

Standards for the provision of an ultrasound service

THE SOCIETY AND COLLEGE OF RADIOGRAPHERS





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## Contents

Fo	preword	3
1.	Introduction	4
2.	Standards for ultrasound equipment	5
	Background	5
	Performance metrics	5
	Transducers	5
	Scanners	6
	Functions	6
	Image quality requirements	9
	Quality assurance, governance and safety	9
	Acoustic	10
	Biological	10
	Electrical	10
	Mechanical	10
	Physiological	10
	User demands, support and lifetime	10
	Support	10
	Replacement	11
	The scanning environment	11
 3.	Training and education	
	Background	
	Training and education – minimum standards	S
	for provision of an ultrasound service	
	Registration	
4	Examination specific standards	
	Ultrasound departments	10
	and providers should have written	13
	guidelines for the range of ultrasound	
	examinations that are undertaken	
	All ultrasound examinations should be	13
	justified	
	A range of images should be saved to	13
	PACS to provide a record of the examination	
	for case review and audit nurnoses	

	Contrast-enhanced ultrasound (CEUS)	13
	Standards and guidance already published	14
	relating to specific types of ultrasound	
	examinations	
5.	Ultrasound examination report	14
	Background	14
	Components of the report	14
	Report style	15
6.	Auditing of ultrasound practice and	16
	report quality	
	Background	16
	Example 1. Clinical governance and quality	18
	standards – a case study of a programme	
	in action	
	Example 2. Ultrasound practitioner	20
	reporting audit	
	Example 3B. Portsmouth	21
	audit methodology: acute abdominal	
	ultrasound	
7.	Image management	
	Image capture	
	Image storage	
	Image access and review	
	Image transfer	
Re	ferences	23
Ap	opendix 1. Contributing authors	26
an	id reviewers	
Ar	opendix 2. Glossary	
		•••••
Ap	opendix 3. Abbreviations	28

## Foreword

Ultrasound, if carried out correctly in the appropriate clinical situation, is one of the most effective diagnostic tools in healthcare. It is therefore not surprising that the use of ultrasound has increased markedly over the last ten years and continues to do so. The fact that it is safe to carry out, relatively inexpensive and can be provided in most clinical facilities makes ultrasound one of the most commonly requested examinations in the field of diagnostic imaging.

For these reasons, ultrasound examinations are undertaken by practitioners from a wide range of professional backgrounds and in many different clinical settings.

The Royal College of Radiologists (RCR) and the Society and College of Radiographers (SCoR) believe it is important that the patient who undergoes an ultrasound examination is assured of the quality of the examination and its interpretation. Ultrasound is a highly operator-dependent imaging modality and requires skills that take time to acquire. Imaging must be undertaken by trained and experienced practitioners and, even then, perfect images may not be obtained in every patient.<sup>1</sup> Regardless of who undertakes them or where they are undertaken, ultrasound examinations must be of a high quality as they have a direct effect on patient management.

The RCR and the SCoR have produced this document which sets standards in key areas that are seen as essential for the delivery of high-quality and effective ultrasound imaging services and examinations. This standards document clarifies the components of a clinically safe and efficient ultrasound service. It is relevant to all services that carry out ultrasound and to those individuals responsible for the commissioning of such services.

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### 1. Introduction

The primary focus of this document is the provision of general medical, gynaecological and musculoskeletal ultrasound imaging, but its good practice principles extend to all areas of ultrasound service provision.

Ultrasound examinations are among the most commonly requested examinations in the field of diagnostic imaging.<sup>1,2</sup> The absence of ionising radiation, the ability to deliver in the community, closer to the patient's home and comparatively low cost of the equipment, make ultrasound the first-choice examination for many clinical conditions.<sup>1,2</sup>

Ultrasound examinations are undertaken by practitioners from a wide range of professional backgrounds and in many different clinical settings. These include imaging departments within National Health Service (NHS) trusts and Health Boards, independent or private clinics and hospitals, and within the community. Following the passing of the Health and Social Care Act 2012 (England) there is a specific focus on the commissioning of clinical imaging services.<sup>3</sup> Non-obstetric ultrasound was selected as one of the services that can be commissioned under the provisions of 'Any Qualified Provider' (AQP) and an implementation pack was made available for commissioners which provided a suggested service specification.<sup>4</sup> Central support for the provision of AQP was devolved to the commissioners at the end of March 2014. There is a drive to improve support for patients by enhancing primary care services and this is likely to result in an increase in the number of examinations undertaken away from traditional imaging departments.<sup>5</sup>

The environment in which ultrasound services are delivered is therefore becoming increasingly complex and fragmented.

Ultrasound is a highly operatordependent imaging modality and must be undertaken by trained and experienced practitioners. The uncontrolled expansion of the use of ultrasound represents a significant clinical risk if:

- Examinations are undertaken by untrained or poorly trained individuals
- Equipment is poorly specified or poorly maintained
- It is undertaken in the absence of clinical audit of performance and/or outcome
- There is no effective clinical governance framework.<sup>6</sup>

There is ever increasing pressure on ultrasound services due to the number of requests, changing patterns of service delivery and the shortfall in the overall numbers of the qualified workforce. It is readily acknowledged that there is much good practice to commend, but there have been concerns that the quality of some ultrasound examinations has been affected: there have been instances of sometimes large groups of patients having to be recalled for repeat ultrasound examinations. Reports and images of examinations performed by one provider are also not always available to others, which has led to instances of individual scans having to be repeated before treatment in secondary care is initiated.

There are many factors affecting the quality of ultrasound examinations, including appropriate training, experience, the equipment itself, clinical leadership, audit, general support and having sufficient time to undertake the examination and compile a clinically relevant report. Further advice on this is available from SCoR and RCR.<sup>7,8</sup>

Those undertaking ultrasound examinations, regardless of their professional background, are expected to meet the standards of best clinical practice, substantiated by appropriate audit and good governance processes. Neither the RCR nor the SCoR will provide support for their respective members working outside a clinical governance framework.<sup>9</sup>

Clear, effective clinical leadership is also essential if the ultrasound service provider is to achieve the desired outcome of timely, accurate, clinically relevant reports where patient safety is the paramount concern.<sup>9</sup> Clinical leadership may be provided by a consultant medical practitioner, for example, a consultant radiologist, or by a consultant sonographer. The important requirement is that the clinical lead possesses the necessary expert clinical skills as well as the required leadership skills.9

There are already many documents relating to ultrasound service provision available from organisations such as the RCR, SCoR, the British Medical Ultrasound Society (BMUS) and the former United Kingdom Association of Sonographers (UKAS) (UKAS merged with the SCoR on 1 January 2009). These provide valuable advice on a wide range of related topics and have played an important role in setting and helping to maintain standards of ultrasound in the United Kingdom (UK). This document draws and builds on this previously published advice to update and define standards for high-quality ultrasound examinations and to identify ways in which they can be quality assured.

Ultrasound providers are encouraged to seek accreditation from the Imaging Services Accreditation Scheme (ISAS).<sup>10</sup> This is a joint initiative of the RCR and SCoR and is specifically aimed at organisations providing diagnostic imaging in the UK in both the NHS and independent sector. Patients, general practitioners (GPs), referrers and commissioners can be assured that ISAS-accredited services are delivering the highest quality of services and have embedded good governance principles in the way they work.<sup>10</sup>

In England, it is a legal requirement that providers of diagnostic and screening ultrasound services are registered with the Care Quality Commission (CQC).<sup>11</sup> Commissioners of ultrasound services also have an important role in setting and monitoring compliance with appropriate standards.

# 2. Standards for ultrasound equipment

### Background

The specific requirements for an ultrasound machine differ with each clinical task.

Technology has developed rapidly in many ways and continues to do so. This can make the specification and selection of equipment difficult. Ultrasound scanners can be physically moved with ease, presenting a risk that machines may be inappropriately used for clinical tasks for which they were never intended and to which they may be ill suited.

The role of the operator is critical and the matching of the operator knowledge and competence level to the equipment features is essential.

Specifically the following points require clarification.

- What are the key machine characteristics?
- How are these characteristics best matched to clinical need?
- What features should be considered when purchasing a machine?
- What associated environmental and organisational systems need to be considered and specified for good-quality service delivery?
- How can service providers best ensure that equipment continues to perform at the required level and identify when this is no longer the case?

### Performance metrics

The desired standard is for the ultrasound scanner to provide excellent images of diagnostic quality at all times. However, this is not particularly helpful for providing an objective description of machine performance and it ignores the fact that, however good the machine might be, some patients will present insurmountable challenges. Objective parameters which are related to performance are:

- 1. Transducers
- 2. Scanners
- 3. Functions
- 4. Image quality and quality assurance (QA)
- 5. Safety
- 6. User demands, support and lifetime
- 7. The scanning environment.

### Transducers

Transducers need to be matched to the anatomical region to be scanned.

Scanners are normally purchased and supplied with a number of transducers which differ in their mode of action, their 'footprint' and the shape of their field of view. These can be assigned to one of three categories.

- Linear arrays (LA)
- Curvilinear arrays (CLA)
- Phased arrays (PA).

Each transducer type can be subdivided in terms of its frequency range. With higher frequencies giving superior image quality at the expense of penetration.

In addition there are a variety of specialist transducers for:

- Endoscopic use
- Transvaginal (TV) use
- Transrectal use
- Transesophageal (TOE) use.

Examples of suitable combinations of transducers and applications are shown in Table 1. Note that it is likely that more than one transducer will be required to cover the recommended frequency range in many cases. Table 1. Transducer requirements for specific applications

Application	Transducer type	Frequency range megahertz (MHz)
General abdominal	CLA or PA	2–10
Small parts	LA	5–18
Vascular	LA and CLA	2–15
Cardiac	PA and TOE	2–10
Obstetrics/gynaecology	CLA and TV	3–15

#### Scanners

The choice of scanner should be matched to the type and nature of the workload.

A single location and heavy routine workload will favour a larger mainframe machine with a larger display. The reverse will favour a portable system.

Most scanners have the potential to be used with all types of transducers and frequencies.

The quality of the image will be determined by the selection of scanner and its software and functions.

With advancing technology, it is no longer true that there is a direct trade-off between size and quality. However, occasionally functionality may be sacrificed with reduced size and weight (see section on The scanning environment, page 11).

Although a small machine may be ideal for rapid deployment in a clinic, ward or theatre, the ergonomics may not be ideal. A small screen and simple control panel may lead to operator fatigue, particularly with long lists.

Some portable scanners are difficult to link to picture archiving and communications systems (PACS). However, for the purposes of review and audit, all images obtained should be recorded, stored on PACS and linked to the report (see Image management, page 22).

### Functions

As mentioned previously, the specification of scanner functions needs to be matched to clinical workload.

The following functions should be regarded as essential for all clinical machines unless there is a valid reason for omission or an alternative process available. A wide range of approaches can be taken by different manufacturers to achieve the same aim:

- Brightness (B) mode with tissue harmonic imaging
- Facility to adjust the frequency range on all transducers
- Facility to swap between at least two transducers without physical reconnection
- Gain and time gain compensation (TGC) control
- Operator-controlled multiple and adjustable focal zones
- Colour and power Doppler
- Provision of scanning pre-sets
- Measurement of linear and curved distances, areas and volumes
- Look-up tables to link measurements to relevant clinical applications
- Cine-loop facility
- Magnification using both read and write zoom

- Patient identification (ID) and entry of other relevant clinical information
- Local digital image archiving and facility for local printing
- Adjustable power output with facility to make lowest output value a default
- PACS and digital imaging and communications in medicine (DICOM) compatibility (including colour and work list)
- Display of safety indices (mechanical index [MI] and thermal index [TI]) conforming to American Institute of Ultrasound in Medicine (AIUM)/National Electrical Manufacturers Association (NEMA) display standard<sup>12</sup>
- Compliance with the Medicines and Healthcare products
  Regulatory Agency (MHRA)
  Device Bulletin DB2006(05)<sup>13</sup>
- Compliance with the Medical Devices Directive, which stipulates the requirement for CE marking of all electro-medical equipment.<sup>14</sup>

There are additional functions which are essential for specific clinical applications. Examples are given in Tables 2–5.

## Application – specific functions

### Table 2. General abdominal ultrasound (essential)

Feature	Detail
Adequate resolution	Axial <0.5 mm, lateral <5 mm at all depths and <2 mm in focal zones Slice thickness <8 mm at all depths
Adequate penetration	At least 15 cm of normal tissue
Random image review	
Multiple image display	Facility to display at least two images in same mode simultaneously
Spectral Doppler	Range gate accuracy <1 mm
Colour Doppler	Adjustable wall thump filter
Calculation of waveform indices	Automatic and manual
Microbubble imaging	Suitable scanning mode available
Multimode display	Simultaneous display of B, spectral, colour Doppler (CD), power Doppler modes
Application presets	Facility to have operator-created presets
Image-guided biopsy facility	
Extended field of view	
Compounding	
Specialist transducer (optional)	Transrectal

### Small parts (including paediatrics, musculoskeletal, thyroid and breast) (essential)

As for general abdominal above, but penetration limited to 7 cm and resolution requirements modified to: axial <0.3 mm, lateral <3 mm at all depths and <1 mm in focal zones, slice thickness <5 mm at all relevant depths.

### Table 3. Obstetrics/gynaecology (essential)

Feature	Detail
Adequate resolution	Axial <0.5 mm, lateral <5 mm at all depths and <2 mm in focal zones Slice thickness <8 mm at all depths
Random image review	
Multiple image display	Facility to display at least two images in the same mode simultaneously
Spectral Doppler	Range gate accuracy <1 mm
Colour Doppler	Adjustable wall thump filter
Calculation of waveform indices	Automatic and manual
Multimode display	Simultaneous display of B, motion (M), spectral, colour and power Doppler modes
Application presets	Facility to have operator-created presets
Adequate penetration	At least 15 cm of normal tissue
Specialist transducer	TV 3D/4D (optional)

### Table 4. Cardiology (adult) (essential)

Feature	Detail
Display channel	Electrocardiogram (ECG) amplifier and display in addition to at least one other physiological channel amplifier and display
Adequate resolution	Axial <0.5 mm, lateral <5 mm at all depths and <2 mm in focal zones Slice thickness <8 mm at all depths
Random image review	
Multiple image display	Facility to display at least two images in same mode simultaneously
Spectral Doppler	Range gate accuracy <1 mm
Colour Doppler	Adjustable wall thump filter
Calculation of waveform indices	Automatic and manual
Microbubble imaging	Suitable scanning mode available
Multi-mode display	Simultaneous display of B, M spectral, CD and power Doppler modes
Application presets	Facility to have operator-created presets
Adequate penetration	At least 15 cm of normal tissue
Specialist transducer (optional)	TOE

### Cardiology paediatric

As cardiology (above), but penetration limited to 7 cm and resolution requirements modified to: axial <0.3 mm, lateral <3 mm at all depths and <1 mm in focal zones, slice thickness <5 mm at all relevant depths.

### Table 5. Vascular (essential)

Feature	Detail
Adequate resolution	Axial <0.5 mm, lateral <5 mm at all depths and <2 mm in focal zones Slice thickness <8 mm at all depths
Random image review	
Multiple image display	Facility to display at least two images in same mode simultaneously
Spectral Doppler	Range gate accuracy <1 mm
Colour Doppler	Adjustable wall thump filter
Calculation of waveform indices	Automatic and manual
Multimode display	Simultaneous display of B, spectral, CD and power Doppler modes
Application presets	Facility to have operator-created presets
Adequate penetration	At least 15 cm of normal tissue

### Image quality requirements

The concept of image quality is complicated by its subjective nature and the absence of firm scientific evidence relating measurable parameters to diagnostic accuracy.

It is generally accepted that signal processing and functions on machines which optimise them for one clinical application will make them suboptimal for others. In addition, the ergonomics of control layouts are likely to favour specific applications. It follows that it is not possible to use a machine optimally for a wide variety of applications using only presets to move between them.

Good spatial and contrast resolution are always important, but there is less clarity about optimisation of dynamic range, grey-scale transfer scales and smoothing, among other functions. Trade-offs inevitably exist, in particular, between frame rate and image quality and between the quality of the B-mode image and various Doppler modes.

The user needs to be clear about which applications are paramount for each scanner, devise metrics of quality and take and archive representative images demonstrating those features. This will enable the stability of machine performance to be mapped over time. For example, in abdominal scanning in which it is critical to detect and display small, subtle lesions with little to distinguish them from their surroundings, contrast resolution may be more important than frame rate. This is also true of breast imaging, since frame rate can be relaxed considerably.

In cardiac applications, the frame rate is paramount and optimisation may be achieved at the expense of other factors. In vascular applications, the ability to detect low-volume arterial and venous flow will be the most important and this may require the Doppler modes to have increased priority relative to B-mode imaging.

The following approach is therefore recommended.

- The user should specify, as precisely as possible, the investigation(s) for which each machine is optimised.
- Representative images indicating the performance of each machine should be archived on an annual basis and these should be monitored as part of the audit system in place in the department and also with any bench-top testing which takes place.
- Whenever a machine is modified or repaired, new representative images and relevant bench-top data should be acquired immediately to act as updated reference points.
- Whenever the range of applications of a machine is extended or modified, this should be clearly recorded, new reference images should be acquired and there should be consideration as to whether the existing presets, software and hardware require update.

## Quality assurance, governance and safety

### Quality assurance (QA)

A formal QA programme to monitor scanner performance should be organised within an imaging department. This should comply with the BMUS guidelines for the regular quality assurance testing of ultrasound scanners by sonographers.<sup>15</sup>

Key features include defined responsibilities for ultrasound users to carry out routine testing.

### Governance

Governance arrangements specific to the ultrasound service should be embedded within the imaging department's policies as part of the overall governance of the organisation.<sup>6,16</sup>

### Safety

Ultrasound enjoys a strong reputation as being a very safe and non-invasive imaging modality.

To minimise potential risk:

- Use of ultrasound should be consistent with maximising the clinical benefit of the investigation
- Ultrasound examinations should only be undertaken for a clinical reason
- The duration of the scan should be limited to that required for clinical reasons.

Authoritative advice on policies and procedures is given in the publication *Guidelines for the safe use of diagnostic ultrasound equipment* and on the safety of ultrasound page of the BMUS website.<sup>17,18</sup> Users should assess risk in the following categories.

### Acoustic

Ultrasound safety is addressed by a variety of bodies internationally. In the United States (US), the Food and Drug Administration, Centre for Devices and Radiological Health, USA (FDA) imposes upper limits on the acoustic output of diagnostic scanners under the 510 (k) Track 3 route to market.<sup>19</sup> Although these legal requirements only apply to North America, the majority of ultrasound scanner manufacturers comply with them for all their markets and it is to be expected that all equipment used in the UK would conform to this.

The International Electrotechnical Commission (IEC) has published a number of relevant standards documents including standard IEC60601-2-37(2007), which imposes limits on the surface temperature that transducers can reach under diagnostic operating conditions.<sup>20</sup> For details of these and other documents, readers are referred to the Safe Use of Ultrasound in Medical Diagnosis.<sup>21</sup> A key element of the advice in this publication relates to the use of MI and TI. It is suggested that each department has a published policy on MI and TI values for its various clinical applications.

### Biological

The risk of cross infection from equipment which comes into physical contact with many staff and patients is always present and this is especially relevant where endoprobes are used and/or immune-compromised patients are involved. Attention is brought to the MHRA alert on the cleaning and disinfection of endoprobes.<sup>22</sup> Transducers should be cleaned regularly in accordance with manufacturers' instructions.<sup>23</sup> Advice on this should be part of the specification process. Each machine and its approved users should be part of the wider infection-control procedures within the trust or organisation, and there should be a clear audit trail showing monitoring. It should be noted that the risk is not confined to the transducers themselves and that cables, keyboards and other machine parts may carry infection.

For endovaginal and endorectal probes effective disposable probe covers must be used.

### Electrical

All equipment should conform to published electrical safety standards. These are especially stringent for endoprobes and transducers to be used intraoperatively.

### Mechanical

It is reasonable to assume that ultrasound scanners are mechanically safe if they carry the appropriate CE mark. However, there is a risk, especially for portable equipment, of mechanical damage while in use.

It is the responsibility of users to report any damage and to ensure that action is taken when damage is suspected.

### Physiological

Regular users of ultrasound scanners may experience long-term musculoskeletal injuries in upper limbs, neck or spine.<sup>24</sup>

Appropriate policies should be in place to monitor staff at risk and respond to problems if and when they arise.

Evaluation of a scanner for new purchases or applications should include an assessment of its ergonomic features.

## User demands, support and lifetime

Ultrasound is unique among imaging modalities in its widespread range of applications and operator types. Virtually all branches of medicine now include some ultrasound applications, and operators can be those for whom imaging is not a major role, for example, the use of ultrasound guidance for insertion of central venous access lines.

Operators who have received focused training in a specific defined area of ultrasound application will not be able to exploit all of the many functions of a sophisticated machine. It follows that the specification for machines to be used by such staff and for such applications will differ from those for one of the mainstream applications discussed earlier.

It is critical that the machine is matched as closely as possible to its use, and that the user is adequately trained. In particular, use of machines away from specified clinical areas should be avoided and operators must be clearly instructed not to go beyond their defined and agreed protocols.

Focused Ultrasound Training Standards have been published by the RCR.<sup>25</sup>

### Support

The nature and level of support provided by the manufacturer is important and should be included in the list of considerations when a machine is purchased.

Support should include:

- Availability of clinical applications specialists
- Appropriate training courses
- Repair and maintenance resources.

Manufacturers should be required to specify the minimum number of years over which they will supply spare parts and the necessary resources for repairs.

### Replacement

The 2005 *RCR* Standards for ultrasound equipment stated that a formally agreed equipment review and replacement programme is highly desirable because of rapid changes in technology and changing clinical expectations and needs.<sup>26</sup> High-specification ultrasound scanners will often have a longer useful life than basic- or middle-range equipment. Review is typically undertaken between four to six years following installation.

Depending on the outcomes of this review, a decision can then be made whether to continue to use the equipment or to obtain a replacement machine.

Equipment should be replaced under the following circumstances:

- 1. It has become demonstrably unreliable
- 2. It has broken down and the manufacturer is unwilling or unable to repair it
- 3. There is evidence of a clinically significant deterioration in performance
- 4. The clinical role for which it was purchased has now been extended or changed and the machine is no longer fit for purpose.

The case for replacement under the above criteria is strengthened if there is objective evidence of change in the scanner performance, highlighting the need for regular QA (as in The scanners, page 6) and for a clear statement of the intended clinical role of the machine at the time of purchase.

Consideration should be given to the subjective recognition by the experienced practitioner of poorer image quality when compared to newer ultrasound machines. This can contribute to lack of confidence in the equipment which may result in an increase in inconclusive reports.

### The scanning environment

The environment in which the ultrasound scanner is used will have a profound effect on its efficacy. The issue of portability has been discussed in Standards for ultrasound equipment (page 5) and this can be extended to a consideration of the size of the machine relative to the size of the room in which it is to be used. However, other issues should also be included:

- The scanning couch and operator seating
- The display monitor
- Room heating and lighting
- Hygiene, infection and cleanliness
- Electrical and information technology (IT) provision.

The couch, the seating, the transducer and the display should be chosen together, with an emphasis on ergonomics and efficiency. Angle and height adjustment are important and the maximum weight restriction for the couch should be clearly posted. If transvaginal or transrectal examinations are to be performed, the couch should be selected with this in mind. It is likely that secondary display monitors will be useful and consideration should be given as to whether the images should be seen by the patient during the scan.

The size of the display monitor may be a matter for compromise. Too big a monitor makes the system unwieldy and difficult to adjust. Too small a display leads to operator fatigue and may limit resolution and diagnostic efficacy. In any case, the monitor should be checked independently of the scanner for its grey-scale performance and spatial fidelity. The modern flat screen display has an unknown lifetime but gradual deterioration will have profound consequences.

More detailed information on how equipment choice and room design can be risk managed to minimise musculoskeletal disorders in ultrasound practitioners is available in *Risk management of musculoskeletal disorders in sonography work.*<sup>27</sup>

There are standards for room lighting and room temperature.

- Room lighting should be subdued but not to the point that movement is hazardous.<sup>28</sup>
- Lack of air conditioning within the scanning room can result in excess room temperatures.<sup>29</sup>
- Electrical supplies need to be sufficient to cope with the demands of the scanner, the couch and any accessories.
- The IT requirements to link to PACS systems are important, as is the location of the machine if trailing leads are to be avoided.

# 3. Training and education

### Background

Ultrasound is highly operator dependent, requiring specialist skills and knowledge. Formal training programmes are designed to ensure the operator is able to produce diagnostic images and in circumstances where this proves difficult, differentiate between technical barriers and patientrelated barriers. It is essential that operators are aware of their limitations, depending on their level of experience, and have access to senior operators for guidance and advice. This is particularly appropriate in difficult scanning conditions, so that appropriate clinical advice can be given to the referrer.

### Training and education – minimum standards for provision of an ultrasound service

- The employer/manager should hold an up-to-date record of the statutory or voluntary registration status of all ultrasound practitioners.
- All ultrasound practitioners should be registered with the relevant statutory regulatory body where appropriate, or with the relevant voluntary registration body.
- The employer/manager should hold an up-to-date record of all ultrasound practitioners' relevant qualifications and the awarding institution.

- Ultrasound practitioners must hold recognised qualifications, including:
  - Qualifications approved by the Consortium for the Accreditation of Sonographic Education (CASE), or equivalent, either from overseas or within the UK.
  - Qualifications awarded as part of medical postgraduate education and training (for example, by the RCR or the Royal College of Obstetricians and Gynaecologists [RCOG]).
- Support from experienced supervisors with relevant qualifications, ideally including a teaching qualification, should be provided for students and trainees.
- Newly qualified staff should undergo a six-month preceptorship phase following completion of their studies, to enable the appropriate support to be provided.
- An assessment of theoretical knowledge and practical scanning abilities at interview or before appointment should be undertaken where a new member of staff's skills and competence are not known to the employer.
- An appropriate induction process for all new and temporary staff should be implemented to ensure they are fully aware of departmental procedures and protocols and that they are working to the same standards.
- A formalised period of monitoring by a senior member of staff should be implemented for all new and temporary staff to confirm their scanning, interpretation and reporting abilities.

- Regular continuing professional development (CPD) activities and opportunities for attending workshops, conferences and so on should be monitored by employers/managers. Records of CPD activity should be kept by the individual and the employer/ manager.
- A performance development review should take place at least annually.

Note: Standards for competence assessment and testing are not included in this document. CASE-accredited universities and professional bodies such as the RCR and RCOG will include these as a component of their qualificatory courses. A range of different methods are used.

Additional sources that may be helpful, include the SCoR publication Ultrasound Training, Employment and Registration.<sup>30</sup>

### Registration

Ultrasound practitioners come from a wide range of professional backgrounds which will include radiologists, radiographers, nurses, midwives, physicists, physiotherapists, obstetricians and clinical scientists. Those ultrasound practitioners who are medically qualified and are able to do so will be registered with the General Medical Council (GMC) as a doctor with a licence to practise. Ultrasound practitioners who are not registered with the GMC will often be registered with a statutory regulatory body such as the Health and Care Professions Council (HCPC) or the Nursing and Midwifery Council (NMC). Examples would be radiographers, physiotherapists and some clinical scientists with the HCPC and nurses and midwives with the NMC.

For some ultrasound practitioners, through no fault of their own, statutory registration is not possible due to (for example) having trained overseas or coming from a professional background that is not recognised for statutory registration purposes. It is recommended that ultrasound practitioners who do not hold statutory registration apply for voluntary registration with the Public Voluntary Register of Sonographers (PVRS) which is administered by the College of Radiographers, and for those clinical physiologists specialising in cardiac ultrasound, to the voluntary register administered by the Registration Council for Clinical Physiology (RCCP).<sup>31,32</sup>

There is no statutory registration available as a sonographer in the UK, and the widely used titles of 'sonographer' and 'ultrasonographer' are not protected. Statutory registration for sonographers was recommended by the HCPC to the Secretary of State for Health in 2009 but following the 2010 election, the coalition government policy is not giving new groups statutory registration unless there is a solid body of evidence demonstrating a level of risk to the public that warrants the costs imposed by that regulation.33

Overall, the situation with respect to the registration of ultrasound practitioners is surprisingly complex. A full review of the situation was published in the February 2014 edition of *Ultrasound* and has been made available for access by the BMUS and Sage Publications.<sup>34</sup>

# 4. Examination-specific standards

Ultrasound departments and providers should have written guidelines for the range of ultrasound examinations that are undertaken

Written guidelines serve several purposes, including supporting a defence against litigation and helping to maintain minimum standards, they can also be used as a reference for audit purposes. Guidelines should be flexible and broadly based enough to allow practitioners to respond to different clinical situations in an appropriate way - those that are too prescriptive may be disregarded by practitioners as impractical. There will be occasions when guidelines cannot be adhered to and this should be stated in the report, for example, when a structure cannot be clearly demonstrated due to overlying bowel gas.<sup>35</sup>

## All ultrasound examinations should be justified

Ultrasound is at its most effective when addressing a particular clinical question, but many of the requests received are very open in nature and often no provisional diagnosis has been made or can be made by the referrer. This is particularly the case with many 'general' abdominal ultrasound requests, and such requests are likely to increase in number with the current emphasis on early cancer diagnosis. All ultrasound examinations should be justified and departments should have clear guidelines as to what should be included in any abdominal/pelvic ultrasound examination for vague and non-specific symptomology, for both male and female patients.

Examinations may need to be extended as necessary depending on initial findings and information obtained from the patient and/or from other tests. Both transabdominal and endovaginal ultrasound approaches are likely to be required to fully evaluate suspected gynaecological pathology.

### A range of images should be saved to PACS to provide a record of the examination for case review and audit purposes

Unless the entire examination is recorded, these images can only ever be representative of the overall real time examination, but will provide support for the written report and can help to confirm that the examination was performed competently. All images must include patient and provider identification, date and time of examination and an appropriate annotation with respect to the section, structure or pathology recorded.<sup>36</sup>

## Contrast-enhanced ultrasound (CEUS)

There is a small risk of lifethreatening anaphylactoid reactions to CEUS, and resuscitation facilities with emergency equipment and personnel trained in its use should be available.<sup>37</sup> The rate is estimated at one in 10,000.<sup>38</sup> It is recommended to keep the patient under close medical supervision during, and for at least 30 minutes following, the administration of sulphur hexafluoride.<sup>39,40</sup> The following are also recommended.

- Ensure that a protocol is in place for the delegation and injection of contrast agent.
- Ensure that a protocol is in place for carrying out and reporting of CEUS.
- Ensure that a programme of annual basic life support training is in place for staff.<sup>36</sup>

### Standards and guidance already published relating to specific types of ultrasound examinations

This document does not further specify what should or should not be included in a given type of ultrasound examination and does not include advice on wider aspects of service delivery, such as patient preparation or obtaining consent. Practitioners should refer to existing local guidelines and the published good practice standards and guidelines.<sup>36</sup> Advice on aspects such as obtaining consent and the use of chaperones is already available via the RCR and SCoR and other professional bodies.<sup>41,42</sup>

Commissioners may need to specify what is expected to be included within the various types of ultrasound examinations that may be requested to allow full comparison between providers.

Please see the references section for a full list of useful standards and guidance.  $^{36,43-60}$ 

# 5. Ultrasound examination report

### Background

The purpose of an imaging report is to provide a specialist interpretation of images and relate the findings – both anticipated and unexpected – to the patient's current clinical symptoms and signs, and to diagnose or contribute to the understanding of their medical condition or clinical state. It often incorporates advice to the referring clinician on appropriate further investigation or management.

Any individual issuing an imaging report, whether they be medically qualified, must ensure that they are appropriately trained and practice within their competence. All individuals issuing reports should work within a robust clinical governance programme. Useful advice is obtained from the RCR's publication Standards for the reporting and interpretation of imaging investigations.<sup>61</sup>

The report of an ultrasound examination constitutes a legal document. The responsibility for its accuracy lies with the person verifying the scan who, ordinarily, should be the person performing and reporting the scan (after obtaining advice if necessary, especially if issuing the report requires medical knowledge the person does not possess).

Its ultimate purpose is to address the clinical question being asked of the ultrasound scan.

### Components of the report

- 1. Patient's ID
- Date of the scan and of the report
  If significantly apart, consider giving the explanation for the delay in reporting.
- Clinical information provided in the request for the examination This should be transcribed as accurately as possible, including indications for the examination and clinical question(s) being asked. If important clinical information has come to light since the request was made, this (and its source) should also be included.

4. Name of the examination performed

This should include usage of endocavitary probe or contrast, as well as patient's consent and presence of a chaperone where appropriate. Any variations from a standard protocol, such as targeting scan to some organs only, should be explained.

5. Name(s) and status of the person(s) performing the scan and reporting the examination If the operator and reporter are not the same person, the exact role each one played should be explained.

- 6. Description of findings
  - Location.
  - Size, accompanied by exact measurements in clinically relevant planes.
  - Common widely used anatomical measurements (for example, kidneys, common duct and spleen) should be used. Variations from normal size should include an explanation (for example, common duct dilated measuring 12 mm, moderate post-micturition residue of 150 ml).
  - Internal characteristics, including sound attenuation. This should include important organs, whether normal (for example, normal liver echogenicity, increased echogenicity of renal parenchyma, inhomogeneous spleen echogenicity).
  - Borders/outline; for example, lobulated liver contour, poorly defined mass.
  - Blood flow characteristics this should be included where relevant to do so (for example, mass with increased blood flow on Doppler interrogation, normal direction of flow in portal vein).
- 7. Limitations

State the nature of any limitations if diagnostic certainty has been impaired by their presence (for example, limited views of pancreas due to overlying bowel gas, only intercostal imaging of the liver achieved).  Comparison with previous relevant imaging.
Both with ultrasound and other

modalities. If the person writing the report is not competent in interpreting images of other modalities, an appropriately qualified reporter's opinion should be sought.

9. Conclusion. This should be included except in brief self-explanatory reports. Wherever possible, this should start with the answers to the main clinical question(s), including either a specific diagnosis where certain, or a shortlist of differential diagnoses in order of probability. The report should clearly state the incidental nature of observed abnormalities. The conclusion

should include recommendations for further investigation(s), principally imaging, or a specialist referral where indicated.

10. Documentation of communication with the referrer when findings are important or unexpected, as per the RCR, Standards for the communication of critical, urgent and unexpected significant radiological findings, second edition.<sup>62</sup> This should include an alert if in

use in the local department, including date/time and name/ position of the person to who any life-threatening findings were communicated.

### Report style

Reports should take into consideration the local practice. They should be:

- Concise
- Easy to understand
- Without ambiguity
- Omitting irrelevant statements/ measurements
- Using technical terms (such as echogenicity, acoustic shadowing/ enhancement) only if instrumental in achieving diagnosis
- Explaining the significance of measurements and appearances
- Using only commonly known abbreviations/explaining less well known ones in full
- Using templates if appropriate. It is acceptable to abbreviate completely normal reports.

## 6. Auditing of ultrasound practice and report quality

### Background

Robust QA of non-obstetric ultrasound imaging is difficult due to the nature of the imaging specialty. It is one of the only imaging modalities where image assessment and diagnosis occurs in real-time. The production of standard, protocol-driven ultrasound imaging is possible, but it must be recognised that one of the great strengths of ultrasound is the ability to image anatomical structures in real-time, in a variety of different planes, using a variety of machine settings to optimise visualisation of anatomical and pathological structures. It is common practice for ultrasound studies to be documented as a series of static images, but it should be recognised that static images are only representative of the examination, rather than a complete record. Undertaking QA of ultrasound studies under these conditions is challenging.

The subjectivity and operator dependence of ultrasound imaging needs to be recognised within any QA programme involving nonobstetric ultrasound. While it is acknowledged that there are unique challenges in designing a robust QA programme in ultrasound, these should not be used as a reason for not undertaking such a programme. It is also important to be clear what a QA programme is trying to achieve. While it may be used to provide evidence of satisfactory standards during commissioning, QA should be viewed as a process rather than simply a means to an end. It should highlight areas where improvements can be made, but support, resources and educational opportunities will be required for ultrasound practitioners to make continual improvements. Such practices are already embedded in many ultrasound departments and include follow-up of individual cases, image/discrepancy review sessions, attendance at multidisciplinary team meetings (MDTMs), seminars and journal clubs as well as more formal CPD activities. While such CPD activities are vital in securing the quality of ultrasound scanning and reporting, they should be used in conjunction with, rather than instead of, a more formal QA programme.

It is important to take a holistic view of the quality of an ultrasound examination. While image quality and overall report accuracy are important, it is vital to recognise wider factors of report quality such as clarity, content, readability and relevance.<sup>63–67</sup> Ultrasound providers should seek to encompass these factors into their QA programme both to enable a broad overview of ultrasound examination quality and to provide information on where specific improvements are required. There are some published data describing methods of ultrasound audit but little primary research evidence is available to favour one method of QA over another.<sup>68–75</sup> All methods have some flaws due to the nature of the imaging modality.

A QA programme for ultrasound should include the following.

- Use of expert reviewer(s) to retrospectively assess ultrasound images and accompanying reports using a variety of audit tools Retrospective analysis of hardcopy imaging is a longestablished and generally effective method of assessing report accuracy for many medical imaging modalities.<sup>76-79</sup> This approach is more challenging in medical ultrasound, given the difficulties inherent in retrospective review of static images, but it is the most commonly described method of QA in the literature.
- An outcomes approach using patient outcome (as documented in the patient record) or results of further investigations where undertaken

Use of other diagnostic tests as a reference standard runs the risk of biasing the QA programme to those patients with positive ultrasound findings which are subsequently confirmed or refuted with additional tests or treatments. As a result of ultrasound being viewed as safe and easily available, it is often the firstline investigation in patients with vague and non-specific symptomology. Ultrasound examinations with negative findings often have no further diagnostic investigations or treatments to confirm or refute findings. However, this method has been used successfully as an adjunct to other audit methods.

- Comparison of practitioner and expert practitioner findings after both have scanned the patient This seems to be a robust audit method but published data using this method included significantly fewer cases than retrospective audit methods, implying that this method is likely to be costly in time and resources.
- Peer audit among ultrasound practitioners
- This has currently only been trialled in the assessment of ultrasound image quality. There are benefits in applying staff expertise more widely and engaging ultrasound practitioners more deeply within the audit process. However, utilising auditors of a similar clinical grade has implications in setting a clear reference standard against which to create robust audit outcome measures.

An audit programme should be sufficiently comprehensive to ensure that a wide variety of patient presentations and outcomes are included, and practical enough to ensure that it can be repeated on a regular basis. The QA programme should be monitored against well-defined outcomes.

An audit programme will concentrate predominantly on an ultrasound service as a whole, however, such a programme will also give data on individual practitioner performance. Given the inherent operator dependence of ultrasound, significant variation in individual performance is likely. Assessment of individual performance may be perceived as threatening by some ultrasound practitioners, therefore sensitive management of individual performance issues may be required. Assessment of individual performance should provide valuable CPD opportunities for ultrasound practitioners, both in providing evidence of existing good clinical practice and highlighting specific areas for professional development. Time, resources and support for CPD should be available to ensure that any areas of identified weakness can be satisfactorily addressed.

Audit is only useful as a tool to improve quality within the ceiling of expertise of an organisation. The fragmentation of ultrasound service delivery means that the various organisations involved may be providing ultrasound services at different levels of expertise. Some providers will have access to a wider range of outcome data for audit purposes, as well as more readily available clinical leadership than others. Examples of sources of feedback to inform audit include multidisciplinary teams (MDTs), clinicians, general practitioners, surgeons and pathologists.

Without objective evidence of the value of any particular way of auditing practice, no one method can be recommended. For consideration and interest, three examples of audit in current practice are given below.

### Example 1. Clinical governance and quality standards – a case study of a programme in action

### Background

Various methods of audit were reviewed with all the sonographers in the team to achieve a consensus view on how they would like their practice to be measured. While not without issues, it was agreed that a retrospective review of hard-copy images and reports would be implemented, as this most closely matched the information referrers had available to them.

Finding an audit tool which met the team's needs from published literature proved ineffective, therefore a data collection form specific to the service needs was designed and, importantly, agreed with the trust clinical governance team as an appropriate method for measuring quality.

#### Audit tool

The ultrasound team consists of a group of eight clinical specialist sonographers (CSSs), each overseeing a specific clinical specialty. This is a group of experienced senior sonographers. On a weekly basis, one of the team is allocated a 3.5 hour session where they review a randomly selected 5% of all AQP and, subsequently, GP non-obstetric practice. The aim is to extend this to include obstetric imaging in due course.

The previous week's activity is made available for the review. A random 5% is selected by the CSS and the referral details, the images and the verified report are reviewed.

The audit tool (Opposite Hull and East Yorkshire Hospitals NHS Trust [HEYT] ultrasound 5% audit) is used for data collection. This has been written as a web-based programme by the trust's IT department, however, initially a monthly spreadsheet covering all the questions and comments was populated. The web-based system has advantages as the patient information is uploaded directly from the trust's patient information system and the scores and comments are easily collated and exported on an Excel spreadsheets for analysis.

Only three scoring categories are available in this audit system. Any images or reports scoring 1 ('poor image quality with inadequate attempt to optimise')/1a ('disagreement of interpretation: requiring action') are communicated to the ultrasound manager for immediate attention. These cases and any others scoring 1b ('disagreement of interpretation: not requiring action') are discussed at a monthly case review meeting.

### Audit review

On a monthly basis the results of the weekly audits are collated and any cases demonstrating a disagreement between the sonographer and the reviewer are discussed with the sonography team.

The meeting is attended by as many sonographers and radiologists as possible. The meeting is chaired by the ultrasound manager or lead radiologist, who also has the casting vote if required. Cases with disagreements are presented and discussed. A case review disagreement form is used to direct discussion. Learning points and actions are discussed and agreed by the team.

Feedback is given to the individual sonographers either at the meeting or by follow-up by the manager.

The cases discussed and final outcomes are recorded electronically for feedback and review.

For their annual appraisal, the sonographers are required to review the previous year's case review outcomes and evaluate their average performance. Reflection and learning outcomes are an important part of this audit process.

### Conclusion

A web-based system has improved the efficiency of the audit process and has simplified collation of data for discussion.

Shared learning points can highlight areas of weakness or knowledge deficit within the team and can direct clinical presentations in future meetings.

Actions points have led to sonographers meeting surgeons and other healthcare providers as a means of increasing understanding of where their scans fit in patient management pathways.

The importance of feedback to sonographers was not initially recognised, but implementing self-review as part of appraisal ensures that all staff are included in the process.

Pamela Parker, Ultrasound specialty manager Ultrasound department: Hull and East Yorkshire Hospitals NHS Trust

## Hull and East Yorkshire Hospitals NHS Trust (HEYT) ultrasound 5% audit

Date of scan	Sonographer	Site	Machine
Date of review	Reviewer	Time	HEY number

### Image quality

1		Score	Comments
3	High-quality examination or suboptimal images with evidence that this was due to patient factors and attempts have been made to address these		
2	Reasonable image quality but a few poorer quality images (incorrect focus, measurement, protocol, colour, label etc)		
1	Poor quality image with inadequate attempt to optimise		

## Report quality

R		Score	Comments
3	Content and structure optimal		
2	Report satisfactory but additional diagnosis or advice could have been provided		
1a	Disagreement of interpretation: requiring action		Action required:
1b	Disagreement of interpretation: not requiring action		Reasons:

## Clinical opinion

	Yes	No	Comments
Diagnosis made			
Follow-up imaging			
Second opinion sought			
Cause for symptoms found			
Descriptive report only			

### Date of disagreement meeting:

## Example 2. Ultrasound practitioner reporting audit

#### Aim

To audit the standards of reporting performed by ultrasound practitioners and to compare these with the previously set benchmarks.

### Method

The static images and reports of approximately 400 general ultrasound examinations (including abdominal, pelvic and small-parts work) performed and reported by sonographers are reviewed. Care is taken to obtain an equal proportion of work for each sonographer. This audit encompasses all grades of reporting sonographer including superintendent, allied health professional (AHP) consultant grade and agenda for change (AFC) Band 7 ultrasound practitioners. Audit takes place on an annual basis.

Four reviewers, comprising three consultant radiologists and one AHP consultant sonographer are each allocated a proportion of studies to review. The allocation of studies is designed to ensure that each reviewer is assigned a proportion of studies from all ultrasound practitioners. The only exception to this is the AHP consultant sonographer who cannot audit his own studies.

### Standard

The overall standard is to have 95% of reports in categories three, four and five. Reports in categories three and four will be assessed to target-specific support, education and interventions to facilitate continuous improvement of ultrasound report quality. Reviewers are asked to grade the reports into one of five categories, outlined below.

Category 5	Complete agreement with report or only minor changes in wording or structure
Category 4	Minor additional comment/s required
Category 3	Additional differential diagnoses on review of images
Category 2	Disagree with interpretation of images
Category 1	Clinical question not answered and cannot be inferred

### AQP criteria

In addition, reviewers are asked to review the studies using criteria suggested under the AQP scheme, to ensure adherence to service contracts.<sup>80</sup> These are listed below.

### Standard

Mean score for both image quality and report quality should be a minimum of 3.8.

## Results

- Overall results are discussed as a department and any educational/CPD activities are agreed to facilitate continuous improvement.
- Individual results are also given to each ultrasound practitioner with support, guidance and training provided where necessary.

Peter Cantin, Consultant Sonographer, Derriford Hospital

#### Image quality

- 5 High-quality examination
- 4 Reasonable image optimisation but with a few poorer quality images (inappropriate focus etc) absent measurements or annotation
- 3 Suboptimal images but with evidence that this was due to patient factors and attempts made to address the difficulties
- 2 Poor image quality with inadequate attempts to optimise. Clinical question answered correctly
- 1 Poor image quality unacceptable standard

### **Report quality**

- 5 Content and structure optimal
- 4 Essence of report satisfactory slight modification of emphasis or advice
- 3 Report satisfactory but additional differential diagnosis or advice could have been provided. Unlikely to lead to patient harm
- 2 Discrepancy of measurement or interpretation. No immediate harm to patient but requires amended report
- 1 Unnecessary advice leading to inappropriate further investigation. For example, 'can't exclude malignancy,' in clearly defined condition, leading to invasive test or one involving ionising radiation, when unnecessary. Inappropriate follow-up recommended leading to downstream costs and patient anxiety
- 0 Poor report with risk of inappropriate management pathway

20

### Example 3A. Portsmouth audit methodology: non-acute abdominal ultrasound

### Background

The value of specialist opinion on diagnostic pathways has previously been difficult to quantify as, within an integrated department, consultant opinion is available to ultrasound practitioners in most cases, including hands-on scanning prior to the requirement to issue a definitive report. The pathway may include recall to a specialist radiology consultant list with access to contrast ultrasound.

Over reporting of benign incidental findings and normal appearances is of particular importance in populations with a low prevalence of pathology (GP and outpatient ultrasound referrals).

### Standards

No patient should be told they have cancer when they do not as a result of the construction of the report making reference to a 'lesion' or 'mass' implying the presence of cancer to the referrer.

There must be access to contrast ultrasound examinations to allow National Institute of Health and Care Excellence (NICE) guidelines to be followed.<sup>81</sup>

### Main outcome measures

- Number of patients without cancer discussed at the MDTMs as a result of ultrasound reports
- Number of unnecessary tests performed involving interventional procedures or ionising radiation, including computed tomography (CT)

 Number of inconclusive ultrasound reports resulting in diagnostic uncertainty and, by implication, the presence of serious pathology, where intervention of a specialist radiologist has prevented discussion at an MDTM or unnecessary tests 'hedging'.<sup>82</sup>

### Methodology

- Define time period for audit
- Collect data on total number of GP and outpatient examinations resulting in an ultrasound examination of the abdomen over this time period 'the audit group'
- Collect data on total number of proven cancers referred to MDTs in this period, who had ultrasound as the first examination in their pathway as a GP or outpatient referral, classify this as 'incidence of cancer' or 'true positive'
- Collect all unnecessary referrals to MDTs for each disease group being audited, for example, hepatobiliary (HPB) MDT, classify as 'false-positive' and score audit as category 'may or would lead to patient harm'
- Collect all unnecessary examinations performed, for example, CT, colonoscopy and 'false-positive', and score as category 1 'patient harm'
- Define 'unnecessary' as cases in who specialist radiology expertise would have avoided referrals and examinations by issuing more definitive report. If a report results in referral due to indeterminate reporting of ultrasound findings, irrespective as to whether the word cancer is used, still define as false-positive.

Dr Tony Higginson, Queen Alexandra Hospital, Portsmouth

### Example 3B. Portsmouth audit methodology: acute abdominal ultrasound

### Background

There is a high prevalence of pathology in ultrasound for acute abdominal symptoms.

Assessment of diagnostic accuracy is therefore more achievable in an acute hospital setting as a benchmark of the quality of an ultrasound service.

The value of ultrasound in acute abdominal imaging has highly variable ranges for sensitivity and specificity. Sensitivity for the diagnosis of appendicitis is up to 90% for skilled operators and 92% for acute diverticulitis.<sup>83</sup>

The use of ultrasound in the diagnostic strategy can reduce the number of patients requiring CT.<sup>84</sup>

### Standards

- For localised abdominal symptoms, sensitivity and specificity for different pathologies such as appendicitis or diverticulitis can be used to set the standard.
- Where the approach is to look at diagnostic strategies, standards should be set to reduce the conversion rate to CT and reduce negative laparotomy rates, for example, for appendicitis.
- Gold standards include surgical findings and interval clinical follow-up.
- There are no studies that look at the range of ultrasound diagnoses as a marker of ultrasound quality. This is potentially the most useful measure of ultrasound quality within a patient group with a wide range of possible diagnostic findings and non-specific abdominal symptoms.

Dr Tony Higginson, Queen Alexandra Hospital, Portsmouth

## 7. Image management

Images obtained as part of an ultrasound examination provide a valuable record of the findings and should be used to support the final report.

All providers of an ultrasound service should have the facility to store whole studies.

Image transfer between providers is now routine. To minimise the possibility of patient harm from reviewing images in the absence of a report, the ultrasound images and reports should be stored/ linked together.

The linked report and image can be useful as part of an audit of practitioner accuracy and competency.

### Image capture

- Patient demographics should be passed to the acquisition device using DICOM modality work-list (DMWL) Health Language level 7 (HL7)<sup>85</sup>.
- The capture of images should always be undertaken on the acquisition device.
- Images should be captured and labelled using a minimum dataset.
- Current requirements are as follows:
- NHS number (whenever possible)<sup>86</sup>.
- Given name
- Family name
- Date of birth
- Gender
- Postcode.
- Site markers, labelling and measurements should be saved as a separate image.

- Images should be acquired in DICOM format, ready for export to a DICOM archive.
- Images should also be stored locally on the acquisition device, to ensure any transmission failures can be resent.

### Image storage

- Images should be archived in a DICOM format in a DICOM WES compliant archive.<sup>87</sup>
- Image archives should be replicated so that more than one instance of an image is available should one copy fail.<sup>88</sup>
- The two copies of images should be stored and managed separately, ideally in separate geographical locations.
- Images should be stored for an appropriate length of time according to the RCR.<sup>89</sup>
- Images should be linked to reports and be able to be viewed as a record together in a PACS.<sup>90</sup>

### Image access and review

- Images should be accessible through an enterprise-wide viewing application or DICOM viewer. Diagnostic image viewing should be undertaken using DICOM images.<sup>91</sup>
- Digital images should be retrievable in a timely manner, at the point of clinical need, across 24/7/365.<sup>92</sup>
- Reports should be linked to images using desktop integration at the reporting stage.
- Access to images should be restricted to those users with a legitimate relationship to the patient. Role-based access control (RBAC) can be used to provide image/report access to appropriate individuals.<sup>93</sup>

#### Image transfer

- Digital images should be imported/exported in DICOM, in line with current guidance on data security. The primary and preferred route for this is to transfer information in an electronic format and not to use removable media.<sup>94</sup>
- Formats include compact disk (CD), Digital Versatile Disc (DVD), Universal Serial Bus (USB), PACS to PACS N3 DICOM link or via a third-party transfer service such as the Image Exchange Portal (IEP).<sup>94</sup>
- Images and reports ideally should be transferred together.
- Where transportable media (for example, CDs) are used, an approved encryption system should be employed and password sent under separate cover.<sup>95</sup>
- Patient demographics, incorporating NHS number, should be included to allow receiving organisations to accurately process the data.
- Audit mechanisms should be employed to evidence transmission and receipt of any transfers.

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## Appendix 2. Glossary

### Any qualified provider (AQP)

For some tests and procedures, including non-obstetric ultrasound, patients are able to choose from a range of approved and qualified providers. AQP is an NHS provision and is commissioned by local NHS commissioning groups. Since the beginning of March 2014, central support for AQP has been devolved to the commissioners.

### Audit

A process that seeks to improve the quality of ultrasound examinations through systematic review against explicit criteria and the implementation of change. Audit processes may be applied to the delivery of the ultrasound service as a whole or to the work of individual practitioners.

### Care Quality Commission (CQC)

The body that regulates and inspects providers of health and social care in both the public and independent sectors in England. Unless exempted, all providers (but not employees of providers) of regulated services must, by law, be registered with the CQC. Full details are given in the CQC Scope of Registration.<sup>96</sup>

### **Clinical governance**

A system through which NHS organisations and independent providers are accountable for continuously improving the quality of the service and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

### Consortium for the Accreditation of Sonographic Education (CASE)

CASE accredits postgraduate ultrasound programmes and focused courses. It has five constituent member organisations.

British Medical Ultrasound Society (BMUS)

British Society of Echocardiography (BSE)

Institute of Physics in Engineering and Medicine (IPEM)

Society and College of Radiographers (SCoR)

Society for Vascular Technology of Great Britain and Ireland (SVT)

### Guideline

A general rule, principle or piece of advice. Guidelines provide recommendations on how ultrasound examinations should be performed and are based on the best available evidence. They help ultrasound practitioners in their work but they do not replace their knowledge and skills.

### Imaging Services Accreditation Scheme (ISAS)

An accreditation scheme developed by the RCR and the SCoR to help diagnostic services ensure that their patients consistently receive high-quality services delivered by competent staff working in safe environments. The UKAS delivers and manages ISAS on behalf of the two colleges.

### Mentor

An experienced ultrasound practitioner who is continuously and willingly available to assist with an essentially private process of guidance and support for a less experienced ultrasound practitioner.

### Operator

A generic term used for someone who uses ultrasound equipment. It does not imply that they hold recognised ultrasound qualifications as would an ultrasound practitioner.

### Preceptor

An experienced ultrasound practitioner who has been given a formal responsibility by an organisation to support a newly qualified ultrasound practitioner through a period of preceptorship.

### Preceptorship

A period of structured transition for the newly qualified ultrasound practitioner during which he or she will be supported by a preceptor to develop confidence and skills as an autonomous professional.

### Protocol

An agreement, preferably based on research, between practitioners to ensure the delivery of high-quality, standardised ultrasound examinations.

### Quality assurance (QA)

Activities intended to assure or improve the quality of care in either a defined medical setting or programme. QA activities and programmes can also be applied to ultrasound equipment.

### Registration

The purpose of registration is to protect the public by promoting high standards of professional conduct and professional education, training and competence among the registrants. Registration may be with one of the nine statutory regulators (which include GMC, HCPC and NMC) or with a voluntary regulator. Statutory registration is not achievable for all ultrasound practitioners.

### Sonographer

A healthcare professional who undertakes and reports on diagnostic, screening or interventional ultrasound examinations. They will hold qualifications equivalent to a postgraduate certificate or postgraduate diploma that has been accredited by the CASE. They are either not medically qualified or hold medical qualifications but are not registered as a doctor in the UK. (Definition from the SCoR Public Voluntary Register of Sonographers.)<sup>97</sup>

### Standard

A required or agreed level of quality or attainment. A standard is a way of ensuring optimum levels of care or service delivery. Standards promote the likelihood of an ultrasound service being delivered safely and effectively, are clear about what needs to be done to comply, are informed by an evidence base and are effectively measurable.

### Ultrasound practitioner

A healthcare professional who holds recognised qualifications in medical ultrasound and is able to competently perform ultrasound examinations falling within their personal scope of practice. The professional background of ultrasound practitioners can be very varied and will include radiologists, radiographers, sonographers, midwives, physiotherapists, obstetricians, physicists and clinical scientists.

### 29

## Appendix 3. Abbreviations

AQP	Any Qualified Provider
BMUS	British Medical Ultrasound Society
CASE	Consortium for the Accreditation of Sonographic Education
DH	Department of Health
CQC	Care Quality Commission
GMC	General Medical Council
HCPC	Health and Care Professions Council
ISAS	Imaging Services Accreditation Scheme
NMC	Nursing and Midwifery Council
PVRS	Public Voluntary Register of Sonographers
RCCP	Registration Council for Clinical Physiologists
RCOG	Royal College of Obstetricians and Gynaecologists
RCR	The Royal College of Radiologists
SCoR	Society and College of Radiographers
UKAS	United Kingdom Accreditation Service

Standards for the provision of an ultrasound service

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