The management of ultrasound equipment at Sheffield Teaching Hospitals NHS Foundation Trust

PK Verma and M Peacock

Department of Medical Imaging & Medical Physics, Sheffield Teaching Hospitals NHS Foundation Trust, Glossop Road, Sheffield, UK
Corresponding author: PK Verma. Email: Prashant.verma@sth.nhs.uk

Abstract

Management of ultrasound equipment at Sheffield Teaching Hospitals NHS Foundation Trust is described. The organisation and input of various stakeholders and their involvement with ultrasound equipment management and scientific ultrasound is discussed. Two important stakeholders are the Medical Equipment Management Group and the Radiation Safety Steering Committee. The Medical Equipment Management Group has a specific sub-group, the Ultrasound sub-group, and its role is to coordinate the purchase, replacement and quality assurance of ultrasound equipment in the Trust. The Radiation Safety Steering Committee has a non-ionising radiation representative and the role of this committee is to provide corporate assurance that any health and safety issues arising from the use of radiation to either patients, members of the public or staff within the Trust are being effectively managed. The Ultrasound sub-group of the Medical Equipment Management Group has successfully brought together management of all ultrasound equipment within the Trust and is in the process of fulfilling the quality assurance and training milestones set out by the Medical Equipment Management Group. Advice from the Radiation Safety Steering Committee has helped to increase awareness of ultrasound safety and good scanning practice, especially in the case of neonatal ultrasound imaging, within the Trust. In addition, the RSSC has given advice on clinical pathways for patients undergoing ionising radiation imaging while being treated by extra-corporeal shockwave lithotripsy.

Keywords: Ultrasound, quality assurance, equipment management

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Introduction

In the last 10 years, the use of ultrasound in the clinical environment has increased rapidly, from a total worldwide market of \$1.5B in 2008 to a market of \$4.6B by 2012, with an average predicted growth of 7% until 2019.¹ The increase has in part been achieved by growth in established areas of imaging, such as vascular imaging, abdominal imaging, cardiac imaging and obstetric imaging. However, there has also been expansion into other areas, such as neonatal imaging, urological imaging, ophthalmic imaging and the use of ultrasound imaging for vascular access and line placement. With this proliferation has come the added cost of ultrasound equipment to large NHS hospitals. At Sheffield Teaching Hospitals NHS Foundation Trust (STHFT) ultrasound equipment has an asset cost of over £5M.

The market for medical ultrasound is expected to grow further over the next five years and there is expected to be an increase in the number of medical applications of ultrasound, ranging from the already established clinical areas mentioned above to more therapeutic applications, ranging

from healing for soft tissue, healing for bone fracture, wound healing, lithotripsy treatment for ureteral calculi and bone spurs, uterine fibroid ablation and cancer therapy via tumour ablation. Support for this can be found in the literature² or by analysing recent calls for unmet research needs³ within the NHS, where some related to therapeutic ultrasound can be found.

Clearly, large NHS hospital trusts could benefit from management practices that keep abreast of the developments in medical ultrasound, so that financial, logistic and scientific aspects of this technology can be put to the best public use.

This paper describes some of the management structures that have been put in place at Sheffield Teaching Hospitals NHS Foundation Trust (STHFT). These management structures have, in the main, been based on recommendations from national bodies that deal with ultrasound⁴ and imaging equipment.⁵ The paper focuses on areas where input from the scientific ultrasound group has facilitated decision making. Logistic management, clinical training and procurement management are not covered in any detail.

In addition, clinical engineering aspects of ultrasound equipment management, although closely related to ultrasound quality assurance, is also not dealt with explicitly.

Ultrasound at Sheffield Teaching Hospitals Foundation NHS Trust

The Trust is organised into a number of directorates, one of which is the Medical Imaging and Medical Physics directorate (MIMP), consisting of the departments of Radiology and Medical Physics. Over the last 5 years, STHFT has developed strategies for the management of ultrasound equipment within the Trust. This work has been led by the Directorate Manager of Medical Imaging and Medical Physics and the Scientific Director of Medical Imaging & Medical Physics, with support from the ultrasound manager, the scientific lead for non-ionising services, the supplies management team, the clinical engineering management team and a number of clinicians.

Advice into the Trust's decision-making process has progressed down two distinct but related routes. The first path is through the Trust's Medical Equipment Management Group, as recommended by national guidance.⁵ The second path is through the Trust's Radiation Safety Steering Group. Figures 1 and 2 provide an organisational structure for both these groups.

The Medical Equipment Management Ultrasound sub-group

The Medical Equipment Management Group (MEMG) is tasked with oversight and authority on the purchase of all medical equipment up to a value of £150 K within the Trust. Due to the proliferation in ultrasound equipment within the Trust, an ultrasound sub-group has been formed with the

remit of providing advice to MEMG on a number of issues related to ultrasound equipment. This includes purchase, replacement, appropriate utilisation and training. This group is drawn from Trust staff groups that are involved with ultrasound equipment, including clinical, scientific, managerial, technical and purchasing personnel. The group has drawn up a list of all the ultrasound equipment within the Trust. The database contains key information, including purchase date, cost, location, transducer information and department. Added to this there is a specification of the imaging capability for ultrasound imaging scanners; high, medium or low.

High specification scanners are those that require good quality clinical images for primary diagnosis. These include traditional cardiology, radiology and obstetrics & gynaecology machines to several specialist machines, such as those used in urology. The low-imaging capability machines tend to be portable scanners used primarily for needle visualisation or line placement. The medium specification scanners are a more difficult group to classify. However, we generally classify these scanners for clinical use in areas where there is already known pathology. Examples of these clinical areas include the assisted conception unit, renal biopsy and for use in the operating theatre. Some scanners are also classified in the medium specification bracket based on their limited overall capability in supporting a range of transducers and post-processing software.

The ultrasound sub-group deals either with replacement of existing equipment or purchase of new additional equipment. In the latter case, the clinical speciality requiring a new additional piece of equipment completes a standard equipment business case form and then attends an ultrasound sub-group meeting to discuss the bid. The group assesses the bid and a successful bid is then passed onto

Figure 1 The organisation chart for the Ultrasound Equipment Sub-group at Sheffield Teaching Hospitals NHS Foundation Trust

the MEMG for further assessment and confirmation of purchase. For equipment that is due for replacement, a business case is not required and the ultrasound sub-group consider replacement on other criteria described below.

Nominally, equipment is put on a ten-year replacement programme, in line with the Trust's asset register. However, equipment can be replaced earlier or later than the ten-year cycle. This judgement is reached by members of the MEMG ultrasound sub-group and other interested parties. Decisions are based on equipment performance, new clinical pathways, new technology and financial considerations. In order to gauge equipment performance, the Trust has set up a quality assurance programme for ultrasound scanners. The programme is now underway and is based on national guidelines⁶ on ultrasound equipment quality assurance and performance. The implementation of the quality assurance programme is carried out by Medical Physics and Clinical Engineering staff. An important aspect of the quality assurance programme is that it looks primarily at changes in the imaging performance of a scanner. Whether a new additional scanner or a replacement scanner is being considered, the ultrasound sub-group also considers whether existing equipment within the Trust can be used to fulfil the clinical requirements.

For the purchase of new scanners, the ultrasound sub-group has set up policies and procedures that include a scored evaluation system, which is used to aid in the selection of new equipment. The evaluation is based on a number of factors, which include features such as ease of use, manufacturer support, clinical needs, cost, enhanced imaging features, clinical imaging assessment and scientific imaging assessment.

The Radiation Safety Steering Committee

The Trust Radiation Safety Steering committee reports to the Trust's Executive Group and is chaired by the Medical Director. The group is primarily concerned with corporate

assurance that any health and safety issues arising from the use of radiation to either patients, members of the public or staff within the Trust are being effectively managed. The majority of these cases involve ionising radiation and the statutory legal regulations that the Trust is obliged to comply with. However, non-ionising radiation is also included, as there are clear health and safety issues with modalities such as magnetic resonance imaging and there is now a legal framework of regulations controlling the use of artificial optical radiation within the workplace.

For diagnostic ultrasound, safety is dealt with by two bodies, the FDA⁷ (Food and Drug Administration, Centre for Devices and Radiological Health, USA) and the IEC.⁸ The FDA imposes upper limits on the acoustic output of diagnostic scanners under the 510(k) Track 3 route to market. Although these legal requirements only apply to North America, the majority of ultrasound scanner manufacturers comply with them for all their markets. The IEC standard IEC60601-2-37 (2007) imposes limits on the surface temperature that transducers can reach under diagnostic operating conditions. The combination of FDA legislation and IEC standards effectively limits the acoustic output from diagnostic transducers to what are currently regarded as safe limits.⁹ However, there are still areas where concern and vigilance is required, such as in Obstetrics and Gynaecology, and in the use of contrast agents in imaging. The British Medical Ultrasound Society¹⁰ and other international bodies^{11,12} have safety guidance documents¹³ related to both these areas of use.

The use of ultrasound for therapeutic applications is growing² and there is awareness of the need to establish managerial mechanisms and scientific quality assurance programmes to ensure the safe use of this ultrasound modality. At STHFT, therapeutic ultrasound is used in physiotherapy, for soft tissue healing, and in extra-corporeal shock wave lithotripsy for the treatment of ureteral calculi. Ultrasound physiotherapy does not form part of any clinical pathways within the secondary care setting.

Figure 2 The organisation chart for the Trust Radiation Safety Steering Committee at Sheffield Teaching Hospitals NHS Foundation Trust

However, it is used in the community through primary care referrals, and the performance of this equipment is managed by STHFT.

Discussion

STHFT has put in place management and operational structures to provide for efficient and safe use of ultrasound devices within the Trust. The purchase and replacement of equipment is done under the auspices of a sub-group of the Medical Equipment Management Group. The working of this group is in its early phase, but there have already been some successes.

- In general, by having oversight of all ultrasound equipment within the Trust, the Trust has been able to get a handle on the financial implications of equipment replacement and been able to plan around a yearly expenditure figure.
- There has been some benefit in consolidating equipment from one manufacturer within a department. For example, there are advantages in designing and performing quality assurance tests. In particular, it has been easier to assess performance between scanners from one manufacturer.
- There has been success in re-distributing equipment, which may otherwise have been discarded, between Trust departments.
- Cases where ultrasound equipment is purchased through research funding have been addressed. In such cases, departments that purchase the equipment are asked to consider Trust maintenance costs after the research grant period has expired. The implication of introducing such ultrasound machines into the NHS clinical pathway, in terms of future replacement machines, is also highlighted.

Although safety issues in clinical ultrasound are not prevalent in this Trust, access to the Trust's Radiation Safety Committee has been of benefit.

- A scanner not thought to be performing to standard can be put on the Trust risk register, with feedback provided to the Radiation Safety Steering Committee.
- Safety issues in the use of clinical ultrasound for neonatal cardiac scanning have been raised with the Trust and at a wider level.¹⁴ Clinical staff have been encouraged to follow recommended national safety guidelines for such scanning.
- In order to manage risk for patients undergoing extracorporeal shockwave lithotripsy (ESWL) treatment, it is important to establish whether they are pregnant. Lithotripsy treatment is contra-indicated for pregnant patients due to potential harm to the foetus.¹⁵ Under the present ionising radiation regulations (Ionising Radiation [Medical Exposure] Regulations 2000 (IR[ME]R 2000),¹⁶ female patients are asked about their last menstrual period (LMP) under the 28-day rule. The Trust was planning to roll this policy out on a Trust-wide basis. However, it has been successfully

advised that female patients having X-ray or fluoroscopy imaging as part of ESWL treatment should be asked about their LMP under the 10-day rule. The reasoning for this is based on the potential harm to an undetected early developing foetus from ESWL treatment. It should be stressed that the Urology Department does use the 10-day rule, but there was a possibility for them to move to the 28-day rule in line with other departments that offer X-ray or fluoroscopic imaging.

- During an overview of patient pathways for ESWL treatment, the Urology Department has been made aware of European guidance on contra-indications to ESWL.¹⁵ In particular, the guidance advises that patients undergoing nuclear medicine renal scans should not undergo ESWL treatment for at least two days after scanning. The Urology Department has introduced this into their booking checklist.

Conclusions

Management and safety issues, relating to scientific ultrasound, for ultrasound equipment within STHFT have been described. Through the MEMG and RSSC management structures, we have provided a framework with which to manage the purchase, replacement, training and quality assurance of ultrasound equipment within the Trust. In addition, there are now routes through which issues or advice relating to the safety of ultrasound equipment can be disseminated in the Trust.

There remain many challenges, including better communication between stakeholders in the process of purchase, replacement and maintenance and quality assurance. In addition, there are further policies and protocols that need to be developed in order to concur with the objectives set out in national guidance.⁵ An audit of trained clinical users of ultrasound equipment is not the subject of this work but is of importance in terms of governance issues for NHS Trusts.⁴ There are further issues related to the availability of qualified staff groups to provide scientific and technical support for an imaging modality that has expanded rapidly over the last decade. In terms of quality assurance of ultrasound equipment, one of the key challenges is to achieve better data on the performance of ultrasound equipment. In particular, there are challenges in identifying and implementing successful quality assurance programmes for non-traditional ultrasound devices. These include ophthalmic ultrasound scanners, trans-oesophageal transducers, other cardiac transducers and therapeutic devices. There are also likely to be challenges with quality assurance for new ultrasound imaging technologies such as elastography and 3-D imaging. Improvements in digital electronics and signal processing and reductions in cost of ultrasound imaging equipment are also beginning to blur the boundaries between scanners that have traditionally been regarded as high-specification machines (used for primary diagnosis) and those machines that are cheaper but classified as medium or low specification. There is a need to re-assess the imaging performance capability of the wide range of

ultrasound imaging equipment that is available on the market. This work could be beneficial to NHS Trusts in planning for budgets to replace existing equipment. It is hoped that by putting in place the correct structures, the Trust can successfully achieve its goals in the management of ultrasound equipment.

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