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FOREWORD

Change your thoughts and you change your world*



Welcome to the 2008 edition of *Imaging & Oncology*, the annual publication that asks eminent authors to identify and chart the issues and trends that will determine the future of clinical imaging and oncology. None of them presumes to see as far as 60 years ahead to the 120th anniversary of the National Health Service – if such an organisation exists in 2068 – but they do agree that yet more change is inevitable.

I can hear the sighs and exclamations: “Hasn’t there been enough change? Isn’t it time to leave us all to get on with our jobs? If we didn’t have to spend so much time planning and implementing change, we would be able to get on and do the job for which we were employed!”

Lord Darzi, writing in the NHS Next Review Leading Local Change document[§], comes to a different conclusion: “... World-class quality of care is a moving target – what was high quality in 1948 or 1998 is often not regarded that way in 2008. High quality care cannot be achieved through one last heave, but only by recognising the need to accept, embrace and lead change. Standing still won’t meet the expectations of our patients, the ambitions of our staff or the interests of the public. Such an approach would frustrate staff, work against the interests of patients, and is necessarily doomed to failure.” He goes on to outline five pledges: change that is patient centred, clinically led, locally led, involves staff, and maintains existing services until new ones are up and running.

The young have the enthusiasm, energy and arrogance to change the world; they fight every battle as if it will be the one that wins the war. Age brings realisation that it is more realistic (and productive) to choose the battles and to be strategic.

The great mass of change will continue, without doubt. Some of it the clinical imaging and oncology community will welcome; some of it will act as a ‘call to arms’. The key battles we choose to fight will be won provided the critical, key principle is always in sight: any change must be patient centred – if it isn’t, then it must be resisted fiercely.

People fear change because it shatters their comfort zones; they feel they are no longer in control. But, provided the professions do not flinch from the fundamental tenet that patients come first, then we will control our future.



Zena Mitton
President
The Society and College of Radiographers

* *Norman Peale, clergyman*
§ www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_084644

Forensic investigation – How effective is the medical imaging contribution?

Mark Viner

On 28 December 1895, Wilhelm Conrad Röntgen submitted his manuscript, 'On a New Kind of Ray' to the Würzburg Physical Medical Institute¹. To the scientists of the late 19th century, the ability to conduct non-invasive examinations of animate and inanimate objects was nothing short of miraculous, and made readily accessible by the fact that such examinations could be achieved with equipment that was relatively simple to assemble from instruments easily available throughout the western world².

It was no surprise, then, that this new tool was quickly applied to forensic examinations and to the examination of the deceased. Within months, x-ray examinations had contributed to the forensic investigation of the cause of death and injury in murder and attempted murder cases in the United Kingdom (UK) and the United States of America (USA); negligence cases in the UK, USA and Canada; the examination of suspicious packages; archaeological examination of Egyptian mummies; authentication of oil paintings, and numerous other forensic applications^{3,4,5,6}.

There has been an explosion of interest in the forensic sciences in recent years. In almost every avenue of science and technology, the pace of change brought about by the microchip revolution has resulted in ground-breaking applications within forensic investigation of which Alec Jeffreys' work on DNA 'finger-printing' is, perhaps, the most significant example.

Clinical radiology has also seen enormous changes in the last 30 years as a result of the application of computer sciences to imaging technology. Developments such as multi-slice computed tomography (CT), ultrasound, magnetic resonance imaging (MRI), positron emission tomography (PET) and others have enabled imaging of the human body to diagnose disease and display information in such a manner as can only have been dreamed of in the very early days. The application of this imaging technology to treat disease in increasingly less invasive ways has revolutionised surgical practice and delivered considerable benefits to society.

These new technologies would appear to offer significant opportunities to the forensic investigator. Medical imaging can be used to document both external and internal structures of the human body, the nature of injuries, and non-natural causes of disease using truly non-invasive techniques within the context of forensic investigation. How effective then is the contribution of medical imaging to forensic investigation today?

What is forensic medical imaging?

Forensic medicine, otherwise referred to as legal medicine or medical jurisprudence, has been described as the interaction of medical science and the law⁷.

Forensic science applies specialised scientific and technical knowledge to legal questions arising from civil or criminal proceedings. Hence, forensic medicine is the science of applying medical knowledge and techniques to such questions. Accordingly, it embraces all branches

of medicine including anatomy, pathology, dentistry, biochemistry, paediatrics and radiology. Forensic medical investigations cover a broad spectrum - medical negligence, product liability, smuggling, the nature and extent of injuries, as well as determining age, gender and identification of deceased persons, and establishing cause of death. Forensic medical imaging uses the interpretation of medical imaging examinations to answer legal questions in support of forensic investigation. It can be described, therefore, as the application of specialised scientific and technical knowledge to legal questions arising from civil or criminal proceedings.

Although forensic medical imaging is often used in the course of a post-mortem examination to assist with the determination of the cause of death, or to assist with the identification of a deceased individual, forensic medical imaging is more frequently used on the living, particularly in cases of suspected child or elder abuse. It can also be applied within a range of other fields including forensic dentistry and forensic anthropology.

How is forensic medical imaging used?

The forensic use of medical imaging falls broadly into three functional categories: Diagnosis of cause of death or injury, Identification, and Detection and retrieval of objects concealed or embedded about the person.

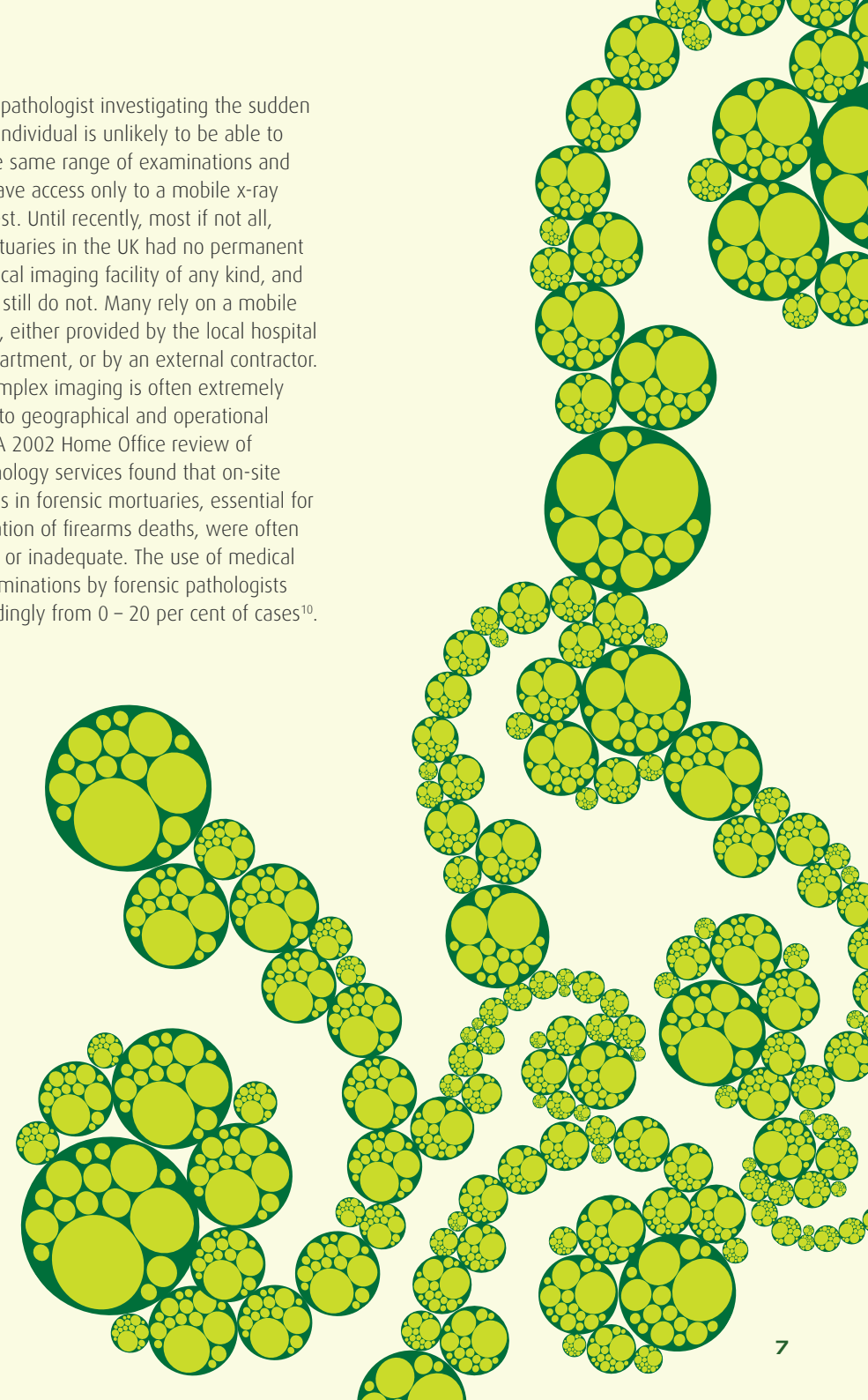
Despite its early application within forensic medicine, forensic radiology is an area of practice that appears to have been somewhat neglected by recent developments in the field of medical imaging. The greater majority of forensic images are acquired using essentially the same techniques of radiography and fluoroscopy that Röntgen himself would recognise^{8,9}. With a very small number of notable exceptions, there have been very few attempts to explore the advantages of applying modern medical imaging techniques within forensic investigation; as Brogdon observed: "...a rather sad commentary on most forensic research employing radiological methods and modalities, is that the overwhelming majority of investigators have been non-radiologists..."²


A distinction should, perhaps, be made here between those examinations that are purely forensic in nature, and those that are primarily clinical, but of forensic interest. A further distinction exists between the examination of live and deceased subjects.

To the physician or surgeon investigating a living subject following cases of inflicted trauma, accidental or industrial injury, the full arsenal of imaging techniques is available in pursuit of a diagnosis. He or she can call upon the services of highly specialised medical and other clinical staff to investigate and diagnose disease or injury patterns. Such personnel will have specialist training and extensive experience as radiologists and radiographers, will be conversant with the latest equipment and techniques, and will apply current best practice whilst adhering to legislation and guidelines pertinent to their sphere of expertise.

Of course, the examinations that are performed on such subjects may later prove to be of forensic significance, or may give rise to the need for a further, purely forensic examination. An example is the case of suspected non accidental injury, where initial examination and diagnosis of one injury may lead to a skeletal survey in pursuit of other previously undiagnosed and healed injuries resulting from systematic physical abuse.

The forensic pathologist investigating the sudden death of an individual is unlikely to be able to call upon the same range of examinations and is likely to have access only to a mobile x-ray service at best. Until recently, most if not all, forensic mortuaries in the UK had no permanent on-site medical imaging facility of any kind, and the majority still do not. Many rely on a mobile x-ray service, either provided by the local hospital imaging department, or by an external contractor. Access to complex imaging is often extremely difficult due to geographical and operational constraints. A 2002 Home Office review of forensic pathology services found that on-site x-ray facilities in forensic mortuaries, essential for the investigation of firearms deaths, were often non-existent or inadequate. The use of medical imaging examinations by forensic pathologists varied accordingly from 0 – 20 per cent of cases¹⁰.





In the case of both live and deceased subjects, it is unlikely that the radiographers and radiologists undertaking such examinations will have received any specialist forensic training and, whilst they will be experts in the field of medical imaging, they may be largely ignorant of the legal process regarding continuity and rules of evidence or, indeed, of the requirements of the forensic investigator.

The situation in other countries is not much different. In the USA, most forensic mortuaries have on-site imaging but this is almost always limited to plain film x-ray and occasional fluoroscopy. Very few centres use trained radiographers or rely on radiologists. Indeed, there are only three radiologists in the USA who are board certified by the American Academy of Forensic Sciences. Centres that are supported by radiographer and radiologist led services are twice as likely to use imaging in support of their investigations, and utilisation of imaging can rise to as high as 50 per cent in some centres where forensically trained imaging staff are available^{11,12}.

In South Africa, where the investigation of firearms deaths contributes significantly to the work of forensic pathologists, most university forensic mortuaries have basic on-site imaging but few, if any, use the services of qualified radiographers or radiologists¹¹. In

“Evidence is beyond question and can be traced by an unbroken chain”

both the USA and South Africa, the operators have received training in forensic procedures but they lack the specialist skills and expertise in medical imaging to perform an optimum examination. As a result, vital evidence may be missed, and operators and others may be placed in danger from the unsafe use of x-ray equipment.

There are a few centres (perhaps as few as six sites worldwide) in which the potential for the use of advanced cross sectional imaging (CT and MRI) at forensic post-mortem is routinely performed and is being evaluated, notably in Berne, home to the Virtopsy Project, and at the University of Leicester, in the UK. Even so, not all of the non-UK centres rely on the services of radiographers or radiologists to perform these examinations.

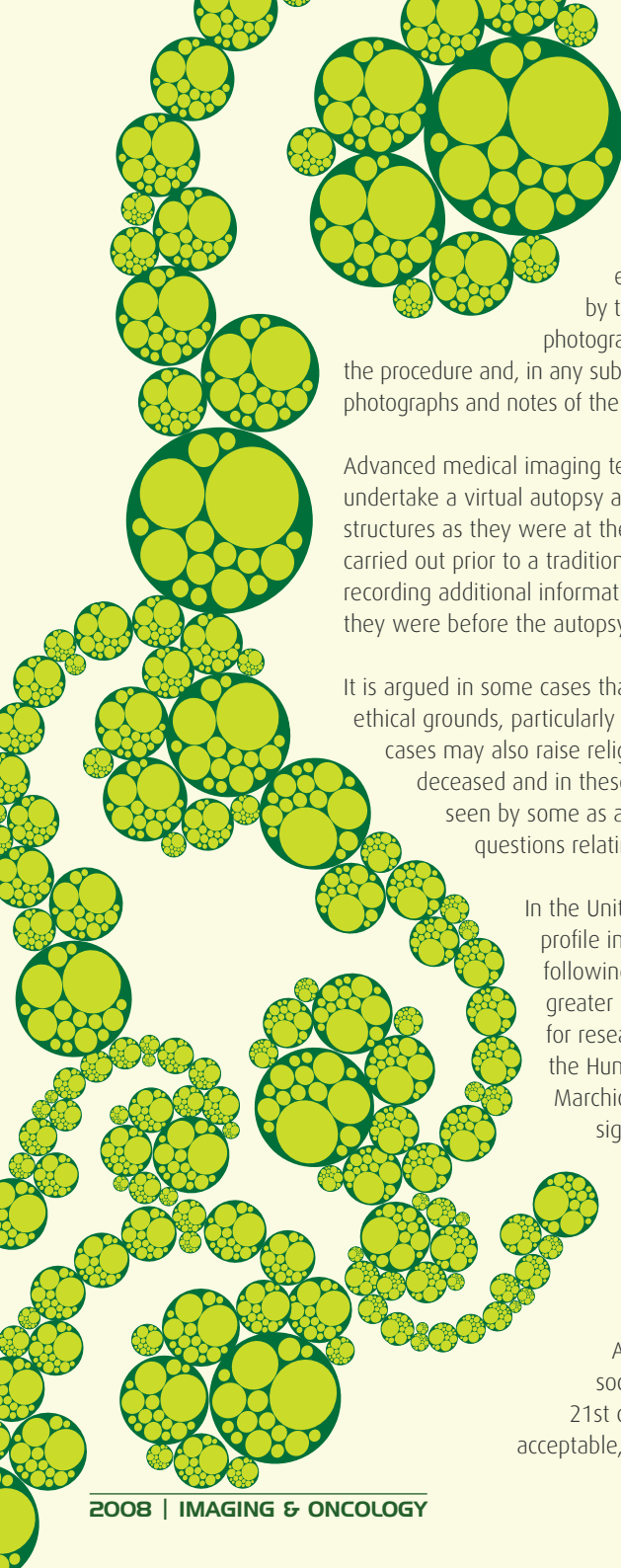
What is the potential?

It is clear from those forensic practitioners that do have access to medical imaging, that its use is invaluable in many cases. Even without the advent of new technology, greater access to basic imaging undertaken by trained, qualified staff would result in increased utilisation and, most importantly, improved standards of evidence and justice.

An increased awareness, and a resultant increased incidence of reported cases of abuse in vulnerable groups such as the elderly and the disabled, has generated an additional requirement for forensic medical investigation. This, coupled with the increase in firearms injuries and crimes involving knives, and in human drug trafficking, combines to make forensic medical imaging a growing speciality.

The ability of modern modalities to allow accurate visualisation of the internal structures of the bodies of living subjects provides unique opportunities to gather hitherto unexamined evidence; such techniques have been swiftly incorporated into standard protocols for some investigations on live subjects, for example in the now routine use of CT scans in the examination of paediatric non-accidental injury.

In the case of deceased subjects, the invasive autopsy has traditionally been seen as the gold standard. The body can be surgically examined after death in a way that would not, of course, be possible in the live subject, and the pathologist can evaluate the evidence with his or her own eyes. This has, undoubtedly, been one of the major factors that has inhibited the use of cross



sectional imaging techniques, post-mortem. By its very nature, however, autopsy is a destructive process. Following a thorough external examination, the meticulous dissection process slowly destroys much of the very evidence that is later evaluated and presented by the expert witness. It is heavily reliant upon photographic documentation at each and every stage of the procedure and, in any subsequent re-examination of the case, it is these photographs and notes of the examination that will yield the most information.

Advanced medical imaging techniques offer the advantage of being able to undertake a virtual autopsy and permanently record internal and external structures as they were at the time that the body was examined. If this is carried out prior to a traditional autopsy, it offers the advantages of both recording additional information and in documenting the internal structures as they were before the autopsy commenced.

It is argued in some cases that the invasive autopsy cannot be justified on ethical grounds, particularly if there are no suspicious circumstances. Such cases may also raise religious sensitivities regarding the treatment of the deceased and in these circumstances advanced medical imaging is seen by some as a truly viable alternative to answer the coroner's questions relating to cause and nature of death.

In the United Kingdom, there have been a series of high profile inquiries into the retention of organs for research following post-mortem and these ultimately resulted in greater regulation regarding the use of human tissue for research in the form of the Human Tissue Act and the Human Tissue Authority¹³. The Inquiry into the Marchioness disaster by Lord Justice Clarke¹⁴ raised significant questions regarding the treatment of the deceased and the identification methods used during the identification of the victims of this tragedy, causing a re-examination of the procedures used in mass fatality incidents, and a greater reliance upon non-invasive methods.

As a result of these and other similar cases, society is beginning to ask whether, in the early 21st century, there are not other, more ethically acceptable, non-invasive techniques for examining the

human body after death. Increasingly, therefore, the forensic scientific community is looking for non-invasive methods of research. In particular, the potential of CT and MRI scanning to gather population specific data on, for example, skeletal maturation and stature, as an aid to forensic human identification, is of increasing interest to forensic anthropologists.


And yet, with few exceptions, the radiological professions appear to be either ignorant of their potential role in this revolution, or indifferent to the challenges and opportunities that it presents. This is undoubtedly due, in the main, to the way in which forensic medicine and the coronial system in the United Kingdom, and particularly in England and Wales, is funded and organised; and how, over recent years, this specialty has become increasingly divorced from the hospitals and medical institutions from which it originally evolved.

The recommendations of the *Home Office Review of Forensic Pathology Services in England & Wales*¹⁰ envisaged the establishment of regional referral centres for forensic pathology, adequately resourced and equipped; and access to medical imaging was cited as a key requirement. Such centres have already been established in some regions, and have seen some capital investment in dedicated imaging equipment, albeit on a small scale. It is the intention that forensic pathology cases be concentrated in these centres and, with the development of postgraduate medical training and academic departments of forensic pathology, that they should become centres of excellence for teaching and research. Possibly, this latter intention will bring about an increased dialogue between forensic pathology and medical imaging, with the potential to realise the benefits of recent imaging advances not only within forensic medical examination, but also within the wider field of forensic scientific investigation.

What are our professional responsibilities?

The emergence and application of new scientific methods within forensic science brings with it responsibilities to ensure that they are applied fairly and rigorously in pursuit of the truth. In the past 20 years there have been a number of landmark appeal cases in which it has been shown that expert forensic testimony has been based upon unsound scientific evidence. In many cases this has been shown to be due to a lack of procedures to safeguard the continuity of that evidence, or to prevent contamination, or a failure to give weight to other possible interpretations that may be drawn from analysis of that evidence.

"Forensic use of newer imaging technologies will be a viable alternative to invasive methods"



The study by Hughes and Baker¹⁵ showed that a significant majority of radiographers undertaking forensic examinations were unaware of the correct procedures to be followed to maintain continuity of evidence. Since the results of their research in 1998 became known, this situation has improved. Both the Association of Forensic Radiographers (AFR) and the Society & College of Radiographers (SCoR) have led the way on this, with the publication of Guidance for the Provision of Forensic Imaging Services¹⁶; and greater awareness within the profession has led to the establishment of several post-graduate courses in forensic imaging and continuing professional development (CPD) events dedicated to this subject.

The Code of Good Practice of the Council of Forensic Practitioners¹⁷ (CRFP) states that the overriding duty of all those engaged in scientific forensic investigation is to the court and the administration of justice. With effect from January 2008, radiographers have been eligible for registration as forensic practitioners with the CRFP. This registration, whilst voluntary, is increasingly seen by the courts and judicial system as a requirement for those undertaking forensic work, and particularly for those giving evidence as an expert witness to a court, either in person or by provision of statements or reports.

The Home Office guidance for identification and investigation of the deceased following mass fatality incidents has been completely revised with assistance from the AFR and SCoR; and the UK National Disaster Victim Identification Team is now able to deploy modern digital imaging equipment and mobilise experienced, trained forensic radiographers, organised by AFR.

Future challenges

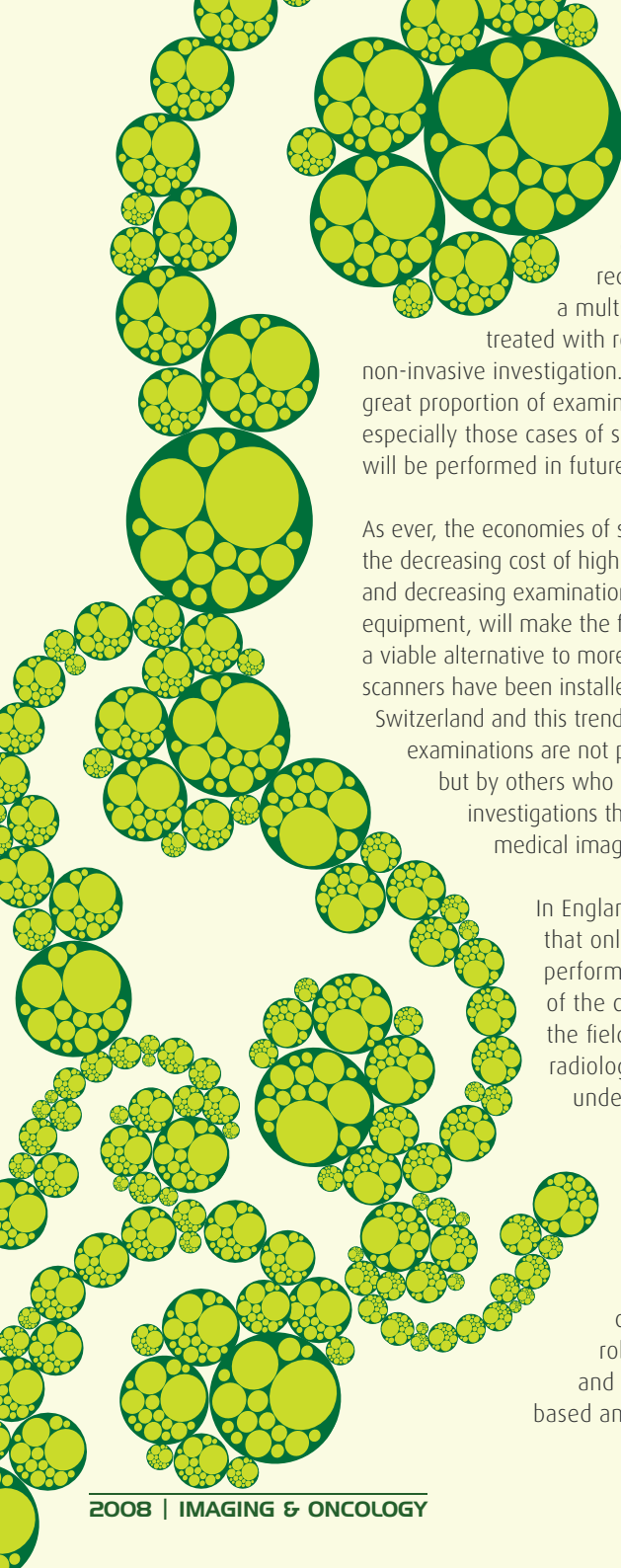
Over the past 20 years there have been far reaching changes not only within the fields of medicine and science but also within the civil and criminal justice systems, and in society as a whole. In a society increasingly concerned with human rights, openness and transparency of government, and celebrating diversity and multiculturalism, it is incumbent upon those engaged in the application of science and medicine to the law to ensure that the most appropriate methods of investigation are employed, and are done so fairly and rigorously.

Even if there is to be no widespread adoption of newer modalities within post-mortem imaging, the increasing incidence of crimes against the

person involving knives and firearms, the increase in human drug trafficking, and greater awareness of the systematic abuse of vulnerable individuals, will require detailed examination of current policies and procedures for forensic medical imaging and the devotion of more resources to this hitherto neglected area of practice. Increasingly, the courts will seek to ensure that scientific methods and evidence are robust and meticulously executed. This increasing emphasis and the regulation of forensic professionals will require forensic medical imaging practitioners to demonstrate that the examinations they have undertaken and documented have been conducted in such a way that the evidence provided is beyond question, and can be traced back to the scene of an incident by an unbroken and clearly documented chain of evidence. Those giving evidence in the courts will need to be able to demonstrate commitment to the highest standards of evidence and expertise, together with currency of practice and evidence of continuing professional development in the forensic sciences.

The rapid technological changes that have occurred within medical imaging over the past 30 years have only recently begun to

“Forensic radiology has been neglected by recent developments”



be routinely applied within the forensic context. However, it is clear that they offer enormous benefits to the forensic investigation and, in the case of the deceased, have the possibility to greatly reduce the distress to their relatives. Increasingly, a multicultural society will insist that the dead are treated with respect and that new technology is used for non-invasive investigation. It is not inconceivable, therefore, that a great proportion of examinations now subject to invasive autopsy, and especially those cases of sudden, unexplained, but non-suspicious death, will be performed in future by virtual autopsy, using CT or MRI scanning.

As ever, the economies of such changes are far from straightforward. But the decreasing cost of high technology alongside ever increasing resolution and decreasing examination times available from modern medical imaging equipment, will make the forensic use of newer imaging technologies a viable alternative to more invasive methods. Already, dedicated CT scanners have been installed in forensic institutes in Australia, Denmark and Switzerland and this trend looks set to continue. In some of these centres, examinations are not performed by radiographers or radiologists, but by others who may lack the expertise to achieve optimum investigations that comes from a training and background in the medical imaging sciences.

In England and Wales, the Coroners Act 1988 requires that only specially qualified persons be employed to perform a special examination of the body on behalf of the coroner¹⁸. As 'specially qualified' persons in the field of medical imaging, radiographers and radiologists are the appropriate professionals to undertake forensic medical imaging examinations of cadavers, or pathological specimens, where such examinations are deemed necessary to establish the facts of a case¹⁶. If justice is to be served, then both professions need to ensure that they are adequately prepared to meet future challenges by ensuring that procedures are robust, practitioners are appropriately educated and experienced, and that practice is evidence-based and underpinned by sound research.

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Ultrasound contrast agents: The future

Paul Sidhu

Ultrasound is the most frequently performed imaging technique; it is a low cost, safe and accessible imaging modality, although often perceived as inferior to computed tomography (CT) and magnetic resonance (MR), particularly by practitioners unfamiliar with imaging techniques. Both CT and MR imaging make use of well established contrast agents to improve the image and, hence, the diagnostic potential. However, there are caveats to the indiscriminate use of CT and MR, in terms of radiation dose with CT and cost with both CT and MR. Furthermore, the use of contrast medium with CT and MR, often a requirement for diagnostic clarification, is not without risk.

Until recently, ultrasound had no effective contrast agent to improve imaging. The advent of microbubble contrast agents has brought new possibilities, and recent advancements in ultrasound have been driven by research into the properties and clinical applications of these agents. Microbubble agents are injected intravenously and do not cross cell membranes, remaining in the intravascular compartment, a distinct difference from other radiological contrast media. Microbubbles therefore give information of the vascularity and enhancement characteristics of a tissue, rather than the functional properties. Imaging focal liver lesions with contrast-enhanced ultrasound (CEUS) is now well established with an excellent level of accuracy. A number of groups have explored niche applications of CEUS outside the liver with success, particularly in cardiac, renal and vascular applications.

Physical properties and imaging techniques

Ultrasound contrast was first observed in cardiology practice when it was noted on echocardiography that air bubbles surrounding a catheter tip placed in the left ventricle during cardiac catheterization produced transient high reflections. Technological advances have allowed microbubbles with the necessary characteristics (ie stable in the circulation, traversing the pulmonary circulation and safe to the patient), to be developed and to be diagnostically useful. The agents in clinical use are SonoVue (Bracco SpA, Milan, sulphur hexachloride with a phospholipid shell), Optison (GE Healthcare, Oslo, octafluoropropane with an albumin shell), and Definity (Bristol-Meyers-Squibb, New York, octafluoropropane with a lipid shell). Levovist (Schering AG, Berlin, air with a galactose/palmitic acid surfactant), a second generation microbubble, is no longer manufactured in Europe.

To achieve trans-pulmonary recirculation, the microbubbles need to pass through the capillary system intact. For this to occur, microbubbles are between 2 and 8 μm . Microbubble stability is increased by external bubble encapsulation (galactose, phospholipids, denatured albumin or poly-butyl-cyanoacrylate), with or without surfactants and using gases with a low diffusion coefficient (perfluorocarbons), or a combination of both. The gas components of the microbubbles are normally eliminated via the lungs, whilst the stabilising components are eliminated via the hepatorenal route.

Microbubbles behave as echo enhancers by creating backscatter and, on exposure to an ultrasound beam, they resonate by expanding and contracting, increasing the backscatter by

>300 fold. At low ultrasound beam power (low mechanical index, a measure of the acoustic energy of the ultrasound beam calculated from the frequency and power), the expansion and contraction is symmetrical; the microbubbles oscillate in a 'linear' fashion and the frequency of the scattered signal is unaltered.

At higher power (high mechanical index) the microbubbles behave in 'non-linear' fashion as they resist contraction more than expansion. This results in emission of harmonics specific to the microbubbles. These harmonics occur within the range (1-20MHz) allowing an ultrasound scanner to 'tune' in and enabling preferential imaging of microbubbles compared to the surrounding tissues. A further increase in mechanical index results in the destruction of the microbubbles, causing strong 'non-linear' echoes to be produced. This phenomenon is transient and no further diagnostic information can be obtained from the area under examination until there is reperfusion by intact microbubbles. By imaging with a low mechanical index that allows for a non-linear response, the amount of microbubble destruction is minimised, prolonging the effective period for diagnostic imaging.

To process the resultant signal from the microbubbles, imaging techniques are needed which selectively display the 'non-linear' response from the microbubbles preferentially. Pulse inversion harmonic imaging relies on the different behaviour of microbubbles exposed to consecutive pulses of inverted phase; linear signals from normal tissue cancels out whilst non-linear signals from microbubbles summate to produce an image. Pulse inversion harmonic imaging requires the use of a broader transmit and receive bandwidth.

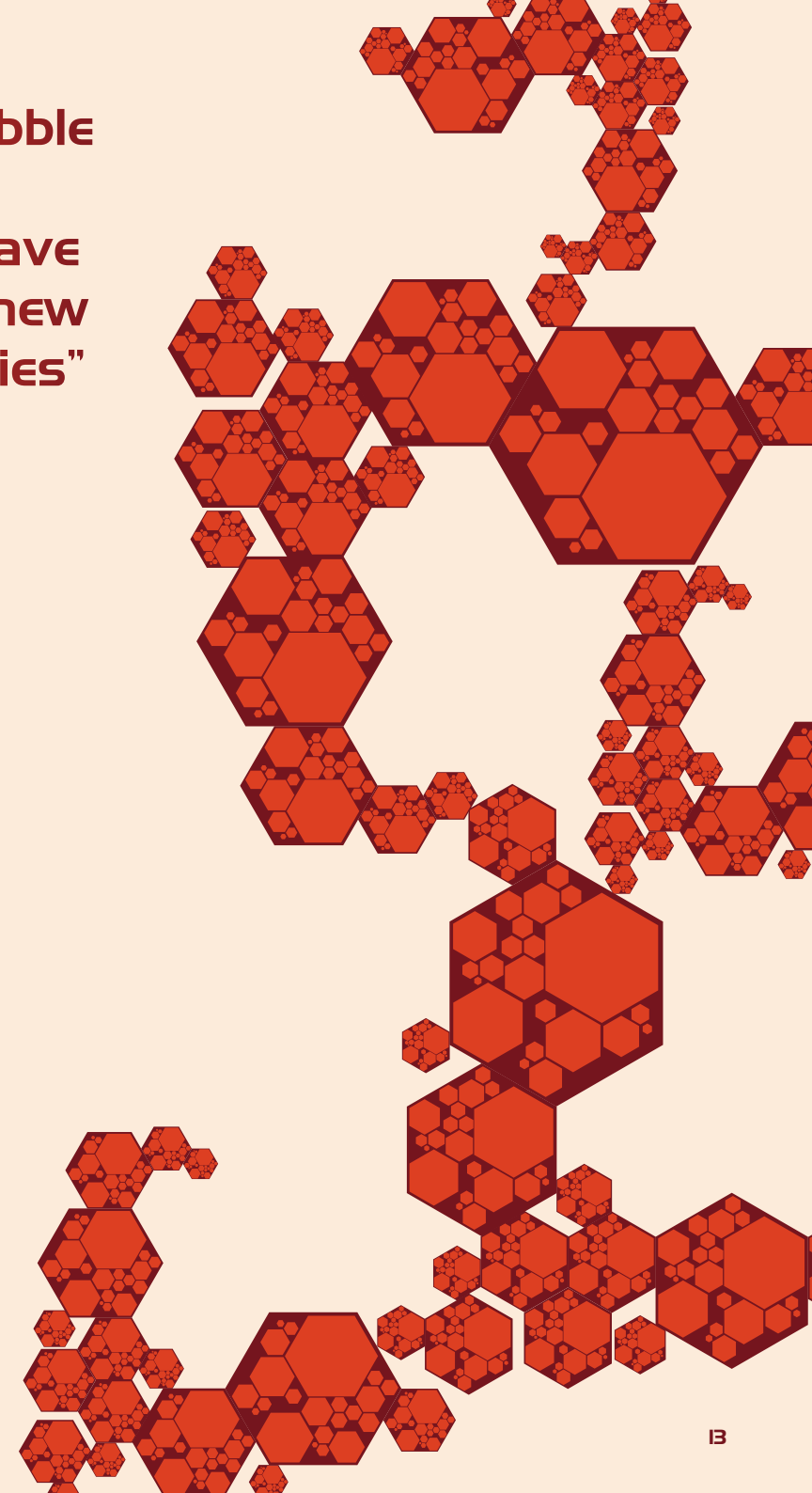
Another phenomenon observed with certain microbubble contrast agents (Levovist and Sonazoid, an agent not licensed) is the display of a delayed phase in the liver, with signal displayed from stationary microbubbles. Uncertainty surrounds the exact reason for the persistence of microbubbles in the liver; speculation is that the microbubbles are trapped in the liver sinusoids¹ or taken up by the reticulo-endothelial system². This phase occurs at two minutes post initial perfusion and lasts for a variable period of time; about three further minutes with Levovist. A 'destructive' mode using high machine power with conventional colour Doppler is used to image; a method, known as stimulated acoustic emission (or loss of correlation mode). A transient colour mosaic in liver tissue containing normal cells,

and a 'black-hole' in malignant tissue containing no normal liver cells, is observed^{3,4}. This method of imaging microbubble contrast in the liver, excellent for detecting the presence of liver metastasis, is less favoured in comparison to low mechanical index techniques.

Current and future applications

Microbubble contrast has been most widely used in imaging of the liver where it has a number of established applications. Originally the application for microbubbles was in 'Doppler rescue', with improvement in detection of colour Doppler signal from large vessels, particularly the portal vein and hepatic artery in transplantation⁵⁻⁷, and in the identification of abnormal vessels in liver tumours⁸. With low mechanical index (MI) imaging coupled with pulse inversion techniques, liver tumour imaging is now far more refined, with the consensus guidelines for identifying contrast enhancement patterns in various focal liver lesions published recently⁹. Microbubble contrast, originally developed for 'Doppler rescue', remains invaluable in demonstrating vessel patency, firmly established in such diverse areas as transcranial Doppler, echocardiography, liver transplantation, and in the diagnosis of renal artery stenosis.

"Microbubble contrast agents have brought new possibilities"



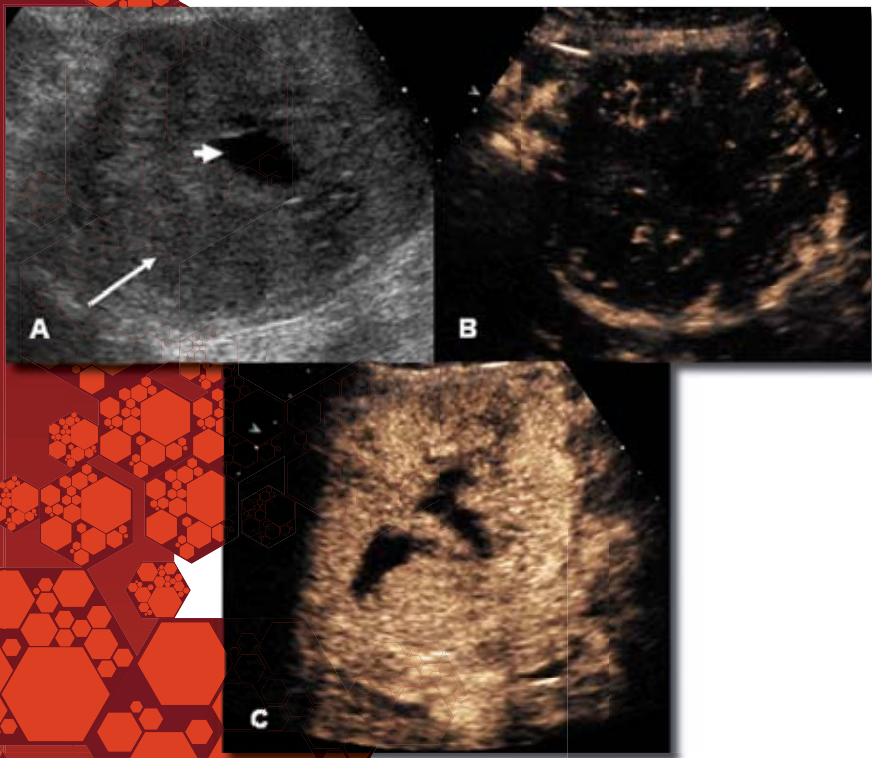


Figure 1

- a) A large focal iso-reflective liver lesion (arrow) with a central scar (arrowhead).
- b) In the early arterial phase following administration of microbubble contrast (SonoVue), there is a 'spoke-and-wheel' vascular pattern noted.
- c) In the late portal venous phase, there is enhancement of the focal lesion with the central 'scars' remaining hypoechoic; appearances consistent with Focal Nodular Hyperplasia.

When distinctive enhancement patterns are observed with focal liver lesions, microbubble contrast enables accurate characterisation of lesions so that other more expensive imaging techniques need not be undertaken. Studies have established that characterisation of focal liver lesions is accurate in 85-96 per cent of cases in determining benign from malignant lesions^{4,10,11}. Benign lesions tend to enhance in the arterial phase and retain microbubble contrast through the different vascular phases (arterial 10-35 seconds, early portal-venous 30-120 seconds, and late portal-venous phases >120 seconds after administration), whereas malignant lesions tend to lose the enhancement in the late phase. Benign lesions often demonstrate characteristic enhancement patterns, such as peripheral nodular enhancement in haemangioma and homogenous arterial enhancement with a central 'spoke wheel' arterial pattern in focal nodular hyperplasia¹¹ (see Figure 1).

Metastases demonstrate variable enhancement patterns in the arterial phase and may be hypo or hypervascular, but often display peripheral rim enhancement. The enhancement fades in the portal venous phase and the metastases become of decreased reflectivity compared to normal hepatic parenchyma¹⁰. This appearance is accentuated by those microbubble contrast agents (Levovist and Sonazoid) which display a late delayed parenchyma phase; increased conspicuity may be against the enhancing normal liver tissue with a 'destructive' mode using high MI^{4,10}. This has given rise to the general concept that a 'black-hole' at the end of the phases is almost certainly an indication of a malignant lesion (see Figure 2). However, confusion may arise if imaging is performed in the late delayed phase only; multiple hepatic abscesses¹² or biliary hamartomas¹³ may present as areas of low reflectivity, mimicking metastases. A full three-phase study would eliminate this problem; demonstrating vessels within the lesion with metastases or septations with an abscess. Intra-operative ultrasound during surgery for resection of metastases identifies metastases more readily than any other examination. Logically, the addition of microbubble contrast ultrasound at the intra-operative stage should improve the detection of metastases; an increased sensitivity and a capability of detecting lesions as small as 2-3mm in diameter has been demonstrated^{14,15}.

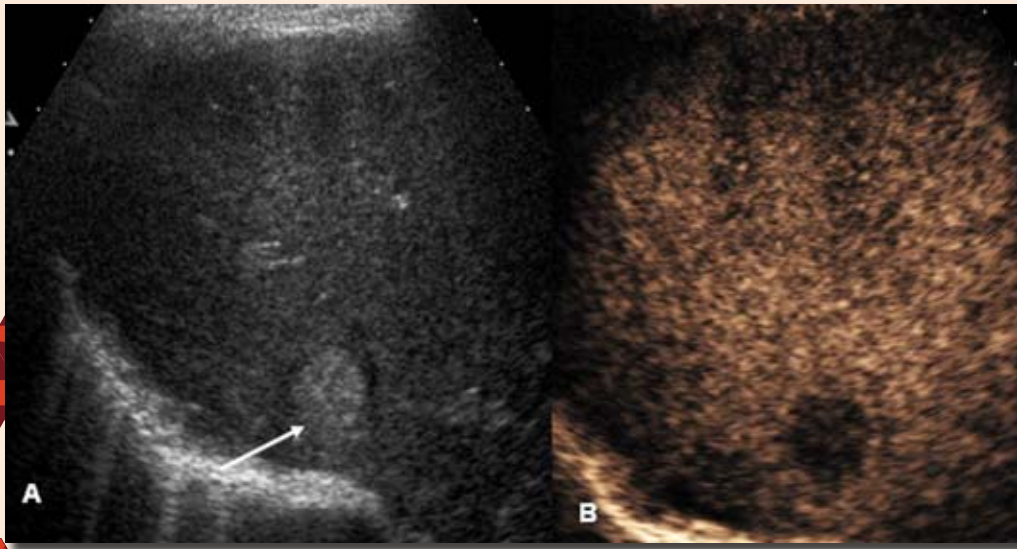


Figure 2

a) A solitary hyperechoic lesion (arrow) in the posterior aspect of the right lobe.

b) Following administration of microbubble contrast (SonoVue), there is washout of contrast in the late portal venous phase; the 'black-hole' characteristic of a metastasis.

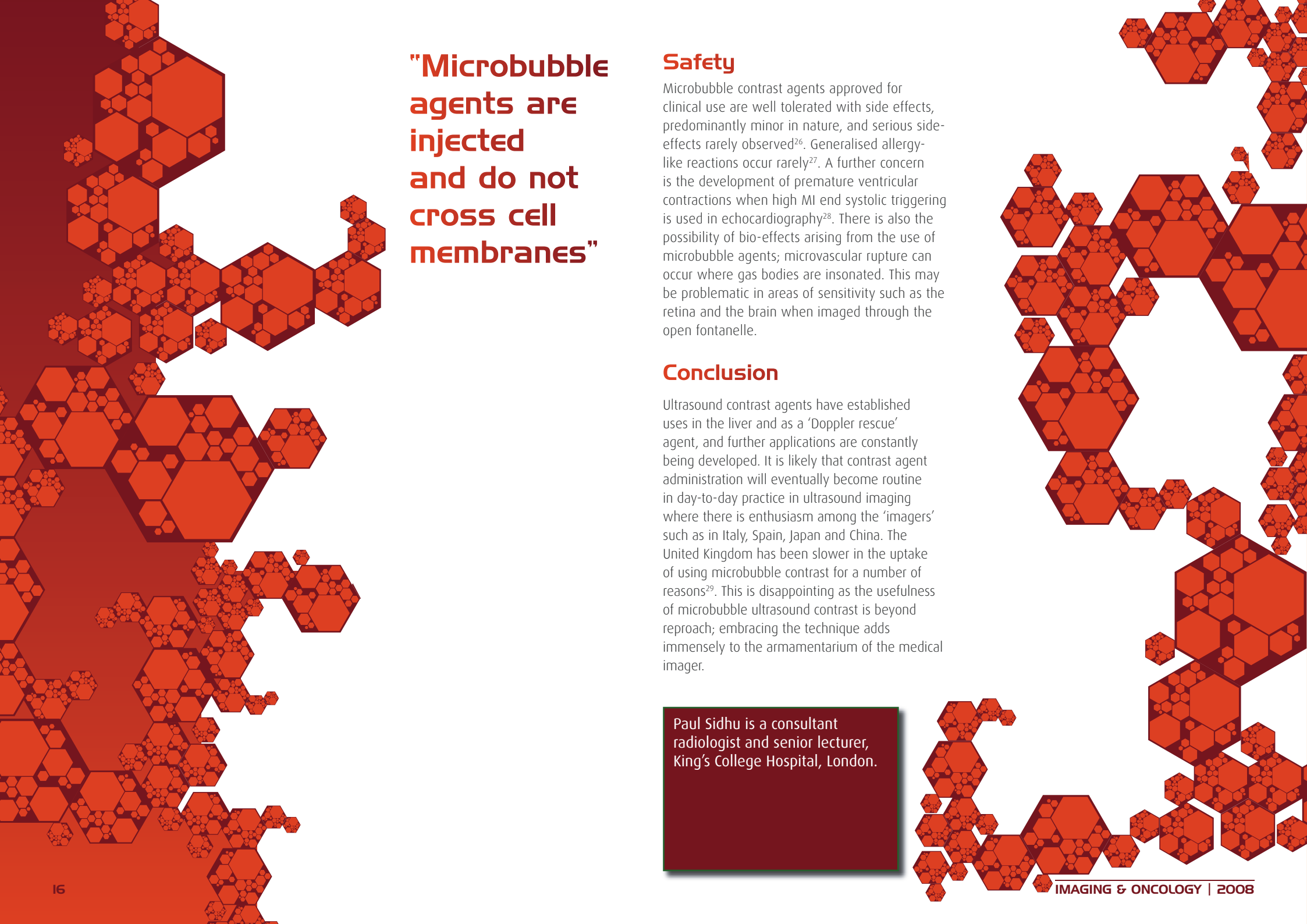
Radiofrequency ablation is an established aspect of the management of malignant liver disease. Ultrasound is the modality of choice for performing ablation techniques because it allows real time visualisation of electrode placement. The effect of radiofrequency ablation is dependant on attaining a successful 'tumour-free' margin and complete necrosis of the tumour¹⁶. Performing biphasic CT, or contrast enhanced MR imaging peri-procedure, is relatively impractical in delineating this margin, but microbubble contrast will demonstrate residual tumour enhancement. Ablation therapy, followed by contrast enhanced ultrasound imaging 10 minutes post procedure, will demonstrate residual tumour as an irregular margin that maintains the enhancement pattern seen prior to ablative therapy¹⁷. If performed following ablation, microbubble contrast allows immediate further therapy if required, decreasing the number of treatment sessions.

In the assessment of breast disease, studies have established an increased sensitivity in vascularity

with microbubble contrast, but with inconsistent findings on the specificity of differentiating benign and malignant lesions^{18,19}. These studies were performed with high MI techniques; with the newer harmonic and phase inversion techniques, analysis of breast masses with microbubble contrast may become more useful. Identification of the sentinel node is all important in the surgical treatment of cancer of any type, particularly of the breast, predicting the need to remove the regional lymph nodes. Microbubble contrast may play a role in this situation; sentinel nodes in the swine model with melanoma demonstrated sentinel node enhancement within seconds of peri-tumour injection of microbubble contrast, with signal void within the lymph nodes representative of intra-nodal metastasis²⁰. Another group have developed a specific microbubble that targets lymph nodes, using the stimulated acoustic emission ultrasound imaging method, with success²¹.

The use of microbubble contrast in gene therapy and targeted delivery of drugs is an area of active research, where microbubbles are engineered to carry antibodies, drugs or DNA to target tissues²². With gene therapy, a particular area that shows promise is skeletal muscle^{23,24}. Ultrasound improves gene transfer by increasing cell permeability, termed 'sonoporation', a process enhanced by microbubble contrast, believed to occur by lowering the threshold for ultrasound bioeffects²⁵.

"The UK has been slower in the uptake of microbubble contrast"



"Microbubble agents are injected and do not cross cell membranes"

Safety

Microbubble contrast agents approved for clinical use are well tolerated with side effects, predominantly minor in nature, and serious side-effects rarely observed²⁶. Generalised allergy-like reactions occur rarely²⁷. A further concern is the development of premature ventricular contractions when high MI end systolic triggering is used in echocardiography²⁸. There is also the possibility of bio-effects arising from the use of microbubble agents; microvascular rupture can occur where gas bodies are insonated. This may be problematic in areas of sensitivity such as the retina and the brain when imaged through the open fontanelle.

Conclusion

Ultrasound contrast agents have established uses in the liver and as a 'Doppler rescue' agent, and further applications are constantly being developed. It is likely that contrast agent administration will eventually become routine in day-to-day practice in ultrasound imaging where there is enthusiasm among the 'imagers' such as in Italy, Spain, Japan and China. The United Kingdom has been slower in the uptake of using microbubble contrast for a number of reasons²⁹. This is disappointing as the usefulness of microbubble ultrasound contrast is beyond reproach; embracing the technique adds immensely to the armamentarium of the medical imager.

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Radiation induced secondary cancer and the radiotherapy patient

Edwin Aird

Radiotherapy patients are in a unique position regarding the amounts of radiation they are subjected to. The treatment target volume itself receives radiation doses between 40 and 80Gy depending on the type of treatment and level of conformity of the dose, (some brachytherapy volumes receive even more than this because the tissues are in direct contact with the radioactive sources, but this type of treatment will not be discussed in this article). Tissues immediately adjacent to the target volume may receive doses between 20 and 100 per cent of this target dose. At distances further from the target site, the dose continually falls as the scattered radiation reduces.

The whole of the body also receives a minimum dose from leakage radiation, typically 0.1-0.2 per cent of the target dose. Concomitant imaging provides an additional small dose to parts of the body exposed to the x-rays with the main contribution to these doses (discussed further below) being from the verification imaging techniques: portal imaging with both kV and MV x-rays and computed tomography (CT) with kV and MV x-rays.

Linear accelerator (linac) manufacturers have now designed x-ray sets that are attached to the linac gantry in order to provide both kV portal imaging (which provides a lower radiation dose to the patient than MV imaging) and CT. The CT can be cone-beam CT (CBCT) which images a volume of tissue in a single rotation. This is essential on a linear accelerator where the gantry can only rotate through 360 degrees in one minute compared with the sub-second speeds of fan beam (conventional) CT. As image guided radiotherapy (IGRT) techniques become used more widely, the doses from verification imaging will increase. It is essential to consider how important are these doses to the patient, whilst recognising that the tumour must be treated with as tight a margin as possible, without missing any part of it to ensure maximum tumour control is achieved, and that critical structures must be avoided as well as possible, to reduce morbidity.

Both these damaging effects (the sterilisation of the tumour and the morbidity of normal tissue) are known as deterministic effects of radiation exposure. For a deterministic effect to occur, the dose must be above a threshold level and the severity of the effect has been demonstrated to increase with dose. For the large doses in and around the target, these effects occur within weeks or months of exposure. Some values for the tolerance doses (TD) of various structures are shown in table 1¹. [TD_{5/5} is the tolerance dose above which the effect in each organ will be produced in 5 per cent of patients at five years (for different proportions of the organ irradiated, either 1/3 or all (3/3))]

Table 1: Tolerance doses for the kidney, lung and spinal cord

Organ	Effect	TD _{5/5} (1/3 irradiated)	TD _{5/5} (3/3 irradiated)
Kidney	Clinical nephritis	50Gy	23Gy
Lung	Pneumonitis	45Gy	17.5Gy
Spinal cord	Myelitis/necrosis	(5cm) 50Gy	(20cm) 47Gy
			Little variation with length of cord exposed, 5 or 20cm. (a 'serial' structure)

At lower doses, fewer cells are killed and any harm is thought to depend on the probability that a damaged cell is miss-repaired and continues to proliferate. There is an assumption that this can occur at any dose level, but that the chance of it occurring increases with dose. The model used to describe this 'stochastic' effect is known as the 'linear-no threshold' (LNT) model; ie the risk of an effect occurring is linearly dependent on any dose (so no dose 'threshold'). Generally, the concomitant imaging doses will contribute a low risk for cancer induction. The high doses near the target from the therapy beams are likely to provide a high risk for cancer induction. But this is studied in more depth below.

Cancer induction

The stochastic effect of greatest interest is that of cancer induction. Although there was some evidence of this during the first decades of the use of ionising radiation (1900-1945), it was not until the 1950s, when the long term effects on survivors of the atomic bombs had been analysed², that the link between dose and cancer induction could be demonstrated. Evidence for cancer induction also came from other sources:

- Workers painting radium on clock and watch faces;
- Women receiving relatively large doses of radiation to their breasts during fluoroscopy for tuberculosis (using antero-posterior (AP) fields);
- Patients receiving high doses of therapy radiation for non-malignant diseases such as ankylosing spondylitis, and in young persons for tinea capitis (ring worm).

It is clear from this evidence that there is a correlation between dose received by the various exposed populations and the rate of cancer induction. However, it still is not clearly demonstrated either way whether or not there exists a threshold dose. Some distinguished bodies³ have questioned the LNT model but ICRP has continued to state formally that the LNT model must be used, for example, in their most recent report⁴:

"Therefore the practical system of radiological protection recommended by the commission will continue to be based upon the assumption that at doses below (around) 100mSv a given increment in dose will produce a directly proportionate increment in the probability of incurring cancer...attributable to radiation...the commission considers that the adoption of the LNT model combined with a judged value of a dose and dose rate effectiveness factor (DDREF) provides a prudent basis for practical purposes of radiological protection."

The DDREF factor will not be discussed in detail in this article. It is sufficient to say that it is used to determine risk factors for the exposure rates that are used typically in medicine, compared with the exposure rates suffered by atomic bomb victims.

It is also important to recognise that there is an 'induction' period during which the cancer has the chance to express itself. For a few of the solid cancers the induction period is considered to be as follows:

- Breast cancer (evidence from women irradiated for medical reasons). Induction period minimum: 10 years.
- Thyroid cancer (evidence from tinea capitis patients). Minimum induction period: 5 years.

Leukaemia is the exception to this in that the induction period (for the Japanese atomic bomb survivors) appeared to reach a maximum at seven years.

Dose

The normal way to express dose is using the standard unit of 'absorbed dose', the Gray (1 Joule per kilogram). It is also necessary to have some means by which the different types of radiation experienced by atomic bomb victims and patients could be compared because neutrons (particularly) have a different radiobiological effect per unit dose compared with X or gamma radiation. The 'equivalent dose' concept was introduced to allow for this difference and the unit of equivalent dose is the Sievert. For X and gamma radiation, 1 Gray = 1 Sievert, but for neutrons 1 Sievert may be equivalent to 20Gy.

A further dose concept is necessary when discussing diagnostic levels of radiation. Different organs in the body have been found to have different rates of cancer induction. In order to be able to compare different diagnostic examinations (and for the therapy patient, the verification imaging) when various organs may be irradiated it has been found to be useful to introduce the concept of effective dose (E). This is the dose to the whole body that would incur the same risk as a partial exposure of the body when specific tissues receive an equivalent dose of H_T :

Effective Dose $E = \sum w_T H_T$ where w_T is the weighting factor for the specific tissue.



This sum is performed over all organs and tissues of the body considered to be sensitive to the induction of stochastic effects. The value given to w_T reflects the radiation sensitivity of the tissue (averaged over both sexes and all ages for convenience). Some values of effective doses for some of the examinations performed during the radiotherapy workup are shown in table 2.

Table 2: Effective doses for pre-treatment investigations and procedures

Examination	Typical E	Risk of fatal cancer induction
Pretreatment images		
CT	10mSv	0.05%
Diagnostic positron emission tomography (PET) (400 MBq FDG)	11mSv	0.05%
Simulator fluoroscopy For one minute (pelvic area)	2.5mSv	0.01%

Risk factors

Extensive analysis of the groups of people exposed to high doses of radiation has concluded^{4,5} that the risk factor for fatal cancer induction (averaged between sexes and across all ages) is 5 per cent per Sievert (normally the effective dose). Together with studies of what is an acceptable risk, this has led to the concept of 'dose limit' for the radiation worker (20mSv per year) and a member of the public (1mSv per year). No such limits are stipulated for patients since it is part of Ionising Radiation (Medical Exposure) Regulations⁶ (IRMER, 2000) for the clinician (practitioner) to justify all medical exposures. For diagnostic exposures, the concept of Diagnostic Reference Levels is used; and in radiotherapy the concept of optimisation is evident both in the treatment plan and in the careful use of additional exposures used for imaging (see below).

It is important to recognise that this average risk factor should not be used when considering particular groups of patients. For example, for young female patients the risk to the breast by itself may be very large compared with the older women (see table 3).

Dose received by the radiotherapy patient

The effective doses received by the radiotherapy patient during the work-up period and during treatment are similar to those discussed above.

The doses received by a prostate patient during verification are shown in table 4. Three regimes are shown with different amounts of verification imaging.

Table 3: Age/risk relationship for irradiation of female breast tissue

Age years	Risk per million women per mGy (dose to breast)
5	43
15	43
20	18
40	16
50	14
60	10
70	6
80	2.5

"Secondary cancer is an issue for the radiotherapy patient"

Verification imaging (Effective dose per image)	Typical E mSv	Risk of Fatal Cancer Induction
Cone-beam CT (kV)	5-15	-----
Portal imaging 6MV per image per MU	0.34	-----
Portal imaging kV per image	0.1	-----
Verification regimes (Total Effective Dose)		
1) high dose (3 CT of 50cm + portal 6MV, 36pairs of 2MU).	75	0.38%
2) CBCT (with kV) (Daily for 37 fractions)	185-555	0.9-2.8%
2) typical UK (1 CT + portal 6MV, 10 pairs of 2MU)	24	0.12%
3) low UK (1 CT of 50cm + Portal kV, 10 pairs)	13	0.07%

Table 4: Typical doses for prostate patients during verification imaging

The risk factors associated with the verification regimes are also given in table 4. It will be seen that for individual exposures the risk factors are not very large because the doses are relatively small. However, when multiple examinations are made, particularly for verification exposures using CBCT in the extreme case of every day of radiotherapy, then the risk factor begins to look significant (see also cases 2 & 3 below); although, for the prostate patient, the induction period will take them towards the end of their life and into a period where non-cancer related health conditions are more likely to arise. [It is also important to recognise that the dose from kV portal imaging is considerably less than that from MV portal imaging.]

The amount of exposure can also be shown using individual organ doses for some of the most critical organs that may be exposed by the verification beams. It is important to show dose in this way because there is another source of radiation to doses even when they are

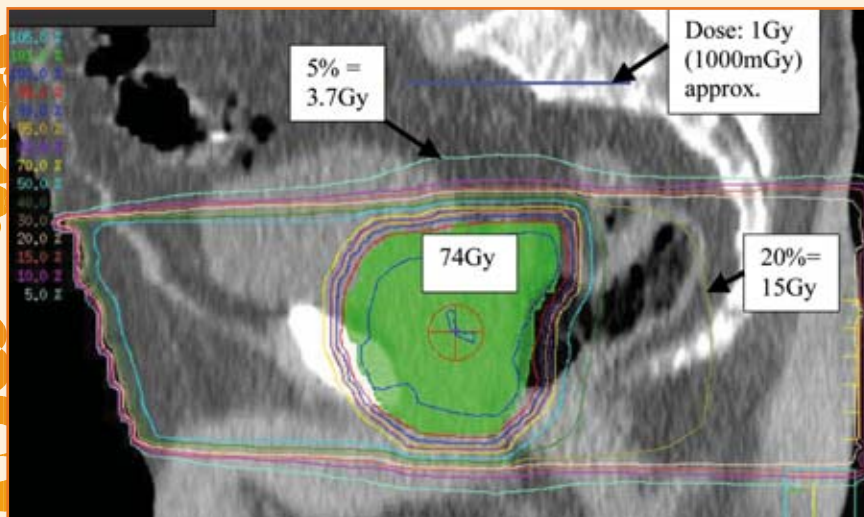


Figure 1: A sagittal section through the prostate showing a typical set of isodose curves for a conformally planned radiotherapy treatment.

not in the beam. X-ray beams produced by linear accelerators have other sources of radiation, scatter and leakage radiation. The leakage radiation is that radiation coming from the target (and its immediate surroundings) that penetrates through the shielding of the treatment head and “bathes” the patient to a level of 0.1%-0.2% of the total given dose (as determined by the total monitor units to give the treatment); the scatter is the amount of radiation coming from the primary beam incident on the patient tissues and is dependent on field size and quality of beam. It can vary from a few per cent to 90 per cent of the target dose depending on these factors and the distance from the edge of the beam. These doses can be illustrated in the case of a prostate patient in figure 1.

Harrison et al^{7,8} have made measurements in phantoms to discover what proportion of radiation to different organs for specific treatments (prostate, breast, larynx) comes from the radiotherapy itself and what comes from a typical set of imaging used to plan and verify these treatments. Their conclusion is that broadly the ‘concomitant’ imaging doses do not contribute more than a few per cent of the total dose to the critical organs and tissues.

This is an important result for the delivery of radical radiotherapy, and to allow for tumour position from day-to-day verification imaging to be used (eg CBCT for imaging the prostate each day). This has the benefit of ensuring the target is hit every treatment fraction (maximising local tumour control) and reducing the amount of critical structures suffering high dose (minimising morbidity).

The American Association of Physicists in Medicine (AAPM) produced a report⁹ in 2007 (TG 75) ‘The management of imaging dose during image-guided radiotherapy’, that outlines the doses received by radiotherapy patients. The Royal

College of Radiologists (RCR) is also producing a document¹⁰ to be published in 2008, entitled ‘Verification for the Radiotherapy Patient’, which also estimates doses to the patient. Both these documents arrive at similar figures for the prostate patient (see case 1 below) when expressing the dose in effective dose. Calculations have also been made locally for two rather more important groups of patients: case 2, the young female breast patient and case 3, the young female lymphoma patient, with results as shown below.

Case 1. For a prostate treatment routine that involves a conventional CT scan followed by 10 daily MV portal imaging pairs at 2 MU each. The total effective dose is about 20 mSv. Using the ICRP 605 risk factor of 5 per cent per Sv there is an estimated probability of a 0.1% risk of radiation induced cancer in the patient’s lifetime (for the 70 year old this might be considered an inconsequential risk)

Case 2. For an 18 year old female treated for breast cancer receiving a CT scan and the same number (10) of portal images, the effective dose is about 20mSv and, if the appropriate risk factor for breast tissue at this age is taken, the risk of inducing a fatal breast cancer is 0.5 per cent, with a greater chance of expressing a secondary cancer because of the life expectancy (unless the initial cancer is a very aggressive one).

Case 3. An 18 year old female lymphoma patient receiving 4-5 PET-CTs and 10 pairs of portal images. The effective dose is about 180mSv (giving a risk of about 1 per cent if the common risk factor is used; but possibly 4 per cent if the appropriate breast risk factor is used). Control of the imaging doses is essential for these patient, but so is the control of the radiotherapy volumes, to reduce the doses to critical structures outside the target volume, where the doses may be higher than those from the imaging doses.

It is evident from the young female results that great care is needed for these (and younger patients) when planning and verifying their treatments. The risk factors are much greater than for the older patients, a fact that is supported by the analyses of secondary cancer induction for radiotherapy patients where the breast tissue has been included in the field (or was just in the field margin where the dose is still high from scattered radiation.) See below.

Secondary cancer in the radiotherapy patient

Some of the most important evidence for secondary cancer in radiotherapy patients has been acquired recently from the cohorts of young patients treated for Hodgkin's disease from the 1960s. These young people, typically between ages 0.5 year and 17 years were treated using mantle fields. Some older patient groups were also treated similarly, but it is the young patients who have far greater risk of cancer induction.

The typical fields for treating the upper volumes of the trunk would generally have included shielding for parts of critical structures, particularly the lungs. The shielding blocks used for patients treated in 1960s were relatively crude (later the blocks were individualised) and, in young women, allowed some exposure of the breast and lung to high levels of radiation (as well as larger volumes receiving up to 20 per cent of the dose to the tumour). The doses to the tumour were typically 30-40Gy.

It is evident from these analyses of the mantle fields that secondary cancer does occur at a relatively high frequency for these young patients^{11,12}. There is also some evidence for older patients¹³⁻¹⁵ but it is mainly fairly tentative and low levels with poor confidence. Clinical oncologists tend to think in terms of a risk of a maximum of a few per cent for their long term surviving patients possibly succumbing to a radiation induced cancer (from the radiotherapy, not from the imaging doses).

In their publication¹³ 'Risks of Second Cancer in Therapeutically Irradiated Populations', the NRPB recommends the following:

- With increasing numbers of patients being successfully treated with radiotherapy...and surviving longer, the available data on radiation-induced cancer should increase. It is recommended that the assessment of cancer incidence in all these and other groups exposed to high doses of ionising radiation be maintained and enhanced.
- The Royal College of Radiologists (1996) has recommended that "The medical records relating to radiotherapy and chemotherapy... should be kept...for at least 15 years". The RCR also highlights the need for records of children and young adults treated for malignant disease to be kept permanently.

It seems obvious that these records for young adults and children should also include a summary of the concomitant exposures received during their radiotherapy episodes.

"The practitioner managing treatment must judge place of ionising radiation within the management of each and every patient"



"Lower doses do need evaluating and to be kept as low as practicable"



Conclusion

Secondary cancer is an issue for the radiotherapy patient. Opinion has varied over the last decade as to the main causes of this. Most recently there appears to be a consensus forming that it is within the high dose regions, including those just outside the treatment volume, where these solid cancers are most likely to be expressed.

Although lower doses, both those from the leakage radiation and from concomitant imaging exposures do need evaluating and need to be kept **as low as reasonably practicable**, there should be no limitation put on these exposures by operators. The protocol for each treatment site should state both the typical set of verification exposures and a recommended maximum number to perform on each patient. In the extreme case where this maximum has to be exceeded, the operator will ask the clinical oncologist or consultant radiographer to justify and authorise further exposures. A record of these will be put in the patient's notes. These levels should be under continual review by the medical exposures group and site specific team within each cancer centre.

At the present time, the maximum concomitant exposures will present a theoretical risk of cancer induction of no more than a few per cent. This level needs continual monitoring by the radiotherapy community, in the same way that dose reference levels are monitored in diagnostic radiology. In particular, a close watch is needed on the levels to which children and young adults are exposed, especially as more PET-CT is requested for some of these patients.

However, it remains the role of the practitioner who is managing the whole of the patient's treatment to be aware of the extra risks from all the various insults that the patient is exposed to (including chemotherapy), and to make judgments on the place of ionising radiation (optimisation and justification) within the management of each and every patient.

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The new IR(ME)R regulator, England

Cliff Double

As the new regulator in England responsible for the Ionising Radiation (Medical Exposure) Regulations 2000, the Healthcare Commission has had an active first 14 months.

The Healthcare Commission is the independent health watchdog in England. It has a statutory duty to assess and report on the quality and safety of services provided by organisations in the National Health Service (NHS) and the independent healthcare sector, to ensure that they are providing a high standard of care and to promote continuous improvement in healthcare for the benefit of patients and the public.

On 1 November 2006, responsibility for enforcing the ionising radiation regulations passed from the Department of Health to the Healthcare Commission, when the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 came into force. To fit in with its other regulatory activities, the Healthcare Commission began to regulate and enforce IR(ME)R through a robust programme of assessment and inspection.

The safety of patients and the public, in hospitals and other healthcare settings, is a top priority for the Healthcare Commission. One of its first activities as new regulator was to develop a system for handling notifications of incidents where a patient is exposed to ionising radiation to an extent that is 'much greater than intended'. A new online notification system was introduced and has simplified the process, as well as being able to collect more comprehensive information on each incident.

The notifications

In its 14 months of regulating IR(ME)R (from 1 November 2006 to 31 December 2007), the Commission received 329 notifications of incidents (see table 1). The average weekly number was just over five, compared to the three notifications per week typically received previously by the Department of Health. Although the reasons for this increase may be complex, it is possible that raised awareness of IR(ME)R, associated with the transfer of responsibility to the Healthcare Commission, improved governance processes by employers, and the introduction of the online notification system, may all have contributed.

The 329 notifications came from 112 institutions; nine from the independent sector, two from primary care trusts (PCTs) and the remainder from NHS acute trusts. As might be expected, some organisations reported a number of incidents, while many other healthcare providers using ionising radiation have not yet notified any incidents.

In radiology, the use of computed tomography (CT) continues to expand and accounts for a significant proportion of all exposures using diagnostic x-rays. In specialised centres, x-rays are also increasingly being used for x-ray guided interventional radiology and cardiology procedures as an alternative to major surgery and, although they are extremely useful, individuals can be exposed to high doses. There are over 50 radiotherapy centres in England using linear accelerators for x-ray megavoltage beam therapy and some

"Safety of patients and the public is a top priority"

also providing superficial x-ray and brachytherapy treatments using sealed radioactive sources.

The basic types of ionising radiation were used to categorise the notifications received in the first 14 months: 'diagnostic x-ray', 'nuclear medicine' and 'radiotherapy'.

The geographical spread of reporting across England is generally consistent and shows no regional trends. As more notifications are received, the Commission will analyse the geographic data more closely, to highlight where there may be good culture in incident-reporting. It will also inspect a random selection of services that have not reported any incidents, to determine whether zero notification is a sign of best practice in action, or reflects a poor culture of incident-reporting.

The data collection tool has recently been refined to include an analysis of the type of notification. For example, in diagnostic radiology, the Commission can now report on whether plain film/computed radiography/digital radiography, CT-scanning, bone density scanning (DEXA), cardiology, interventional radiology, mammography, dental, or fluoroscopy is used.

Diagnostic x-ray notifications

The Commission received 240 diagnostic x-ray notifications, mostly from hospital x-ray departments, amounting to 73 per cent of the total. Most of these related to simple radiographic exposures and were generally of low dose and low risk. However, approximately one third

Month	Diagnostic x-ray	Nuclear medicine	Radiotherapy	Total
November 2006	12	1	3	16
December 2006	14	1	7	22
January 2007	22	1	5	28
February 2007	18	3	3	24
March 2007	16	4	5	25
April 2007	18	3	1	22
May 2007	13	2	6	21
June 2007	16	1	6	23
July 2007	16	2	2	20
August 2007	12	0	4	16
September 2007	8	0	7	15
October 2007	34	2	7	43
November 2007	23	3	6	32
December 2007	18	0	4	22
Total (14 months)	240	23	66	329
Monthly average	17.14	1.64	4.71	23.50

Table 1: Number of notifications by modality

involved CT scanning, where doses are at the upper end of the spectrum in diagnostic radiology.

Interventional radiology and cardiology represent some of the very highest doses within diagnostic x-ray and continue to provide an alternative to surgery. There were no notifications of incidents involving these types of exposure.

The type of incidents varied widely, but the most frequent cause of failure was carrying out an x-ray examination on the wrong patient. As shown in figure 1, other notifications arose from imaging the wrong part of the body, from errors by the operator in performing the exposure and from imaging procedures being unnecessarily repeated. Clerical or booking errors account for some notifications, in particular those involving duplicate request forms, films incorrectly filed or labelled, or the wrong set of patient demographic labels filed inside a patient's notes.

Data collected by the Department of Health suggest that the NHS carries out approximately 25 million diagnostic imaging examinations involving ionising radiation each year, in addition to those

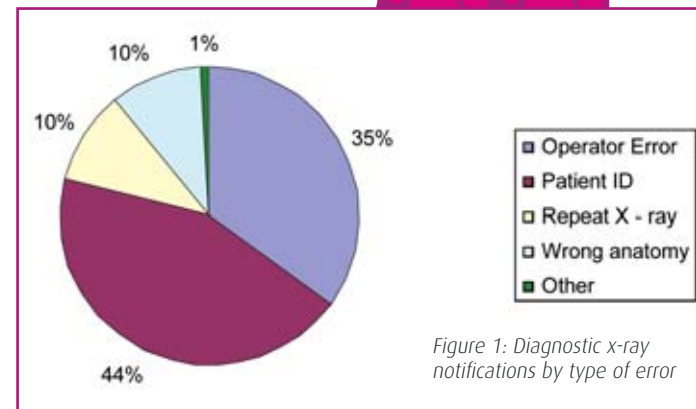


Figure 1: Diagnostic x-ray notifications by type of error

carried out in the independent sector. This figure is even higher when dental examinations are included. Therefore, the vast majority of exposures are performed without incident.

Nuclear medicine notifications

There were 23 notifications relating to nuclear medicine in the first 14 months of regulation, almost all of which were from diagnostic nuclear medicine investigations (see figure 2).

Approximately one third arose from patient identification errors – a smaller proportion than for diagnostic x-rays. Half of the notifications involved performing the wrong examination, for example, carrying out the wrong type of test or administering the wrong radiopharmaceutical to the patient, or carrying out a bone mineral density scan instead of a bone scan. Three notifications were received following administration of radiopharmaceuticals to patients who did not declare a pregnancy. Two of these involved therapeutic administrations of I-131.

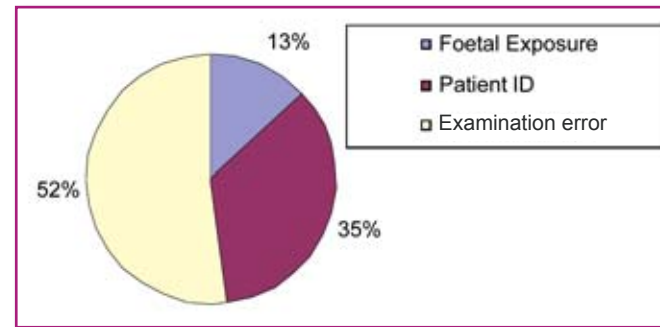


Figure 2: Nuclear medicine notifications by type of error

Radiotherapy notifications

Radiotherapy departments in England made 66 notifications. To date, fewer than half of the organisations providing a radiotherapy service have notified the Healthcare Commission of exposures under regulation 4(5).

Of the 66 notifications, almost two thirds (64%) involved a treatment error (see figure 3). Of these, approximately one third involved a geographic miss of one fraction only during a course of treatment, with a smaller proportion involving the delivery of more than one fraction to the wrong part of the body or at the wrong fractionation rate. Errors happened when staff in pre-treatment imaging did not record machine or couch movements correctly or did not write down correct instructions for colleagues. In other cases, treatment staff did not interpret the setting-up instructions correctly or used incorrect positioning marks on the patient from which to position them relative to the treatment beam. In some notifications, operators omitted to fit shielding designed to safeguard critical organs. A small number of notifications involved errors in prescribing the patient's dose and fractionation. Three notifications related to pre-treatment imaging or 'planning' exposures in radiotherapy.

Notifications by age of patient

The range of notifications grouped by the age of patients is broadly as expected, reflecting typical ages of patients attending for radiological examination (see figure 4). This will be used, together with new data being collected, as a baseline to review any changing trends over time.

Notifications involving children remain of particular concern. There were a small number of notifications of foetal exposures where a woman, unknowingly pregnant, had undergone radiological investigation. However, the Commission did not establish any actual failures in IR(ME)R procedures or practice relating to these unintended exposures.

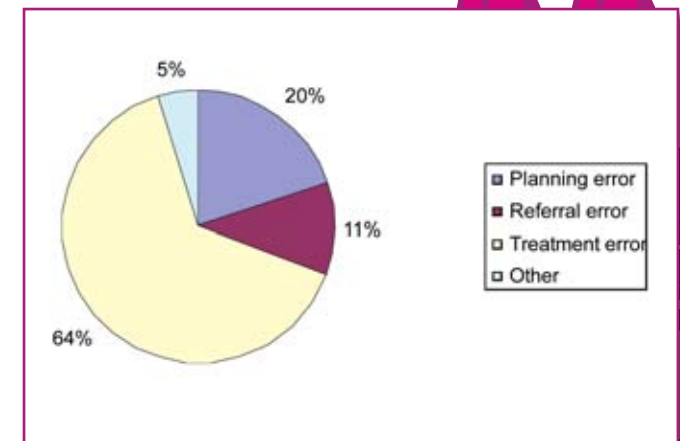


Figure 3: Radiotherapy notifications by type of error

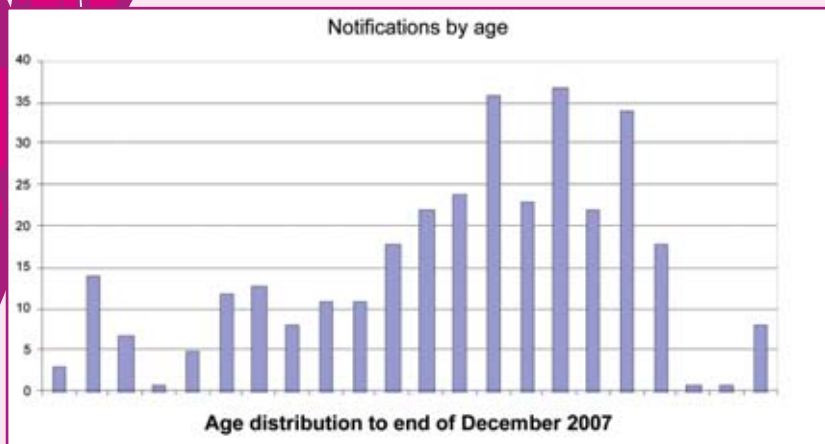


Figure 4:
Notifications by
age of patient

Patient identification issues

Correctly identifying patients is recognised as a cornerstone of patient safety and is embedded in the requirements for employers' written procedures in Regulation 4(1), Schedule 1(a). However, failures in patient identification accounted for almost half of all notifications from diagnostic x-ray and nuclear medicine. These are often mistakes made by the referrer who attaches the wrong patient identification label to the x-ray request form. Sometimes this can occur using computer-based x-ray request systems, where a clinician inadvertently selects the wrong patient for examination.

Subsequently the operator in the radiology or nuclear medicine department, who is responsible for carrying out a final identity check prior to the exposure, may not discover the mistake unless the clinical detail on the request is at variance with symptoms presented by the patient who arrives for examination.

Other unintended exposures have occurred when the wrong patient presents for examination and the operator performing the final identity check fails to follow the employer's written IR(ME)R procedures, which normally requires a three-point check of date of birth and address in addition to asking the patient to give their full name. Sometimes, the wrong inpatient may be collected

"Failures in patient identification accounted for almost half the notifications"

from the ward and taken to the x-ray department because of inadequate checks made between nursing staff and porters. These errors can be compounded when patients have identical or similar names. However, they should be detected by complete three-point checks, or checks of wristbands made in the radiology department.

Identification errors made on vulnerable patients are of particular concern. These include children, the elderly and confused, and patients whose first language is not English. The Healthcare Commission will continue to monitor trends in such errors and use these as part of risk profiling for inspections.

Proactive inspections and assessments

All radiotherapy centres in England will be assessed twice over a five-year period, which started from April 2007. Between July and the end of December 2007, the Commission carried out 15 inspections.

Future inspections will also include a random selection of other radiological practices, drawn from areas such as diagnostic radiology, dentistry, nuclear medicine, chiropractic and cardiology.

The inspection methodology is in line with the Healthcare Commission's overall work and is targeted and risk-based. Risk-based and responsive assessments are part of a long-term strategy on intelligent regulation. This direction is in line with the work of many other regulators and the recommendations of the Better Regulation Task Force.

An additional aim of the Commission is to map

and continue to integrate key IR(ME)R compliances into assessments, including the annual health check. Reports on all proactive inspections will be published on the Healthcare Commission website.

Reactive inspections and assessments

Staff assess each notification made under regulation 4(5) according to the risk presented to individual patients. Most of these notifications have not resulted in significant deterioration in the patient's condition or prognosis.

However, where an incident is high-risk and may have significant implications, fully-trained inspectors may inspect a premises to investigate more fully, take witness statements from individuals, or, in more extreme cases, interview witnesses under caution. One such reactive inspection took place in the first year, which concerned the complete geographical miss of the intended target of a patient undergoing radiotherapy treatment.

The Commission has a duty to safeguard the public by responding swiftly and appropriately to complaints, concerns and significant failings in the provision of healthcare. It is currently gathering evidence to assess whether regulatory action is required after a complaint was received concerning poor radiological practice.

To find out more about the Commission's other regulatory activities, visit: www.healthcarecommission.org.uk

Cliff Double is the IR(ME)R inspector at the Healthcare Commission.

Independent sector provision of radiotherapy

Sarah Hynd and Karol Sikora

Over a century of using radiotherapy for the treatment of cancer, there has been amazing evolution in its use, with tremendous change, too, in the interlinking disciplines of physics, imaging, dosimetry, delivery of treatment, and computerisation.

In much more recent times, there has also been a considerable increase in the amount of money spent on the management of cancer as a whole. The current total expenditure in the United Kingdom (UK) is difficult to calculate but, in England, it is certainly more than the baseline given in the Cancer Reform Strategy; some £4.35bn per year. This does not include primary care trusts' (PCTs) and Department of Health's (DH) costs or, indeed, the costs borne by the 12 per cent of the population who are treated privately. The true cost per head of population, per year is more than £100, a sum very similar to that spent by our European neighbours. Over the past decade, the injection of funds for cancer treatment has supported the installation of more and more equipment able to deliver complex radiotherapy. It has also improved workforce numbers and a plethora of policy documentation has been produced to point towards the future for cancer services in the UK.

Challenges ahead

Despite increasing expenditure, continuing, enormous challenges face all those involved in cancer treatment. These include:

- The rising incidence of cancer in an ageing population (with the additional health problems associated with aging);
- The increasing prevalence of cancer, with better outcomes;
- Increased early detection, patient knowledge, awareness and expectations;
- Under-capacity in radiotherapy and chemotherapy provision;
- Changes in scheduling patterns;
- Waiting times that are still too long for too many;
- Diversity of tariffs and charges;
- New and growing diagnostics such as combined magnetic resonance imaging (MRI) and positron emission tomography (PET); and,
- Exciting new and evolving radiotherapy tools.

The variation in the delivery of radiotherapy across the UK is considerable, with radiotherapy departments varying in size from two linear accelerator (linac) departments, to departments with 12. There are also many different treatment schedules, fractionation regimes, and practices.

Treatment machines are not necessarily used to full capacity, due to workforce deficiencies, or inefficiencies in process. Work patterns and treatment appointments tend to still follow the historical '9 to 5' day and these do not necessarily fit in with patients' work or family plans.

Many patients receive long courses of radiotherapy and chemotherapy which, typically, involve an extended series of short, daily visits to a cancer unit within a hospital. Increasing the convenience

and choice for patients receiving this therapy could make a real difference to those looking to incorporate their cancer care as seamlessly as possible into their every day routines. At present, many of these patients have to make daily, round trip journeys of more than 40 miles which can be tiring, is costly, and comes at a time when they are already under great strain (see Figure 1).

What needs to be done?

Not all of the challenges can be controlled but those associated with delivering treatment services can be addressed. There needs to be a major shift in the way in which treatment delivery is organised, and new ways of working need to be introduced to achieve more efficient systems and practices. Computed tomography (CT) scanners and linear accelerators could be utilised for longer working days; traditional usage of physics and engineering services could be altered to night or weekend working, and much can be learned from European and North American colleagues. The aim should be to achieve a 'no waiting lists' status, and new practices and technologies are making this possible.

The independent sector and radiotherapy

Within the UK to date, there are only three independent sector hospitals delivering radiotherapy: Cromwell, Harley Street Clinic, and Parkside. All of these are based in London. Two others outside London (Midhurst in Sussex and Glasgow Clydebank) ceased delivering radiotherapy two years ago. So, there is an obvious and very heavily weighted bias to National Health Service (NHS) led services currently.

The Cancer Reform Strategy pledges that "your care will be delivered in the most clinically appropriate and convenient setting for you". To achieve this, it is essential that the independent sector is a partner in the provision of radiotherapy and chemotherapy provision into the future. The independent sector has a major part to play in examining service delivery practices and can help to introduce the changes that are necessary. A particular example is the development of satellite treatment centres; independent providers can ensure that these are built, bringing more choice and flexibility to patients. But, collaboration not competition with the NHS is a key message.

There is a need for new approaches to clinics and departments to make compact units a reality. However, appropriate skills-mix is necessary, together with a real commitment to change from all who are involved. Good information technology (IT) infrastructure, remote planning and internet

access for radiotherapy information are also important and will aid change. It is also imperative that there is full liaison with the appropriate professional bodies and training institutions to support high quality, initial training and ongoing continual professional development. The outcome should be an acceleration of throughput for patients along the radiotherapy pathway.

It is envisaged that such radiotherapy centres run by the independent sector would have dedicated CT scanner access, state-of-the-art linear accelerators with full image guided radiotherapy (IGRT) and intensity modulated radiotherapy (IMRT) capabilities. There would be no traditional simulators or conventional mould rooms. Initially, newer technologies such as TomoTherapy, or Cyberknife, would not be used. Radiographers, dosimetrists and physicists would be expected to work in a more flexible way, with centralised planning a real possibility. Engineering and

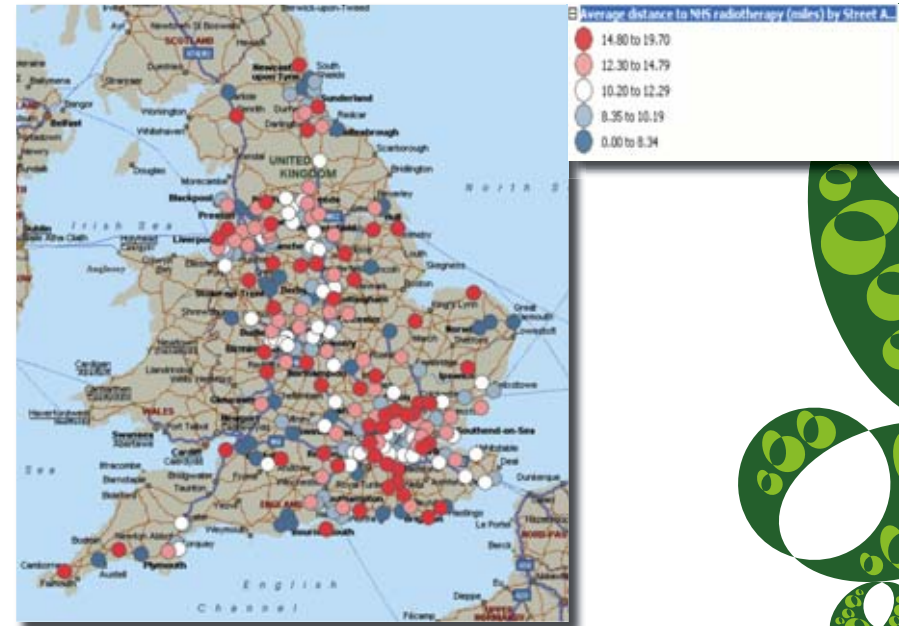



Figure 1: Distance from radiotherapy centre by PCT (England only) (Dr Foster Intelligence, 2006)

“Physics teams would need to adapt commissioning, quality assurance and ongoing machine maintenance”



servicing schedules could also be addressed in a more centralised way; and a comprehensive IT platform would be essential to make these satellite units as 'paper-light' as possible.

The common cancers of the breast, lung, gastro-intestinal tract and prostate lend themselves readily to being treated in such units, while specialist work such as paediatric cancers and transplant patients would continue to be cared for in the larger, established departments with the relevant, associated infrastructure support. The common cancers would be treated in compact, well-run satellite units following the most efficient treatment pathways and using the most up-to-date techniques on modern scanners and linear accelerators.

These independent units can also support fully the training of the radiotherapy workforce. Currently, there are 14 higher education institutes in the UK that train radiographers, with many making considerable contributions to support implementation of the profession's career progression framework (the 4-tier structure). However, very high student attrition is reported (up to 35 per cent from some universities as documented in the 2007 National Radiotherapy Advisory Group's report), with 'poor experience' for students cited as a contributing factor. More clinical departments in the UK would mean that there could be more placements commissioned, and students would receive a more varied overview of radiotherapy delivery and equipment, enhancing their clinical education experiences. Independent sector treatment units would also support advanced practice, for example, site-specific practice, tumour-delineation, IGRT-specialism, and IMRT-specialism. In time, consultant roles and assistant practitioner roles could also be supported. Apart from radiographers, independent sector

establishments would also need all of the other disciplines that make up the radiotherapy workforce to work differently. For example, the physics and engineering teams would need to adapt the commissioning, quality assurance and ongoing machine maintenance regimens to fit around treatment scheduling; oncologists would have to move away from their traditional 'sessions' working. Like radiographers, it will be essential for these two groups to be supported by a robust IT infrastructure and training.

So, what can independent sector providers offer?

The most effective way to reduce the costs and improve the effectiveness of cancer care is to ensure that the right patient gets the right treatment in a timely and efficient manner. Investing in sophisticated diagnostics, for example, imaging, tissue analysis and biomarker development, is a clear imperative if personalised

"The aim should be to achieve a 'no waiting lists' status"

“Investing in sophisticated diagnostics is a clear imperative if personalised cancer medicine is to be a reality”

medicine for cancer is to be made a reality. Similarly, delivering both radiotherapy and chemotherapy as close as possible to patients' homes is also essential. As cancer becomes a chronic controllable illness, a critical new force is required to deliver innovative and dynamic services and to provide what patients and their families really want – rapid, high quality and effective treatment, excellent support, and as little disruption to their normal lives as possible.

There are now new types of independent sector providers of cancer services, aiming to bring the latest international clinical best practice to the UK, whilst building on the many excellent aspects of British cancer medicine. Working in partnership with NHS organisations, cancer professionals and the voluntary sector, these new providers are able to create a novel network of cancer care centres through a series of joint ventures.

These centres will provide patient-driven, holistic services, including chemotherapy, radiotherapy, complementary therapy and some diagnostics in convenient locations outside the traditional hospital setting.

The centres will treat everyone on an outpatient basis, with no need for overnight stays. This model has been received positively by a large number of cancer networks, the DH, oncologists, and NHS based cancer centres. Leading cancer care charities have also signed up to the model. There is capital available to create approximately



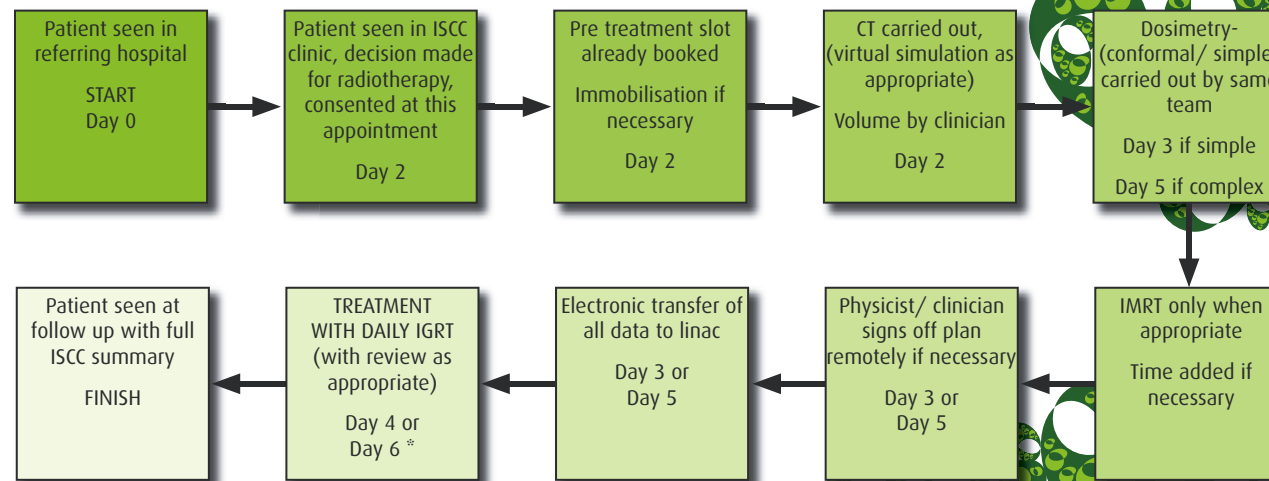
10 centres and the first wave is likely to be opened in the UK in the coming months.

The new model will be implemented alongside existing models of cancer care provision, and a template exists for rolling out these outpatient cancer centres linked to existing cancer hospitals. Centres will be open from early morning until late; and they will have a social as well as a medical function. Key characteristics include:


- Being placed in cities and large towns throughout the UK, establishing a local cancer care network for patients;
- A mixture of independent ventures, and partnerships with the NHS, existing private healthcare providers and charities;
- Being built in existing hospital campuses, or in primary care, business and retail park settings;
- Architecturally pleasing environments, and being fully equipped to deliver chemotherapy and/or radiotherapy, so providing a focal point for all non-surgical treatment of cancer;
- Different levels of centre, with clinics ranging from small outpatient clinics offering chemotherapy only, to larger outpatient clinics offering chemotherapy and radiotherapy with two linear accelerators;
- Full quality control and audit from the outset.

Independent sector providers are creating a new, distinctive cancer care service which will be far more efficient and cost effective than those existing currently. Figure 2 shows the typical radiotherapy pathway within this new type of service. The emphasis will be on patient convenience, and attention to technical detail within a fully quality assured environment. This will ensure that the service is welcomed universally by patients, staff and those purchasing and managing services for their population catchments. Networks of centres will encourage new ways of interaction between professionals to increase efficiency, while maintaining 'the personal touch' essential to patients' well-being. In summary, independent sector providers will be a powerful driver of change in the delivery of cancer care.

Figure 2: Typical Radiotherapy Pathway in an Independent Sector Cancer Centre (ISCC)



*Urgent/ palliative cases would be less because no need for full dosimetry (virtual simulation only).



“Centres will have a social as well as a medical function”



Conclusion

Patients with cancer and undergoing radiotherapy wish for their care to be normalised into their work and family lives, bringing increased quality to their lives. They want speedier and more convenient access to treatment, as well as quality treatment from the associated fully-trained health professionals. They wish for:

- The best chance of cure, with good quality of life;
- Honest, clear information on available options;
- The diagnostics to be fast-tracked and treatment started within 14 days;
- The same specialist to see them at every visit;
- Convenient, streamlined services close to home with dedicated car parking;
- Treatment to be provided in a decent environment, and with dignity;

- The best care without worrying about its cost.

The independent sector is now beginning to assist the NHS to deliver 21st century cancer medicine in pleasant environments as close to patients' homes as possible. Almost certainly, this will enhance the future practice and delivery of radiotherapy in the UK.

Sarah Hynd is head of radiotherapy services, and Karol Sikora is a director of CancerPartnersUK Ltd.

Radiographer-led diagnostic imaging in primary care: A case study

Leslie Eddowes

The case study described in this article tracks the development of a radiographer-led diagnostic imaging service (DIS). The project to develop this service began in the final years of life of an old cottage hospital, and the first year of operation of a 'one stop' centre in primary care established as a local investment finance trust (LIFT) to replace the cottage hospital. Planning for the project began in 2002 but, over the five years taken to realise the project, major shifts in health policy and administration occurred; these have impacted both upon the DIS and the project.

The project began before the reconfiguration of primary care trusts and the creation of the new model of the commissioner/provider split¹. At the outset, it was proposed that the three primary care trusts (PCTs) that had invested in the project would have, in partnership with a private sector partner, exclusive rights to develop local health care projects. However, before completion of the project, several partners, including the acute trust that had provided imaging, withdrew and National Health Service (NHS) policy changes to drive forward a patient-led NHS had begun to take effect. By the time the new building was opened, provider organisations were no longer the lead bodies in determining what health care projects would be developed, because such decisions had become the province of PCT commissioners, supporting practice-based commissioning.

This changing context during the project gave rise to some challenges, and to opportunities that permitted the development of a new model for diagnostic imaging service in primary care, and which preserved x-ray diagnostics in a town that had enjoyed such a service for nearly a century. The town is typical of many – steeped in history, situated on a major trunk road, ripe for further housing and industrial development, some distance from acute hospital facilities, and in need of significant investment.

The vision

This LIFT project was conceived in 2002 as a 'one-stop' facility to provide both health and social care services. The project team intended the integration of services to be core, with staff from differing organisations freed from associated administrative barriers and able to make the overall service truly patient and user centred. This was and remains a great ambition, and a significant challenge. The building would contain an x-ray department; a physiotherapy & rehabilitation department; podiatry services; out-patient clinic rooms; mental health services; another general practitioner surgery for the town with out of hours support; a community children's dental service, and a community alcohol and drugs service. It would also provide office space for a volunteer bureau; adult social services, and PCT community staff.

The new building and the services it was to provide were an expression of the then PCT's wish to provide excellent services in a first rate setting. Recognising that the NHS was in the midst of significant change with unclear endpoints, it would give the community an excellent platform for whatever services the PCT decided to provide.

Relative to the diagnostic imaging service, what was wanted was a service that was manifestly personalised; a service that welcomed families in every way and made Virginia Bottomley's words in *The Welfare of Children and Young People in Hospital*² (1993) a lively reality: "... families and their carers should experience a seamless web of care ..." Donald Winnicott's³ "facilitating environment" for patients and staff was also part of the vision. The services provided would show demonstrable respect for adult patients whose taxes funded the project and who would privilege the LIFT in accepting its care. For children and, indeed, for all those attending the centre, the aim was to have fun, whilst engaging in the serious business of health and social care delivery. The ambitions were, and remain, high.

Emerging problems

To begin with, there was a PCT director champion who drove the project forward. When the acute trust providing the diagnostic imaging service pulled out from the LIFT partnership, the LIFT project itself continued to provide x-ray services as a satellite unit from the acute trust but, eventually, notice of intention to withdraw the x-ray service completely was given by the acute trust as part of the resolution of its (then) over-spend situation. Although the acute trust withdrew altogether, the ongoing professional support of its radiology services manager was to prove to be a major help in setting up a new radiographer-led service.

Before the new LIFT project building was completed, the social services partners withdrew and the PCT champion left the NHS; and when the LIFT finally opened, it was as a new facility co-owned by the a newly created PCT, itself in a financial turnaround situation, and a private sector partner.

Maintaining an imaging service in the LIFT

During the period of the project it would have been easy to lose diagnostic imaging to the town, and the eventual outcome of a radiographer-led service was one that was grasped opportunistically when events came together to make it an attractive solution. Many members of the project team felt a keen sense of responsibility to keep a well established imaging service in the town and were determined to fill the vacuum created when the acute trust withdrew. But there were several questions to be answered:

- Could so small a service be run by a radiographer?
- Could such a service be run along the lines of a private sector provider, albeit firmly within an NHS unit?

- How far could the radiographer go in providing a reporting service without recourse to a radiologist?
- What was the limit to which a radiographer-led service could go?
- Would the GPs trust the radiographer?

A time for personal reflection

It was time for serious personal reflection; was I capable of fulfilling the task and willing to take on the risks of the project? Apart from the excitement involved in giving up a very old two-pulse x-ray unit and film, in favour of a medium frequency unit with computed radiography and modern information technology, I had a sense that an experiment was possible and I realised that I could do it. Twenty five years earlier I had risen to the challenge of carrying out lymphangiograms and sialograms,



"The project remains a mixture of struggle and joy"

undertaking the cannulations and administering ionic contrast media. I also had significant experience of implementing new imaging technologies. But I had never formally trained in reporting.

Running an x-ray department, albeit a small one, without a radiologist to refer to was both attractive and challenging. However, the opportunity to contribute to a development in radiographic practice was irresistible. I was fortunate in having a radiologist mentor who has been outstanding in his support of radiographers over many years. A number of radiologists were also instrumental in supporting my ambitions for the project and without such support it would have foundered.

So, following the withdrawal of the acute trust, I took the plunge and transferred my employment to the PCT, to develop a radiographer-led service.

Getting a radiographer-led imaging service off the ground *Approval and principles*

The first step was to do some thorough research and write a paper for presentation to the PCT professional executive committee (PEC), and on to the PCT Board. This outlined what shape a radiographer-led service might take and was approved. In preparation, the range of Department of Health (DH)/NHS initiatives and documents that were relevant and current at the time

were examined, together with those applicable to radiography, and expressed in the proposals for a radiographer-led diagnostic imaging service.

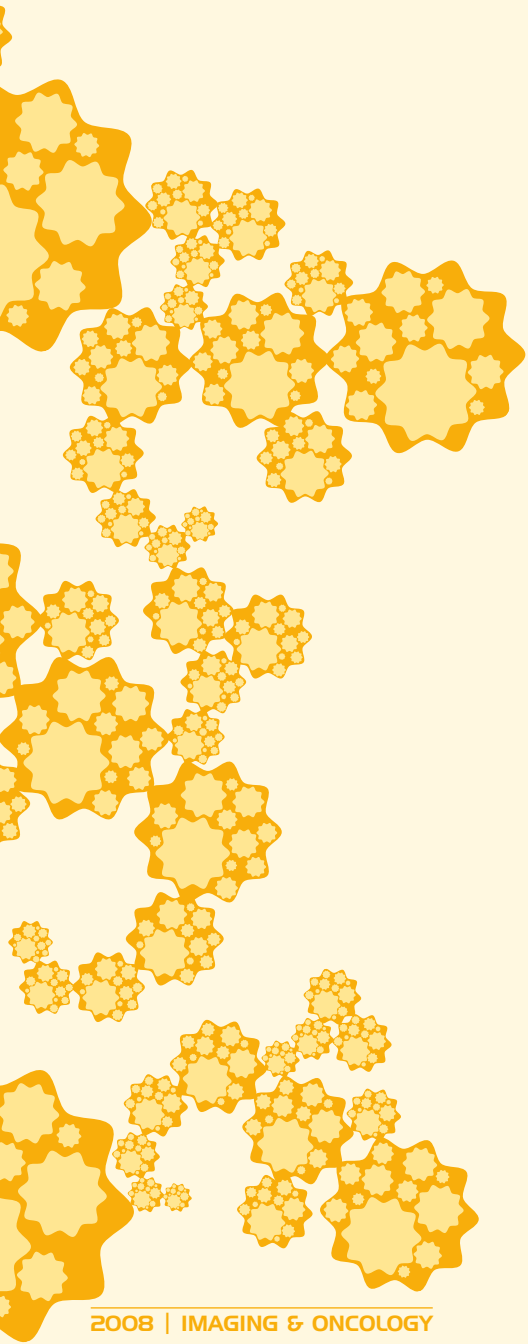
The project team had strong sympathy for the essence of the NHS reforms of the 2000s and particularly the notion that the NHS needs to be patient centred; and to challenge assumptions, behaviours and practices that contradict that principle. *Creating a Patient Led NHS*¹ was not published until the final stage of the project but its underlying principles were well mapped in the project plan.

Hardware

A room suitable for general radiography and a computed radiography (CR) reader were procured. This was straightforward using Safespec and standard procurement procedures.

The issue of information technology (IT) was very different. Equipping the new service with a film based system would have been easy but complete madness, and a digital solution was needed. This meant that a PACS (picture archiving and communications system) resource was required. Early efforts to get an adequate, local response through the Connecting for Health

"The market and the system need not be contradictory"



(CfH) programme yielded nothing. Engaging at regional level speeded things up but the project was considered to be too small to be part of the national programme as an entity in its own right. In fact, this decision proved beneficial as the business plan for the project demanded a future-proofed service platform that could link with any healthcare provider; simply hooking up to an acute trust to provide the IT infrastructure within the CfH national programme would not meet this need. A solution was required that would allow collaboration with multiple acute trusts and other providers as flexibly as possible; it also needed to be affordable. The outcome was to work with an IT/software provider to tailor a solution to meet present needs and support any ongoing development as the service develops. The freedom to develop a bespoke IT solution has provided clear operational benefits; for example, following the maxim that image handling via PACS should be at least as fast as handling hardcopy film, an electronic diary for the department has been introduced that is as fast to use as a paper-based one. Developments of this sort have only been possible because the software developer engaged is fleet enough to employ development tools in Java as they emerge.

The CfH programme is moving towards including existing service providers so, ultimately, inclusion in the national programme is inevitable. In the interim, however, a very effective, affordable, non-corporate solution has been found and implemented. Currently, the CfH model for imaging services is based upon the functional unit being acute trusts as the entities for connection to the central data store. Corporate PACS providers are reluctant to engage with others and allow access to their systems. This is a 'compromise and use our solution' approach which runs counter to an open systems interconnection model.

One obvious alternative is for existing acute trusts

to extend their radiology IT systems into primary care units. This would maintain the CfH model based on existing entities but, equally, it would consolidate the grip of acute trusts on diagnostic imaging in primary care; over many years, GPs have suffered the slowness of imaging services provided by acute trusts and it is questionable as to whether they will accept this. What is clear is that, at present, major corporate solutions for IT are not a sufficiently useful answer to support the provision of diagnostic imaging in primary care, unless primary care imaging is to be provided as satellite sites of acute trusts. If small providers of care, able and hungry to provide quality clinical services, including imaging services, close to patients, are to be encouraged, smaller IT solutions must also be supported, notably in relation to the national IT solution for radiology.

System or market?

In her 2008 conference speech, the Chief Allied Health Professions Officer, Karen Middleton, stressed that "We don't operate in a market. We operate in a system". The distinction is highly relevant to this project, and to others of a similar nature. The traditional 'system' has a number of attributes that no longer serve patients well and these have provoked the reform agenda of the current decade. However, the 'market' has connotations of brute commercialism, and gives rise to fears that the ethics of the market run counter to the best values of the NHS, much prized by its staff and patients. It may be caricature and over-simplification but, at best, markets respond in agile ways seeking to meet customer expectations while, at worst, state systems (like the NHS) perpetuate practices that seek to meet administrative purposes largely for their own sake. A 'system' is needed with which the nation can continue to identify and trust; but a system that is market based insofar as competition optimises value for money and, above all, remembers that the customer (tax-payer) is paying. Ultimately, what will define NHS care will be those commissioning it, not those providing it. The NHS can enjoy the benefits of the market through competition between providers and also retain the benefits of a system, mediated by commissioning, which meets local needs, in tune with broad, national strategic direction.

The market and the system need not be contradictory. The traditional best values of the NHS and those of the market could be expressed in a set of clear principles that are required to be applied to everything the NHS pays for, directly and indirectly. A new system, including the best from inside and outside the NHS, working together to provide a 'seamless web of care', should be the goal.

In a small way, all of these issues are part of the experiment to create and sustain a tiny NHS radiographer-led imaging service inside a LIFT. It will be interesting to see how it fares, operating like a business in a new NHS 'systemplace' and

"The future of the project feels uncertain"

its particular challenges of tariffs, pay, the separation of commissioner and provider roles in PCTs, and relationships with other imaging service providers.

Tariffs

Key concerns about tariffs for imaging investigations and the un-bundling of those tariffs have yet to be fully addressed. Being able to vary (reduce) tariff charges by derivation from reference costs will result in the economies of scale available to the big providers of imaging services, such as acute trusts. These stand to lose by locally provided services and may want to squeeze out small, emerging community based services. There is also the practice of forcing service providers to accept sub-tariff prices or lose business; this affects large and small providers alike but the effect on small providers is disproportionately greater. Tariff values need to be fixed, and need to reflect a dimension related to quality of service.

Staff interests

Despite considerable effort to reform pay and conditions, dialogue between staff and employers continues to marginalise the best interests of patients. Professional bodies give much attention to the protection of their members' interests but this can disincentivise members to embrace NHS reforms to the benefit of patients. In the field of imaging, there are perceived threats to staff interests in the reforms, but what of patients? Imaging services will progress and develop faster when the professional bodies in diagnostic imaging prize innovative projects and advocate appropriate resources to support such developments.

PCT roles

Managers in the NHS face considerable uncertainty at present. Within PCTs, their role as providers of services is yet unclear. Providers will need to react to the demands of commissioners; commissioning is still in its early days, and commissioners are still finding their feet. For the project, what services are to be commissioned into the future remains to be seen. And, at present, PCT administrations seem heavily engaged in the development of new policies, or the translation of old ones, to address the new context of larger commissioning PCTs and arms length trading organisations. There is no shortage of policy development and it is difficult to see how such a bureaucratic overhead can be sustained by small provider services competing in the provider market.

**“Working together for a
'seamless web of care' ”**

Relationships with other service providers

Primary care based imaging needs the collaboration of major hospital-based imaging departments, but not their control. There is a risk that if radiology departments based in large acute trusts do not support more local imaging services, then those services may be forced to look further afield, even offshore, for radiological support. This risks a real tragedy. The best care pathways for patients must include clinicians of all relevant disciplines collaborating in a way that starts with a common-sense appraisal of what makes life easier for patients, and proceeds to identifying how they can collaborate to make effective solutions happen. There is much to be said for care pathways that combine local primary care diagnostics, including imaging, followed by care in the more distant acute trust.

Looking ahead

The project to develop a radiographer-led imaging service in primary care has been, and remains, a mixture of struggle and joy. There were, and are, very few places to go for practical support; professional bodies are pre-occupied with a trade union focus, NHS managers are not natural free-marketeters, and the NHS market, free or managed, does not have a known and understood form.

The future of the project feels very uncertain. The high ambitions from the start of the project are still there but the NHS world has changed and the commissioner is now king. The early not-for-profit entrepreneurs in PCT provider arms and social enterprise trusts that are trying to provide solutions for imaging within primary care settings may well be suffocated.

In one small town, at least, imaging services have moved out from the traditional NHS model

and into a new environment. They have also moved into a new era, both in terms of being radiographer-led, and in terms of a market based NHS system. It remains to be seen whether both the service and the era survive.

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Meeting the workforce challenge in cardiac catheter laboratories

Rob Henderson

Over the last two decades there has been increasing use of percutaneous catheter-based interventions to investigate and treat cardiac disease. This change in the practice of cardiology has been driven partly by advances in technology, but also by clinician and patient preference for less invasive treatment strategies. In particular, the advent of coronary stents has increased the use of percutaneous coronary interventions, and, in the United Kingdom (UK), the number of these procedures has risen four-fold. Moreover, demand for other percutaneous cardiac interventions is likely to continue to grow with the introduction of heart attack centres providing primary angioplasty for ST-elevation myocardial infarction, and increasing use of device-based therapies for cardiac rhythm and heart failure management. In addition, novel techniques for the percutaneous treatment of congenital and structural heart disease are being developed, and over the last few years percutaneous replacement of the aortic valve has become a real treatment option for selected patients with aortic valve disease.

This growing demand for percutaneous cardiac interventions requires additional infrastructure and, in 2002, the National Health Service (NHS) initiated a major programme to expand cardiac catheter laboratory capacity. Over the last five years the number of catheter laboratories in England

has increased by 50 per cent and, although capacity has increased at a slower rate in Wales, Scotland, and Northern Ireland, there are now a total of 266 cardiac catheter laboratories across the UK. Full utilisation of this extra catheter laboratory capacity will only be possible if there is a commensurate increase in the size of the catheter laboratory workforce, but available evidence suggests that growth in catheter laboratory staffing has occurred at a much slower rate.

Catheter laboratory staffing

Accurate data on the size of the non-medical catheter laboratory workforce are not collected routinely but, in 2006, a British Cardiovascular Society survey estimated that 2095 whole-time-equivalent (wte) non-medical professional staff work in UK catheter laboratories. These staff include 1106 nurses, 511 physiologists, and 478 radiographers dedicated to catheter laboratory work. The survey also suggested that more than 12 per cent of catheter laboratory posts are currently vacant, a substantially higher vacancy rate than in other areas of the NHS. By contrast, a separate report from the British Cardiovascular Society estimated that a national invasive cardiology service (providing 2000-3000 percutaneous coronary interventions and 350-700 electrophysiology procedures per million population) will require over 3000 wte professional

"Extra capacity will be possible only if there is an increase in the workforce"

non-medical catheter laboratory staff. Taken together, these data suggest that further significant increases in the number of catheter laboratory procedures will be difficult with existing staffing levels. Hence, there is a need to expand current workforce capacity, preferably with experienced staff from each of the three professional disciplines associated with catheter laboratory work.

Unfortunately, there are currently shortages of such experienced clinical staff across the UK. For example, in England, the National Workforce Review Team Recommendations for 2007/8 highlighted uncertainties about the capacity of the radiography workforce to meet the growing demand for diagnostic imaging services. The number of students graduating from radiography courses in the UK has increased substantially in recent years and there is now a small excess of radiographers relative to the number of available radiography posts, but most of these staff are relatively junior and inexperienced. Moreover, new policy initiatives and changes in skill mix continue to provide radiographers with a range of new opportunities, and these changes in practice are challenging the capacity of the radiography workforce and the wider health service. It is therefore possible that the number of radiographers available to work in catheter laboratories will be insufficient to meet future demand.

There is also uncertainty about the capacity of the nursing profession relative to demand for these staff in the UK. Recent financial pressures within the NHS have created uncertainty about the future employment prospects for the nursing workforce which may lead to nursing unemployment in the short-term. On the other hand, many experienced nurses are likely to retire in the coming years and, in future, the NHS is unlikely to be able to recruit large numbers of trained nurses from overseas. Hence, the National Workforce Review Team has also recently expressed concern that current training capacity for nursing staff will be unable to meet future demand.

The precise number of cardiac physiologists in the UK is unknown but is estimated to be between 2000-3000. By comparison, in 2005 the British Cardiovascular Society estimated the national requirement for cardiac physiologists to be at least 3800 wte staff; taken together, these figures suggest that there is a significant national shortage of cardiac physiologists. At the same time there is a high and growing demand for these staff in interventional cardiology, electrophysiology and cardiac rhythm management, and as the main providers of echocardiography services. Training capacity for clinical physiologists is very limited and there is some evidence that the number of students enrolling on clinical physiology degree courses is declining. As a result, the number of cardiac physiologists is unlikely to grow significantly over the next few years and the number of physiologists available to work in catheter

laboratories will remain unchanged for the foreseeable future.

In summary, this workforce information suggests that catheter laboratories may be unable to recruit and retain sufficient numbers of professional non-medical staff to maintain current working practices and to meet the rising demand for catheter laboratory activity. Catheter laboratories will continue therefore to face staffing shortages but at the same time will be required to provide timely access to a range of invasive cardiology services.

“National training for catheter lab multi-skilling”

Possible solutions

Ideally, catheter laboratory staffing shortages should be addressed by increasing the supply of appropriately qualified personnel through sustained investment in undergraduate and postgraduate training, and by coordinated efforts to attract greater numbers of students and graduates into catheter laboratory work. This optimal solution to catheter laboratory staffing shortages must be a long-term objective but is unrealistic in the prevailing NHS climate and could not be implemented in the short-term. Alternative workforce solutions, which recognise the full range of competences that different healthcare professionals contribute to catheter laboratory services, will therefore have to be considered.

Staffing levels vary widely within catheter laboratories across the UK, and some of this variation may be associated with differences in productivity and efficiency. Hence, there may be opportunities to review and revise the roles of professional catheter laboratory staff and to encourage more widespread use of best and most effective practice. For example, many senior catheter laboratory staff are responsible for stock control, and aspects of material and personnel management, but many of these tasks could be devolved to clerical and administrative assistants. Appropriate investment in information technology can also reduce the administrative burden associated with stock management of consumables, and can allow professional clinical staff to spend more time on clinical activity.

There is also increasing recognition of the importance of unregistered staff in the delivery of healthcare in the UK and, in some catheter laboratories, catheter laboratory assistants carry out a range of duties which were previously the responsibility of registered catheter laboratory staff. These duties vary widely between institutions but include, for example, preparation



of patients for procedures, phlebotomy and venous cannulation, preparation of sterile trolleys, setting up pressure transducers, assisting at procedures, and arterial sheath removal. The use of catheter laboratory assistants should be determined by service requirements at a local level but more widespread use of these staff could potentially relieve senior staff of many routine activities that do not require high level competences.

More efficient rostering of medical and other clinical staff might also help to improve efficiency and reduce the number of catheter laboratory sessions lost through periods of planned leave. Clinicians and managers should review working practices in catheter laboratories with the objective of maximising efficiency and productivity. However, this process is unlikely to mitigate all of the effects of catheter laboratory staffing shortages and alternative workforce models may need to be considered.

Alternative workforce models

Traditionally, the catheter laboratory workforce has included nurses, physiologists, and radiographers, and each of these professional groups has had a clearly defined but circumscribed role within the catheter laboratory team. In most laboratories newly appointed professional staff will undergo a period of orientation during which they will learn through supervised practice, acquiring a range of competences from more experienced staff. Formal opportunities for training of catheter laboratory staff are very limited and consist mainly of ad hoc local programmes, and regional or national conferences. This pattern of workforce development has served cardiology services well for many years but staffing shortages and demand for staff elsewhere in the NHS suggest that current practices may be unable to sustain catheter laboratory activity in the future. It is therefore appropriate to consider alternative workforce models to fully utilise the additional catheter laboratory capacity now available in the UK.

In catheter laboratories across the UK, there is increasing recognition that many of the tasks undertaken by catheter laboratory staff are not specific to a particular professional group, and with appropriate training some of these tasks can be carried out by any healthcare professional. Multi-skilling of the catheter laboratory workforce has therefore been proposed as a method of extending the role of established healthcare professionals in one discipline to include competences that are usually the responsibility of another discipline. Multi-skilling can increase workforce flexibility by reducing reliance on particular professional groups,

“Alternative workforce solutions have to be considered”

and may mitigate (at least in part) the effects of non-medical catheter laboratory staff shortages.

The introduction of multi-skilling into the catheter laboratory environment may be difficult, however, because it challenges professional boundaries, and pre-existing differences in work rotas and pay banding may impede efforts to integrate different professional groups into a unified workforce. Multi-skilling projects must also comply

with relevant legislation including the Ionising Radiation (Medical Exposure) Regulations, which require that radiographic exposures in the catheter laboratory are carried out by a healthcare worker with appropriate training and entitlement from the employing health service institution.

Ongoing projects to implement multi-skilling vary widely in scope, and range from pilot projects to structured training programmes. In some catheter laboratories these projects have been driven by local shortages in a particular staff group. For example, at hospitals in Nottingham there has been a long-term shortage of experienced radiography staff, and nursing and physiology staff have been trained to carry out radiographic duties in the catheter laboratory. The ad hoc training programme for this role extension includes a period of tuition to provide the trainee with the requisite knowledge, followed by a period of supervised practical experience. The time taken to complete this training varies according to individual progress, and the supervisor has to be satisfied that the trainee can practice safely in the extended role before he/she is allowed to operate independently.

At other hospitals there has been a shortage of cardiac physiologists, and radiographers and nurses have been trained to take on the physiologist's role during cardiac catheterisation and coronary intervention procedures. Importantly, such multi-skilling imparts competences required to carry out a specific task, but is not a substitute for formal training in any of the professional disciplines involved in catheter laboratory work. Nevertheless, local training programmes for multi-skilling often successfully maintain service delivery in the face of severe staff shortages in one or more professional disciplines, although they do not conform to any national or other practice standards, or provide a transferable qualification.

In an alternative approach, the Cardiac Catheter Laboratory Practitioner project has successfully established a training course for catheter laboratory staff at London South Bank University. This course is designed to develop competences across traditional professional boundaries, involves five weeks of academic tuition followed by a four month period of supernumerary clinical experience, and leads to a postgraduate certificate in cardiac angiography. To date a relatively small number of catheter laboratory staff in London have successfully completed the course and are now working in extended roles. An evaluation of the course is ongoing but anecdotal feedback suggests that individuals who have completed the course can have a positive impact on catheter laboratory efficiency. The main limitation of this course, however, is that it requires catheter laboratories to release staff from their usual activities for up to six months, and this may be difficult in catheter laboratories already facing staff shortages.

Future training programmes

Recently, a working group of the British Cardiovascular Society brought together representatives from a number of professional bodies (including the Society of Radiographers, Royal College of Nursing, British Association for Nursing in Cardiac Care, and the Society for Cardiological Science and Technology) to discuss catheter laboratory staffing. The working group considered the apparent success of existing multi-skilling programmes, and concluded that there is a need for a national training programme designed to introduce multi-skilling into catheter laboratories across the UK. Such a programme will need to deliver training to agreed standards and should lead to a transferrable qualification that will be recognised across the country. In addition, the programme must be accessible to existing catheter laboratory staff and deliver flexible training, both in terms of location and timing. However, it will require release of staff from some routine duties to allow them to attend components of the course and this will require appropriate financial and other support.

In response to the working group's proposals, the British Cardiovascular Society, British Heart Foundation, and London South Bank University are collaborating to develop a national training programme for catheter laboratory multi-skilling. The programme will allow existing non-medical catheter laboratory personnel to develop competences in all three of the disciplines traditionally associated with catheter laboratory work, and will lead to a nationally recognised and transferrable qualification. It is anticipated that the first course will start in early 2009 and it will, hopefully, attract radiographers, cardiac physiologists, and nurses involved in catheter laboratory work. In the future, it may be appropriate to extend the course to develop

"Labs may be unable to recruit and retain staff to meet the rising demand for services"

a generic catheter laboratory worker role, which will involve training graduates in all of the competences required to work within the catheter laboratory environment.

These are challenging times for catheter laboratory workers, with a rising demand for catheter laboratory activity but significant shortages of experienced catheter laboratory staff. Multi-skilling of the catheter laboratory workforce cannot provide the complete solution to these problems but, with appropriate investment in training, it may be possible to develop a more flexible workforce capable of maintaining and expanding catheter laboratory services in the future.

The British Cardiovascular Society Working Group Report (Non-medical catheter laboratory staffing working group report. March 2007) is available at www.bcs.com.

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Radiology Academies: Three years on

Matthew Wallis

In 2001 there were fewer than 1800 consultant radiologists in the United Kingdom (UK); per capita less than the rest of western Europe and the United States of America. The UK also had the lowest radiology intervention rates, with very long waiting lists that were politically unacceptable (at least in England). Despite skill mix and gradually increasing the numbers of radiology trainees, there was seen to be a need to increase consultant radiologist numbers drastically, but the traditional training schemes available in 2001 could not provide the required increase.

A new approach to radiology training: R-ITI

It was felt that a new approach to training radiology registrars was required and, as a result, R-ITI (Radiology Integrated Training Initiative) was born: a collaboration between the Department of Health (England), the Royal College of Radiologists (RCR) and the National Health Service (NHS) to make use of exciting information technology (IT) developments becoming available in education and the fledgling IT infrastructure in the NHS.

R-ITI aimed to provide specifically designed educational resources, capable of reproducing a clinical environment, through which clinical practice and skills could be developed. In particular, the R-ITI project sought to deliver a new approach to the first three years of a radiologist's training and to:

- Increase the number of high-quality trained radiologists;
- Evaluate whether the approach would be acceptable to trainers and service, using new technology effectively and delivering value for money;
- Assess its potential for and applicability to other staff groups, and
- Ensure that a significant investment in IT and skills laboratory equipment would be used by the NHS.

The nature of R-ITI

R-ITI consisted of academies and an e-learning resource, namely the e-Learning Database (e-LD), the Validated Case Archive (VCA), and a Learning Management System (LMS) to manage the e-learning, and to facilitate shared learning between sites using video conferencing.

The tools

The e-learning resource was one of the two planks of R-ITI, and has won numerous national and international awards. It is now being used as a template for the rest of the NHS under the umbrella of e-Learning for Health Care. In the UK, pathology, emergency medicine and anaesthetics specialties are all interested, as are countries from Poland to Singapore.

The E-Learning Database consists of a series of interactive tutorials covering the whole of the radiology training syllabus, encompassing both theory and practical procedures. All were written by experienced trainers and the RCR sub-speciality groups. Each tutorial covers the core knowledge specified in the syllabus, as well as demonstrations, tests and links to other resources.

The Validated Case Archive is really a digital film library but the traditional yellowing scraps of paper associated with a hard-copy film library have been replaced by full annotation, differential diagnoses and the 'correct answer', complete with histology, where available, and all carefully checked and externally validated. This is backed up by a sophisticated programme so that the cases can be used as a teaching tool, or as self evaluation test sets. Cases can be selected by body system, examination type, radiological sign, disease process, etc forming an ideal and flexible partner to e-LD.

All of this is supported by a Learning Management System which can be used to track each trainee's use of the tools and individual progress, allowing trainees to monitor their own training, development and learning.

The academies

The initial concept was that trainees would be based during alternate weeks in an academy, so spending half their time in a structured learning environment and allowing teaching to be delivered to a larger number of registrars than could be supported in a clinical training department. The other half of their time was to be spent in the more traditional apprenticeship training mode seeing real patients in clinical departments. This model automatically doubled training capacity.

Three radiology academies were commissioned: Norwich Radiology Academy sits in the Norwich Research Park, adjacent to the Norfolk and Norwich Hospital; Peninsula Radiology Academy is located at the Plymouth International Business Park, close to Plymouth airport; and Leeds & West Yorkshire Radiology Academy is adjacent to the radiology department within Leeds General Infirmary.

Each academy was set up slightly differently, but facilities in all three include PACS (picture archiving and communications systems), lecture theatres, e-learning rooms, skills laboratories, including vascular simulators, and ultrasound equipment. There are also audio visual links to enable the three academies to link together, and to communicate to other centres. Each academy is linked directly to its own hospital's PACS and RIS (radiology information system) so trainees can do real reporting in the academy under supervision, which is varied according to the individual trainee's experience.

Progress was very rapid (for an NHS programme), with the academies recruiting new trainees in the spring of 2005, opening for business in October of the same year, and offering considerably more than double the number of training places than previously (see table 1).

Table 1

SpR Cohort intake				
	Pre academy 2004/5	2005/6	2006/7	2007/8
Leeds & West Yorkshire	6	16	15	13
Norfolk & Norwich	2	10	11	10
Peninsula	3	18	16	13
Total	12	44	42*	36*
				122
*numbers reduced to meet clinical placement capacity				

**"Are the
academies
the
future of
radiology
training?"**

This rapid implementation brought its own problems. While the physical facilities were up and running, the IT infra-structure took longer to develop: e-LD took nearly two years to complete; and entering cases on to the VCA was found to be very time consuming initially, especially when compared to other systems such as EuroRad. This acted as a disincentive and meant that the VCA was slow to grow.

Sharing of teaching and tutorials between the academies, while laudable in theory, never really got off the ground. This is probably due to the usual problems with video conferencing - a vicious circle of equipment idiosyncrasies and lack of experience leading to disappointment and distrust.

Taken together, these various factors meant that significantly more consultant radiologist support was required than had been initially anticipated. The Norwich and Peninsula academies appointed consultant staff, while Leeds and West Yorkshire, in part, used post CCST teaching fellows with an interest in education, so offering them a unique opportunity to develop and train in their clinical sub-speciality and in medical education.

All three academies have appointed senior radiographer-sonographers to teach ultrasound either, as in the case of Leeds and West

Yorkshire, one full time consultant radiographer in the academy, or by increasing the existing pool of sonographers in the associated clinical departments who then share the teaching. In all cases, the 'academy ultrasound machine' has generated additional clinical capacity in the form of dedicated ultrasound/teaching lists.

Where are the academies now?

Three radiology trainee cohorts are in place, giving 86 additional trainees in total over the three cohorts. The fourth (2008) cohort is in the process of being recruited. All three academies report high pass rates for both part 1 and part 2a of the Fellowship examinations of the RCR (FRCR). Anecdotally, the trainees are felt to be competent in practical skills (now measured by formal assessment) earlier than had been the case historically. So, on average, they are undertaking 'real' work three months earlier than customary and, hence, are contributing additional service support, predominantly plain film reporting and ultrasound. This is both in the academies in a directly taught environment, and in the traditional fashion in their clinical placements. The integration of the academy PACS workstations into the associated hospital's system provides additional work station capacity and means that examinations other than plain film work can be reported in shadow form, with subsequent double reading by consultant staff. This provides the trainees with access to large volumes of 'non library' examinations.

**"Vision and courage:
more academies"**

The physical environment of the academies and larger numbers of trainees in one place at one time fosters creativity both educationally and in terms of research. The trainees (all with less than two years' experience) on all three sites have set up courses for medical students and junior doctors, and some of these generate income that is fed back in to their study leave budgets. Trainees are already presenting and winning prizes for oral papers and posters at both national and international meetings, and have also had papers published in peer review journals.

The 'one week in, one week out' model has been modified variously, with more intensive support given to first year trainees and more flexible timing for the more experienced year two and year three trainees to enable them to maintain greater continuity in their clinical placements.

The academies offer greater access to multi-disciplinary team meetings (MDTs) by means of video conferencing or, in the case of Leeds and West Yorkshire, by moving all the MDTs into one of the academy lecture theatres. This allows the trainees to attend these meetings as part of their 'academy time' earlier and more frequently than otherwise would be the case. It also exposes them to a larger case mix and enables them to experience multi-disciplinary working and decision making from very early in their training. These are becoming, and will become, a larger part of the radiologist's role in the future.

Where next?

In April 2007, the R-ITI was wound down and split into two projects. The e-LD is now available to all trainees and is supervised by an editorial board at the RCR; and the national e-learning development strategy will concentrate on developing e-learning for the NHS as a whole. The academies are temporarily being looked after by the National Imaging Board (NIB) at the Department of Health (England) with a view to being managed/funded via the Office of the Strategic Health Authorities in the

medium term. Given the recently published Tooke¹ enquiry into modernising medical careers, it is now less clear how training will be organised or funded in the future and will remain so until the report is formally accepted.

What has been missed in these various changes is formal evaluation of the quality of the R-ITI experience, to sit alongside the quantitative outcomes. Anecdotally, the academies' method of training seems to be producing better results in terms of earlier and controlled transition to independent working, and examination success. Of course, these are proxy measures from the first two and a half years; the real test of success is when the trainees become consultant radiologists, and the longer term effects 5 to 10 years later.

"Beacons of good training practice"

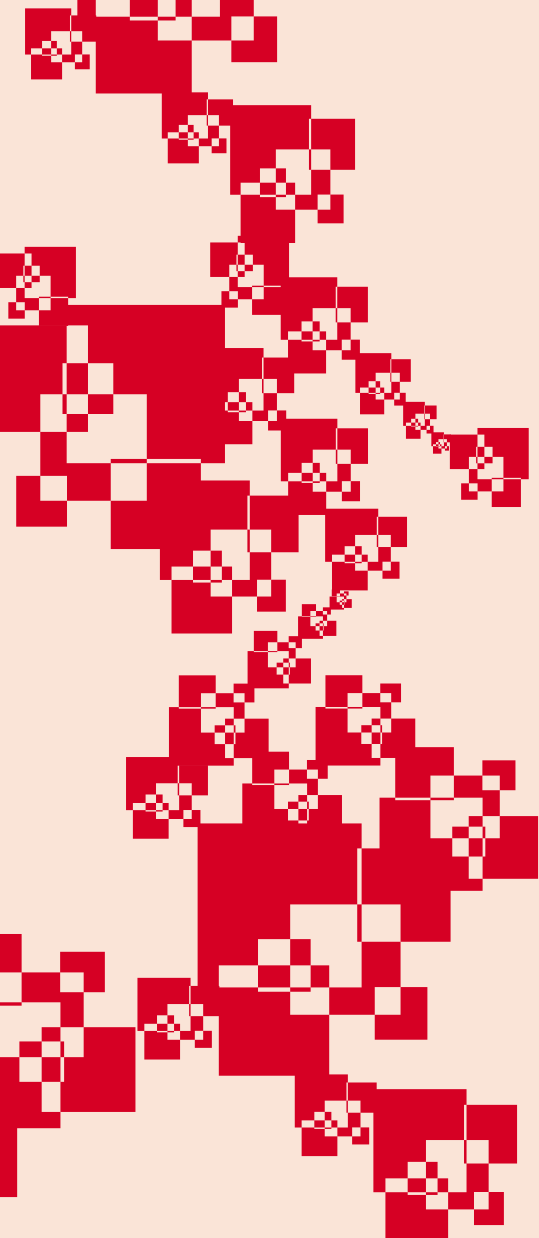


“It will take years to evaluate ‘the product’ ”

e-Learning for Health and the NIB are planning an early evaluation but the confounding factors are significant: relatively, there are only a few trainees in years two and three in the academies; and the publicity associated with R-ITI could have produced a selection or, more likely, an application bias in favour of academies. Historical information will also be difficult to interpret as the academies started recruiting just as the FRCR examination format changed and formative assessments were introduced.

At first glance, the costs associated with the R-ITI project, and setting up and running the academies, seem to be large but this could well be an unexpected side effect of the project. To date, there have been no attempts to calculate the costs to an organisation of running a radiology training scheme. Currently, in the traditional training schemes, these costs are all lost as ‘overheads’. However, when money truly follows patients, these will be subject to increasing and quite intense scrutiny - and Mr Micawber’s maxim for happiness surely will define the success or failure of an NHS trust.

The academies already see themselves as beacons of good training practice and in the vanguard of educational change. They have started to look externally to make fuller use of their facilities and expertise, and to generate income streams. They are working with their local universities to assist in the teaching of medical students, and professions allied to medicine and nurses at the undergraduate level. They hope that F1 and F2 junior doctors will be more likely to take an interest in radiology in the high-tech teaching environments that are the academies; and, whether the imaging professions like it or not, ultrasound is being used increasingly outside of the radiology department, with a real need for proper training and evaluation.



The academies have the expertise, facilities and numbers to test new and innovative methods of work place assessment at every level and profession in the imaging department. They seem ideal sites for evaluating methods of revalidation and re-certification; to put these centrally driven initiatives on an academic and evidence based footing, and to provide consultant radiologists with the help that they will indubitably need as revalidation/re-certification is introduced.

The academies already use the PACS/RIS interface with their host hospitals to provide what is essentially 'off site reporting'. Now that PACS is implemented through out the NHS in England, could this be extended to a network for all the hospitals within each of the three academies' training schemes to support them in their routine work? This might encourage existing sites to offer additional clinical placements and persuade new sites to join.

Summary

The radiology academies are still young but there is no doubt that they have fulfilled their first objective of delivering a rapid increase in the number of trainees in radiology at equivalent, if not better, quality. This is not just the result of the e-LD and VCA, which were in development in the initial year (two years) and are now rolled out to the rest of the country; it is about the whole environment and ethos of the training. Additionally, by funding training directly, the true costs of providing that training are now apparent for anyone who wants to look; as they surely will in the future when trying to disaggregate the costs of care from other costs, such as that for education and training.

Are the academies the future of radiology training? Who knows? Certainly, the trainers in the academies would not want to go back to 'the good old days'. But, it will take years to properly evaluate 'the product' of the academies, the consultant radiologists of the future and, in the meantime, vision and courage will be needed if there are to be more academies. Whether this will be forthcoming remains to be seen but I, for one, certainly hope so.

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Why be a radiology manager in the future?

Lyn McKay

Running a radiology department today is a bit like trying to herd cats; managers are faced with sudden changes in direction, find themselves forced to go round in ever decreasing circles, claws lash out when least expected, and there are constant miaows trying to attract attention - and this is just in a typical day.

At certain times, some things may rise to the top and become a bit more important than the others but, in reality, managing a radiology department requires constant attention to everything. This means trying to plan for the future, as well as undertaking day-to-day management; looking ahead, but always knowing what is going on in the present. Continuous manoeuvrability in both thought and action are, undoubtedly, the skills a radiology manager must possess.

Choosing to become a radiology manager – a personal reflection

When I was a junior radiographer in the early 1970s, the thought of becoming a radiology manager did not cross my mind – and, if it did, I thought anybody could manage a radiology department. After all, all that was required was to be professional in appearance (you remember, American tan tights, black shoes, hair neat and short, etc), keep lots of charts with coloured stickers, and to always answer “Yes, of course, I’ll see to it right away” to everything a radiologist asked.

How exciting was that? - definitely NOT for me!

As my career progressed, I found myself becoming a good radiographer but ‘with attitude’. I was probably a radiology manager’s nightmare because I questioned everything. It had dawned on me at a very early stage that, although I did not have the medical knowledge of the doctors, I did have pattern recognition skills and I knew whether or not an x-ray would be of use in their diagnoses. It did not take much longer to realise that the only way I would be able to change working practices and ways of thinking was to become a radiology manager, but a radiology manager ‘with attitude’ willing and able to change the service from within.

Why did the radiology service have to change?

The main drivers for change in the 1970s and 1980s, were the shortage of radiologists, an increasing workload and advances in technology¹. Radiographers were best placed to help with the shortage of radiologists and certain like-minded people in various parts of the United Kingdom (UK) agreed that radiographers could be trained to report x-ray examinations.

They were already equipped in the art of pattern recognition, so formal training to enable them to produce written reports seemed a sensible way forward.

One brave radiologist, Swinburne², wrote an article in 1971, which recognised the potential of radiographers to comment on x-ray images as a means of alleviating radiologists' workloads. Unfortunately, his proposals were not accepted at the time, but it did begin a debate about whether radiologists should report upon every x-ray examination, and whether radiographers could be trained to do things other than image acquisition.

In the 1980s, role boundaries between radiologists and radiographers began to change. In some departments, radiographers were using the red-dot system³ and sonographers were advancing their roles into reporting non-obstetric ultrasound, interestingly, without too much opposition from radiologists. Perhaps, they did not believe that ultrasound had the same spectrum of uses, or did not feel their role was threatened by reporting sonographers compared to reporting radiographers?

It was when the new technologies of computed tomography (CT) and magnetic resonance imaging (MRI) became accepted, main stream, imaging tools in the early 1990s that roles really began to alter and professional boundaries began to erode⁴. Radiologists wanted to get more involved with these two modalities so something had to give and, to begin with, it was plain film reporting. As a consequence, radiographer reporting courses were developed in a few regions of the country, the two most prominent being Leeds and Christ Church, Canterbury. Other role extension followed and, by 1998, radiographers were performing barium enemas and meals. Indeed, in some hospitals, radiographers were reporting their own barium studies⁵.

These were exciting times. Radiography education had reached graduate status, and this enabled a structured career progression to be established. In turn, this helped in the recruitment of students and the retention of radiographers in the workforce. Clinical radiology was becoming much more central to the delivery of healthcare and government bodies were recognising radiology as one of the diagnostic services that needed to be further developed to deliver waiting time targets⁶. Both radiologists and radiographers faced the challenges of changing their

usual working practices to enable the delivery of more complex imaging investigations.

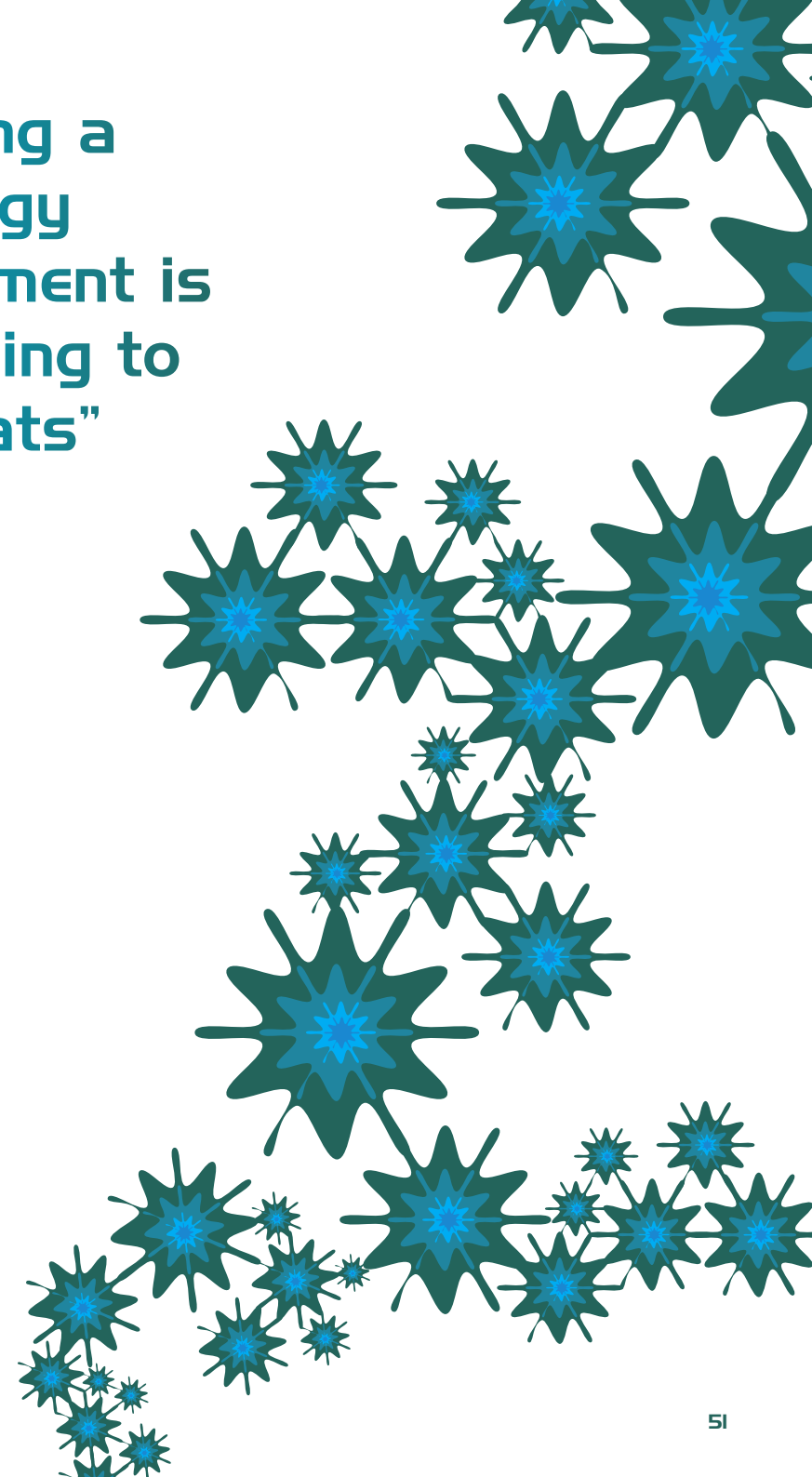
What role did the radiology manager play at this time?


One of the key roles of radiology managers in the early 1990s was to fight to establish recognition of the extended roles of radiographers, and to introduce and change working practices within radiology services. Often this fight was with the hospital executive team and, not infrequently, with the radiologists in the hospital - no easy feat.

But, most forward thinking executives and radiologists recognised the logic of training radiographers to undertake extended roles and the reality was that managers needed to make the most of the skills and expertise within their existing workforce. They needed to create opportunities to enhance skills development so that all staff were working to their full potential, and utilising their skills to meet service needs and to benefit patients. This still holds true today.

It was also important to get the message across

“Running a radiology department is like trying to herd cats”





“Managers have to have a sense of fun, otherwise they risk becoming bitter and twisted”

that skills mix and use of career pathways needed to embrace all staff. Although, to some, it appeared to be a ‘radiologist bashing’ time, radiology managers knew they were right to continue breaking down professional boundaries and barriers. Fortunately, there were radiologists who agreed, and a number of articles⁷ by radiologists at this time supported extending the roles of radiographers.


What role does a radiology manager play today?

Peter Drucker⁸ once said that being effective is “doing the right things” while being efficient is “doing things right”.

“Doing the right things” can be interpreted as the ability to identify critical issues and/or seize opportunities that can change and develop the radiology department for the better; developing and implementing strategies that energise and maximise the potential of the department and the trust. The “doing things right” part is then necessary for maintaining and sustaining that change and growth.

Of course, this can mean different things to different radiology managers depending on the size and set up of their departments but, overall, it means being ready for anything, and being prepared to stand up for what the service and patients really need. Quality of patient care depends not only on good clinical practice, but also on how services are organised and delivered and radiology managers should hold that as their mantra.

To deliver the radiology service expected today, radiology managers need to have a flexible workforce, with both radiologists and radiographers that can rise to the challenges of changes in technology and working practices without compromising patient care. The adoption of the career progression framework (the 4-tier structure) within radiography has enabled radiographers to advance their practice these past 10 years - but there is still have some way to go to make the whole career framework a reality generally⁹. Radiologists also need to be supported in their endeavours in the field of interventional imaging, and be encouraged to undertake training to understand just what can be achieved using the advanced technology and equipment available to them.



Creating team working should also be high on any radiology manager's agenda. Working together brings benefits for individual staff members, the radiology department team as a collective and, most importantly, patients. The professions that make up radiology should not work in isolation as, together, they can respond to the ever increasing external pressures and demands for radiology services. Interprofessional disputes will still occur and, probably, always will, but this is healthy. This is how the professions learn and grow.

It is encouraging to see that both professional colleges, The Royal College of Radiologists and The Society and College of Radiographers, have been, and are continuing, to work together in promoting skills mix and role development initiatives¹⁰ and, with their help, appropriate standards of practice can be developed based upon their national, accredited education frameworks. This will assist those staff who develop their skills in a local context to have those skills valued nationally and, hence, be transferable.

Working smarter, efficiently, and extending skills and competence of the whole workforce will enable delivery of the referral to treatment (18 weeks and similar) targets. It also recognises that this is the way services need to be delivered in the future as it makes best use of investment in people and resources, and provides value for money¹¹.

So, why be a radiology manager in the future?

The continuous development of the roles of the radiographer and radiologist, the advances in technology, the erosion of traditional working boundaries and practices, and the many changes within the National Health Service itself, requires a comprehensive and on-going development programme. In turn, this needs a multifaceted and talented radiology manager to lead it.

Radiology is now at in its most exciting and challenging phase since the discovery of x-rays. Radiologists and radiographers have a duty of care not just to sit back and accept the changes that have happened, but to move yet further forward and enhance their skills to an even greater extent for the benefit of patients. There is still much that can be done to enhance radiology services in the United Kingdom, and forward thinking radiology managers are needed to make this happen.



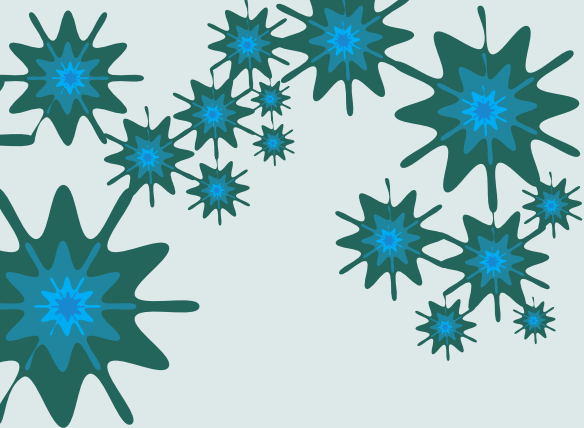
“Quality of patient care depends on how services are organised and delivered”

Although the ‘four-tier’ career structure has been adopted in many areas, the assistant practitioner element still has a long way to go before it is accepted fully by radiographers. Interestingly, the situation is not dissimilar to the opposition from radiologists that radiographers experienced a few years ago when they were extending their roles into the radiologists’ field. Obviously, not much has been learned from the past but it is this type of challenge a radiology manager ‘with attitude’ can help to sort!

The consultant radiographer level of the career framework has also been dispiriting; there are many fewer consultant radiographers than there should be by this time. It is true that there have been considerable changes in the recent past, but these are insufficient and need to be built on, so more managers ‘with attitude’ are needed to make things happen. Within education institutions, the elements are all in place to aid radiographers to attain the consultant level but it is radiology managers who have the power to make these posts a reality in their departments.

When all staff groups in radiology are pulling together towards the same goals and bringing about changes that are good for the patients (and it does happen at times), the feeling is great. Watching a radiographer develop into a field of work that, only a few years ago, was undreamed of is enormously satisfying. But, radiology management is not a career path for everybody; much ‘attitude’ is required and the list of required characteristics is long. Radiology managers have to:

- Know themselves and their capabilities;
- Like responsibility;
- Enjoy working with people to get the best out of them;
- Have to have a sense of fun, otherwise they risk becoming bitter and twisted;



- Enjoy a good argument, be prepared to stand firm and have a very broad back;
- Know when they are wrong and admit it, otherwise they will not retain respect;
- Be able to deal with uncertainty and make decisions when they never seem to have all the facts in time.

Managers probably will be paid a bit more but, without doubt, they will earn it.

If anyone is thinking of becoming a radiology manager, remember that nobody likes the boss and it's lonely at the top - but it is very rewarding, particularly when hard fought developments and improvements make a visible difference to staff and patients. Rarely are there pats on the back for 'doing a good job' but lots of brickbats are guaranteed when others think the manager has got it wrong.

The bottom line is that being a radiology manager is a tough job, but individuals with the attributes listed above would miss a great opportunity for enhancing the radiography profession and themselves if they did not choose radiology management as a career.

So, would I do this all again?

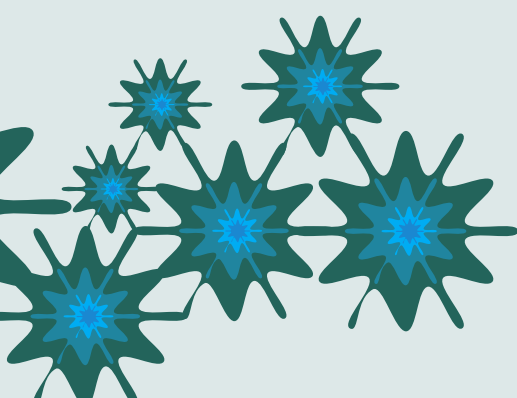
Undoubtedly!

I also believe the radiology managers of yesteryear did have a point about being professional in appearance. That should always be the case - although the American tan tights have most definitely disappeared. The "Yes of course, I'll see to it right away" reply has also gone - replaced with "No, you can't unless you can find the funds to train the staff and buy the equipment to do it".

I do confess, though, to having a penchant for charts with coloured stickers!

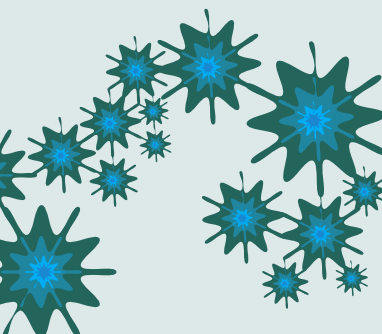
"Watching a radiographer develop into an undreamed field of work is enormously satisfying"

Lyn McKay is radiology general manager at Maidstone and Tunbridge Wells NHS Trust.



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Delivering 24/7 – The challenge for imaging services

Sue Johnson

The best way to provide effective, efficient health care services has always been a controversial topic in the United Kingdom (UK). Much has been written about the National Health Service (NHS) since its inception in 1948, and politicians, health care experts, patient pressure groups, economists and other interested parties have long debated about how health care can be improved. As a result, the NHS is in constant flux - new paradigms influence how services are organised; new technologies influence diagnosis and treatment, and new management theories influence the organisations providing health care.

Radiology services are not immune to these influences and the provision of imaging services in acute hospital trusts is as hot a topic now, as ever. There is great pressure for staff and equipment to be used efficiently and cost effectively. Lean management theories push radiology services to reduce waste and address the factors that delay the diagnosis or treatment of patients. In England, the 18-week referral to treatment target influences how waiting lists are managed and have put a real focus on utilising expensive equipment in a more effective manner. The maximum four hour wait in accident and emergency departments has, for many years, provided imaging services with the challenge to identify how to speed patients through the imaging phase of their journeys. There is real pressure for services to be provided in a timely manner with as little delay as possible.

Perhaps for the first time ever, there is now a co-ordinated approach and a target driven emphasis on imaging services. Added to this are recent changes in terms and conditions of employment for all NHS workers, changes in working time legislation, constraints on recruitment, and pressures to modernise the way health care is delivered. No longer is the nine-to-five day the norm for hospital activity, and imaging services are looking seriously at how and when they can increase capacity. This article proposes that now is the right time to leave the old on-call systems dating back to the early days of the NHS behind, and move to structured shift systems with all the benefits that they can bring to imaging services and staff.

No more on-call

The article will focus on the challenges faced in 24/7 service provision and the need for radiographers to provide radiographic services across the entire day and night. Few people reading this article will be unaware that, in the UK, the traditional way of providing out-of-hours radiography to cover emergency services and urgent cases has been through using an on-call or stand-by system, or a combination of the two.

The Whitley Council¹ defined terms of employment for radiographers in 1948 at the inception of the NHS, and pay awards and terms of employment were then negotiated and developed over the subsequent years. Radiographers (and others providing significant on-call and stand-by services) were able to earn substantial sums when the 'on-call' element was added to the basic pay. This year, 60 years on from the beginning of the NHS, a new pay system, Agenda for Change, brings

in a new scheme for on-call and unsocial hours working, removing the old 'Whitley' provisions from employment contracts. The aim is to harmonise across professions, and acute trusts will be scrutinising their budgets to identify cost pressures and savings from the new on-call and unsocial hours pay structures. The time is ripe, therefore, to find an alternative way to organise and pay for radiographic services outside of the normal nine-to-five day. On-call has had its day and radiographic services need to move to shift working to provide the service in a safe and controlled way.

Shift working and shift systems for radiographers are not new. A significant number of hospitals have had some elements of shift work for many years. However, there is no single system that fits all service needs and, indeed, the requirements of managers, staff and patients will differ depending on the healthcare facility in question and the views of those negotiating new arrangements.

Drivers for change

So, what do radiographers, managers, employers and patients want for 24-hour radiographic service provision? Probably, there is no single answer and devising shift work systems to provide safer services for patients, predictable costs for managers, enhanced work-life balance for radiographers, and increased capacity for expensive equipment must be considered on a case-by-case basis.

Now seems the right time to change how out-of-hours services are provided. The 'do today's work today' ethos of the modern NHS encourages imaging services to be provided as soon as possible across all types of examinations and for all patients. New diagnosis and treatment guidelines^{2,3} for stroke and cardiac patients require imaging services to be delivered within narrow timescales to ensure that patients receive the best, most effective treatments. Reducing waiting lists and trying to provide imaging services more quickly are key expectations in service improvements and those working in the high demand areas of computed tomography (CT) and ultrasound will be fully aware of the 'scan faster, scan more' pressures that they are under. Reducing waste and smoothing pathways is crucial to hitting healthcare delivery targets, but both staff and

equipment are being pushed to capacity every day as a means to gain efficiency savings.

Working hours

Working hours and service provision are intimately linked. A standard working week can leave much equipment standing idle in the evenings and at weekends. Staff numbers impact on the ability to deliver high quality, out-of-hours care. In terms of staff availability, the situation has vacillated between bust and boom over the last 20 years, with chronic shortages of radiographers the norm. More recently, in the past two years, some newly qualified radiographers, especially those tied to a particular location for family reasons, have struggled to find permanent jobs.

Technological and scientific advances such as picture archiving and communication systems (PACS) and safer contrast agents are enabling services to be provided in a different way. No longer does a contrast enhanced CT scan necessitate a radiologist to be in the scan room with the patient; safe systems of work can be developed that enable the radiographer to perform the scan and report it, or direct the images to a home-based radiologist for review and report. There is very little research on radiographers and their working hours. The Health and Safety

"Full shift systems require more staff. There is no easy answer and no single 'right' method"

Executive (HSE) has identified clearly that the risk of errors occurring increases with unsocial hours working. Tired staff are more likely to make mistakes. Fatigue also plays a significant part in the ability of an employee to perform at work and maintain a healthy lifestyle; in turn, this impacts on sickness absence and longevity. On-call provides the same sort of disruption as unsocial hours working to peoples' lives, with the added, detrimental factor that the hours worked are, generally, in addition to the standard working week hours.

As well as there being little research on radiographers and their working hours, there is also very little relative to on-call work patterns in other fields of work. But health problems associated with working shifts have been found to include peptic ulcers, cardiovascular disease, chronic fatigue, excessive sleepiness and difficulty in sleeping. Shift workers also tend to be more overweight due to poor eating habits and lack of exercise; they have a higher rate of divorce, worse rates of substance abuse and depression, and are more likely to view their jobs as stressful⁴. Such research has been used as an argument against shift working by many radiographers and



their managers. However, the lack of research for on-call does not mean that this system is better from a health point of view as the review⁵ of recent English language research published by Nicols and Botteril in 2004 showed; increased stress levels, poorer sleep quality, poorer mental health and reduced personal safety were experienced by those working on-call. This evidence would appear to be equally as damning as that from the research on shift work. Radiographers may well argue

"Radiography is physically and mentally demanding"

to retain on-call systems for the pay enhancement it provides. But radiography is physically and mentally demanding, and requires staff to be fresh and fit to provide the service. Shift working would appear to allow staff better access to rest, and an ability to take more control over their working hours.

Three perspectives *Radiographers*

Radiographers are not alone in wanting good financial

recompense for working unsocial hours and the opportunity to attain a good work-life balance. This is not being greedy; rather, it is being right. Those working, or who have worked, unsocial hours will have experienced the disruption to family life; to their own body rhythms, and on activities out side of the workplace either due to fatigue, or to a rota requirement to be at work.

Shift working can support career and role development as services move away from using the most junior staff to provide out-of-hours services. Imaging procedures and examinations out-of-hours are increasing and the need for advanced and specialist technical skills require greater numbers of staff to be developed to cover the spectrum of imaging modalities. Radiologists are also being urged to perform more, quicker and better, and sharing this burden with experienced and advanced practice radiographers is essential. Reporting, for example, should not be solely a nine-to-five activity, and using radiographers to improve the reporting service across broader working hours can have a positive impact, both on reporting turn-round times and on patient care.


Managers

Managers want systems that are safe for patients and staff, and meet the needs of referrers and the hospital trust; they want controllable budgets with little variation and which are straightforward to administer; and they want to provide satisfying work patterns, defensible cost-wise, to support staff recruitment and retention. They also want value for money.

On-call costs are rising with busier out of hours demand; the lack of defined costs can make managing the imaging services budget very difficult. The working time directive, whilst not the strongest piece of legislation to protect

workers, has placed limits on average working week hours, and direction on rest times between shifts. Many managers have found themselves falling foul of the law and having to adapt their out-of-hours work systems to enable their staff to work safely within the law. Sickness and absence management is another concern, and tired workers are likely to be absent more frequently due to sickness. Covering duties for absent members of staff can also be difficult if the pool of staff providing the cover is small. The system used to cover out of hours work is of importance to potential employees applying for posts, and plays a part in staff retention. If the system is seen as too onerous; paying too poorly, or is too inflexible radiographers will vote with their feet and go elsewhere.

It is also important to consider the nature of the work covered out of hours. CT is no longer the realm of the specialist radiographer only, particularly when considering emergency trauma and neurology scanning. Training and developing staff in modalities such as CT and magnetic resonance imaging (MRI) allows them to be used in a shift



system and enables the service to provide these modalities outside standard hours. The use of a shift system means a greater number of staff need be involved, posing a dual challenge; that of providing sufficient experience for staff to maintain competency and ensuring that sufficient staff have the necessary enhanced skills in CT to carry out the more complex scanning protocols. Of course, all imaging services managers want to provide a high quality service at all times, and ensuring that staff work only a 35 or 37.5 hour week is one way of addressing the problem of over-tired, un-rested staff. The safety of patients and staff is paramount and the effects on staff of long working hours must be considered.

Patients

Patients want a safe service. Probably, they rarely consider the working time of staff that treat them in emergency scenarios. However, when a patient is less unwell they do ask staff about when their shifts finish, and pass comments about 'looking tired'. Most patients are usually horrified to hear of the long hours in the responses. Tired staff can lead to standards slipping.

Patients also know their rights and, rightly, question the need to wait in hospital until Monday for a barium test if a negative result on a Friday would mean they could go home. Likewise, patients on waiting lists question why CT and MRI units sit unused over the weekend hours. Even with reducing waiting lists, is it appropriate to procure new equipment when there is a large amount of unused weekend capacity?

Can the circle be squared?

There is no doubt that working on-call in busy imaging departments is tiring; and there is still a sizeable number of departments that have not grasped the concepts of employee-friendly working, or implemented the working time directive in full. On-call working is not a healthier way of working than shifts. Indeed, a sizeable body of research shows that any disruptions (on-call or night shift work patterns, for example) to circadian rhythms may have negative impacts on health. So, how can the circle (the need to provide 24/7 services) be squared (the need to provide safe, healthy work systems for staff)?

There is no easy answer and no single 'right' method; much will depend on the circumstances of a particular service; its catchment population, its proximity to major road networks, its geographical location, and the nature of the service it provides overall. In some departments, hybrid shift and on-call systems may be appropriate, with on-call used to cover a period of the night or

parts of the weekend when work load is likely to be low. At other times, or in other departments, when patient flows are relentless, it may be better to provide the service by shifts of staff.

As noted earlier, many service providers are pushing to maximise the use of expensive imaging equipment and reduce waiting lists by extending the working day and/or utilising weekends. The argument for this is difficult to refute but ensuring that these 'extra hours' are covered and resourced appropriately requires care if the provision of the service in 'normal' hours is to be maintained effectively. Many employers may be looking to provide these 'extended hours' from within current resources but, unless departments are overstaffed, this is highly unlikely. Inevitably, full shift systems require more staff, and more of all staff groups providing the service, so budgets are likely to remain under pressure.

One of the arguments for retaining an on-call system is to enable staff to boost their incomes, particularly in high cost areas. This is not an appropriate argument and should not feature

when designing systems to minimise waiting times for patients, to provide work patterns that are safe for both staff and patients, and to make best use of capital resources. Of course, in moving from a traditional on-call based system, staff earnings need to be taken into account, but not as the sole consideration.

Conclusion

Imaging services can be provided 24/7 without expecting radiographers to work more (or significantly more) than a 35 or 37.5 hour working week but this is only achievable by moving to a system of shift working. Very careful rostering is essential, as is giving staff some control and flexibility over their rostered shifts. Some back-up on-call duties may be necessary but with the expectation that staff on-call would be called in infrequently and for quite short periods of time. Staff are able to add to their base pay as some overtime and additional shifts are likely to be available in times of annual, maternity and other leave, and absences due to sickness.

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