equipment and fault reporting ▪ Adhere to equipment and ultrasound gel hygiene recommendations ▪ Keep a record of users and their training ▪ Observe national data security recommendations
Governance of equipment users	▪ Understand basic ultrasound physics and machine controls ▪ Adhere to current safety guidelines regarding acoustic output in relation to safety indices ▪ Adhere to best practice regarding secure data storage ▪ Seek appropriate training and education ▪ Maintain CPD and perform regular audit ▪ Avoid working in isolation ▪ Where possible, engage with imaging specialists

5 Conclusion and recommendations

This document outlines the standards expected of all clinical ultrasound users and emphasises the need for good governance ranging from equipment safety and clinical competence to image storage and record-keeping. It is essential that there is good ongoing support for and collaboration between radiology departments and the wider community of ultrasound users in the UK and that these standards set an exemplary format that can be translated and recognised worldwide.

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Appendix 1
POCUS acceptance testing, imaging performance and safety

Appropriate equipment governance starts with pre-purchase specification and ends with equipment disposal.

Responsibilities

- A clinical lead should be determined to take responsibility for appropriate pre-purchase specification and ongoing equipment governance.
- Clinical users of ultrasound equipment are required to ensure that the equipment used is fit for purpose and that the integrity and image quality of the equipment continue to meet the required specification.

Pre-purchase/pre-delivery

- A specification should be outlined with the minimum requirements for the proposed applications. These may include:
  - Transducer type
  - Imaging depth
  - Image contrast and resolution requirements (such as ability to image specific anatomical features)
  - Availability of Doppler modes and elastography modes.
- All devices should have application-specific presets. In particular, power output settings for lung, neonatal/obstetric and ophthalmic scanning should be within BMUS guidelines (see Appendix 2) and Food and Drug Administration (FDA) limits.[i]
  - Ophthalmic scanning: keep outputs very low at MI <0.23 and $I_{spta0.3}$ <17 mW cm^{-2}.
  - Obstetric scanning: TI <0.7. Note time restrictions are associated with values >0.7.
  - Lung scanning: MI <0.3. There is a possibility of minor damage to neonatal lung or intestine with values >0.3. If such exposure is necessary, try to reduce the exposure time as much as possible.
- All devices should have CE marking with an associated four-digit number representing an appropriate notified body.
- All devices should operate within FDA regulations.[i]
- The device must be designed in such a way that it can be cleaned to an adequate standard, depending on the required clinical application. POCUS units have the potential to act as fomites, and those used in clinical areas where there is a high risk of infection may require thorough disinfection between patients. Probes with smooth surfaces and limited notches or buttons may be easier to clean. Similarly, tablets and touchscreen devices may have lower fomite potential than devices with traditional keyboards or internal cooling fans. Users should follow BMUS guidelines for probe disinfection procedures.[ii]
- A pre-purchase trial should be used to assess the suitability of the device.

Routine checks

- Commissioning checks should be performed by a medical physicist, clinical engineer or other suitably trained individual on arrival, before any clinical use. These may follow the guidance published in the Institute of Physics and Engineering in Medicine (IPEM) Report 102.[iii] They will include:
  - A visual check of the device for damage sustained during transport or issues with manufacture
  - Ensuring connectivity with the imaging network, if required
  - Appropriate image performance tests.
- Annual checks should be performed by a medical physicist, clinical engineer or other suitably trained individual and may follow the guidance published in IPEM Report 102.[iii] In addition, all devices should have regular electrical safety tests following IEC 62353 (MHRA guidelines).
- Users are responsible for ensuring that equipment remains in suitable condition for continued use. As well as acting on any concerns as they arise during routine use, users should also carry out routine checks on POCUS units. The frequency of these routine checks depends upon the frequency of use of the equipment and may include:
  - A visual inspection of the device, including the probe face, any cables and the controls and image display
  - A simple assessment of image quality.

References

i. Food and Drug Administration (FDA). *Marketing clearance of diagnostic ultrasound systems and transducers: guidance for industry and Food and Drug Administration staff*. FDA, 2019. www.fda.gov/media/71100/download

ii. BMUS, SCoR, AXREM. *Ultrasound transducer decontamination: best practice summary*. BMUS, SCoR, AXREM, 2020. www.bmus.org//static/uploads/resources/Best_Practice_Summary_-_probe_decontamination_-_FINAL_13_02_2020.pdf

iii. Institute of Physics and Engineering in Medicine (IPEM). *Quality assurance of ultrasound imaging systems*. Report no. 102. York: IPEM, 2010.

Appendix 2
Current ultrasound safety recommendations

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Table 1. Recommended exposure time and index values for obstetric and neonatal ultrasound

Application	Values to monitor	Thermal index value			Mechanical index value		
		0–0.7	0.7–3.0	>3.0	0–0.3	>0.3	>0.7
Obstetrics up to 10 weeks after LMP (and gynaecology when pregnancy is possible)	TIS and MI	✓	(B) restrict time to 0.7<TIS≤1.0 : 60 min 1.0<TIS≤1.5 : 30 min 1.5<TIS≤2.0 : 15 min 2.0<TIS≤2.5 : 4 min 2.5<TIS≤3.0 : 1 min	Scanning of an embryo or fetus is not recommended, however briefly	✓	✓	(E) risk of cavitation with contrast agents
Obstetrics more than 10 weeks after LMP	TIB and MI	✓	(B) restrict time to 0.7<TIB≤1.0 : 60 min 1.0<TIB≤1.5 : 30 min 1.5<TIB≤2.0 15 min 2.0<TIB≤2.5 : 4 min 2.5<TIB≤3.0 : 1 min	Scanning of an embryo or fetus is not recommended, however briefly	✓	✓	(E) risk of cavitation with contrast agents
Neonatal – transcranial and spinal	TIC and MI	✓	(B) restrict time to 0.7<TIC≤1.0 : 60 min 1.0<TIC≤1.5 : 30 min 1.5<TIC≤2.0 : 15 min 2.0<TIC≤2.5 : 4 min 2.5<TIC≤3.0 : 1 min	Scanning of the central nervous system is not recommended, however briefly	✓	✓	(E) risk of cavitation with contrast agents

Application	Values to monitor	Thermal index value			Mechanical index value		
Neonatal – general and cardiac imaging	TIB and MI recommended	✓	(C) restrict time to 1.0<TIB≤1.5 : 120 min 1.5<TIB≤2.0 : 60 min 2.0<TIB≤2.5 : 15 min 2.5<TIB≤3.0 : 4 min	3.0<TIB≤4.0 : 1 min 4.0<TIB≤5.0 : 15 sec 5.0<TIB≤6.0 : 5 sec TIB>6: not recommended	✓	(D) Possibility of minor damage to lung or intestine Minimise exposure time	(E) risk of cavitation with contrast agents
Fetal Doppler heart monitoring	TI or MI are not usually available for dedicated fetal heart monitors	The power levels used by dedicated fetal heart monitors are sufficiently low that the use of this modality is not contraindicated, on safety grounds, even when it is to be used for extended periods					

✓ There is no known reason to restrict scanning times in this region.

A Many scanners allow MI and one of the TI values to be displayed simultaneously: the most appropriate TI value depends on the clinical application.

B TI >0.7 – the overall exposure time (including pauses) of an embryo or fetus or of the neonatal central nervous system should be restricted.

C TI >1.0 – the overall exposure time (including pauses) of other parts of the neonate should be restricted.

D MI >0.3 – there is a possibility of minor damage to neonatal lung or intestine. If such exposure is necessary, try to reduce the exposure time as much as possible.

E MI >0.7 – there is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.

Table 2. Recommended exposure time and index values for non-obstetric and non-neonatal ultrasound

Application	Values to monitor (A)	Thermal index value		Mechanical index value	
		0–1.0	> 1.0	0–0.3	>0.7
General abdominal **Peripheral vascular** **Unlisted applications**	Usually TIB and MI [use TIC and MI if bone closer than 1 cm TIS and MI only if bone does not come into the image]	✓	(B) restrict time to 1.0<TIB≤1.5 : 120 min 1.5<TIB≤2.0 : 60 min 2.0<TIB≤2.5 : 15 min 2.5<TIB≤3.0 : 4 min 3.0<TIB≤4.0 . 1 min 4.0<TIB≤5.0 : 15 sec 5.0<TIB≤6.0 : 5 sec TIB>6: not recommended	✓	(C) risk of cavitation with contrast agents
Eye	TIS and MI recommended	✓	Scanning of the eye is not recommended	✓	(C) risk of cavitation with contrast agents
Adult transcranial (imaging and standalone) (D)	TIC and MI	✓	(B) restrict time to 0.7<TIC≤1.0 : 60 min 1.0<TIC≤1.5 : 30 min 1.5<TIC≤2.0 : 15 min 2.0<TIC≤2.5 : 4 min 2.5<TIC≤3.0 : 1 min TIC>3: not recommended	✓	(C) risk of cavitation with contrast agents
Peripheral pulse monitoring	TI or MI are not usually available for dedicated peripheral pulse monitors	The output from CW Doppler devices intended for monitoring peripheral pulses is sufficiently low that their use is not contraindicated, on safety grounds			

✓ There is no known reason to restrict scanning times in this region.

A Many scanners allow MI and one of the TI values to be displayed simultaneously: the most appropriate TI value depends on the clinical application.

B TI >1.0 – the overall exposure time (including pauses) should be restricted.

C MI >0.7 – there is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.

D Transcranial ultrasound investigations may require higher acoustic output or longer monitoring times than other applications. When times longer than those recommended here are required, it is recommended that monitoring is paused regularly to minimise exposure.

Full guidance is available at www.bmus.org/static/uploads/resources/BMUS-Safety-Guidelines-2009-revision-FINAL-Nov-2009.pdf.

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