Ultrasound quality assurance and equipment governance

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Abstract

A case is presented to show the importance of good governance of ultrasound medical imaging equipment. Issues relating to the large numbers and diverse range of users and equipment are identified. Based on experience gained over 25 years, supporting upwards of 1000 systems, discussions consider why and how the testing of ultrasound systems should be approached by both the medical physics expert and end user. The management of the process is presented in the context of professional guidance and monitoring organisations' standards are considered to give a suggested best practice.

Keywords: Ultrasound quality assurance, governance, medical device management

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Introduction

There has, for sometime, been controversy associated with both the need to undertake ultrasound quality assurance (QA) and its effectiveness when in place.¹ Over the years, systems have moved from heavily analogue-based devices with a need for frequent checks and calibration to mostly digital systems, which are presumed to be stable and therefore require few if any checks. However, there are clearly aspects of even the most modern system that are still subject to degradation.^{2,3} Underlying the arguments as to the efficacy of QA has been the question of how measurements, which have been made to identify system performance changes, ultimately relate to the clinical impact of those changes observed. An on/off approach to local and/or specialist physics-based QA has been the pervading response of most sonographer-led radiology and obstetrics services. Outside of these areas, little QA of any sort is undertaken and these users are generally the least experienced and most likely to overlook faults in the system. This has led to a wide range of systems being used clinically with pre-existing faults which have not been recognised, from minor issues with switches to imaging faults which present a significant risk of misdiagnosis.

There are several reasons why both local and medical physics-based QA is essential for ultrasound systems in clinical use. The ultrasound images upon which a clinical decision is taken are not available for peer review. Rather, only a limited snapshot of the scan reported is recorded, if at all, so there is little evidence of the competence of the scan. The addition of significant image processing algorithms and multi-beam processing to all but the very basic scanners has created a mask which obscures many fundamental faults,

although there may still be identifying features in documented evidence. The ever-expanding application of ultrasound outside imaging specialisms has increased the number of inexperienced operators often relying on automated scan functions and lacking a proper understanding of the technology. The diversification of maintenance services away from the original equipment manufacturer (OEM) implies more rigorous monitoring may be required.

Clinical relevance

So how do QA measurements relate to the clinical efficacy of the system? In fact, we could expand this question to almost all performance measurements made on all diagnostic imaging modalities.⁴ In general, we will find that none of them have an answer, because there is no way of relating changes in imaging parameters to diagnostic efficacy, because in most instances the process is too complex. There is often a presumption that if some parameter degrades, there will be a clinical impact, but in truth no one knows what diagnostically is impacted by any particular parameter change. The key problem here is that there are virtually no measurements relating to the clinical performance of a system to correlate QA measurements against. Even when new imaging systems, with significantly improved performance parameters in any modality, are introduced, there are few if any studies to show a reasonably expected step change in improved diagnosis. The argument is, therefore, that for ongoing QA, the relationship between clinical performance and measurements taken is not directly relevant. Although, there are some cases where it is possible to monitor ongoing clinical outcomes, for example, in image-guided procedures,⁵ and these could be correlated with changes

in measured QA parameters, such as resolution or penetration.

Clinical justification

Unlike most imaging modalities, ultrasound diagnosis is most commonly made on real-time images, with only a subset stored to PACS. In some applications, no images are stored at all. Where the findings of diagnostic scans are challenged, a peer review of the original diagnostic information is not therefore possible. The competence of the original report can only be supported by:

- General peer observation of any images stored indicating they were competent
- Records and documentation of training, local CPD and audit showing good governance of staff
- Records and documentation of maintenance, quality control and management of faults showing good governance of equipment
- Policies and documentation on the use of ultrasound scanning, showing overall governance of the environment

A QA program with clinical outcome monitoring supports the second and third of these. Only by undertaking testing of the clinical impact when parameters are noted to change and thereby establishing evidence-based intervention points can we show compliance. Thus, the design of a QA methodology becomes much clearer with consideration of what may change, whether that change could potentially degrade clinical performance and how can we spot that change initially guiding us.

Context

The management of medical devices, their servicing, quality control and management control has undergone significant revision within the health service, mostly driven by the National Health Service Litigation Authority (NHSLA)⁶ and more recently, by the Care Quality Commission (CQC).⁷ However, in many organisations a substantial number of ultrasound systems have been overlooked, usually because everyone thinks they are someone else's responsibility, which is clearly seen from the poor response and under-reporting of UK systems in the European Society of Radiology (ESR) ultrasound working group report.⁸ Ultrasound systems need to be appropriately governed such that the following points are covered.

- There is an identified equipment manager
- Test results are available from the formal functional acceptance test carried out before first clinical use⁹
- All users are aware of and able to access the user manuals and training material
- The staff qualified to use the equipment unsupervised are identified and recorded and those staff have appropriate evidence of training and qualifications
- The training records are up to date and available to audit

- The equipment is properly maintained and the maintenance records for the equipment are available to audit
- The maintenance records include reports left in respect of faults and repairs in addition to planned preventive maintenance visits
- Regular frequent local QA is performed on the equipment
- Protocols are in place for the management of faults which do not preclude equipment use
- Medical Physics Expert (MPE) QA is regularly performed on the equipment
- The QA records are up to date and available to audit
- There is routine monitoring of equipment clinical performance by outcomes or intersystem comparisons where possible

Our experience

Over the last 25 years in working with over one thousand ultrasound scanners, we have found systems with serious faults, but which were still in clinical use; probes with almost 30% dropout across the entire scan plane from intermittent cable breaks, probes with insulation breakdown leading to electrical properties well outside standards,¹⁰ panels missing on systems, controls contaminated with gel, leading to erratic performance, electrical noise masking image details and many more. In almost all of these cases, inexperienced and sometimes experienced operators were continuing to scan, unaware of the risks they may be placing on their patients. With the single-button operation and advanced image processing of the newer scanners and the further expansion of ultrasound use, my suspicion is that the situation is now worse than ever as diligent users, who would have acted, are unaware of the problems. It is possible that organisations have little or no awareness of who is using their scanners and what they are using them for. With an ever-widening user base, the probability of inappropriate equipment being used for ultrasound scans becomes ever more likely and the potential consequences for patients may be serious.

We have often found that there is a management assumption that if their equipment is serviced, the quality is being monitored and the responsibility for the performance of that equipment is now with the service agent. This is incorrect in both cases; planned preventive maintenance is not quality assurance. It usually does not involve performance measurements, other than those the system can run as software tests on the components and controls. The user is accepting responsibility for the performance of the system on every occasion they scan and report a patient.

Moving forward

There is a genuine need to take control of the situation and there is guidance as to how to do so. For example, the National Ultrasound Steering Group, a subgroup of the National Imaging Board, has recommended the introduction of a Clinical Governance Board for all providers of

ultrasound imaging.¹¹ The purpose of this board would be to oversee the procurement, maintenance and replacement of equipment and ensure that appropriate training, supervision and audit of systems, staff and use are made. Other guidance from professional bodies with similar recommendations often fails to be implemented, presenting significant risk to organisations.

Competent testing

It is important to consider the level of training and experience required to act as an ultrasound MPE for equipment performance, as this is often underestimated. The MPE will often have the ultrasound role added as an adjunct to their main role and be registered in another medical physics specialism, without reference to ultrasound in their registration. The MPE needs to have more experience and understanding of systems and their performance than the users. He/she needs to understand the range and effects of the advanced imaging controls and where and how to disable them. If the MPE covers a wide range of organisations, this may encompass over a hundred system models from a range of manufacturers. Even in a single organisation, there could be twenty or thirty, requiring a considerable investment of time and training. Training in the operation of the systems and a thorough understanding of the testing processes are essential for the QA to be effective. In addition, electrical safety testing of ultrasound systems should always be performed by a specifically trained technician, as systems can be easily damaged from power cycling.

Proposal

So what does this all mean in terms of the practical delivery of QA for ultrasound equipment? The user QA is straightforward and guidance is given within this special issue and in IPEM report 102.¹ The medical physics expert QA is more difficult to tie down, as there is a lack of evidence from specific testing to establish a clear evidence-based test protocol. Even if there were such evidence, with the rapid rate at which ultrasound systems and technology change, it may quickly become obsolete. Issues that developed and were worth testing for may no longer apply; software bugs could mean features which were never considered were a source of problems. So, as evidence-based systems are by their nature historic and QA on new systems may not comply, our approach needs to be more predictive. A sensible way forward is to apply a risk management based technique, as this is not only accepted practice but a required methodology when dealing with such unknowns. This would comprise an initial evaluation of what we expect may be subject to change, a consideration of the impact it may have and a parameter we could measure to indicate change, forming the basis of any system QA. An initial estimation of a reasonable investigation level is followed by feedback from clinical observations when that level is exceeded and where possible, action levels developed. Otherwise, we continue to use the QA to indicate when extra vigilance is required clinically.

At present, there are also elements that are not subject to rapid technological change, where it is likely the issues that exist now will continue and these may form a base level of QA monitoring.

- Connections between the system and crystal elements of the transducer causes signal loss²
- Electrical systems are subject to noise, which changes over time
- Software has bugs and these may change with updates
- Display monitors use light sources which fade with age³
- Doppler measurements may be erroneous due to faults with probe or software
- Software changes or failure of active temperature sensing may cause probes to overheat in air
- Physical damage may occur to a system at any time
- Cables fatigue and may fail over time
- Gel ingress or disinfecting or cleaning chemicals may compromise a system

With appropriate experience, understanding of the operation of a system and suitable test equipment, the above can be evaluated by an ultrasound MPE. Identifying faults early, reducing the risk and perhaps extending the life of the system.

The test equipment is an important part of being able to deliver an MPE service that adds value to the local QA protocols. For example, equipment to cover the range issues noted above requires;

- A B-mode test object with uniform background and assessment targets
- An electrical safety tester with manual power cycling
- A Doppler test object 'String' or 'Flow' type
- An IR thermometer
- A light meter for screen luminance

Decisions about QA are then risk-based, monitoring for changes in areas where although unlikely, the clinical impact is expected to be high and for changes where although the impact is not clear, the change is likely.

It is not enough just to have QA undertaken on a system for it to be effective. The protocols must include methods of managing the findings and ensure that the documents are seen by the equipment manager. It is an essential part of the governance of QA that if issues are noted, actions are taken and recorded. For example, if there is a minor imaging issue with a probe, such as a small area of drop out to one edge, users will probably continue to use the probe normally. This is fine but it needs contemporary documentation as part of the record, for example the equipment manager or clinical lead could write:

The QA carried out on the 3rd of March identified a small region of drop out with no signal from that area. This appears to be due to a cable break, as it can be intermittently recovered. A clinical assessment of the probe has shown that in the current applications, this is unlikely to be detrimental as it is rarely in the region of interest. Rotating the probe to the

contra side can overcome the issue for those rare occasions where it may impact on the area of interest. It is recognised that cable faults are often progressive and daily as opposed to weekly checks will be undertaken to monitor the status. With these conditions in place, the probe is to continue in use for the current range of clinical applications. This situation is to be reviewed subject to any further changes in the probe.

Although this is fictional example, it is typical of the type of findings and represents the process that should be expected from such QA findings.

Conclusion

So overall, what constitutes good governance of system QA? Well, firstly it has to be an integral part of good governance of an ultrasound service, otherwise few benefits will be realised. The key factors for QA governance are that the local QA should be carried out by staff trained on the protocol and on the system with evidence of that training. The MPE QA should be carried out by appropriately qualified staff with evidence of training on systems and with suitable test equipment. Decisions and actions taken as a result of QA findings should be recorded for all QA issues raised and these need to form part of the QA record. All records pertaining to the system installation, acceptance, local QA, MPE QA, servicing and faults should be available to audit at any time during use and for an appropriate number of years post decommissioning, depending on application. All systems should have a clear method of indicating status, such that users are aware of any outstanding issues and can check documentation for any special instructions prior to use.

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