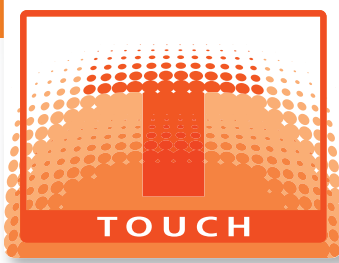


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PRODUCTION Editor

Melanie Armstrong
Publisher Dominic Deeson
Designer Doug MacKay

Display advertising
Melanie Richards

Published by
Deeson Group
deeson.co.uk

Printed by
Thames Print



The Society & College of Radiographers

Deeson.

Imaging & Oncology is a publication of The Society and College of Radiographer, 207 Providence Square, Mill Street, London SE1 2EW
Tel 020 7740 7200 Fax 020 7740 7204
E-mail hazeledwards@sor.org
ISBN 9871 871101 58 1

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Editorial

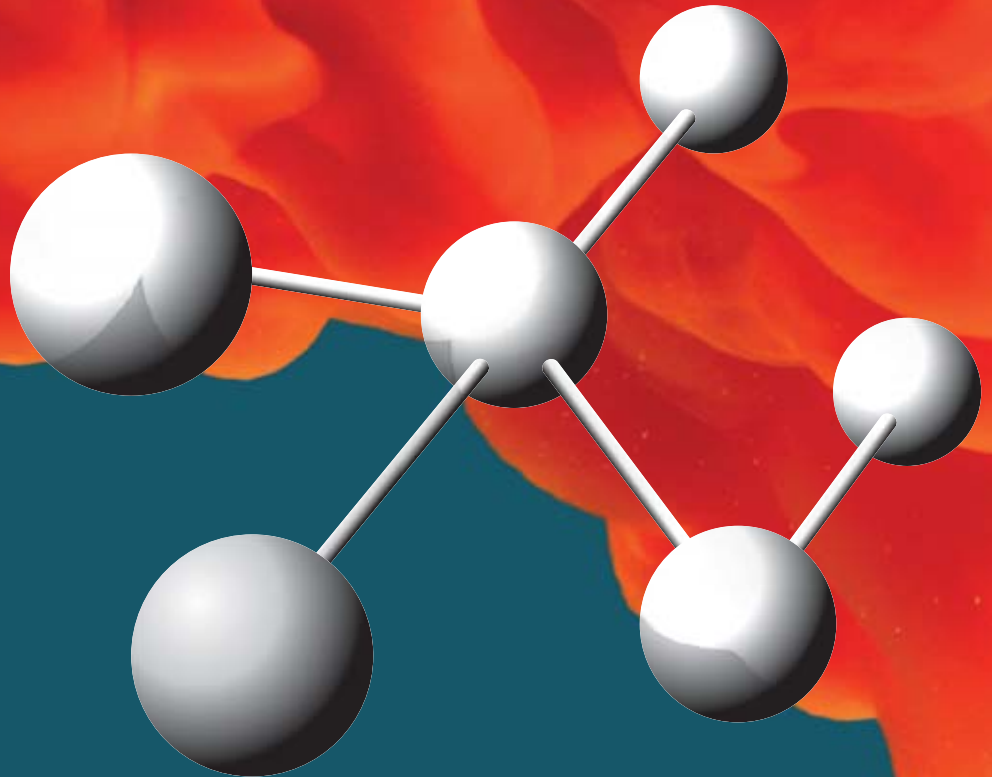
Articles authored by professionals including radiographers, radiologists, nurses and obstetricians are featured in this year's *Imaging & Oncology*. It's a pleasure to have the opportunity to deliver such a diverse selection of topics affecting our professions, all within one publication. Once again, this edition offers sometimes controversial opinions from experts and showcases many great examples of ways to improve patient care.

Helen Best from Public Health England discusses the transparent and open culture of incident reporting within our radiotherapy departments, and how this practice maintains and improves patient safety. Sarah James and Alison Stemp reveal duplication and waste when it comes to patient information resources in radiotherapy and call for an end to what I think can only be described as frequent wheel reinvention.

In UK antenatal imaging services, just when we've all settled nicely into offering first trimester screening for Down's syndrome, along comes another test, which is more sensitive and will likely result in big changes to services again very soon. Kemp and Smith provide a must-read article on the subject. At the other end of the human lifespan, David Fitzgerald talks of imaging for dementia. I acknowledge that some types affect younger adults but it is more commonly associated with older people, and David puts forward a powerful argument for increased funding in this area. Similarly, Knapp et al explain how vertebral fracture assessment enhances DXA services, which are increasingly in demand, due to osteoporosis in the older population and increased fracture risk in the obese. Incidentally, one of the authors of this paper, Robert Meertens, has just won the 2015 ASRT Leadership Academy for Educators Award. Warmest congratulations to him.

The overseas contribution this year is from Cindy Petree, a radiologist assistant from Indiana, USA. Although the role is unique to North America it reminds me very much of that of consultant radiographers in the UK as she explains the diversity, rewards and difficulties associated with it.

Giles Maskell puts forward a bold but balanced argument regarding the current trend of the 'worried well' buying themselves CT scans. Also in this issue, Wotton and Freeman discuss how new multiparametric techniques in ultrasound may offer the chance of conservative management, rather than traditional radical orchidectomy, for some men with testicular lesions. I'm sure that cohort would be very grateful indeed.



As the NHS consults on proposals to allow radiographers to prescribe medicines independently, Hogg et al remind us of the potential benefits were legislation passed. Further papers by Grainger, and Woznitza and Keane, highlight recent new guidance in MRI safety and the ongoing and excellent image interpretation e-Learning for Healthcare resource.

Were I to sum up this issue in seven words it would be; new techniques, new roles, education and safety. Grateful thanks to all the contributors for giving up their time to share their work and ideas, and many thanks also to the newly appointed Advisory Board for *Imaging & Oncology*, which I've assembled to assist me in the review process.

Hazel Edwards

Hazel Edwards, Editor, hazeledwards@sor.org



President's Foreword

It is a pleasure to be able to write the foreword for this important annual publication and in particular to welcome readers to this edition of *Imaging & Oncology*, a compendium of contributions celebrating 11 years of reflecting on practice and looking forward to how the challenges of delivering healthcare in the modern world can be achieved; improving quality and safety of care, and being mindful of patient experience, while achieving huge cost savings as surely we must.

The people delivering imaging and radiotherapy services to patients generate a huge amount of learning through their practice, and this is so much more valuable when it is shared widely through publications such as this one, and where the result has a positive impact on clinical practice.

The way in which we link our theoretical knowledge to our practice is at the very heart of transforming and improving care for patients, whatever our role in that journey. One of the many great reasons why people are encouraged to see their ideas and work published, the concept of sharing best practice, is to be commended indeed. Many of the papers featured here will provoke debate and inspire others.

Care and compassion are central to today's care agenda and this is reflected again in several articles. Two years after the NHS health reforms there is still a huge gap between the present level of care and the best possible care for patients; clearly there is still a lot to do, but at the same time it is so important to recognise the really good work that is going on across the different disciplines everywhere. We are all part of the same community and that community is focused on making a difference for patients.

Certainly the authors who have contributed to *Imaging & Oncology 2015* have provided interesting and innovative pieces, which demonstrate the acquisition of considerable pragmatic knowledge and experience about what works well and what could be done better. Some also offer warnings for the future if certain aspects of services are allowed to continue as they are. If this work had remained unpublished and the experience and ideas unshared, just think what a missed opportunity that would have been.

I recommend this most excellent edition with enthusiasm, to those with an interest in pushing forward all our professions, as we continue to work together to develop and share new knowledge and experience.

Karen Smith
President

The Society and College of Radiographers

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Public Health England patient safety initiatives in radiotherapy across the UK

Helen Best

Although error within radiotherapy is rare, when it does occur the consequence can be significant. With this in mind it is essential for the radiotherapy community to remain aware of the associated risks, avoid complacency and work within a 'safety culture' which underpins practice.

Patient safety has been defined as avoiding harm from the care that is intended to help¹. To maintain or improve patient safety, error has to be prevented, or minimised. When the opportunity for error is weighed against the incidence of error, radiotherapy may be seen as a safe form of treatment for cancer².

National patient safety initiatives

The UK has established an international reputation for its safety initiatives in radiotherapy. One of these initiatives is the voluntary reporting of and learning from radiotherapy errors and near misses. A total of 100% of current UK NHS radiotherapy providers have now shared radiotherapy error reports for inclusion in this initiative. In this post-Francis report³ era the focus on learning from errors is likely to continue, as clinical departments are encouraged and even mandated, to participate in initiatives such as this.

After a number of high profile errors⁴, the Chief Medical Officer (CMO) for England launched and funded a range of initiatives relating to patient safety in radiotherapy in 2006. This included the introduction of a dedicated resource within the Health Protection Agency (now Public Health England [PHE]) to support the radiotherapy community in improving patient safety. Radiotherapy staff at PHE provide independent advice on patient safety and process efficiency in clinical practice across the radiotherapy community. This includes advice to healthcare professionals, members of the public and inspectorates.

A further initiative by the CMO resulted in a joint publication by the professional bodies in 2008, entitled *Towards Safer Radiotherapy*⁵ (TSRT), which set out key recommendations to improve patient safety in radiotherapy. These recommendations to improve patient safety in reporting, analysing and learning from radiation incidents and near misses, were established so that all radiotherapy centres should participate

in this, enabling national learning. The Patient Safety in Radiotherapy Steering Group (PSRT) was tasked with taking this forward. This multidisciplinary group's membership includes representatives from PHE, Society and College of Radiographers (SCoR), Royal College of Radiologists (RCR), Institute of Physics and Engineering in Medicine (IPEM), and a patient representative.

PHE also provides independent advice on patient safety in clinical practice. Interaction with clinical departments depends on the needs of the individual department. This can range from an email or telephone call to a clinical site visit. These visits are at the department's invitation and intended to provide independent on-site support and reassurance on issues surrounding patient safety and process efficiency, within the context of the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R). IR(ME)R is legislation intended to protect the patient from hazards associated with ionising radiation.

Reporting and learning from errors and near misses

The radiotherapy reporting and learning system is a feedback process. Radiotherapy departments across the UK report errors and near misses locally. Classification and pathway coding from TSRT is also assigned by local departments. The classification enables the error to be graded into one of five severity classifications. The departments also code the error, indicating the point in the patient's pathway where the event occurred. Reports from NHS departments are submitted from England and Wales to the National Reporting and Learning System (NRLS) of NHS England, and directly to PHE from Northern Ireland and Scotland. Departments are encouraged to report all classifications of incidents on a monthly basis to allow timely feedback. This voluntary system is not a substitute for legal requirements to report to the appropriate authorities all patient exposures deemed much greater than intended.

The data are then interrogated to produce trend analyses for national learning. These can be in the form of publications, presentations and clinical site visits. The analysis is reviewed by the PSRT whose comments are incorporated into learning publications. The analysis and data are then used by clinical departments and others to learn and feed into the prevention of recurrence.

Dissemination of learning

Dissemination of learning is done in a number of ways. These include a series of publications, including the

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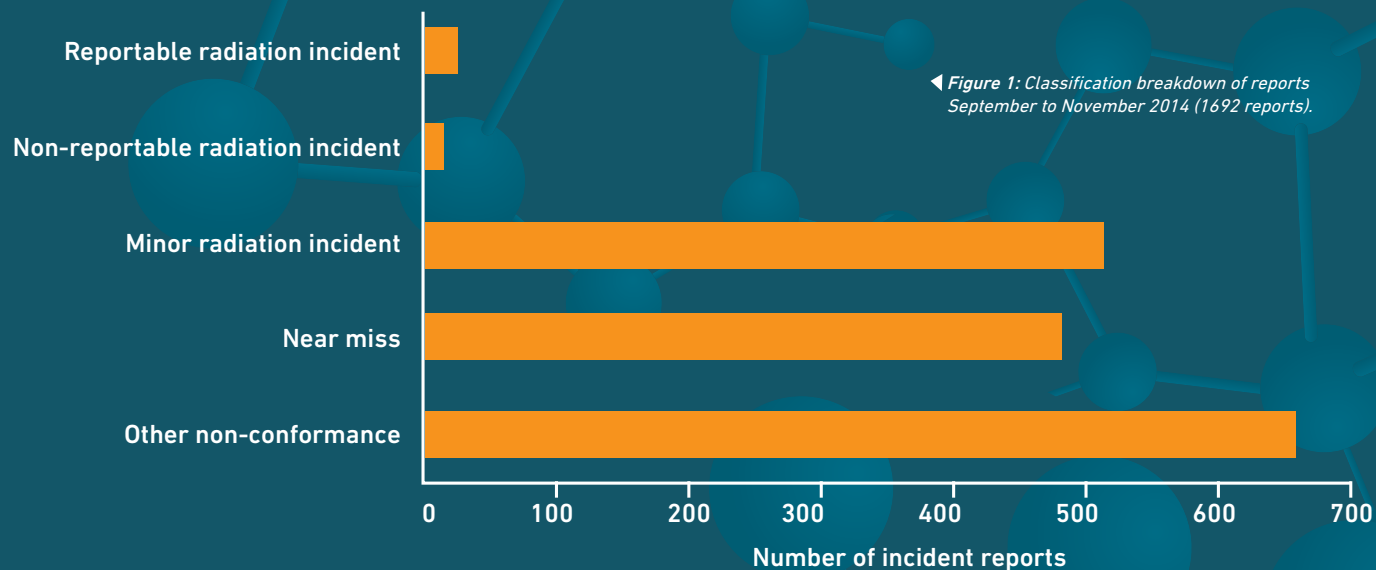
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◀ Figure 1: Classification breakdown of reports September to November 2014 (1692 reports).



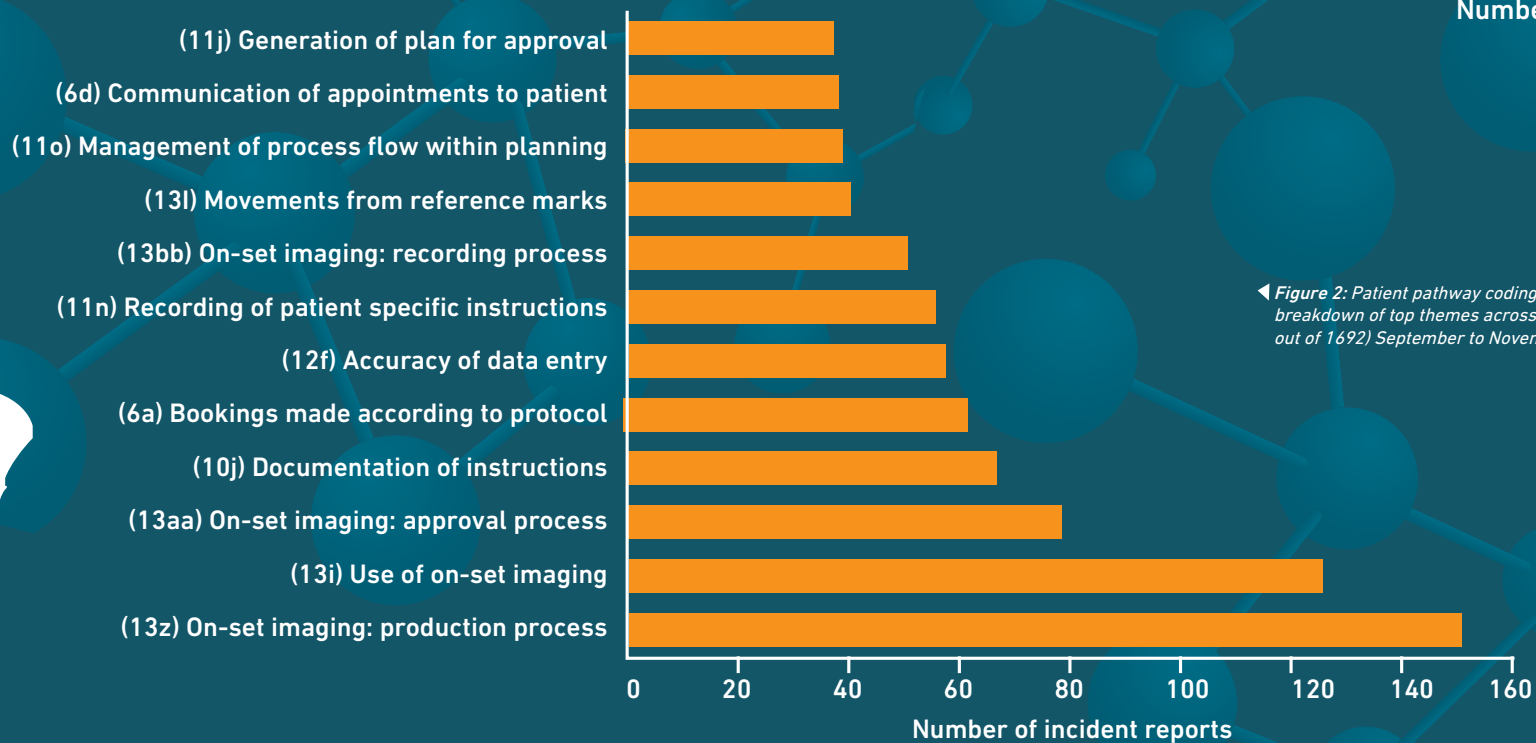
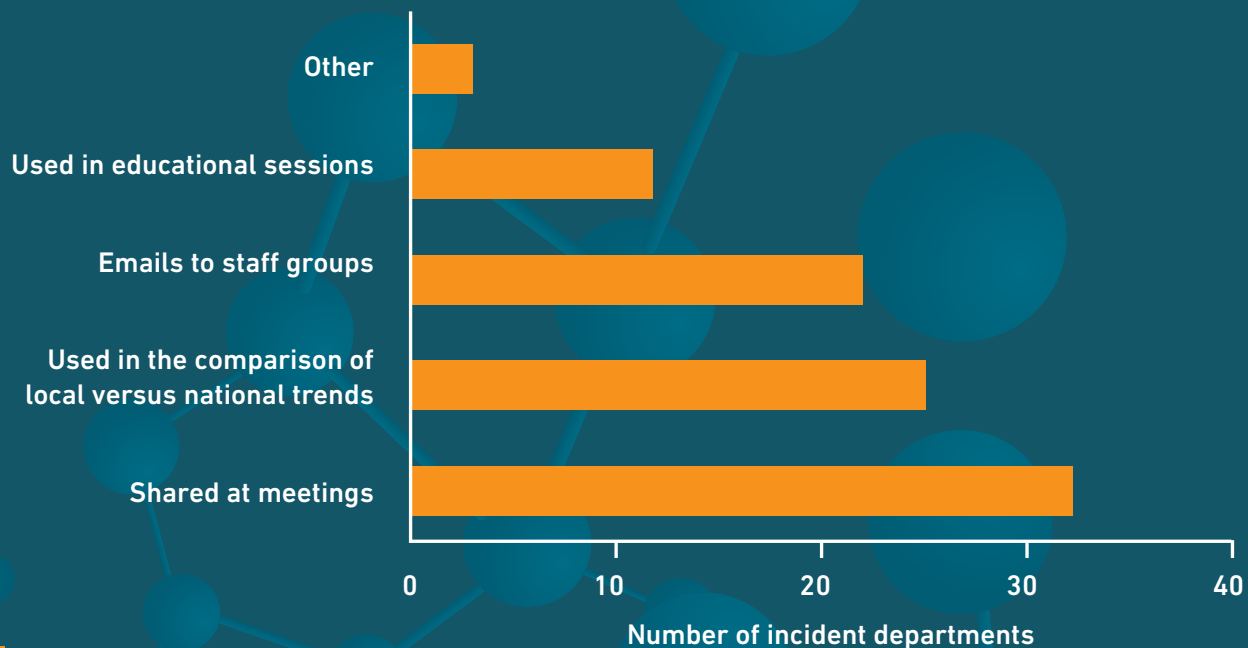
The UK has established an international reputation for its safety initiatives in radiotherapy

newsletter *Safer Radiotherapy* and supplementary data analysis⁶ which were established in 2010. *Safer Radiotherapy* facilitates the comparison of local and national incidents and the dissemination of learning across the UK radiotherapy community. It includes an update on the work of the PSRT and contains advice on preventing recurring errors in the patient pathway. Guest editorials from across the radiotherapy community highlight contemporary issues surrounding patient safety, but most importantly, the newsletter includes radiotherapy error data analysis. This highlights key messages and trends identified from radiotherapy error reports. Examples of this analysis can be seen in figures 1 and 2. Figure 1 demonstrates the breakdown of reports by classification and figure 2 demonstrates the breakdown of reports by patient pathway coding, showing the main themes across the patient pathway. To date, 15 newsletters have been published. Alongside these regular publications, the third in a series of two year reports was published in 2014². This biennial report provided an overview of radiotherapy error data reported as part of the national voluntary reporting scheme from December 2011 until November 2013.

Clinical site visits provide further opportunities for dissemination of learning. These visits have developed in partnership with the clinical community and are informed through working with key stakeholders. Clinical site visits provide independent on-site support and reassurance on issues surrounding patient safety and process efficiency within the context of IR(ME)R. To date, 50 out of 77 departments across the UK have been visited, which affords an opportunity for shared learning. Previous feedback on the site visits from key stakeholders reported that clinical sites valued and benefited from an independent review of all aspects of the patient pathway, without the perceived threat of inspection. These visits allow the sharing of learning from the analysis of radiotherapy errors at a local level. The site visits consist of meetings and informal discussions with staff, providing opportunities to share best practice across departments.

Learning from this work is also shared through national and international presentations, and PHE staff share learning when contributing to national meetings and national guidance.

► *Figure 3: How the national analysis is used as a learning tool (n = 39).*



◀ *Figure 2: Patient pathway coding (TSRT code in brackets) breakdown of top themes across patient pathway, (796 out of 1692) September to November 2014.*

Reporting and learning survey

To learn more about error reporting and how lessons are learnt from local and national analysis, a survey was disseminated in 2014, to all radiotherapy service providers across the UK. The aim of this survey was to build on knowledge gained from previous surveys published in 2008 and 2011, and establish an understanding of trends in reporting and learning cultures. The full analysis of this survey is freely available online⁷.

This survey investigated reporting and learning at a local and national level. Amongst the survey questions, departments were asked how the national analysis of radiotherapy errors was used as a learning tool. The most common response was to share the analysis at meetings (82.1% n = 32), followed by the comparisons of local versus national trends (64.1% n = 25). The most frequent methods are shown in figure 3. Only 12.8% (n = 5) of respondents stated that just one method was used. A common theme was the sharing of the newsletter with staff either as a hard copy or via the department computer network.

Of the 92.7% (n = 38) respondents that stated that the newsletter was used as a learning tool, only 23.7% (n = 9) shared this tool with all staff members. It was shared with a cross-section of staff, including radiographers (65.8% n = 25), physicists (47.7% n = 18) and doctors (18.4% n = 7). Only 15.8% (n = 6) of departments shared this newsletter with radiographers only. The newsletter is shared with all heads of service and designed to disseminate learning from radiotherapy error reports to professionals across the radiotherapy community. The UK radiotherapy communities' continued commitment to improving patient safety, is reflected in the reporting of radiotherapy errors. Ideas and suggestions for improvements to this publication are always gratefully received and should be sent to radiotherapy@phe.gov.uk.

Future work

Many will be aware that the revised basic safety standards directive was published as Council Directive 2013/59/Euratom⁸ in the *Official Journal of the European Union* last year. New regulations will be required by February 2018 to transpose the new directive. This will provide departments with a new instrument for maintaining patient safety in radiotherapy.

It is imperative that radiotherapy error trends continue to be reported, analysed and monitored on a cyclical basis, in order to inform ongoing safe and effective radiotherapy practice. This is especially pertinent as new techniques and technologies are implemented, and as new clinical radiotherapy departments are established. This work supports a risk-based approach to improving safety, both locally and nationally and indicates a culture that is open, transparent and already present in the UK radiotherapy community. Work continues on the development of the national reporting and learning from radiotherapy errors, including the development of a causative factor taxonomy and a review of the patient pathway coding.

Conclusion


All current UK radiotherapy NHS departments have participated in the radiotherapy voluntary reporting and learning system. This is entirely consistent with the Department of Health's drive for a more open and honest patient safety culture across the NHS, and enacts recommendations from the Francis report on openness, transparency and candour. The continued collaboration between these departments and PHE will serve to



not only maintain patient safety, but aims to improve patient safety within this rapidly evolving and vital service.

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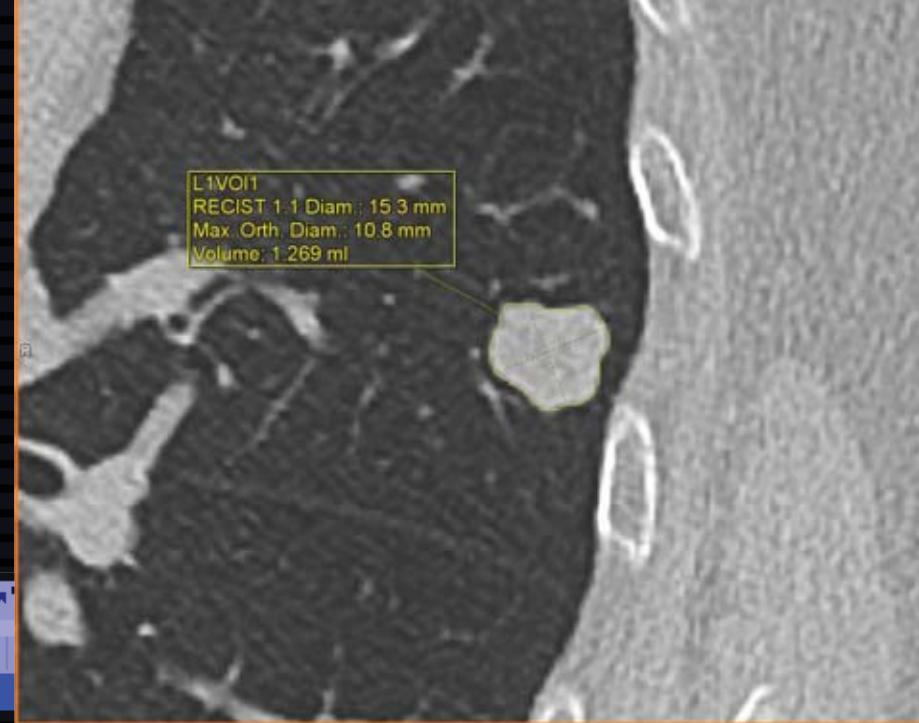
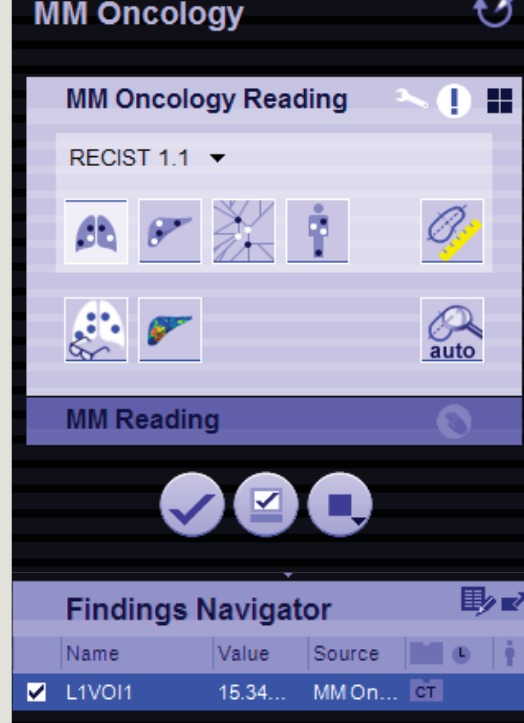


It is imperative that radiotherapy error trends continue to be reported, analysed and monitored on a cyclical basis

ABOUT THE AUTHOR

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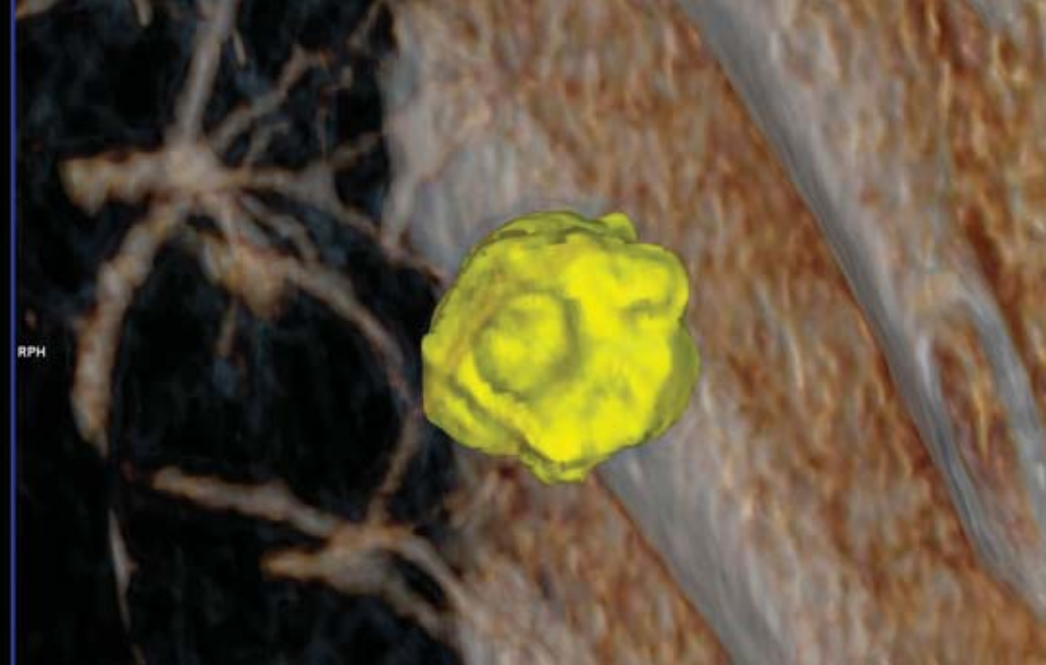
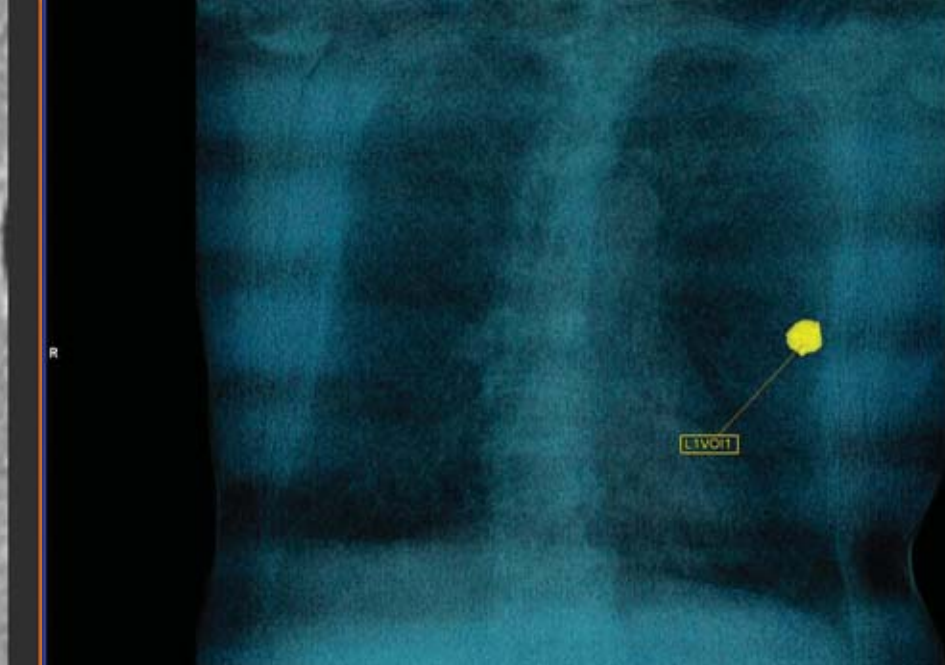


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Radiotherapy patients information: Is a new approach needed?

Sarah James, Alison Stemp

Is the duplication of materials causing cancer patients to experience information overload whilst maintaining a system of waste?

Patients need to be accurately informed to help them understand their cancer diagnosis and its management, to empower them to participate in shared decision-making and provide informed consent for their treatments and care. Up-to-date, understandable, accessible and timely information is critical in helping patients with cancer prepare for their forthcoming treatments; manage both their physical and emotional side-effects; and equip them for their ongoing journey into survivorship¹. Government policy² and national guidance³ are focused on giving patients control of their health, as part of providing patient-centred care, with the overall aim of providing them with a positive experience⁴.

In recent years there have been a variety of initiatives aimed at driving quality improvements in information services. These include

- The implementation of the Information Standard (IS)⁵ to improve the quality of information production processes and resources;
- The implementation of the Information Prescription Service (IPS)⁶ to drive improvements in information delivery by enhancing accessibility to both relevant and timely resources. The aim of this system is to offer a single website portal, for approved information producers to upload their resources in a systematic and accessible way for users, including patients, carers and healthcare professionals.

In addition, more recently there has been a proposal to mandate the implementation of an Accessible Information Standard⁷. This was out for consultation during the latter part of 2014. It is a standard that aims to drive improvements in accessibility for all users in both health and social services, to ensure all patients, clients and carers are given information in the most appropriate format to meet their personal needs. These needs may arise from learning difficulties and/or physical disabilities or sensory

impairment. This standard would apply to all communications with patients, including, for example, notification of appointments.

The development of the Accessible Information Standard has been creating concern amongst the 'information community' as, at the time of writing, it seems likely to overlap significantly with the remit of the already established IS⁸ and appears to be yet another source of duplication and burden to already pressurised health information providers. Current plans are for implementation sometime during 2015, with a year's grace for services to reach compliance.

Where are we now?

Although both the Cancer Patient Experience Survey⁹ and the National Radiotherapy Patient Experience Survey^{10,11} highlighted many positive findings regarding provision of information, there were inconsistencies identified in the provision across the whole of the cancer patients' journey and some aspects of the radiotherapy element in particular. Arguably, the current level of information provision already requires a significant commitment of manpower resources. Many individual cancer centres produce their own dedicated information through a supporting team of expert professionals. This is intensive and may duplicate existing national material. Other cancer centres without such a team, seem



Inconsistencies and unnecessary duplication are inevitable



“

Even where these resources exist, they often do not comply with NHS guidelines

to manage perfectly well by utilising the nationally produced resources, or do they?

Whether centres develop their own information resources or whether they use information produced by one of the many national cancer charities, inconsistencies and unnecessary duplication are inevitable, and this is a problem we face frequently. This issue was also reported by Macmillan Cancer Support (MCS) in their recent report, *Let's talk about it: improving information and support for people affected by cancer*¹². It highlighted gaps in information provision for topics such as chemo-radiation.

Some members of the medical and healthcare professions comment frequently on the matter of multiple producers and the resultant duplication and waste that seemingly arises^{13,14}. McCartney discusses this issue and suggests the current system is "a waste of money" and says it is "stupid" to have so many differing organisations producing information on the same topics. Frustratingly, this in itself most probably contributes to inconsistencies in the quality of the resources that we provide to our patients, and is therefore potentially confusing.

An uncertain future?

Furthermore, as a consequence of NHS reforms introduced by the coalition Government of 2010, which included the demise of the National Radiotherapy Implementation Group (NRIG), there has been much uncertainty regarding the future of both the IPS and IS¹⁵. These changes have reinforced a lack of assurance with regard to the sustainability of IPS and this, along with the IS not being universally implemented, has created concern about aspects of the future of cancer information services from the national perspective. Perhaps this uncertainty helps to fuel cancer centres' motivation for producing their own information resources, but the consequence is to maintain the unwelcome scenario McCartney describes. The impact of the newly elected Government has yet to be felt.

A recent unpublished audit has also demonstrated a wide range of radiotherapy information resources on the same or similar topics. These results show that, out of 37 cancer information centres surveyed across England and Wales, 12 respondents confirmed they produced locally, a significant number of radiotherapy booklets for patients with cancer. Interestingly, this may highlight an apparent disparity in the confidence that healthcare professionals, based at cancer centres, have about national resources produced by MCS, as the survey showed that centres produce fewer resources about chemotherapy compared to radiotherapy. They are confident to use the MCS chemotherapy regime information sheets, but seem reluctant to use radiotherapy information contained within the tumour site-specific booklets. The reasons given for this were that these booklets were too general and not of the required detail to meet their patients' radiotherapy information needs. Consequently, many individual cancer centres continue to produce their own tumour site-specific radiotherapy information booklets for patients. The audit results also highlighted issues around the large size of many MCS booklets and their potential to overwhelm patients.

As leaders of their respective professions, several of the professional bodies have produced guidelines and some patient information resources. Examples can be found from Society and College of Radiographers¹⁶, British Association of Dermatologists¹⁷ and Chartered Society of Physiotherapy¹⁸.


However, it is noticeable that although the Royal College of Radiologists offers a number of patient information leaflets about diagnostic investigations, there are no corresponding ones about radiotherapy. It also has to be noted that even where these resources do exist, they often do not comply with NHS guidelines and IS.

Considering radiotherapy is a rapidly changing, highly technical and sophisticated treatment modality, it is probably unsurprising that national producers have struggled to provide radiotherapy patient information resources that meet the needs of many radiotherapy centres in England and Wales. In the case of the key national cancer charities, their editorial teams comprise nurses and oncologists, so another influencing factor may be that therapeutic radiographers are rarely, if ever, represented on them. It is therefore, reasonable to assume that these teams will inherently have greater insight and understanding of chemotherapy compared to radiotherapy, and thus be more able to produce acceptable chemotherapy information sheets. Surely this needs to change in the future? One way to achieve this could be by encouraging a greater number of the local centre radiotherapy experts, ie both therapeutic radiographers and oncologists, to be involved more actively in the production of nationally produced radiotherapy resources. This could help to ensure they meet the needs of the patients and staff at these cancer centres, reducing the need for so many to be produced locally. In the last three years, the Society and College of Radiographers has been actively engaged with the key national cancer charities with this objective in mind, but it would seem this is still insufficient to ensure the radiotherapy component of nationally produced patient information resources meets the needs of patients, when attending cancer centres for radiotherapy.

The recent Patient Information Forum (PiF) report¹ acknowledges the specialist skills required by information producers and the need for adherence to quality standards such as the IS. More recently, MCS¹² raised concerns regarding inconsistencies in the quality of patient information resources. The plethora of providers, and the fact that the IS is not mandatory, nor has it been widely implemented, means it is probably not achieving its full potential to assist with addressing this issue. MCS¹² recommends that NHS England communicates more widely, the benefits of adopting the IS, to encourage its use and educate patients as to the benefits of looking for IS endorsement on any information they seek for themselves. Currently, for those using the internet for their own research there may be difficulties in establishing which information is from a trustworthy source.

Where do we go from here?

The current wasteful and confusing situation cannot continue. The recent political drive to empower patients and improve health outcomes is likely to continue and may well place a greater reliance on patients being able to self-manage, particularly beyond their acute phase of treatment¹⁹. For this strategy to be safe for patients and acceptable to clinicians, it has to be underpinned by the provision of consistent, high quality support and information for patients. Having therapeutic radiographers appropriately represented on all relevant national groups and actively contributing to the editorial process, will help to ensure that nationally produced patient information resources reflect current radiotherapy practice.



“ Many individual cancer centres produce their own dedicated information through a supporting team of expert professionals



Therapeutic radiographers are rarely, if ever, represented on these editorial teams

Conclusions and recommendations

Continuing with the current approach of mass duplication of information resources on the same topics by many providers is unacceptable and unsustainable, and is unlikely to support a successful self-management approach¹⁹, especially given the current financial climate and restraints faced by healthcare commissioners and service providers²⁰. We know that the existing duplication is already causing inconsistencies, potentially reducing patient confidence and jeopardising patients' ability to effectively self-manage, therefore we endorse the recommendation made recently by MCS¹² to have a nationally driven strategic approach to information provision.

There needs to be an open and honest debate between all relevant stakeholders, to identify a way forward. We all have a duty of care to our patients to provide up to date, accurate, good quality, accessible and timely information resources, as part of providing good quality health services to ensure they have a positive experience. Equally, we have a responsibility to ensure both public and charitable funds are utilised appropriately and prudently.

Acknowledgements

To Charlotte Beardmore, Director of Professional Policy and the Patient and Public Liaison Group (PPLG) at the Society and College of Radiographers for their comments and support in writing this article.

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The impact of free fetal DNA on ultrasound departments and the NHS

Michelle Kemp, Richard Smith

Screening for Down's syndrome has been continually evolving since it first started in the 1960s. The latest development using free fetal DNA (ffDNA) is set to revolutionise the United Kingdom screening system when it finally becomes integrated into the National Health Service (NHS). However, ffDNA technology is not cheap and has its own challenges, which will need to be tackled before implementing new screening tests into a system which is well established.

Currently in the UK, the gold standard for Down's syndrome screening is the combined test. This is performed between 11+2 and 14+1 weeks of gestation and includes the nuchal thickness measurement, maternal age and serum blood tests for beta human chorionic gonadotropin (β hCG) and pregnancy associated plasma protein A (PAPP-A). Introduction of the combined test has put ultrasound departments under increasing pressure to perform scans which take longer than a simple dating scan, and have to be performed within a narrower window. However, it can give a detection rate of 90% with a false positive rate of 3%¹ (refer to table 1 for definitions). It is not a diagnostic test and gives a risk of an individual fetus having trisomy 21. If a pregnancy has a risk higher than 1 in 150 a diagnostic test is offered. This is either an amniocentesis or chorionic villus sampling (CVS). Both of these are invasive and have a miscarriage rate of 0.5-2%.

If a patient books later in pregnancy, or a nuchal thickness measurement cannot be performed, she can undergo quadruple screening, so called because it measures four proteins in the maternal serum. These are hCG, alpha fetoprotein, unconjugated oestriol and inhibin A. This gives a detection rate of 75% with a 5% false positive rate².

In a multiple pregnancy, nuchal thickness can be measured for each fetus, but serum blood tests cannot be divided between the pregnancies. For monochorionic twins, a single risk is given because both twins are genetically identical. For dichorionic twins, two risks are given because the twins are likely to be genetically

different. Invasive diagnostic testing is therefore offered for each fetus, if either has a risk of Down's higher than 1 in 150 using combined screening.

Currently 85% of women in the UK are offered first trimester screening and 15% book later and are therefore offered second trimester screening³. Uptake by those eligible for the screening is about 69%³. About 80-90% of women with a high risk result opt for CVS or amniocentesis, and of those who have a positive result, 92% choose to end the pregnancy³.

ffDNA technology

It has been known for over 50 years that fetal cells can be found in maternal blood, but learning how to exploit that knowledge and isolate fetal DNA from maternal serum to aid diagnosis, is a much more recent discovery.

ffDNA can be detected from seven weeks' gestation and is found at diagnostic levels from eight weeks of pregnancy allowing early screening for trisomies^{1,4,5}. It comprises 3-6% of total cell free DNA in maternal blood^{2,4,5}. The amount found in maternal blood increases as gestation increases¹. It originates from the placenta rather than the fetus and is therefore still a screening test, not a diagnostic test, because placental mosaicism is found in about 1% of pregnancies¹. In order to run the test 7-10ml of maternal venous blood is needed and fetal DNA should comprise at least 4% of the total DNA in the sample^{1,5,6}. Results are available to the patient and clinician within a week^{4,5}. There is a 1% chance of not obtaining a result due to the samples not meeting quality control criteria, however a repeat blood sample usually yields a result^{1,6}. Just as it is harder to obtain an accurate nuchal thickness measurement with maternal obesity, this can also affect the chances of obtaining a result with ffDNA. An increase in maternal weight decreases the percentage of ffDNA in the sample making it more likely the sample will not yield a result¹.

Pregnancies with Down's syndrome have higher than normal concentrations of fetal DNA from chromosome 21. A technique called massive parallel sequencing is used to increase the amount of fetal DNA available for a test and detect certain DNA sequences. There are significantly more sequences from chromosome 21 found when Down's syndrome is present despite the fetal DNA being mixed with maternal cell free DNA¹. Shotgun sequencing is another technique that compares the number of sequences from chromosome 21 with the number of sequences from other chromosomes and is thus able to detect trisomic pregnancies¹.

As discussed, placental mosaicism can still give rise to the occasional false positive result as can a



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Introduction of the combined test has put ultrasound departments under increasing pressure to perform scans, which take longer than a simple dating scan



		Screening Test	
		Positive	Negative
Down's syndrome	Yes	A (true positives)	B (false negatives)
	No	C (false positives)	D (true negatives)

▲ Table 1: Terms used to describe the accuracy of a screening test.

Sensitivity = $(a/a+b) \times 100$

ie the percentage of fetuses with Down's syndrome that test positive for it

Specificity = $(d/c+d) \times 100$

ie the percentage of fetuses without Down's syndrome that test negative for it

Positive predictive value = $(a/a+c) \times 100$

ie the percentage of those who test positive who actually have the condition

Negative predictive value = $(d/b+d) \times 100$

ie the percentage of those who test negative who don't have the condition

	Sensitivity	Specificity	False positive rate	Detection rate
Quadruple test	85.1 % ⁸	91.5% ⁸	5% ²	75% ²
Combined screening	77-84% ⁸	96% ⁸	3% ¹	90% ¹
ffDNA	100% ^{1,3}	100% ^{1,3}	<1% ^{3,9}	99% ^{3,9}

▲ Table 2: The accuracy of different screening tests for Down's syndrome.

ffDNA as a method of screening for Down's syndrome is much more accurate than the current NHS screening tests

'vanishing' twin. This occurs when a demised trisomic twin is found alongside a live twin with normal chromosomes⁷. False negatives are extremely rare but can also still occur. This happens when the levels of fetal DNA are very low in the maternal blood, so the condition is masked by maternal DNA^{1,4,6}. Overall, most studies investigating ffDNA as a method of screening for Down's syndrome, find a sensitivity and specificity close to 100%. It is therefore much more accurate than the current NHS screening tests (table 2).

In twin pregnancies ffDNA doubles, therefore in monochorionic pregnancies ffDNA will be more effective than in singletons as the twins are genetically identical. In dichorionic pregnancies, where twins can be genetically different, a maternal blood sample would need fetal DNA levels of more than 8% in order to be processed as each twin would then contribute 4% of the total DNA¹.

Current status of ffDNA (UK and worldwide)

ffDNA has been used for Down's syndrome screening in the United States since 2011. In 2012, the American College of Obstetricians and Gynecologists advised it should be used only for high risk women. This included women over the age of 40, those who had had a previously affected fetus, or those who had a positive screening test or a known translocation in either parent^{1,4,6}. In 2013 the International Society for Prenatal Diagnosis agreed it could be used for women at high risk of trisomy 21, 18 or 13 using the same criteria to define high risk patients^{1,4}. At that time, evidence about the accuracy of the test in low risk women did not exist. The high sensitivities are now known to be the same in both high risk and low risk groups making it an excellent population screening tool^{6,9}.

In the UK ffDNA is already used for fetal blood grouping in cases of rhesus alloimmunisation¹. However, ffDNA testing for Down's syndrome is not yet available within the NHS. It can be obtained privately at between £400-£800³. A significant number of women are already accessing this test privately, so healthcare professionals need to be aware of the issues surrounding it. Currently, tests are sent to the USA for processing as the UK does not yet have its own laboratory. With increasing public awareness through the media and social networking sites such as *Mumsnet*, the demand for this technology is likely to increase¹⁰. Limited evidence obtained within the UK suggests that uptake for ffDNA would be higher than for the current screening system³. The need for national policies on the use of this new screening tool will be required, particularly when it starts to impact on or replace the national screening program already in place. These policies should be evidence based and driven by scientific research and not influenced purely by public demand.

Service impact

With the introduction of any new service comes a huge shift in the allocation of resources, including finance, technology, and people skilled to provide the service¹¹. Currently, there are two schools of thought as to how ffDNA could be included in the NHS screening program.

The first involves adding ffDNA into the screening program as it stands. All women would be offered the combined screening and those found to have a risk higher than 1 in 150 would then be offered ffDNA. If that test came back positive then the woman would be offered invasive testing. This would decrease the number of invasive tests, which may be enough to cover the costs of the more expensive ffDNA test. Assuming that the current threshold of 1 in 150 was used and that the price of ffDNA was £500 per patient this 'contingent' screening program would cost roughly the same as the current program³. If the test cost more than £750 per pregnancy then ffDNA would not be cost effective to implement³.

The second option would be to use ffDNA as a first line screening tool instead of the combined screening in place now. The money currently spent on Down's screening could then be put towards implementing the new system. Ultrasound in the first trimester would still be needed to confirm location, multiplicity, cardiac activity and to date the pregnancy⁹, but the nuchal and biochemical element of the screening would no longer be required. This would shorten the scan time, dramatically decrease the workload in the biochemistry screening laboratories, and also the cytogenetic labs which analyse the amniocentesis and CVS samples. It would involve setting up a new laboratory service in this country to analyse the ffDNA. This would ultimately make the test cheaper than it is now, as current costs include the expense of sending the serum overseas³. However, there are large costs involved in setting up a new service.

Due to its low false positive rate, if ffDNA became a standard screening test there would be a decrease of around 50-89% in the number of invasive diagnostic procedures^{6,12}. This means the number of miscarriages related to CVS or amniocentesis would be reduced. The fewer invasive tests being performed, the cheaper the screening program becomes. CVS or amniocentesis costs around £480 per test³. As the test can be carried out after eight weeks, any terminations for positive results would also occur at earlier gestations potentially causing less distress for the patient, but also cutting costs for the NHS. A first trimester termination costs around £697 whereas in the second trimester costs rise to £882³. However, despite these savings, replacing the current screening system with ffDNA would be more expensive for the NHS³.

Training impact

As the numbers of amniocentesis and CVS decrease there would be fewer centres needed to perform these invasive tests and therefore fewer training opportunities for fetal medicine trainees to become skilled in these procedures. Ultrasonographers may also become deskilled at measuring nuchal thickness, which may reduce the detection of chromosomal abnormalities other than Down's syndrome. New sonographers would have fewer opportunities to learn this skill if the nuchal thickness is no longer part of the national screening program, although in principle the training could still include nuchal thickness assessment. On the positive side, the first trimester scan will take less time after removing the nuchal element and this may enable



Ultrasonographers may become deskilled at measuring nuchal thickness

ultrasound departments to accommodate the increasing number of third trimester scans which are being requested following the RCOG guidance surrounding detection of small for gestational age fetuses¹³.

Disadvantages to stopping serum screening

HCG and PAPP-A are potentially useful for screening for other conditions, for example in predicting pre-eclampsia or intrauterine growth restriction¹. Alpha fetoprotein is used to screen for open neural defects in the fetus⁴. If these are removed from the screening program for Down's syndrome, fetuses at risk of these conditions may go undetected. The ffDNA test identifies only trisomies 21, 18 and 13 and not the full karyotype. This means invasive testing would still be needed if an increased nuchal or other structural anomalies were detected, so that other chromosomal causes could be excluded³.

Future applications

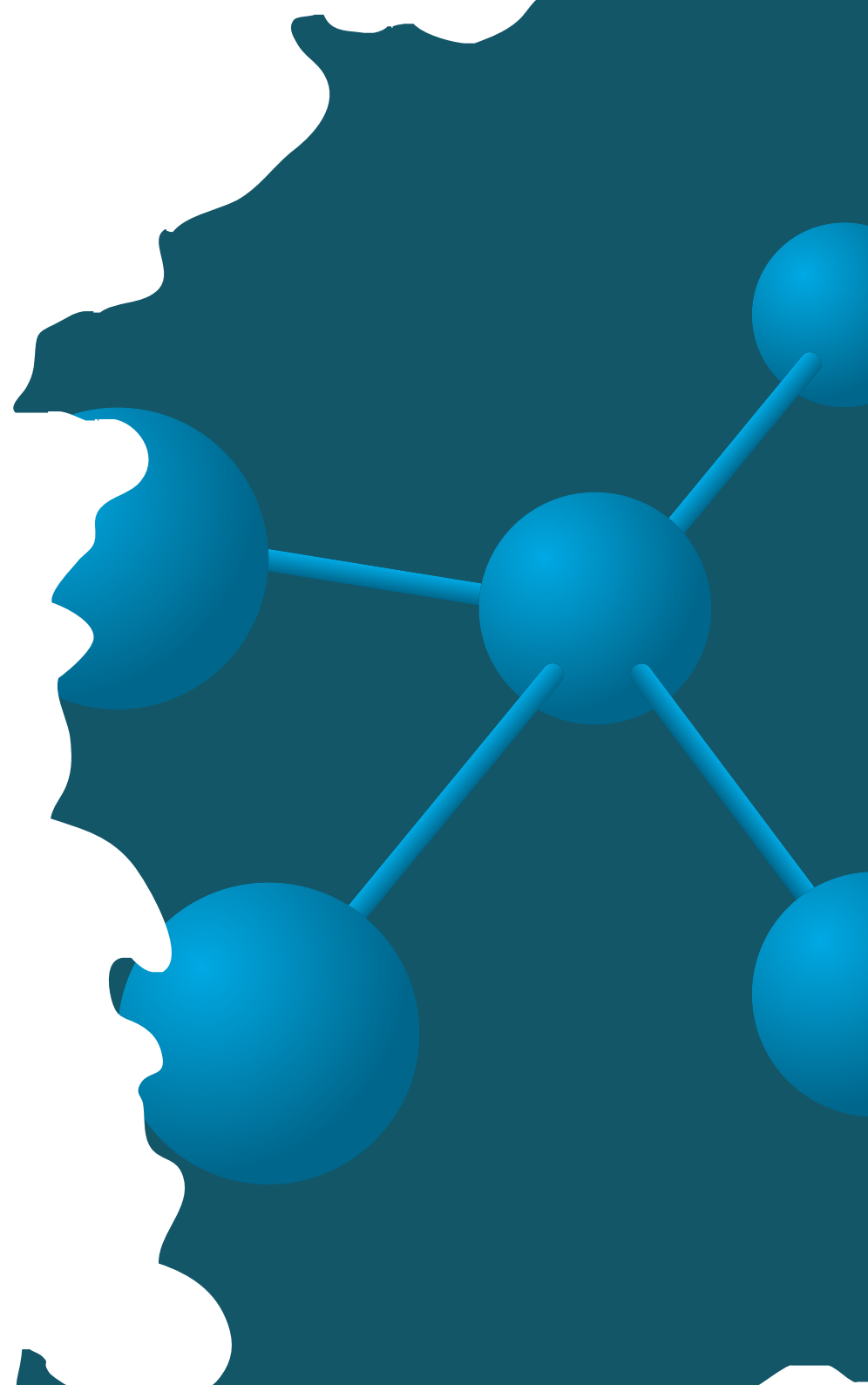
Testing for trisomy 18 and 13 is now also available via ffDNA in the USA, Germany, Hong Kong and China. It is also available privately in the UK³. For trisomy 18 the false positive rate is quoted as 0.2% with a negative predictive value close to 100% and sensitivities and specificities close to 100%^{1,6}. The test for trisomy 13 is not quite as accurate with sensitivities and specificities closer to 90%^{1,3}. Screening for gender with ffDNA is also used for those at risk of sex chromosome linked conditions in some countries.

Ethical challenges

As a straight forward procedure, free of physical danger, there is a concern that ffDNA testing may be taken for granted as a 'routine' blood test. As a result, the importance of thorough counselling into the conditions the test may detect could be forgotten. Informed consent is a vital part of involving parents in the decision making process. Sayres et al found that whilst 47% of individuals were interested in ffDNA testing, 29% of couples were not interested in any form of screening¹⁰. Testing these individuals without thorough counselling compromises their autonomy and leaves them with knowledge they would rather not have.

As it is now possible to screen for more and more genetic conditions using ffDNA, the ethics involved become even more important. It is possible to screen for conditions such as Huntingdon's disease, but should we be screening *in utero* for conditions that may not affect the fetus until it reaches adulthood? If and when the technology advances, should ffDNA be used to look at the whole fetal karyotype, or just specific conditions such as Down's syndrome?

The authors believe ffDNA should, and will, be implemented into the NHS screening program in the medium term as a first line screening tool. However, this cannot occur without careful planning into the consequences of changing established practice, and ensuring that the laboratory capacity is available to meet demand.





Conclusion

With greater accuracy and fewer demands for invasive testing, ffDNA is set to change the way we screen for chromosomal anomalies in pregnancy. However, setting up a new screening program has its challenges and is costly. Discussion as to how the NHS implements ffDNA into the screening service is vital if it is to successfully negotiate changes in service implementation. The importance of counselling and informed consent should not be overlooked when discussing ffDNA with patients, so they can understand the choices they face and the implication of any screening.

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PET-CT in diagnosing dementia: Why bother and who is going to pay for it?

David Fitzgerald

In the absence of disease-modifying treatments, some may find it difficult to justify funding services that provide the latest imaging techniques for diagnosing dementia.

Positron emission tomography fluorine-18 fluorodeoxyglucose integrated with computed tomography (¹⁸F-FDG PET-CT) is an established technique for assisting in the differential diagnosis of mild cognitive impairment, Alzheimer's disease, vascular dementia, dementia with Lewy bodies and fronto-temporal dementia. Amyloid PET-CT imaging is another technique recommended in specific circumstances for differentiating between normal subjects and various dementias. However, these imaging techniques are not centrally funded and this is preventing their widespread implementation in the early diagnosis of dementia, particularly Alzheimer's disease.

Without disease-modifying treatments currently being available, it is difficult to determine if these are services that should be funded before the drugs required to reverse the effects are developed.

The Alzheimer's Society estimates that in 2015 there are 850,000 people with dementia in the United Kingdom (UK) and predicts that this will rise to one million by 2025. It also states that the financial cost related to dementia is £26 billion per year¹. The most startling statistic from the Alzheimer's Society is that only 44% of people with dementia in England, Wales and Northern Ireland receive a diagnosis.

This may lead to the conclusion that there are no diagnostic tests that can aid pure clinical assessment in the diagnosis of dementia. However, nuclear medicine has been providing a number of imaging studies successfully, to aid the diagnosis of dementia including HMPAO single photon emission computed tomography (SPECT) studies and ¹⁸F-FDG and amyloid imaging PET-CT studies over 10 years at least. This article will cover the use of ¹⁸F-FDG and amyloid imaging PET-CT studies only.

World leaders are taking dementia seriously – UK Prime Minister David Cameron introduced the first international dementia summit at the 2013 G8 meeting and was quoted as saying at the Alzheimer's Society Conference in 2012: "One of the greatest challenges of our time is what I'd call the quiet crisis, one that steals lives and tears at the hearts of families, but that relative to its impact is hardly acknowledged. We've got to treat this like the national crisis it is. We need an all-out fight-back against this disease; one that cuts across society²."

In December 2013, the Secretary of State for Health showed commitment by signing up to the 'G8 Dementia Summit Declaration' alongside health ministers from Canada, France, Germany, Italy, Japan, Russia and the USA³.

Dementia is a significant and increasing burden on the health economy and this is one of the major factors behind the international drive to research, treat and cure it.

Approximately 75,000 PET-CT scans were performed in England during 2013/2014⁴ but the majority of these should have been for oncology indications based on the NHS England Clinical Commissioning Policy Statement⁵. Only 10% of the oncology activity was allowed, at the discretion of the ARSAC (administration of radioactive substances advisory committee) licence holder, to be used for non-oncology indications. At most, this could mean that in England 7500 scans may have been performed for diagnosing dementia. However, this is unlikely as the 10% discretion was permitted for a number of indications and not just dementia diagnosis.

This compares with over three million CT scans and over two million MRI scans performed in England during 2013/2014⁴. CT and MRI scans are recommended by the National Institute for Health and Care Excellence in order to exclude other cerebral pathologies in those suspected of a dementia diagnosis from clinical examination⁶. The 30 to 44 fold difference between the activity for PET-CT scans and MRI/CT activity respectively, indicates the disparity in access between the different modalities.

Limited access to PET-CT imaging facilities is probably one factor but with more facilities becoming available and improvements in scanner technology leading to faster scans, this is becoming less of an issue.

The question therefore remains, that if diagnostic imaging exists, able to support clinicians in establishing the diagnosis of dementia and potentially allowing treatment and/or support for patients earlier, why is it not used more widely?

The lack of appropriate commissioning is certainly one very important factor. However, a lack of randomised control trials and large scales reviews studying the effectiveness of ¹⁸F-FDG and amyloid PET-CT imaging, is probably impeding an evidence-based approach to approving the commissioning of these services.

Dementia

Dementia is a syndrome where patients develop a deterioration in memory, thinking and behaviour and the ability to perform everyday activities⁶. This syndrome includes vascular dementia, Alzheimer's disease, dementia with Lewy bodies and fronto-temporal dementia.

Mild cognitive impairment (MCI) is a relatively recent term that is used to describe patients who have memory impairment insufficient to interfere with daily life and do not meet the criteria for a dementia diagnosis. However, more than half of patients with MCI will progress to dementia within five years and so this may be seen as a significant risk factor for dementia⁷.

Alzheimer's disease is the most common cause of dementia⁸ and is the result of neuronal cell loss caused by neurofibrillary tangles due to the presence of tau protein and plaques caused by extracellular β -amyloid ($A\beta$) deposition.

Vascular dementia is caused by vascular disease associated with hypertension, diabetes mellitus and smoking that causes reduction or blockage of cerebral perfusion⁹. The result is single or multiple cortical and/or subcortical infarcts.

Dementia with Lewy bodies is caused by intracellular pathological aggregations of alpha synuclein, that lead to neuronal cell loss resulting in non-specific global and sub-cortical volume loss with relative preservation of the hippocampi⁹. Dementia with Lewy bodies is on a continuum with Parkinson's disease and is differentiated by neuropsychiatric disturbances occurring before, or shortly after, motor symptoms become apparent. Parkinson's disease typically presents with motor symptoms for at least 12 months prior to any symptoms of dementia developing⁹.

Fronto-temporal dementia is caused by degeneration of the fronto-temporal lobes indicated by atrophy of the frontal and temporal lobes of the brain. This is the result of neuronal cell loss in these regions caused by pathological aggregation of tau protein⁹. Fronto-temporal dementia broadly has two main sub-groups – a behaviour-led syndrome (personality changes and alterations in social conduct) and a language-led syndrome (primary progressive aphasia)¹³.

Clinical diagnosis of dementia

Clinical assessment of patients presenting with memory problems to determine if they have dementia, is currently undertaken using memory tests, the most commonly used being the mini mental state examination (MMSE)¹⁴.


The literature suggests that there is a time lag of at least a decade between the start of the pathological process for Alzheimer's disease and clinical symptoms being present and that some experiencing dementia will never show clinical symptoms⁸. Clinical assessment alone is suggested to have sensitivity and specificity of 76-81% and 56-70% respectively, but this is in patients who have usually presented in the later stages of dementia^{8,11}.

Whilst anatomical imaging, as described previously, is useful to rule out structural causes of memory impairment, there are no other diagnostics that are currently utilised, possibly due to lack of funding and an evidence base, to assist clinicians in providing earlier diagnoses of dementia.

Current treatment of dementia

Current treatment of dementia is provided to reduce symptoms of the disease, but does nothing to modify the pathological processes involved and therefore does not provide a curative option¹⁵. The drugs provided to patients diagnosed with Alzheimer's disease may be harmful to those with fronto-temporal dementia, so ensuring the appropriate diagnosis is vitally important¹⁵.

Diagnostic imaging that aids the earlier detection of the pathological processes associated with dementia, could provide information about which patients will benefit from which treatment, and earlier treatment could slow the progression of the disease and allow the patient to have a more independent life for longer. This could also reduce the burden on the health service, therefore appropriate funding of PET-CT imaging services may ultimately reduce cost in the long-term.



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Commissioning of dementia imaging services in the UK

With recent restructuring in the NHS over the time of the last government, the majority of commissioning of PET-CT imaging in England occurred centrally through NHS England.

Previous commissioning policy statements for PET-CT have been guided by evidence-based indications for PET-CT in the UK issued by the Royal College of Radiologists and the Royal College of Physicians. Although ¹⁸F-FDG brain PET-CT imaging is supported in selected patients in these publications, the most recent version is quite clear that amyloid imaging should only be used in very specific cases, ie 'the patient has persistent or progressive unexplained memory impairment confirmed by standard medical tests, an unusual clinical presentation and/or an atypically early age of onset'¹⁸.

Recent consultation with the nuclear medicine community by NHS England, has indicated that this has been interpreted as meaning that amyloid PET-CT imaging should not be funded.

The caveat of the 10% rule⁵, which previously allowed providers to implement low activity services, enabling a body of evidence to be developed to support the wider commissioning of these studies in subsequent financial years, also appears to have been removed from the commissioning policy statement from NHS England. This will mean that providers will have to consider the provision of amyloid imaging either as a cost pressure or as research to enable the evidence to be collected to support future funding of these studies. In the current financial climate, it is unlikely that NHS providers will be in a position to provide this as an unfunded service.

At the time of writing, the effect of the new government is not known and NHS England has not published its commissioning policy statement and so it is unknown whether the consultation document will be implemented without change.

Currently there are no disease-modifying treatments for dementia patients, especially those with Alzheimer's disease. Therefore the argument can be made that it is not cost effective to demonstrate amyloid burden, without the ability to reduce that burden. Therefore commissioning of imaging for this reason could be considered unnecessary until drugs are developed to modify the amyloid burden. However, disease-modifying treatments are being extensively researched and so having a diagnostic service in place should enable a more speedy application of the therapy once available.

¹⁸F-FDG PET-CT in the diagnosis of dementia

¹⁸F-FDG is the most widely used radiopharmaceutical in clinical practice for PET-CT imaging for malignancies in the UK¹⁰. ¹⁸F-FDG PET-CT scanning can also be used to evaluate glucose metabolism within the brain. Dementia is characterised by areas of hypometabolism relative to the glucose metabolism of normal brain tissue. The glucose metabolism of the cerebellum, thalamus and basal ganglia nuclei is not significantly reduced in dementia and so can be used as a reference for 'normal' uptake¹¹.

The diagnosis of different types of dementia is based on recognition of characteristic patterns of regional hypometabolism.

A review by Bohnen et al¹¹ found that ¹⁸F-FDG PET-CT has a sensitivity of between 78% and 96% and specificity of between 73% and 90% when determining the presence or absence of Alzheimer's disease. Vascular dementia displays a pattern of hypometabolism similar to Alzheimer's disease and so differentiating the two with PET-CT scans can be problematic¹².

Studies have shown sensitivity of 90% and specificity of 80% when using ¹⁸F-FDG PET-CT scans to differentiate dementia with Lewy bodies from Alzheimer's disease¹¹. Multicentre studies have demonstrated a 96% accuracy in differentiating between healthy, Alzheimer's disease, dementia with Lewy bodies and fronto-temporal dementia subjects¹¹.

More importantly, there is evidence that for MCI patients without characteristic patterns of regional hypometabolism on

PET-CT, the likelihood of progression to dementia is low. This can provide useful reassurance and prevent the use of costly and unnecessary treatment¹¹.

Brain amyloid PET-CT imaging

As an alternative strategy to imaging regional cerebral glucose metabolism in patients with suspected dementia, tracers have been developed to specifically bind the abnormal β -amyloid (A β) deposition characteristic of this condition.

Currently in the UK, only one radiopharmaceutical is commercially available for amyloid PET-CT imaging – 18F-florbetapir (Amyvid™, Lilly, Indianapolis, IN, USA). Even so, there is evidence in the literature of similar compounds that have proven successful in differentiating between normal volunteers and subjects with Alzheimer's disease, dementia with Lewy bodies, fronto-temporal dementia and mild cognitive impairment (MCI).

The level of uptake in amyloid PET-CT scans is significantly higher in patients with Alzheimer's disease and the pattern of uptake is similar to the regional hypometabolism in 18F-FDG PET-CT scans¹⁷.

Amyloid uptake has also been shown to be higher in subjects with dementia with Lewy bodies than in healthy controls and those with Parkinson's disease or Parkinson's disease with dementia. There is overlap in appearances such that amyloid imaging may not be helpful in differentiating these two dementia types¹⁶.

Since A β deposition is not a feature of fronto-temporal dementia, these patients show scan appearances similar to age-matched healthy subjects; amyloid PET-CT imaging should have a role in differentiating fronto-temporal dementia from Alzheimer's disease¹⁶.

Finally, patients with MCI that are found to have normal, age-matched uptake on amyloid PET-CT imaging are unlikely to progress to dementia¹⁷. Therefore, using this test in MCI patients to differentiate those with normal scan appearances from those with scan features suggestive of Alzheimer's disease, would potentially permit appropriate withholding of expensive treatment from the former group, whilst simultaneously allowing early treatment intervention in the latter, should such treatment become available.

Conclusion

¹⁸F-FDG and amyloid PET-CT imaging studies have been shown to add benefit over clinical assessment alone in the diagnosis of dementia. Anatomical imaging provides greater ease of access and also rules out structural reasons for dementia-like symptoms.

With prominent political figures supporting the drive to better manage dementia, where is the message being lost in gaining the funding from commissioners to support the development of diagnostic tools to enable early dementia diagnosis? A drive to research the use of these imaging techniques in dementia could provide the evidence base to support appropriate commissioning.

Acknowledgements

Bernadette Cronin and Daniel Levine are thanked for their advice and for reviewing this article.

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Prescribing medicines – an essential competence for advanced and consultant radiography practice

Dianne Hogg, Vincent Goodey, Duncan Gavan, Nigel Thomas, Peter Hogg

Does the current inflexibility and limited scope of prescribing and administration of medicines for radiographer-led therapeutic and diagnostic procedures, negatively impact patient care and ultimately cost the NHS more?

It's 2020. The Directorate of Integrated Unscheduled, Urgent and Emergency Care at Anywhere NHS Foundation Trust has just won a *Health Service Journal* award for excellence. Its one-stop shop approach is applauded nationally and the English Minister for Health is to visit to see for herself how the directorate provides such excellent care for its patients. How? By valuing the contribution of all its team members, and enabling appropriate care at the point of contact where and when their patients need it. No professional territory is defended; responsibilities are divided with respect to patient need and professional skills and ability. Irrespective of where the patient steps out of the directorate flow they can leave without undue delay and with the medicines and future appointments they need. The directorate had a financial surplus at the end of the last financial year.

This certainly seems like a pipedream in today's current NHS climate, but it is one possible model of the future NHS¹. This couldn't be achieved overnight; hearts and minds need to change as well as skills and expectations, but we aren't so far away...

Nurses have been able to prescribe a wide range of medicines independently for over twelve years, pharmacists almost ten years, podiatrists and physiotherapists a little over a year. Existing health services have improved and expanded and new ones have developed, because these health professionals can prescribe medicines independently... as part of a team.

The idea of allowing non-medics to prescribe began with nurses almost 30 years ago in part sparked by the realisation that community nurses could not provide adequate care in many

circumstances without asking a GP to prescribe medicines, dressings and so on once the community nurse had identified the need for that product. This continues to some degree, but tens of thousands of community nurses are now nurse prescribers, successfully managing wounds and other conditions within their scope of competence and in a timely manner.

Non-medical prescribing interventions are now common and well-received by patients². They shorten waiting times and also increase job satisfaction for the practitioner. New or expanded roles within healthcare have been developed as a direct result of the postholders being prescribers already³ and specialist role job descriptions increasingly require the postholder to be a prescriber.

Independent prescribing involves prescribing medicines for any medical condition within the prescriber's ability and scope of practice. Doctors and dentists prescribe in this way and now non-medical practitioners independently prescribe on a daily basis in clinical areas such as:

- Emergency medicine, where in urgent care centres nurses prescribe bronchodilators such as salbutamol for acute asthma, antibiotics for urinary tract infections etc;
- Specialist nurses manage patients with heart failure – titrating their medicines up to therapeutic doses in response to tolerance;
- Specialist oncology nurses can prescribe and manage chemotherapy regimes;
- Pharmacists prescribe to amend already prescribed medicines, eg to manage side effects, comply with local formulary or national guidelines; stop antimicrobials where the course end has been reached; or as a result of a medicines use review in a general practice setting to stop/start or alter the dose of a medicine or commence the patient on weight reduction programs or other public health interventions;
- Podiatrists manage the feet of patients with diabetes, prescribing analgesia for neuropathic pain or antimicrobials where appropriate;



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Radiographer independent prescribing for both diagnostic and therapeutic radiography, is an essential component in advanced and consultant practice

- Physiotherapists prescribe botulinum toxin for dystonia or analgesia for pain during physical treatment.

But there is an obvious gap. Patients attending radiology departments still have to see another health professional if they need medicines, before they can step out of the health facility. However, this could be set to change.

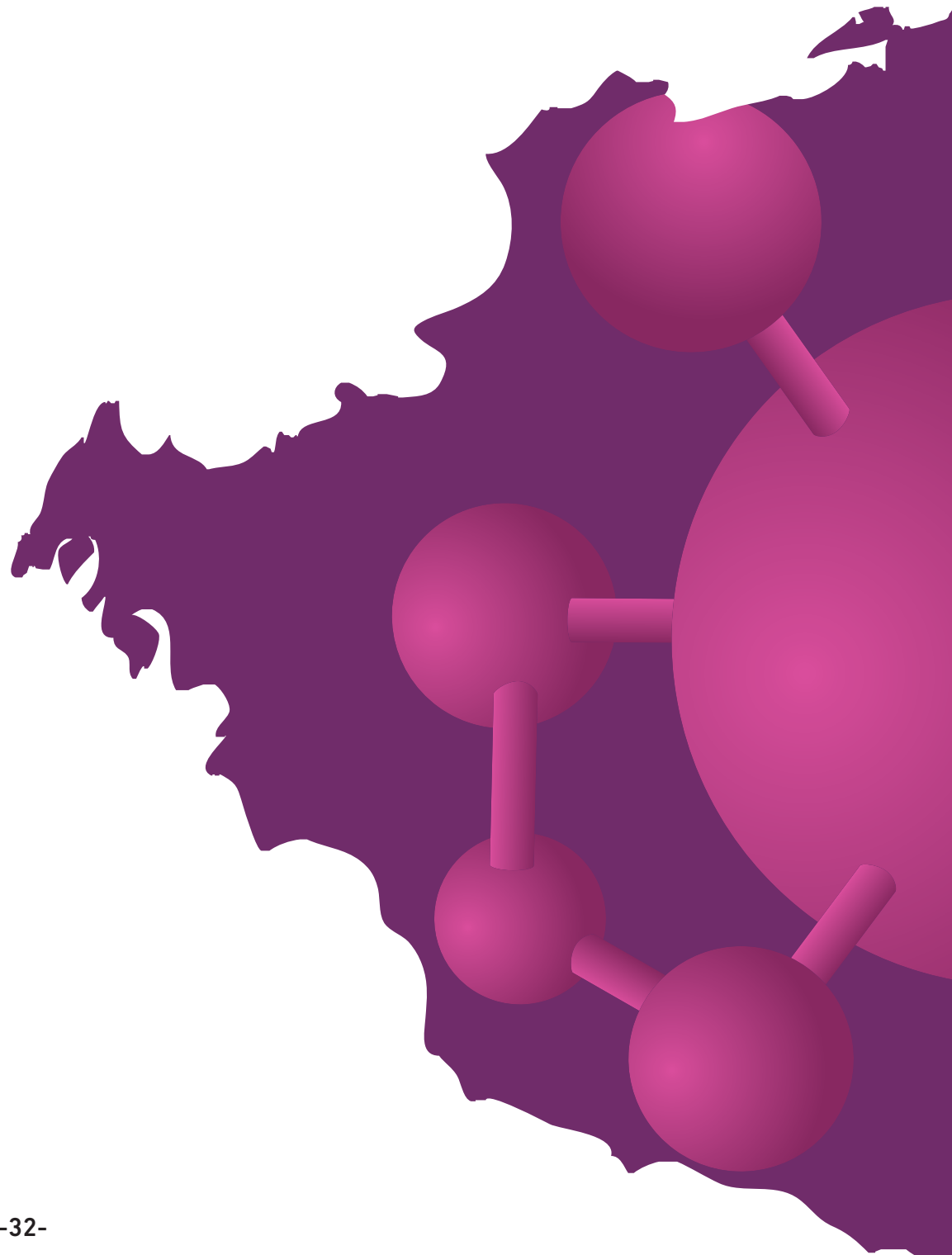
Legislation enabling non-medical prescribing in the UK has allowed radiographers to prescribe as supplementary prescribers since 2005, but not as independent prescribers. Supplementary prescribing involves a written tripartite agreement between a medical prescriber, supplementary prescriber (SP) and patient, known as a clinical management plan, for the SP to prescribe medicines included in the plan for the patient's already diagnosed medical condition. Currently, radiographers are not permitted to progress to independent prescribing, therefore the process by which radiology patients receive medicines is often far from satisfactory.

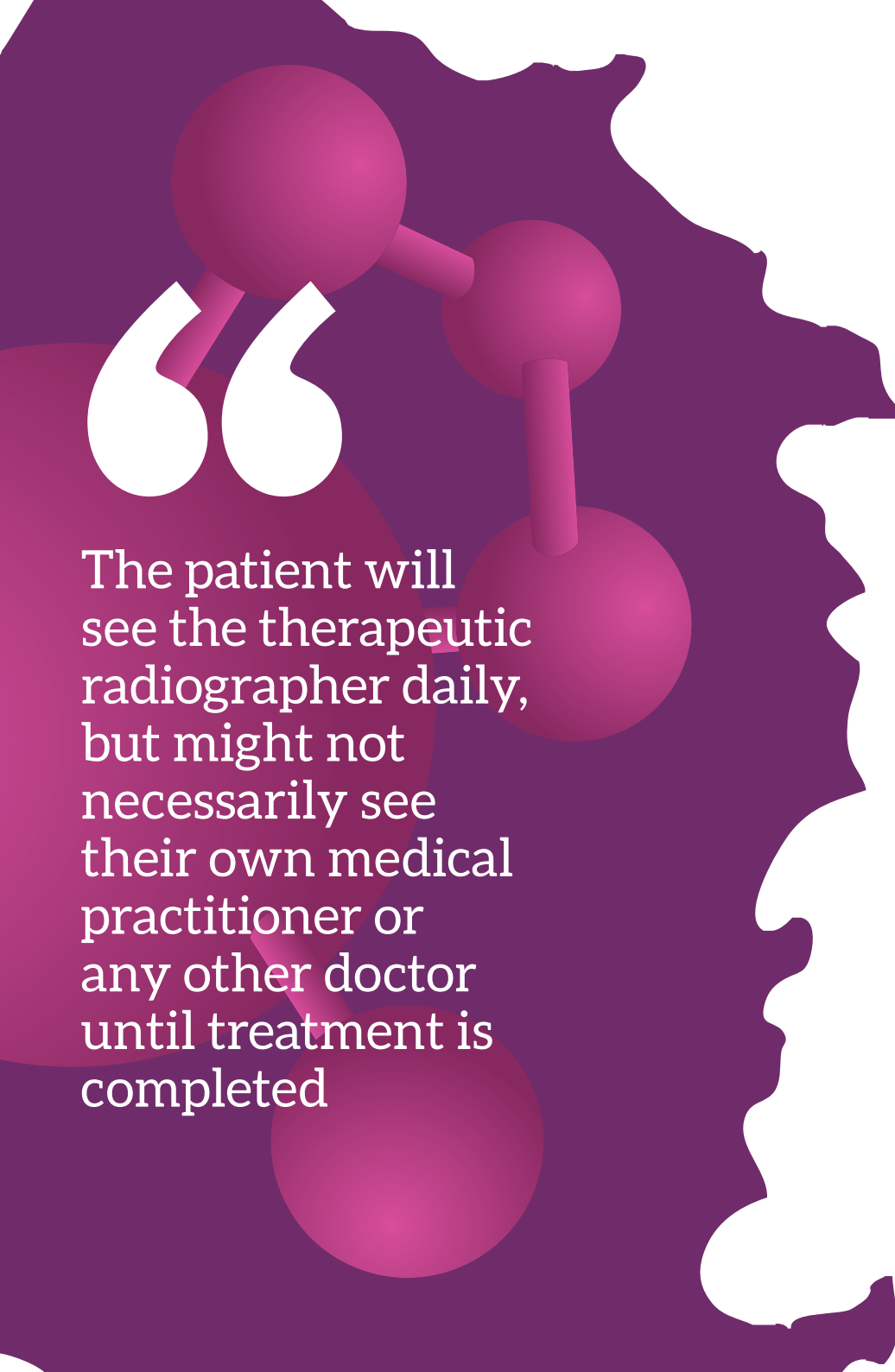
Therapeutic radiographers have been able to use supplementary prescribing with moderate success because of the repeated nature of the contact with their patients; diagnostic radiographers have had considerable difficulty as they see their patients for single episodes of care. Independent prescribing would enable radiographers in both fields to be more responsive to patient need and streamline care, and to play their part in the achievement of the vision of the NHS Five Year Forward View report¹. This article aims to demonstrate the need for radiographer independent prescribing for use in both fields of diagnosis and therapy, by considering current and future radiographer practice.

The need for independent prescribing in effective patient management

As imaging and therapy examinations have evolved, the need for medicines as procedural adjunct or consequence of process/outcome has increased. Examples of adjunct medicines include contrast media, stimulus triggers such as adenosine, a cardiac stress agent or furosemide, a diuretic. These medicines assist demonstration of pathologies by accentuating physiological and/or anatomical phenomena to make pathologies more easily detected and diagnosed during imaging. Medicines required as a consequence of process include antihistamines such as chlorphenamine for managing reactions to contrast media or medicines for controlling diarrhoea arising from radiotherapy treatment. An example of a type of a medicine indicated as a consequence of outcome is analgesia, for controlling pain if no fracture is identified on a radiograph or for managing cancer-related pain during radiotherapy procedures. In short, medicines are a key component of many diagnostic and therapeutic procedures; they are used to enhance the effectiveness of a procedure or manage procedural side effects, and they help manage the patient after a diagnosis is made, pathology excluded or treatment conducted.

In most cases, due to the restrictions on radiographer prescribing, the process by which the patient receives these medicines is indirect at best and mostly circuitous. Radiologists may prescribe from a clinical history and a procedural protocol and not actually see the patient before prescribing. They may disagree with the radiographer's choice of analgesia or other medicine to alleviate side effects of a procedure and, quite rightly, as the prescriber is accountable for his or her own prescribing decisions, prescribe something else.





The patient will see the therapeutic radiographer daily, but might not necessarily see their own medical practitioner or any other doctor until treatment is completed

Radiographers are currently in a similar position to those nurses 30 years ago. Even advanced and consultant radiographers are restricted by the lack of autonomy to prescribe medicines and must approach radiologist colleagues to prescribe so that they can continue their current work; what could they achieve if they could prescribe independently? With resources stretched, a leaner patient journey involving fewer health professionals, but with the skills to provide everything the patient needs must be more cost effective.

Diagnostic radiographers are working with specialised clinical teams and individual radiographers are being drawn into tighter multidisciplinary networks; local angiographic radiographers work alongside nurses and share their scrub duties as well as direct patient handling skills. Their skills and responsibilities are changing and becoming merged, and should also include the ability to prescribe for post-procedural pain.

Often nuclear medicine radiographers work in an isolated environment with, in some places, poor access to general medical staff. There are many drugs used for this speciality which require prescribing to enhance these studies. The commonly used procedure of CT colonography utilises bowel preparation, anti-spasmodics such as hyoscine butylbromide, contrast agents and occasional analgesia – a minefield of prescription types.

Radiographer independent prescribing for both diagnostic and therapeutic radiography, is an essential component in advanced and consultant practice. Clinical decision making and prescribing decision making are inextricably linked; both are fundamental at this level of practice and, if enabled, can complete or enhance the patient's experience.

An unpublished audit undertaken by supplementary prescribing therapeutic radiographers in the North West⁴ considered 186 patient contacts. Of these, 54 patients needed a medicine to be prescribed during the consultation, and in 41 instances the therapeutic radiographer could prescribe. However, the lack of a clinical management plan for the patients in the remaining 13 instances, meant that the patients had a poor experience, delays in their treatment and, for some, prolonged symptoms. The therapeutic radiographers commented that independent prescribing would have enabled them to have quicker access to medicines and provide complete episodes of care to more of their patients. This, in turn, would have resulted in patients needing fewer appointments and having a shorter consultation time.

Examples of scenarios where independent prescribing for radiographers could have positive impact

Radiographer-led discharge of patients in urgent care centres is gaining popularity within the UK. Here the radiographer would interpret the image and if no abnormality is present, they would discharge the patient. In some cases, the patient might complain of discomfort or pain and the radiographer could prescribe analgesia. Small remote x-ray units within community hospitals are excellent examples of where this could happen. In this context a prescribing radiographer could facilitate the following:

- Patient discharge by one health professional would be quicker for the patient; importantly the patient would interact with only one professional who would see to all their needs;
- Radiographer-led discharge with prescribing would minimise or even negate the need for re-involving



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The evidence base of practical examples of radiographer prescribing is tiny, but with an eye on the experiences of the almost 40,000 non-medical prescribers already practising in the UK, the potential of prescribing for future radiographer practice becomes obvious

other urgent care centre staff. This is important, as for quite some time, human resource in emergency care departments has been overstretched;

- Being able to complete the care pathway may increase job satisfaction for the prescribing radiographer and make best use of his/her clinical skills.

Currently, when radiologists review imaging requests they decide whether medicines are required as part of the procedure (eg contrast agent). In some instances the radiologist does not see the patient in person when making the prescribing decision. Whilst examining the patient the prescribing radiographer could interview the patient prior to the examination and prescribe at that point, or decide part way through the examination. In this context a radiographer who has prescribing competence offers the following benefits:

- Seeing and consulting with the patient in person is safer practice and increases adherence to the medicines regimen^{2,5};
- Additional human resource is not required in the decision making. This reduces the burden placed on the radiologist and allows the responsibility for prescribing this medicine to be managed at the most cost effective level⁶.

Sometimes there is need for a change of medicine during a radiotherapy procedure. Even if a radiographer is a supplementary prescriber, this is a situation where they may need to refer the patient back to a medical practitioner (oncologist). Clinical management plans required for supplementary prescribing must list the medicines or class of medicine that the radiographer can prescribe for the patient; if the patient requires a different medicine it may be outside the parameters of the clinical management plan. Independent prescribing would enable responsive change of treatment, if within the competence of the radiographer. In this situation the benefits could be:

- The patient gets prompt appropriate treatment for his condition;
- A further appointment with the patient's medical practitioner is saved – a financial saving;
- The skills and ability of the radiographer are valued; the benefits of the linkage between the traditional skills of the radiographer and prescribing.

In radiotherapy there can be a need to manage side effects. A patient may decide not to proceed with radiotherapy because of debilitating side effects that could be treated with certain medicines. An initial prescription from the patient's medical practitioner may be insufficient or the patient's needs may change during the treatment, requiring additional or alternative medicines to be prescribed. The patient will see the therapeutic radiographer daily, but might not necessarily see their own medical practitioner or any other doctor until treatment is completed. The patient is more likely to complete their treatment with minimised side effects. Similarly, embarrassing side effects may be much more easily disclosed to, and managed by, the therapeutic radiographer who they may see each day and with whom they may have built a relationship.

Changes to working practices such as evening clinics or outreach work in community settings in any of the above scenarios, can add further weight to the benefits that radiographer independent prescribing could bring because of the lack of availability of medical practitioners during these situations. The evidence base of practical examples of radiographer prescribing is tiny, but with an eye on the experiences of the almost 40,000 non-medical prescribers (eg nurses, pharmacists and physiotherapists) already practising in the UK, the potential of prescribing for future radiographer practice becomes obvious.

At the time of writing, the case of need has recently been made for radiographers to become independent prescribers; it has progressed through the review process of the NHS in the UK and has recently become available for public consultation. Timescales are unknown; agreement for radiographer independent prescribing will facilitate realisation, in time, of these benefits and more.

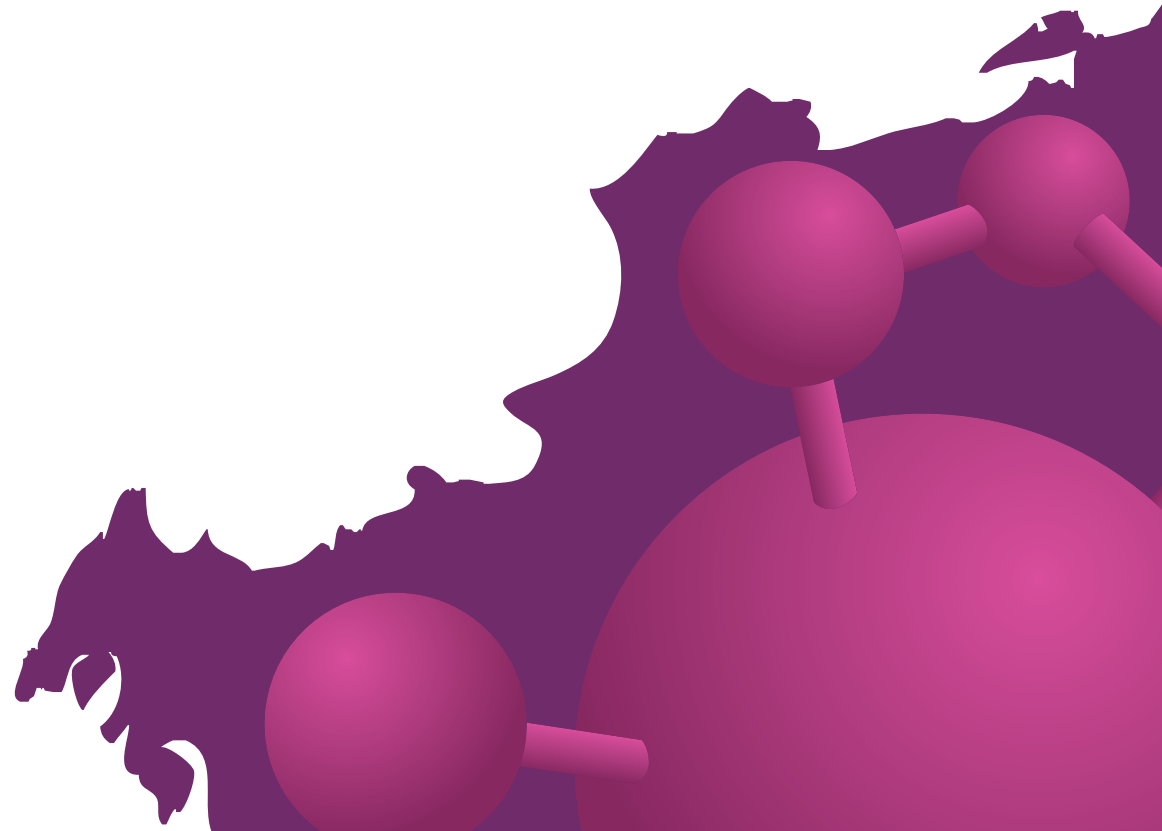
Conclusion

The current situation for prescribing and administration of medicines for radiographer-led therapeutic and diagnostic procedures, under the umbrella of supplementary prescribing, has been in place for 10 years and has worked reasonably well. However, its inflexibility and limited scope, means that the patient's journey through radiology and radiotherapy departments may often be delayed or involve additional visits. While independent prescribing won't replace supplementary prescribing, it will certainly add to the flexibility of practice and, in many circumstances, improve the patient's experience.

It is also important to note that certain treatment types are best undertaken using a team approach, ie as part of a good working relationship with the clinical team caring for the patient. Non-medical prescribing is not about working alone; it is about widening the impact of the clinical team by allowing team members to work to their scope of competence with patients as their focus. That feels a lot like that place at which we would all like to work – Anywhere NHS Foundation Trust.

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Image interpretation – digital learning to support traditional training

Nick Woznitza, Dorothy Keane

Radiology services have seen an unprecedented rise in workload across the United Kingdom, with exponential growth over the last decade¹.

This increase in activity has been driven by an ageing population, the expansion of high technology imaging and renewed focus on the early diagnosis and treatment of cancer². Furthermore, ultrasound as part of radiology services has seen sustained and increasing demand in traditional areas such as abdominal and paediatric examinations as well as growth in the range of applications performed outside the radiology department, such as in emergency, respiratory, intensive care, and sports medicine^{3,4}. Emerging technologies that cross the boundaries of traditional modalities, such as positron emission tomography combined with computed tomography (CT) and magnetic resonance imaging (MRI), have also contributed to increases in imaging examinations; and have also challenged the traditional teaching and mentoring structure of higher education and the NHS⁵. These sustained, indeed escalating, pressures are occurring during times of increased public and political focus on the delivery of safe, effective and patient focused radiology services in the wake of the Francis Report⁶.

Radiographers are pivotal members of the healthcare team and are usually the first practitioners to see the diagnostic image⁷. Radiographers are aware of the pressures of rising demand and the need to maintain momentum through the patient journey. The current pressures facing the NHS, rising emergency activity and delayed patient discharge, magnify bottlenecks and barriers to efficient service delivery⁸. The need for effective and efficient delivery of care that minimises 'double-handling' of patients and seeks to always continue patients through their care pathway is paramount. With the move to seven-day working and the extended provision of specialist imaging modalities^{9,10}, the ability of radiographers to interpret the images that they acquire will only increase, to optimise patient care and to instigate appropriate referral pathways, when serious or unexpected findings are encountered¹¹. Radiographer preliminary clinical evaluation (PCE) and clinical reporting, support efficient and patient focused radiology and remove barriers to delayed diagnosis.

Background

Interpretation of radiographs and other imaging procedures by radiographers is not a new concept. The pioneering work of Berman et al¹² demonstrated that when radiographers, operating as part of an emergency department team, flagged possible abnormalities on skeletal radiographs, there was enhanced fracture detection and improved patient care. The review conducted by Brealey and colleagues, found that radiographers without postgraduate qualifications in clinical reporting had high levels of accuracy when detecting abnormalities on trauma radiographs; sensitivity 87% and 92% specificity¹³.

The 'red dot' or abnormality detection system, where radiographers highlight a suspected abnormality on a radiograph by using a red sticker, has become embedded in many imaging departments¹⁴ and has improved patient care. However, a simple image flag is ambiguous¹¹ and may not have sufficient impact on patient management. In response to these shortcomings, the College of Radiographers has emphasised the need to move from the red dot system into PCE, in which radiographers provide concise written summaries of their imaging findings on plain radiographs¹¹. Replacing the 'red dot' with a written interpretation overcomes many of the shortfalls of the red dot system, however PCE has shown relatively slow uptake across the UK (only 20 of 137 departments)¹⁴. There are a number of logistical issues to be overcome, but there are also other barriers to the implementation of radiographer PCE, particularly ensuring that radiographers are educated for, competent and confident in undertaking PCEs. Several studies have examined the confidence of radiographers when providing initial image interpretation and have found lower radiographer confidence when participating in PCE rather than abnormality detection^{15,16}. However, when compared to junior medical staff and emergency nurse practitioners, radiographers were the only group whose confidence reasonably correlated with their interpretation performance¹⁷. This is important as it demonstrates that some professionals who are expected to act on their findings may, in fact, be acting on erroneous evaluation of the imaging investigation. These professionals clearly need educational support to improve their performance and the Society and College of Radiographers and the e-Learning for Healthcare Image Interpretation project offers this.

Plain imaging is not the only modality where radiographers have a positive impact on patient care through image interpretation and clinical reporting. Sonographers, most of whom are radiographers in the UK, provide a significant contribution to the delivery of an effective ultrasound service, and have been providing independent

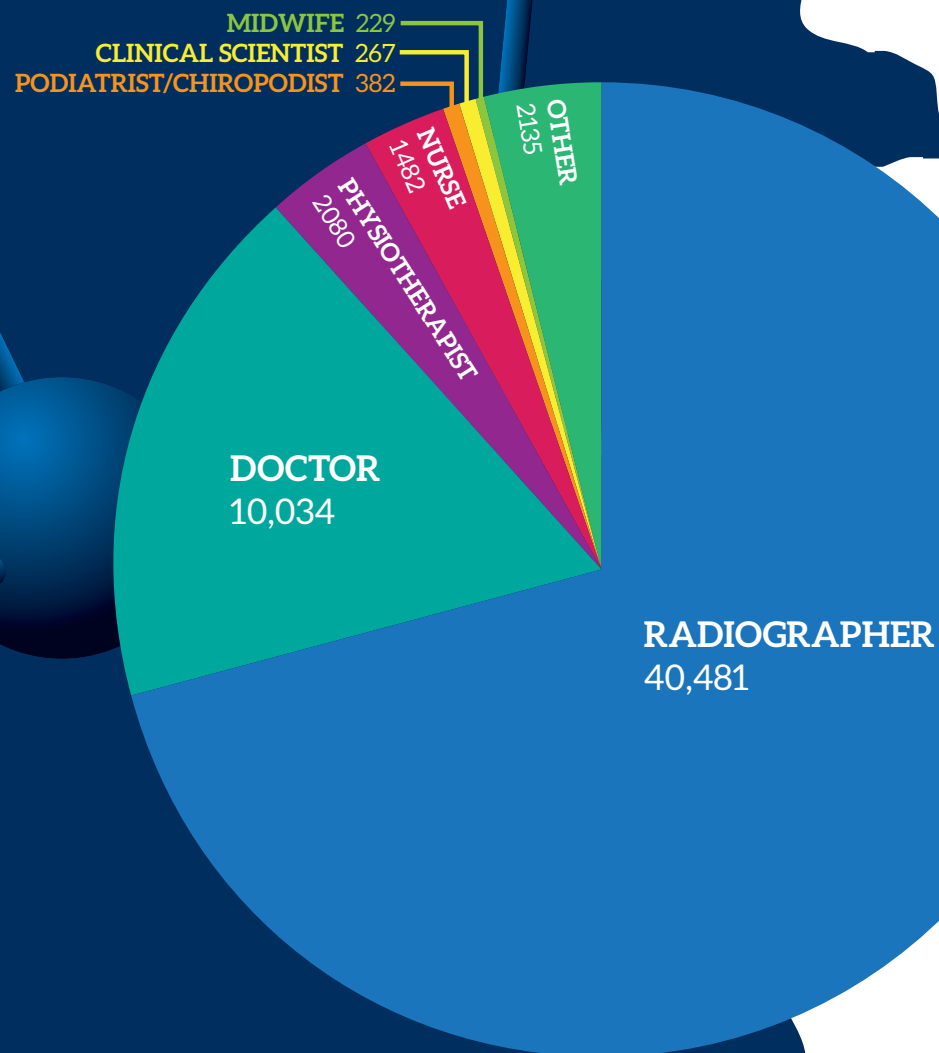


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With additional development, the Image Interpretation project could act not only as a continuing education tool, but also as an assessment tool to help measure competency

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e-Learning for Healthcare is an extensive resource developed in partnership with a spectrum of academic partners and professional bodies



▲ Figure 1: Activity by Professional Group on the Image Interpretation project.

reports for decades^{18,19}. There are also growing numbers of radiographers who provide clinical reports for CT head²⁰, mammography^{21,22} and MRI examinations^{23,24}.

Image interpretation as part of the e-Learning for Healthcare program

Education for radiographers, both in image interpretation itself and in how to accurately communicate findings to clinicians using appropriate terminology, has been identified as fundamental to radiographers participating in PCE^{15,16}. Traditionally, image interpretation training for radiographers consisted of workplace learning or intensive short courses, however growing demand coupled with funding and time pressures meant that a different approach was needed. The Image Interpretation program, an online learning tool, was created to provide a comprehensive educational resource which, in conjunction with local mentorship and work based learning, supports PCE.

E-learning, the delivery of education or training flexibly online, is a growing mechanism for the delivery of training, and healthcare is no exception^{16,25}. In response to the ever increasing demands of continuing professional development for radiographers, and in a drive to improve patient care through the accurate evaluation of radiographic images at time of acquisition, the College of Radiographers and the Department of Health (now Health Education England) developed an interactive, online education resource for image interpretation as a discrete section in the award-winning e-Learning for Healthcare program²⁶. The complete e-Learning for Healthcare program is an extensive resource, developed in partnership with a spectrum of academic partners and professional bodies, including the Royal College of Radiologists, Royal College of General Practitioners, and Institute of Physics and Engineering in Medicine, and covers a vast array of healthcare learning.

The concept of the Image Interpretation program was developed in 2009, in joint discussions between the College of Radiographers and the Department of Health. Sessions, or small units of learning, have been authored by subject matter experts; senior clinical radiographers, academic radiographers, radiologists, medical physicists, emergency physicians, midwives and other healthcare professionals, using a standardised structure and content to ensure consistency across the program. Modules, comprising multiple sessions grouped by topic, for example obstetric ultrasound, are co-ordinated by module editors who facilitated peer review of every session. This has ensured consistency, accurate content and high quality learning. This rigorous process has produced an acclaimed resource to facilitate image interpretation that is available to all NHS practitioners, not just radiographers, free of charge. The content is highly relevant, not only to radiographers but to all healthcare professionals, who are required to evaluate images in order to deliver appropriate care, such as emergency nurse practitioners, nurse consultants, junior medical staff, anaesthetists, midwives and physiotherapists. These sessions offer an opportunity for new learning for novices or provide a 'refresher' and continuing professional development resource for more experienced staff.

The initial Image Interpretation project development consisted of 50 sessions covering plain imaging of the adult axial and appendicular skeleton. Further divided by body region, these sessions provided a comprehensive review of anatomy, mechanisms of injury, image evaluation and pathologic radiographic appearances. These beginnings have now developed into a substantial educational resource on image interpretation, with 284 sessions currently available, growing to more than 300 by July 2015. The entire spectrum of plain imaging has been covered, with 40 sessions covering the paediatric skeleton, 10 sessions on the adult chest, eight sessions

on the adult abdomen and 14 paediatric chest and abdomen sessions. To facilitate new staff beginning their specialist rotations, introductions to the specialist modalities have been constructed, including CT of the head and cervical spine, MRI of musculoskeletal system and internal auditory meati, and nuclear medicine. Breast imaging has also been covered, with 13 sessions including interpretation of pathology demonstrated on ultrasound, mammograms and MRI, and sessions on screening, quality assurance and anatomy.

The e-learning modules can be accessed through the e-Learning for Healthcare Learning Management System (e-LfH LMS) or the National Learning Management System. On the e-LfH LMS alone, since the first skeletal modules were launched, more than 20,000 registered users have accessed the training and have spent the equivalent of nearly 900 days engaged in interactive learning. Over 52,000 sessions have been accessed, with skeletal image interpretation accounting for the majority of sessions undertaken (37,000). Adult sessions have proved the most popular, reflecting the majority of the imaging workload of many radiographers, however 3000 sessions covering the paediatric skeleton have also been used. The multidisciplinary reach of the Image Interpretation project, supporting the learning of all health professionals, is demonstrated in the spectrum of professions who have used the program, including medical students, specialist registrars, physiotherapists, nurses, midwives, paramedics, podiatrists as well as radiographers (*figure 1*). (e-Learning for Healthcare activity data 2010-January 2015).

The importance of imaging in suspected cases of non-accidental injury (NAI) has been reinforced with recent high profile cases²⁷. In order to support radiographers undertaking such examinations, dedicated modules covering forensic imaging and non-accidental injury were developed to explain the principles behind these examinations, to reinforce the need for high quality images and to alert radiographers to findings suspicious for NAI when undertaking paediatric x-ray examinations so that appropriate escalation can be instigated. These dedicated sessions have been completed over 1400 times (880 paediatric NAI accesses and 580 for forensic imaging) on the e-LfH LMS.

The ultrasound aspect of the program was first launched in 2012 with sessions covering gynaecological and abdominal examinations, men's health and vascular ultrasound. The scope has further increased in 2013, with content covering obstetric and musculoskeletal applications. This will support not only sonographers expanding their role, but also extended scope physiotherapists and medical staff who require an increasing level of knowledge in their practice. Ultrasound has proved popular with 6500 sessions completed. Obstetrics, gynaecology and abdominal modules are accessed most frequently.

The value of Image Interpretation

One of the radiographer specific competencies required upon registration with the Health and Care Professions Council (HCPC) is set out as 'be able to distinguish disease and trauma processes as they manifest on diagnostic images'²⁸. This clearly pertains to the evaluation and interpretation of images and, since 2006, the College of Radiographers²⁹ has expected undergraduate education programs for radiographers to ensure that at qualification radiographers are competent to provide written preliminary comments on specified imaging examinations. This should mean that newly qualified radiographers at the point of registration with the HCPC, now have the underpinning education and training to begin to participate in preliminary clinical evaluation. To support students to meet this professional requirement by the time of qualification, the Image Interpretation


project was made available to undergraduate student radiographers and their lecturers in 2013.

The HCPC's Standards of Proficiency²⁸ are mandatory for all radiographers, as are their Standards for Continuing Professional Development³⁰. These, coupled with the requirement for evidence-based care by the College of Radiographers³¹, stretch the limits of traditional methods of workplace learning. Additionally, ever increasing departmental activity and current austerity constraints, limit the ability to release radiographers for short courses and conferences. The use of online learning overcomes many of these limitations and is becoming more frequent in the delivery of radiology training. The flexibility that e-learning can provide through easy access to training materials from any computer at any time, is a key asset and turns a free moment between patients into a meaningful learning opportunity. With each image interpretation session taking an average of 24 minutes to complete, this serves as a perfect example of opportunistic learning in manageable chunks. It also suits a sizeable number of radiographers according to a recent analysis, which found similar preferences in a cohort of qualified radiographers between staggered, incremental learning and short, intensive education when undertaking image interpretation¹⁶.

The need for continued learning to maintain performance and confidence in image interpretation and PCE has been identified¹⁵. McConnell and colleagues found a reduction in abnormality detection accuracy of radiographers six to ten weeks following an intensive training program^{32,33}, mirroring the study by Mackay, who demonstrated declining radiographer performance six months after completion of image interpretation training³⁴. This is a recognised phenomenon and is not limited to image interpretation by radiographers or other health professionals. For example, one of the reasons for strict ongoing training in the aviation industry is to minimise this phenomenon³⁵. The Image Interpretation project, with its flexible online delivery platform, provides an excellent resource for radiographers and others to maintain their knowledge and skills. With additional development, the Image Interpretation project could act not only as a continuing education tool, but also as an assessment tool to help measure competency. This would require ongoing resources to develop and maintain appropriate test banks, but is something that could be achieved and should be considered.

The Image Interpretation project was designed primarily to improve abnormality detection skills of radiographers, and support and facilitate preliminary clinical evaluation by radiographers at the time of image acquisition. However, the program was not designed to train reporting radiographers in the provision of definitive clinical reports, and it is important to recognise this limitation. Reporting radiographers have completed accredited Masters level education, incorporating robust structured clinical examinations¹¹. Similarly, none of the sessions is designed as a 'how to' or DIY training program. For example, one cannot learn technique from the ultrasound sessions, although they offer many useful tips on image acquisition and image optimisation. Again, staff using ultrasound must have completed formal accredited training. The end of current project development is due to be completed in the summer of 2015 and it will then cover the spectrum of diagnostic imaging investigations. Work will not stop at that point however, with an acknowledged need to review and update all learning sessions on a regular, planned schedule, and to add new sessions as new imaging investigations or developments to current investigations occur. Additionally, if the resource is to provide ongoing self-assessment and ongoing competence assessment, further self-test and new assessment testing learning units are needed.

Finally, there is also the need to further promote use of the resource, both to radiographers and to all healthcare professionals who need to understand and/or evaluate the outcomes of imaging investigations. As with all



Radiographer preliminary clinical evaluation and clinical reporting remove barriers to delayed diagnosis

e-learning resources, active promotion is required to raise awareness of this fantastic resource, to maximise use and facilitate improved patient care.

Conclusion

The Image Interpretation project is a substantial resource for practitioners, offering flexible learning in key areas of image interpretation. Improved interpretation skills will contribute to streamlined patient pathways, efficient use of resources and assist in the delivery of a patient focused NHS. e-Learning for Healthcare's award winning pedigree, coupled with content produced over many hundreds of hours by nationally and internationally renowned practitioners and academics, validate the high quality learning available, and the project should act as a barometer by which other programs are judged.

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MHRA MRI safety guidance: Review of key changes and emerging issues

David Grainger

In November 2014, seven years after the previous edition, the Medicines and Healthcare Products Regulatory Agency (MHRA) published the 4th edition of the magnetic resonance imaging (MRI) safety guidelines¹. MHRA now publishes only in electronic form to minimise costs, make it easier to update the content and make it easier for the MRI community to access.

Two stories in the press at the time of its publication highlighted the need for continuous vigilance within the MRI department.

In the first incident², a large oxygen cylinder was accidentally brought into the MRI room by an untrained member of staff and was drawn to the scanner, trapping and seriously injuring two members of staff. This was compounded by the inability of the site to quench the system and release the trapped staff for four hours. It was found that the emergency quench button had been disabled at this site. The manufacturer subsequently launched a worldwide action to check functionality at all sites³. A key message from this story is the importance of ensuring all staff are aware of the hazards and that access to the scanner is controlled.

In the second incident⁴ a patient's knife flew out of his pocket and hit him in the eye causing an orbital fracture. Patients should be screened for metallic items and changed into appropriate clothing provided by the MR unit before entering the room.

Key changes to the guidance

External reference changes

A number of reference documents had been updated since publication of the third edition, notably the Health Protection Agency's *Protection of Patients and Volunteers Undergoing MRI Procedures* in 2008⁵, the International Commission on Non-ionising Radiation Protection's (ICNIRP) amendment to its statement on MRI procedures in 2009⁶ and IEC's equipment standard for MRI systems – IEC 60601-2-33 edition 3.0 in

2010⁷. These recommendations have led to an increase in the upper field strength for normal mode scanning to 4 Tesla (T) from 2.5T.

Other documents that have changed and are referenced in the guidance include:

- Guidelines on limits of exposure to static magnetic fields⁸;
- Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz)⁹;
- Guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz¹⁰;
- Safety in Magnetic Resonance Imaging¹¹;
- Guidance document on MR safe practices¹²;
- Standard F2503-13¹³.

Pregnant patients

There is little evidence of harm from magnetic fields or noise and we now recommend scanning should be based on clinical criteria and completed in normal mode, whenever possible. In normal mode the scanner uses low magnetic fields and the risk of ill effect to the patient is minimised.

MR safety expert

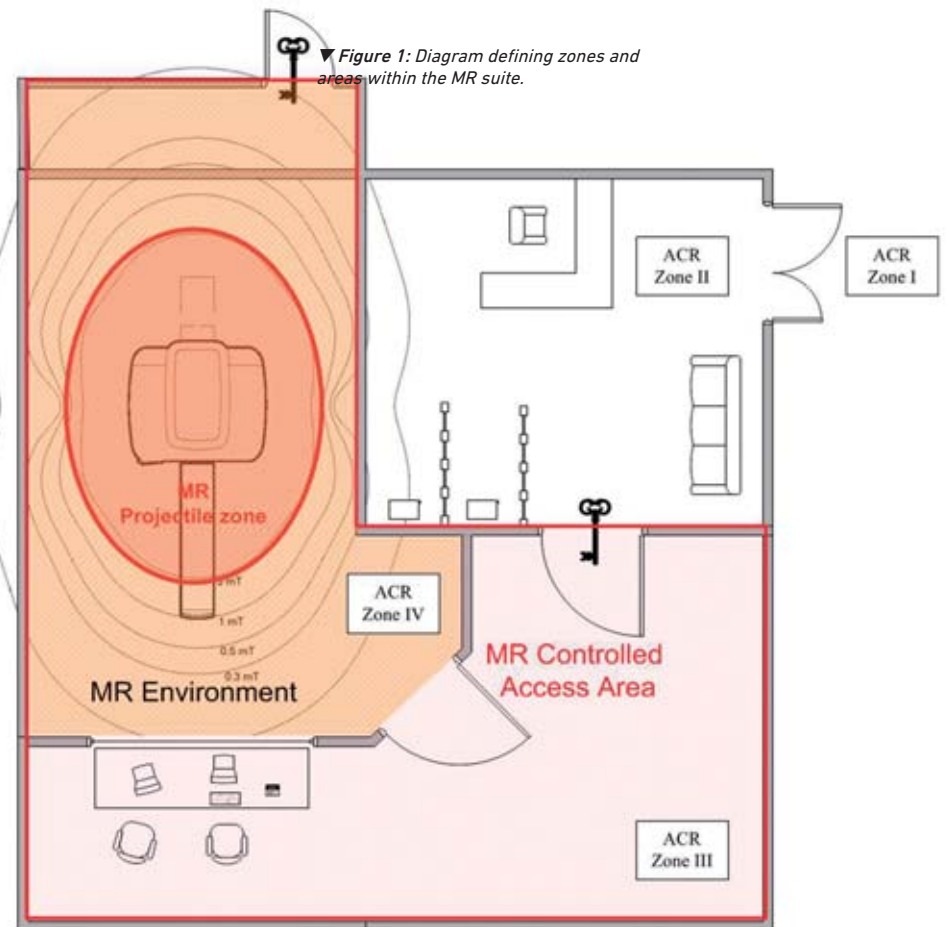
Notable changes are the renaming of 'MR safety advisor' to 'MR safety expert'. This followed publications by EFOMP¹⁴ and IPEM in the UK¹⁵ and mirrors the case of ionising radiation where two levels, an officer level and an expert level, are required.

Defined safety areas

Comments received whilst drafting the new guidance showed a general dislike for the definitions and inconsistent use of 'MR controlled area' and 'MR inner controlled area' in the existing document. It is anticipated that the introduction of the term '**MR controlled access area**', defined such that it contains the '**MR environment**' and that access is controlled, will be clearer. The term 'inner MR controlled area' was

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There is little evidence of harm from magnetic fields



replaced with the optional 'MR projectile zone' which can be linked to the 3mT magnetic field contour. This is the relevant static field action level given in the Physical Agents Directive. These areas are shown in figure 1, as are the American College of Radiology recommended zones for comparison.

MR authorised personnel

Another common area for concern was the issue of access to and supervision in the MR controlled access area and the relevant training requirements. This was considered to be a particular issue for staff that need to enter the MR controlled access area but do not need to enter the MR environment.

It is important that staff working within an MRI unit are suitably trained and aware of their responsibilities for the safety of themselves and others. The guidance has introduced three categories of MR Authorised Personnel:

- MR authorised person (non-MR environment)
- MR authorised person (MR environment)
- MR authorised person (Supervisor)

This may help to better reflect working practice and clarify responsibilities. Access and supervision rights are summarised in figure 2.

Training

The training requirements for staff entering the MR controlled access area has been updated, with the addition of a requirement that operators are fully aware of the relevant content of the MRI instructions for use. This is important in terms of the Physical Agents Directive as its MRI exemption requires that the instructions for use are followed. For staff that enter only the MR controlled access area and not the MR environment, a requirement to remain aware of the location of the MR environment and its hazards has been added.

MR conditional implants

The guidance was also updated to be consistent about when patients with MR conditional implants can and cannot enter the MR controlled access area. Entry is allowed if the device is an MR conditional device and the operator has confirmed that all of the implant manufacturer's stated conditions for safe operation are met.

Ferromagnetic material detectors

Ferromagnetic detection systems are intended as ancillary screening devices and are not intended to be used as a replacement for traditional safety programs, training or primary screening methods, but as a complementary tool. We recommend that the layout configuration of the MRI suite should include provision for the siting of ferromagnetic detection systems.

Physical Agents (electromagnetic fields) Directive

Since 2002 there has been concern in some quarters around the potential threat the Physical Agents Directive is to MRI. It was introduced under the Workplace Health and Safety Directive to protect workers from various

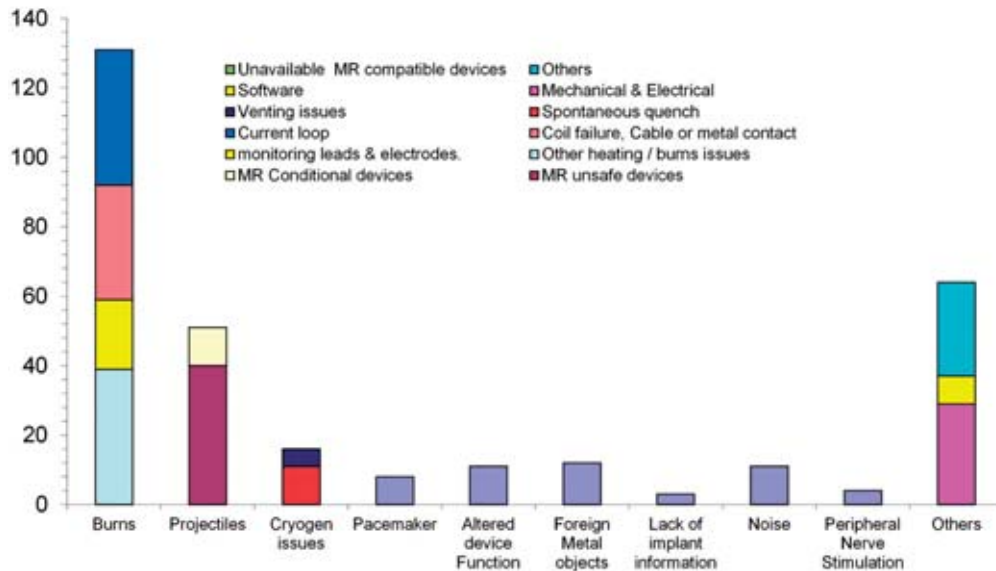
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Increasingly, we are seeing patients reporting MRI issues to us directly

► Figure 2: Table of access and supervision rights.

	Area	
	MR environment	MR controlled access area outside the MR environment
MR authorised person (Non-MR environment)	May not enter without supervision	May enter and supervise
MR authorised person (MR environment)	May enter	May enter and supervise
MR authorised person (Supervisor)	May enter and supervise	May enter and supervise

▼ Figure 3: MRI incidents reported by type over 22 years.



physical agents including noise, vibration and artificial optical radiation.

The directive took guidance values from ICNIRP, which included a large safety factor below levels that may cause adverse health effects, and used them as the limits for exposure. It was published in 2004 amid growing concern from the MRI community. Action in the UK by the charity Sense about Science¹⁶ and the formation of 'Alliance for MRI' in 2007¹⁷ led to lobbying of Members of the European Parliament (MEPs) and the European Commission against the directive. Research commissioned by the Health and Safety Executive¹⁸ had shown that anyone standing within about one metre of an MRI scanner while acquiring images would exceed the exposure limits and that staff walking as slow as 1m/s close to an MRI scanner (approximately one metre) would exceed the limits, even when it was not in use.

In 2007 the commission announced that implementation of the directive would be delayed for four years to allow further research into the potential impact. In 2012 an extra extension of 18 months was given to the implementation date.

The final directive was published in June 2013¹⁹ and includes a conditional exemption for the use of MRI equipment for patients in the health sector. A second exemption is available to member states for 'duly justified circumstances'. This may include veterinary MRI.

The exemptions apply only to the exposure limit values. All other requirements such as performing risk assessments, protecting workers with implanted devices, provision of information and training will still apply.

Our guidance has included minimal information about this as a non-binding practical guide will be published by the European Commission later this year, which will contain specific information for MRI. Some changes have been made to the guidance that are consistent within the text of the directive, specifically:

- Introduction of the MR projectile zone to align with the relevant static field action level given in the Directive;

- Addition of an extra training requirement for MR operators to be fully aware of the relevant content of the MRI instructions for use. Following the equipment instructions is one of the key conditions of the MRI exemption.

Reported incident data

We currently receive between 15-25 MRI incident reports a year. In comparison, in 2014 the agency received around 500 reports of issues with all other types of imaging equipment and approximately 14,000 reports for all devices.

Figure 3 shows a breakdown of MRI incidents reported to us by type since 1993. Burns continue to be the most frequently reported issue we see. Increasingly, we are seeing patients reporting MRI issues to us directly.

In Appendix 4 of the guidance we have provided a list of incidents that should be reported to us. It also has a link to the MHRA's new reporting site: <https://yellowcard.mhra.gov.uk>. The Yellow Card Scheme now supports the reporting of all suspected problems or incidents to all healthcare products, not just suspected side effects to medicines.

Emerging issues

There have been a number of reports in the literature²⁰ of patients suffering burns as a result of wearing fabrics containing conductive fibres. These textiles are coated with silver nano-particles for an 'anti-odour' and 'antimicrobial' action, however when the coating is conductive, there is an increased risk of causing skin burns. This is not an issue if patients are changed into appropriate clothing provided by the MR unit, but staff should check for this when screening patients if there is no intention to change clothing.

We have seen reports of delayed or cancelled scans where patients have come to the department with non-MRI conditional monitoring or infusion devices. Sites should have systems in place to ensure that MRI dedicated monitoring equipment can be used appropriately. This may be an issue at sites that have different makes and models in the department to outside the department. Particular issues are:

- The availability (especially paediatric) of spares, consumables and backup devices;
- Training and familiarity of staff with the MR conditional device.

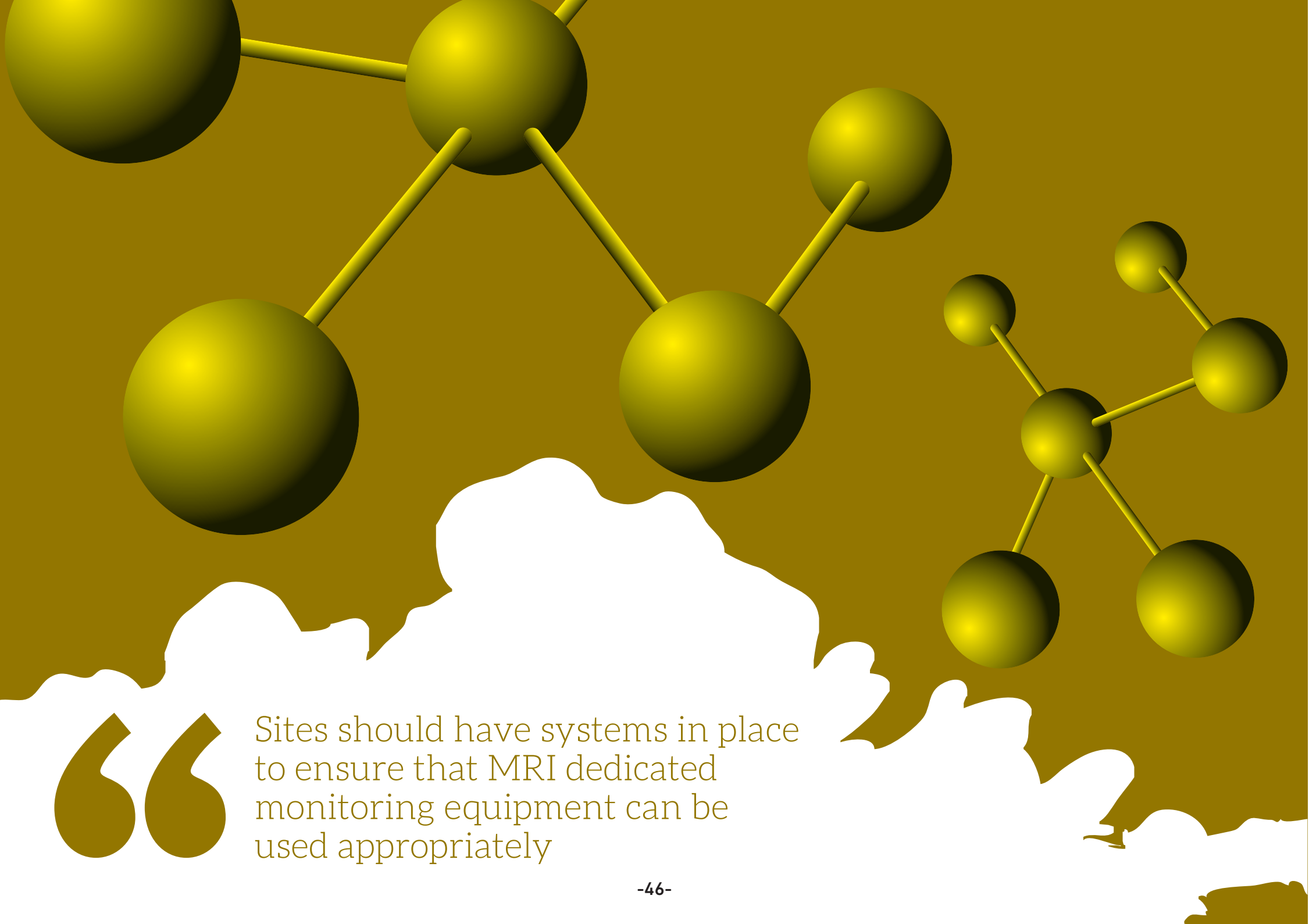
Gadolinium-containing contrast agents

In 2010, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended that further studies should be carried out on the long-term retention of gadolinium in human tissues released from gadolinium-containing contrast agents²¹. These studies were due to be discussed at the CHMP meeting in January 2015²². Recent publications have shown that retention does occur^{23,24} and we encourage sites to report to us on a Yellow Card any suspected adverse reactions, including nephrogenic systemic fibrosis, to gadolinium-containing contrast agents.

Future developments

Scanning patients with contraindicated implants

We have received many requests for advice to users on scanning patients with implants that are not MR



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Sites should have systems in place to ensure that MRI dedicated monitoring equipment can be used appropriately

conditional. Later this year we intend to add a new section giving advice when there is a need to perform an MR examination in the following scenarios:

- the patient has an MR-conditional device but the manufacturer's guidance cannot be met;
- the patient has an implanted device whose compatibility is unknown;
- the patient is implanted with a device known to be MR-unsafe.

Fixed parameter option: Basic (FPO:B) scanning mode

At an international level, active implantable medical device manufacturers and MRI scanner manufacturers have been working on an agreed standard operating mode that can be used to safely scan MR conditional implants. This will be known as FPO scanning.

In this mode, MRI output will be limited for peak and average radiofrequency power, and peak and average gradient switching fields. The initial agreed option, basic, is for 1.5T scanners only. Implant manufacturers can now design devices that can be scanned safely without risk to the patient within these defined limits, and label them as such.

Conclusion

The new guidance produced by MHRA is up to date, consistent and relevant to MRI units today. It provides clarity and may alleviate some previously held concerns. The ability to publish online will allow us to provide relevant and timely advice to MRI healthcare professionals.

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Dual energy x-ray absorptiometry beyond bone mineral density measurement: vertebral fracture assessment

Karen Knapp, Robert Meertens, Lucy Ashton, Susan Hopkins

Osteoporosis is a common musculoskeletal disease in the western world, characterised by reduced bone mineral density (BMD) and micro-architectural deterioration, resulting in an increased risk of fragility fracture¹. Osteoporosis is associated therefore, with significant morbidity and mortality, and remains a major burden for sufferers and healthcare services^{2,3}. The incidence of fracture is considerable, with one in two women and one in five men over the age of 50 sustaining a fracture during their lifetime in the United Kingdom (UK), the majority of which result from osteoporosis⁴

Dual energy x-ray absorptiometry (DXA) is the gold standard for the diagnosis of osteoporosis⁵ and provides an important element of fracture risk assessment. DXA is currently the only imaging technique for the diagnosis of osteoporosis which has a wide evidence base and standard diagnostic criteria⁶. However, the technique is not without its limitations, both in the diagnosis of osteoporosis and in the monitoring of disease progression or therapeutic intervention⁷. Firstly, not all patients diagnosed with osteoporosis using DXA will go on to fracture, whereas conversely the majority of fractures occur in women diagnosed as osteopenic (low bone mass) or as normal by BMD criteria⁸. The potential for spurious results or uninterpretable scans to lead to inappropriate management advice is a frequent problem⁹ and incorrect DXA scanning technique or interpretation can lead to treatment mistakes¹⁰. Furthermore, the populations seen by DXA services are changing, with an increased incidence of secondary osteoporosis resulting from a multitude of causes such as oncological treatments, glucocorticoid use, transplants, gastrointestinal

disorders, neurological disorders and diabetes^{5,11-17}. Different clinical populations are at risk of fracture at different BMD levels and therefore alternative diagnostic thresholds have been developed for particular populations^{17,18}.

Changing populations and increasing levels of obesity¹⁹ have also had an impact on services. Obesity has generally been considered as protective against osteoporosis, largely due to the positive correlation between body mass index and BMD²⁰ and as such, low levels of obese patients were generally seen in DXA services. However, obesity is now known to be related to an increased fracture risk and this is likely to lead to increased numbers of obese patients being seen within DXA services^{21,22}. Obesity can increase precision errors in both bone and body composition measurements when using DXA, and this provides challenges for longitudinal monitoring of obese patients using this modality^{23,24}. Since DXA, despite its limitations, is currently the most available and appropriate tool for diagnosis of osteoporosis, methods to improve the prediction of fracture using this technique have been widely researched³. Clinical risk factors (CRFs) have been demonstrated to predict fracture risk and the opportunity is available to combine BMD results with assessment tools for CRFs, such as FRAX, which provides more accurate fracture risk prediction and can provide a ten year fracture risk assessment^{3,8}.

Fracture prediction can be further improved through identifying the presence of vertebral fractures, a strong predictor of future fracture. DXA affords the ability to undertake imaging for vertebral fractures, while still maintaining a low radiation dose. As a result, the use of vertebral fracture assessment (VFA) is growing in the UK but is still limited, with not all departments having the resources or pathways to implement this useful tool. In some patient groups such as women over 70 and men over 80 with osteopenia²⁵ VFA is an important addition to standard lumbar spine and proximal femur BMD measurements, and one which can help to optimise therapeutic interventions²⁶. Furthermore, in some patients where standard DXA measurement sites are impossible due to fractures, surgical implants or other artefacts, the combination of VFA, with clinical risk factors can provide a better assessment of fracture risk than clinical risk factors alone.

Vertebral fractures – epidemiology

It is estimated that one in twelve men and one in six women will suffer a symptomatic vertebral fracture during their lifetime²⁷, and with the prevalence of osteoporosis predicted to increase by 2021, a rise in fractures will also be realised²⁸.

Vertebral fractures (*figure 1*) pose a significant public health burden with 8% of these patients requiring hospitalisation and 2% requiring long-term nursing care²⁹. They are associated with both increased morbidity and mortality^{30,31}, with significant pain, functional disability, reduced quality of life, gastro-intestinal symptoms, height loss, depression, breathing difficulties and an increased risk of further fractures^{27,32,33}. Peri- and postmenopausal women who have prevalent vertebral fractures have double the risk of sustaining subsequent fractures³⁴. The risk of incident vertebral fractures also increases with the number of prevalent vertebral fractures; the relative risk increasing from 3.2 to 23.3 for one to three or more prevalent vertebral fractures respectively³⁵. One in five women with an incident vertebral fracture will suffer a further vertebral fracture within a year³⁶. These risks can be mitigated through treatment. For example, a 65 year old female with one vertebral fracture has a 25% chance of sustaining a further fracture within five years, but this can be reduced by half with bone-sparing therapies³⁷. However, not all fractures will come to clinical attention and therefore methods are required to identify those with sub-clinical and missed vertebral fractures³⁸.

Vertebral fracture diagnosis

The severity of the negative outcomes associated with vertebral fracture means they are clinically important to detect and report, in order for appropriate treatment to commence. Schousboe et al reported a vertebral fracture prevalence of 20% in an elderly population, leading to their recommendation that lateral spine imaging should be considered in all Caucasian women over the age of 70 years who have low bone density³⁹. Many fractures are clinically silent, whereby patients either do not present to their general practitioner, or are not referred for imaging; other patients have vertebral fractures that are not detected from radiographs or are reported using ambiguous terminology; all of which result in under-diagnosis of vertebral fractures^{38,40,41}. In 2000, it was estimated that less than 30% of vertebral fractures are diagnosed, thus improved strategies to identify those with vertebral fractures are of particular importance⁴². Exploratory imaging in women over 70 to identify prevalent vertebral fractures could therefore be argued as appropriate. However, the use of routine radiographs for the diagnosis of vertebral fractures is associated with a significant radiation burden and is therefore only appropriate for those in whom there is a high level of clinical suspicion. DXA scanners can be utilised to obtain a single lateral or a lateral and a postero-anterior image of the spine from T4 to L4 for VFA.

VFA has a significantly reduced dose when compared to a thoracolumbar projection radiography series⁴³ and reportedly has a high degree of accuracy with regard to fracture diagnosis. In practice, this can allow for the identification of vertebral fractures in those with previously unknown fractures and thus alter management^{26,44}. VFA has been reported to have comparable performance to radiographs for identifying vertebral fractures in community dwelling older adults, particularly if mild fractures are excluded^{45,46}. Vertebral fractures from VFA can be graded using one of a number of scales based on ratios of vertebral height and the pattern of height loss within the vertebrae^{46,47}. From these scales, fractures can be generally



▲ *Figure 1: Projection radiograph of typical osteoporotic vertebral fractures and demonstrating x-ray osteopenia.*

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The use of vertebral fracture assessment is growing in the UK but is still limited



▲ Figure 2: GE Lunar Prodigy dual energy lateral vertebral assessment scan, utilising morphometric software to indicate fracture presence and grade.

classified by severity (mild, moderate or severe) and type such as wedge, biconcave and crush fractures⁴⁷⁻⁵⁰. Varying degrees of accuracy are reported⁴⁶ and the semi quantitative scale (figure 2) is the currently preferred method for grading vertebral fractures from VFA^{47,51}. Since not all patients who have a vertebral fracture are identified as having osteoporosis by DXA⁵², VFA can provide a useful addition to the DXA series and using VFA in practice increases the number of patients requiring therapeutic intervention for osteoporosis^{52,53}.

Vertebral fracture assessment within a DXA service

DXA-based VFA provides an attractive, low dose method for detecting vertebral fractures in the typical populations seen in bone densitometry services and provides a high level of accuracy, particularly in moderate and severe fractures. While it is likely to be cost effective and appropriate to undertake a VFA on all Caucasian women over the age of 70 with a low BMD, as recommended by Schousboe et al³⁹, the risk of vertebral fracture in the younger population is significantly less and therefore time and resources are not best targeted at low risk patient groups⁵⁴. Furthermore, there are training and financial implications if a DXA service wishes to offer VFA as part of their pathway. While VFA is frequently not commissioned in the UK, some services are developing their patient pathways to include this additional measurement where indicated and this appears to be an increasing trend. Training is required to ensure that all staff are suitably qualified and experienced to undertake the extended remit of VFA scanning⁵⁵. Each scan adds extra time and financial costs to the overall examination and for reporting of the VFA scans. In addition to the financial burden, it is important to consider the added radiation dose associated with VFA. On the spectrum of radiation doses used in clinical imaging, DXA and VFA result in very small doses in the microsievert range and by definition are considered to be 'trivial'^{46,56}. However, under the ionising radiation (medical exposure) regulations (IR(ME)R), all radiation exposures in patients for medical reasons must be justified⁵⁷. Therefore, undertaking VFA in a population who are at a low risk of vertebral fracture and without a level of clinical suspicion of a fracture is inappropriate and in breach of IR(ME)R. Robust protocols for patient selection are therefore essential for the use of VFA.

In patients who undergo VFA, where a vertebral fracture is identified on the scan, projection radiographs are recommended to characterise the fracture and exclude any other underlying pathologies. Osteoporosis and other reasons for pathological fracture are not mutually exclusive and therefore other pathologies should be excluded in patients where a fracture is identified^{25,58}. Furthermore, VFA has poor accuracy for detecting mild vertebral fractures^{46,48} and further imaging may be required to confirm an equivocal fracture. Other congenital and developmental pathologies can mimic fractures, particularly with the poorer resolution on VFA compared to projection radiography⁵⁹. Further imaging may be required to differentiate between non-fracture deformities such as Scheuermann's disease, degenerative changes, or to examine for another fracture-causing pathology, such as malignancy or Paget's disease of bone²⁵. This follow-up imaging may include projection radiography, magnetic resonance imaging, computed tomography, nuclear medicine or PET-CT depending on the pathology suspected⁵⁸.

The International Society for Clinical Densitometry recommends undertaking VFA in patients with a T-score of ≤ -1.0 when at least one or more of the following is present: women aged ≥ 70 or men ≥ 80 years;

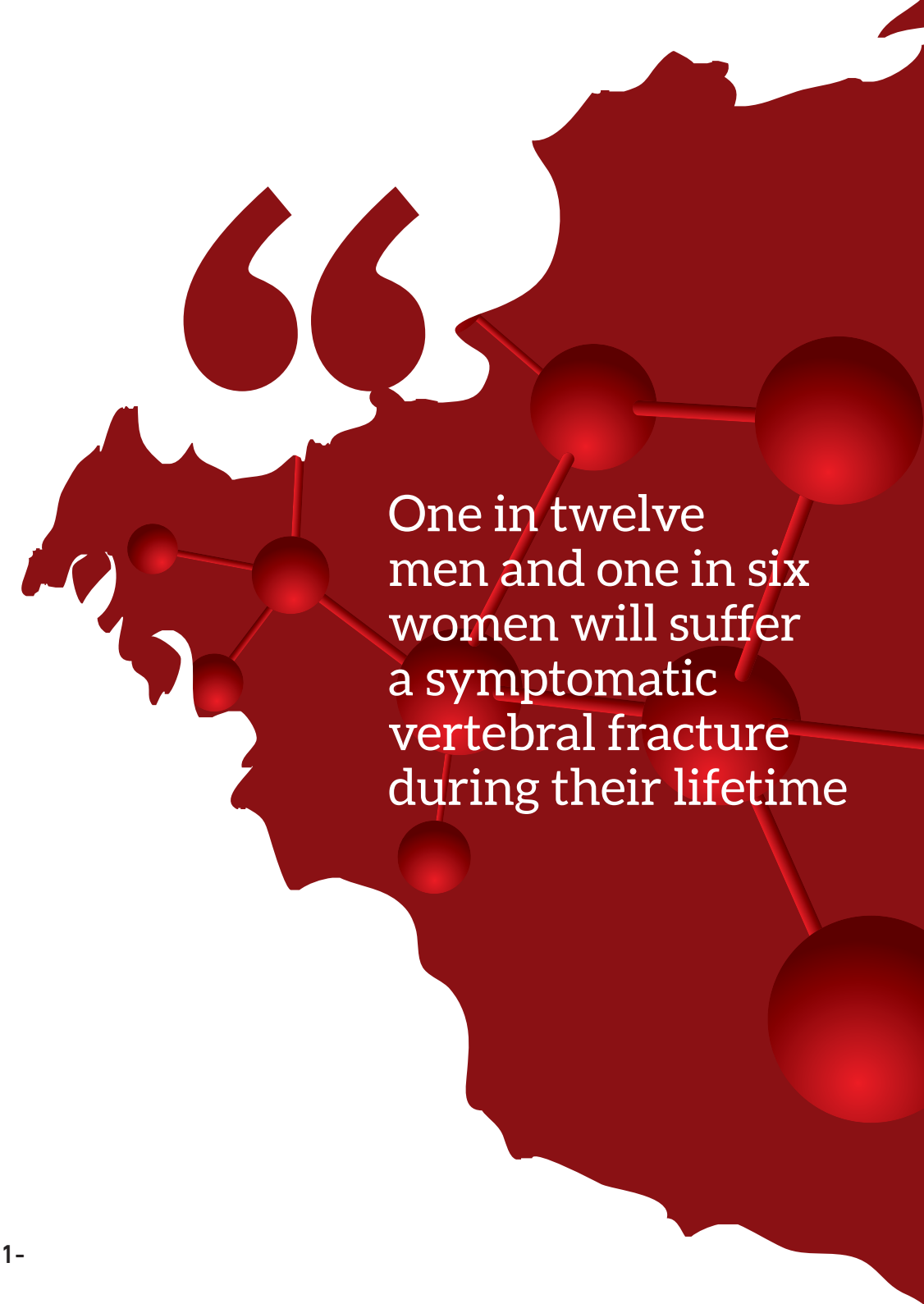
historical height loss ≥ 4 cm; self-reported, but undocumented prior vertebral fracture and glucocorticoid therapy equivalent to ≥ 5 mg prednisolone for \geq three months⁵¹. In practice, adding VFA to a service and scanning those at risk of vertebral fracture can improve targeting of treatment, with a modifiable underlying cause being found in 21% of those diagnosed with vertebral fracture²⁶. Since the presence of a prevalent vertebral fracture is highly predictive of incident fractures, treatment decisions will be influenced by the identification of a vertebral fracture⁶⁰⁻⁶². However, VFA may not be required in patients with documented vertebral fractures unless a change in treatment decision depends on identification of an incident fracture⁶².

Conclusion


The use of VFA enhances DXA services, provides better identification of those who require treatment for fragility fractures and offers additional tools for cases where DXA struggles to achieve an accurate bone measurement. However, VFA is not indicated in all patients attending the service and should be targeted at those for whom epidemiological data demonstrate a heightened risk for vertebral fracture. In this group of patients, the additional costs and burden to the service are outweighed by the overwhelming benefits achieved by the diagnosis of a vertebral fracture. It is therefore an important addition for consideration in DXA services where it is not currently offered.

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Radiologist assistants in North America: How far have we come?

Cindy Petree

The radiologist assistant (RA) is a relatively new role, which has been in place for little more than a decade. Since its inception, the road has been far from smooth not least due to legal inconsistencies across states and among health insurers in recognising the role. However, the continued collaboration of key organisations including the American Society of Radiologic Technologists and the American College of Radiology in support of the role helps to ensure its survival.

This article considers the history and development of the RA. It outlines current scope of practice and discusses the possible future direction for this role.

A radiologist assistant (RA) is defined as 'an advanced level radiographer who could take responsibility for patient assessment, patient education and patient management, perform fluoroscopy and other radiology procedures, and make initial image observations'. This definition was developed by an advance practice advisory panel in 2002¹. The advisory panel consisted of representatives from the American Society of Radiologic Technologists (ASRT), and American Registry of Radiologic Technologists (ARRT), state regulatory agencies, the National Society of Radiology Practitioner Assistants, American College of Radiology (ACR), industry and academic programs. The RA role was created to fill a projected shortage of radiologists, ease the burden of the increase in imaging utilisation, and provide a desirable career pathway for radiologic technologists (the United States equivalent of UK radiographers)².

There are currently 10 RA educational programs in the United States, with the majority of these programs granting master's degrees upon completion. The programs are very similar in content but do vary somewhat in format. Most offer 'hybrid' education, where the student will come to campus for designated periods each semester. There is required book work for each program but most of the learning is obtained in the clinical setting. All programs require students to obtain the same number of clinical hours (approximately

24 hours per week) for five semesters. Only one program organises clinical rotations for the student. The others expect students to have identified their own radiologist preceptor who will have agreed mentoring responsibilities until course completion. RAs must pass a registry administered by the ARRT to earn the title 'registered radiologist assistant'. There are currently 336 registered radiologist assistants in the United States.

The ARRT further defined an entry level radiologist assistant and published its role delineation, eligibility requirements, and examination content specifications in 2005³. In 2012, surveys were sent to all registered radiologist assistants and also the radiologists for whom they worked. This resulted in the second generation document entitled *Entry Level Clinical Activities*, which was implemented in July 2014⁴. This document contains three pages of clinical activities which may be performed by a radiologist assistant. These activities range from physical examinations, non-invasive procedures such as upper gastrointestinal studies, and minimally invasive procedures such as arthrograms.

The role of the radiologist assistant

Radiologist assistant practices can vary considerably between radiology centres. RAs may work in interventional departments or centres doing history and physical examinations, pre-procedure work ups, and post-procedure documentation. My current role consists mostly of performing history and physical examinations for procedures I undertake, consenting patients, barium procedures, cystograms, hysterosalpingograms, arthrograms, lumbar puncture, and myelograms. In addition, I perform paracentesis, thoracentesis, place peripherally inserted central catheters and position central lines. I also do image observation on bone densitometry scans, which go for final approval to the radiologist. All my cases are reviewed by myself and the radiologist before final dictation.

Radiologists who have worked with RAs will likely all agree that an RA can add value to the practice by doing some of the non-invasive and minimally invasive procedures, while the radiologist focuses on more complicated examinations like reading MRI and PET scans. However, the centres for Medicare and Medicaid, which are large government-sponsored programs designed to help meet healthcare costs in the United States, do not recognise the role of radiologist assistant. To them, a radiologist assistant is no different to



The ARRT and ASRT are committed to the success of the radiologist assistant

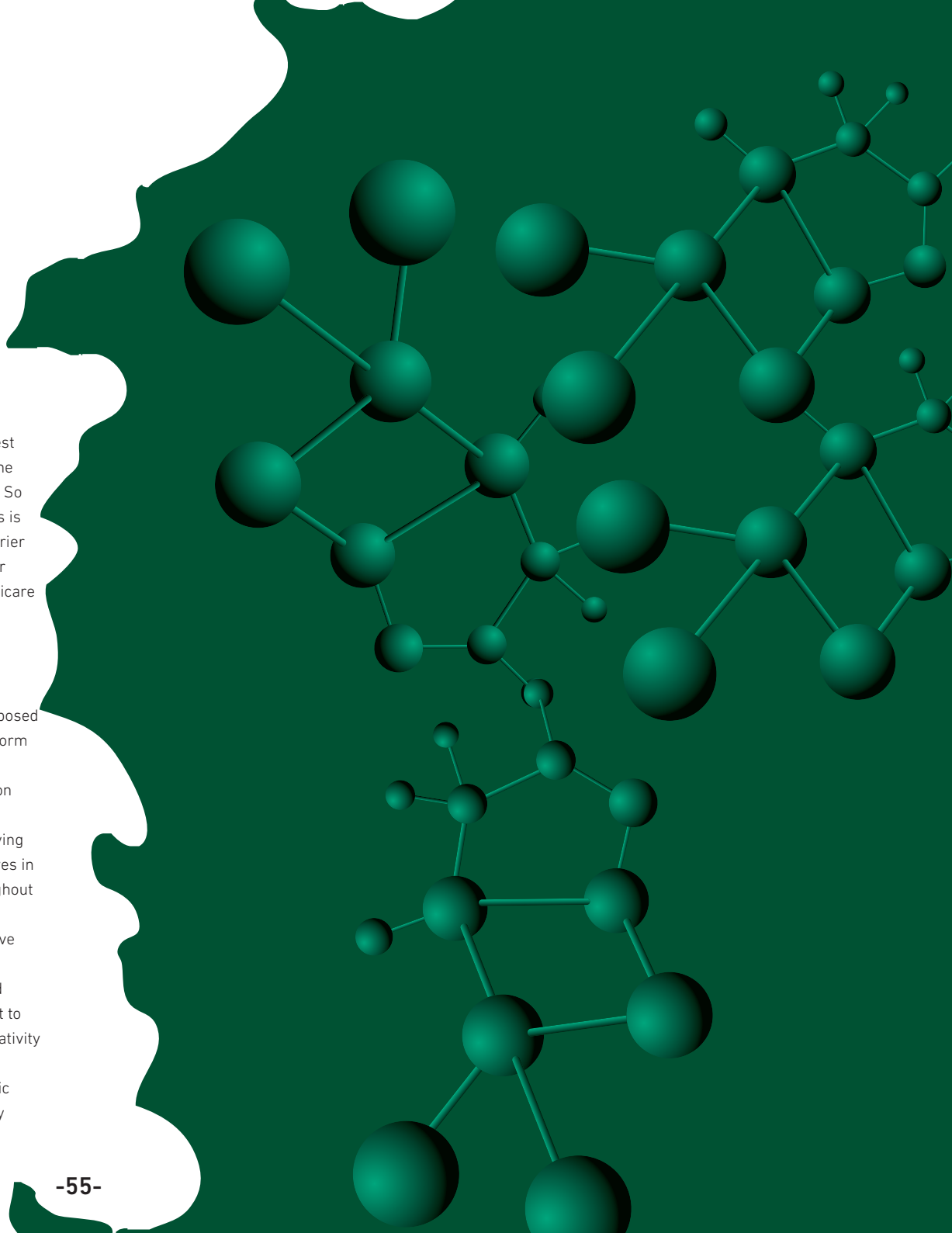
a radiologic technologist, so the supervision of all Medicare and Medicaid procedures is set to the highest level; that of personal supervision. In other words, the radiologist must be present in the room during the performance of the examination or the insurance companies will not reimburse the expenses incurred. So if the radiologist must be present at all times, then why would they hire an RA to do the procedure? This is the question many radiologists' practices and unemployed RAs are struggling with, and is the main barrier to our full utilisation and growth in the field. It is also the reason why many RAs are working below their capabilities. However, some private insurance companies do not have such stringent guidelines as Medicare and Medicaid, therefore RAs can perform procedures on these patients, with the radiologist safe in the knowledge that reimbursement will be obtained.

Working towards federal legislation to recognise the RA

The radiology community is proposing federal legislation, which will solve this problem. Under this proposed legislation, HR 1148, Medicare Access to Radiology Care Act (MARCA), radiologist assistants would perform the procedure with 'direct supervision' and the radiologist would receive 85% reimbursement⁵. This percentage is similar to a nurse practitioner or physician assistant payment schedule. Direct supervision means the radiologist is in the building and readily available.

The ARRT and ASRT are committed to the success of the radiologist assistant and have hired a lobbying firm to help achieve this legislative fix. Grassroots efforts have been going strong and the representatives in Washington DC have been hearing from radiologists, RAs, managers, technologists, and patients throughout the country. It is anticipated that this legislation will be passed soon. Once the legislation passes it will then be up to the 50 individual states to govern how RAs practice. More than half (29 states) already have legislation in place recognising the RA profession, further supporting the need.

Without legislation RAs will continue to struggle to find appropriate employment after qualifying, and university programs are in danger of closing. The lack of recognition makes some radiologists reluctant to hire RAs, not doubting their ability, but doubting the legalities and billing of the profession. Another negativity is that some radiologists see RA students as free labour during their training, but are unwilling to pay them a salary when they qualify, if they cannot do all procedures on all patients. Nevertheless, radiologic technologists are excited about this new advanced clinical pathway and many want to access university courses to become RAs. However, as with many career-advancing opportunities involving formal study,





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qualifying

radiologic technologists would have to limit their 'regular' work schedule to part time at least, to allow for clinical training and studying and some may need financial loans to cover tuition fees. Since only half of RAs are currently working as RAs, many radiologic technologists are not willing to take the risk.

It seems obvious that both Medicare and Medicaid could potentially save millions of dollars and therefore it would be in their interest to recognise the role of the RA (100% reimbursement versus 85% reimbursement = savings for the insurance companies). However, historically when additional healthcare providers, such as nurse practitioners and physician assistants, have been added to the system, Medicare and Medicaid costs increase, since these groups have a tendency to order additional tests such as blood tests and imaging procedures. So this is another hurdle faced by RAs, that of trying to make non-medical legislators understand that staff in radiology generally do not order examinations or make more work. Instead, they carry out what has been requested by others, if deemed appropriate of course. Recognising RAs as suitable healthcare providers would simply improve efficiency of the radiologist and provide him/her additional time to interpret images.

Perhaps fear of litigation is a factor behind the reluctance to recognise RAs. In 2012, \$3.6 billion was awarded against medical malpractice. Medical malpractice lawsuits are relatively common in the United States and are under the authority of the individual states⁶. Several states have enacted a cap on damages. According to the American Medical Association, more than 61% of physicians older than 55 years have been sued at least once. General surgeons and obstetrics/gynaecology specialty physicians are sued most frequently⁷. Radiologists fall near the middle range in types of physicians commonly sued. However, were litigation to be brought against an RA's practice, it would be the radiologist who was named in the case since they are the supervisor at all times.

To date, I am not aware of any litigious situations that have involved an RA but RAs do typically have liability insurance above what a radiologic technologist would carry, which is purchased by the radiologist group employing them. My liability insurance costs \$175 per year whereas my radiologist's insurance costs about \$10,000 per year. I could also purchase additional malpractice insurance separate from my radiologist's should I choose for about \$900 per year, although, arguably, this would be of value only if the radiologists I worked for refused to cover me. Medical malpractice insurance costs and claims vary a lot by state. My state (Indiana) is a relatively inexpensive state compared to most, due to its tort reform imposing a \$1.25 million cap on medical lawsuits.

I feel fortunate to have worked seven years doing what I enjoy as a radiologist assistant but when I think about the future of my career and other radiologist assistants I have more questions than answers. What will the job outlook be five years from now? Will federal legislation pass, allowing us to work to our fullest potential? Will advanced practice, such as the radiologist assistant role, become an option for greater numbers of radiologic technologists? Certainly to improve the chance of widespread adoption, it is vital that members of the profession raise the profile of such roles by belonging to national organisations, increasing their research and publication output, and by presenting at national and international congresses. Some noteworthy topics of RA publication to date include: patient satisfaction with RAs⁸, the value of an RA to a radiology practice^{9,10}, paediatric barium imaging¹¹, and infection control in line insertions¹². These papers span radiologic technologist journals, radiologists' journals, and management publications. Additionally in

2014, in conjunction with the ASRT, we began journal club conference calls every other month with RAs and radiologic technologists. During these calls we discuss and critique publications, discuss current practice, and network with others in the profession.

There are currently 192,000 nurse practitioners and 100,000 physician assistants in the United States. Both of these mid level providers waited nearly 20 years for federal recognition and reimbursement, but now both these professions are strongly utilised in healthcare. RAs and their radiologists can learn lessons from the experiences of these two groups, which may help expedite acceptance of the RA role. I believe RAs have the same potential to become a vital and valued part of the radiology service, but this will not be realised until legislation is passed, forcing the big insurers such as Medicare and Medicaid to recognise us.

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New ultrasound techniques in the assessment of incidental, impalpable, testicular lesions – can radical orchidectomy be avoided?

Franchesca Wotton, Simon Freeman

Scrotal ultrasound is the widely available imaging modality of choice for the assessment of scrotal pathology and remains at the forefront in the diagnosis of testicular cancer.

Whilst some testicular lesions may display characteristic features on conventional B-mode and colour Doppler ultrasound, many lesions are equivocal. Increasing referral for scrotal ultrasound, for a wide variety of scrotal symptoms, combined with improvements in ultrasound resolution, have led to the increased, and often incidental, detection of small impalpable indeterminate lesions, posing a management dilemma. The fear of failing to remove a testicular germ cell tumour (TGCT) has historically led to overtreatment with radical orchidectomy being performed for many patients with benign disease. Newer ultrasound techniques offer the ability to further characterise lesions; contrast enhanced ultrasonography (CEUS) enables improved assessment of lesion vascularity; tissue elastography provides assessment of cellularity by measuring the 'stiffness' of the lesion. Dynamic contrast-enhanced MRI is also an emerging modality to aid differentiating between benign and malignant testicular lesions.

These new imaging techniques could potentially minimise the fertility, endocrine, cosmetic and psychological issues associated with a radical orchidectomy, particularly in the context of benign disease. The purpose of this review, therefore, is to explore the common appearances of intratesticular lesions and in particular focus on the role of new ultrasound techniques in the further characterisation of incidentally discovered, impalpable lesions. Ultimately, can we manage some cases with interval imaging or testicular-sparing surgery (TSS) rather than radical orchidectomy?

The issue

Testicular cancer accounts for 1% of all male cancers in the UK, most commonly affecting young and middle-aged men. B-mode and colour Doppler ultrasound are readily available, non-invasive imaging techniques that are the first-line, and often only, imaging investigation undertaken prior to surgery. Ultrasound is

extremely sensitive in detecting intratesticular lesions and increasingly many small, impalpable lesions are being detected incidentally during conventional testicular ultrasound, performed to investigate a variety of conditions such as infertility, testicular pain or endocrinological abnormalities where clinical examination does not identify a focal testicular lesion. In a series of 4418 men undergoing scrotal ultrasound for infertility, 1% were found to have a sub-centimetre hypoechoic testicular lesion¹. Until recently radical orchidectomy has been the mainstay in the management of all malignant and equivocal intratesticular lesions due to the lack of steadfast ultrasound features that can reliably distinguish benign from malignant lesions². Although the majority of palpable testicular masses are malignant, approximately 80%³ of incidentally discovered impalpable testicular masses are benign. Advocating radical orchidectomy, therefore, as the preferred option for all focal testicular lesions, regardless of their size, presentation and sonographic appearances would result in overtreatment for many patients, with the associated implications for fertility, endocrine function and body image. In many cases, imaging surveillance or testicular-sparing surgical techniques are appropriate rather than radical orchidectomy and are being increasingly advocated, particularly in managing incidentally discovered impalpable lesions³.

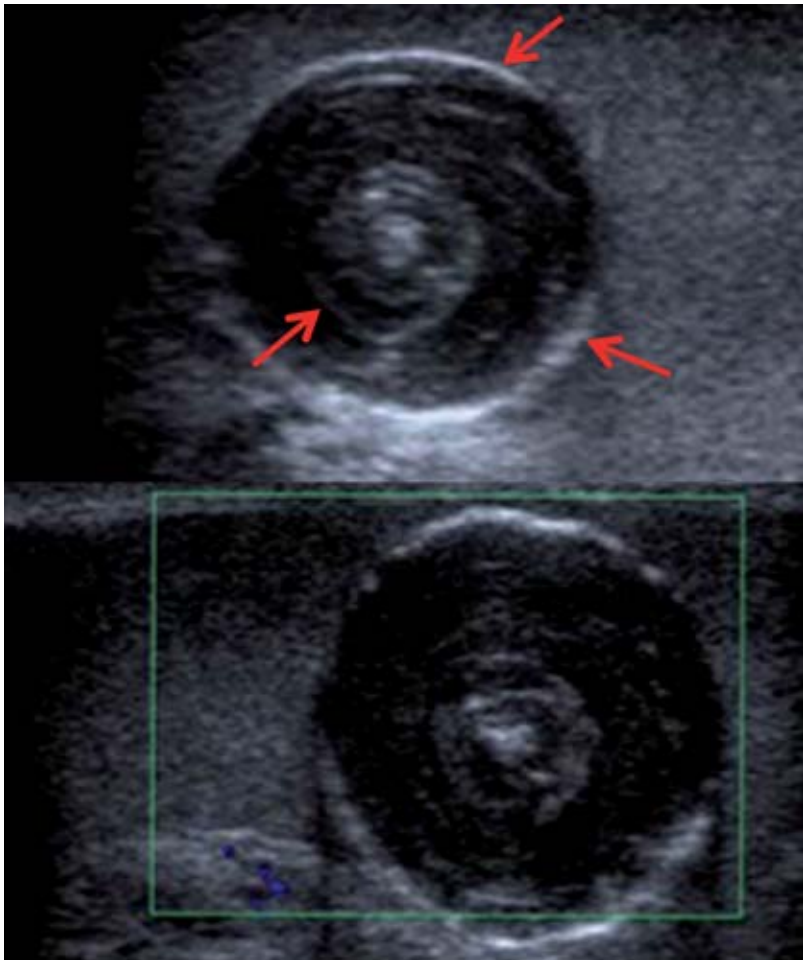
Conventional B-mode and colour Doppler ultrasound

Palpable, rounded and echopoor testicular masses showing evidence of internal vascularity on Doppler examination should still usually be assumed to represent TGCTs, and in this situation radical orchidectomy will usually be recommended.

Certain testicular lesions demonstrate grey-scale features which indicate a benign nature. Epidermoid cysts may demonstrate a characteristic 'onion skin' layered appearance with absent vascularity⁴ (*figure 1*). Simple intratesticular cysts, cystic ectasia of the rete testis and intratesticular varicoceles can be confidently diagnosed by their ultrasound appearances. Wedge shaped avascular lesions without mass effect are likely to represent areas of testicular infarction and can be managed conservatively with interval ultrasound. Uniformly hyperechoic lesions and lesions arising from the testicular tunica are also usually benign and may also be appropriate for interval ultrasound rather than surgical intervention.

“

Until recently, radical orchidectomy has been the mainstay in the management of all malignant and equivocal intratesticular lesions



◀ *Figure 1 A&B: These B-mode (A) and colour Doppler (B) images, demonstrate the classical sonographic appearance of a type 1 epidermoid cyst, showing the concentric 'onion peel' appearance (red arrows) with peripheral calcification but no internal flow on colour Doppler (B).*

In some patients there will be a relevant clinical history that indicates the likely nature of a focal testicular lesion. Examples include intratesticular contusions secondary to trauma, focal orchitis and abscess formation in infection, adrenal rests in patients with congenital adrenal hyperplasia (figure 2), granulomatous masses in patients with sarcoidosis and genitourinary tuberculosis and metastatic tumours in patients with lymphoma or disseminated non-lymphomatous malignancy. Rarely a primary non-germ cell testicular tumour (gonadal stromal tumour) may present with features secondary to tumoural hormone secretion such as gynecomastia.

In many cases however, testicular masses will not have characteristic features or a helpful clinical history; the presence of irregular margins, intra-tumoral calcifications or associated testicular microlithiasis (TML) are all features that indicate an increased probability of malignancy⁵. Lack of vascularity on colour or power Doppler examination increases the probability of a benign aetiology, but blood flow can be difficult to detect within small lesions. In a small series reported in 1992, 86% of tumours smaller than 1.6cm were hypovascular⁶. Colour flow is much more reliably demonstrated in smaller lesions with modern ultrasound systems and absent flow is a reassuring feature in an indeterminate lesion⁷. In all indeterminate lesions, the sonographic findings should be interpreted with knowledge of serum testicular tumour markers (beta-human chorionic gonadotropin, alpha-fetoprotein and lactate dehydrogenase).

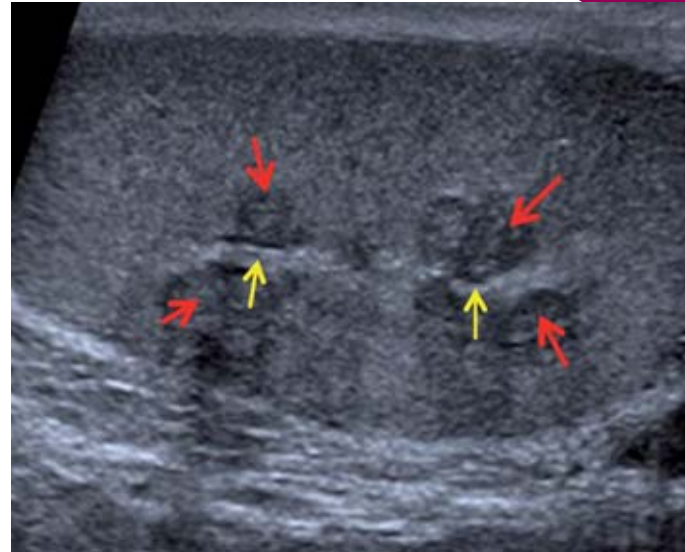
Echopoor, rounded, incidentally discovered impalpable lesions represent the greatest diagnostic challenge, as the majority will have a benign aetiology. However, there are no absolute sonographic features that can differentiate benign from malignant and it is in this group where newer ultrasound techniques are of particular interest.

Contrast-enhanced ultrasound (CEUS)

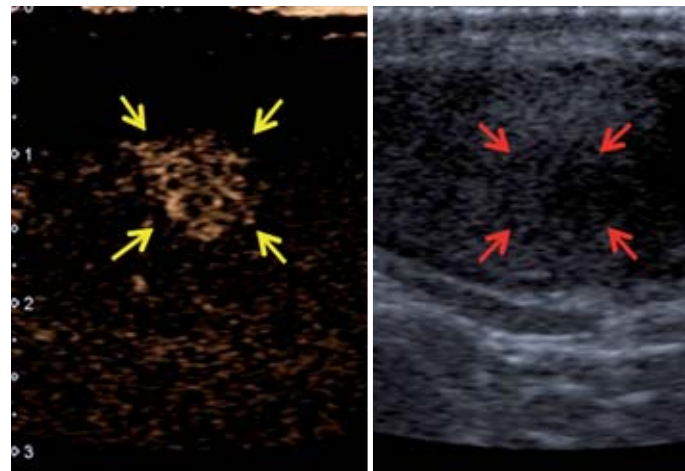
Demonstration of blood flow within hypovascular and small testicular masses may be difficult with conventional Doppler ultrasound. CEUS permits more sensitive demonstration of testicular perfusion through use of microbubble contrast media. Imaging requires specific contrast settings which exploit the harmonic signal generated by microbubble resonance; low acoustic power settings are used to minimise bubble disruption and suppress signal from native tissue. Although B-mode ultrasound is ideally suited to examination of the scrotal contents, the frequency of linear array transducers used for scrotal ultrasound is too high for optimal microbubble resonance; it is often necessary to administer a higher dose of contrast than for abdominal contrast studies and to reduce the transducer frequency to obtain a diagnostic examination.

The advantage of CEUS over conventional ultrasound is increased sensitivity in demonstrating the presence or absence of internal vascularity and particularly to identify those avascular, and therefore likely benign lesions, which could potentially be managed with interval imaging or testicular-sparing surgery. The European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) guidelines⁸ recommends CEUS for this indication. A malignant feature on CEUS is a rapid enhancement with a rapid washout contrast enhancement pattern in comparison to the background parenchyma⁵ (figure 3).

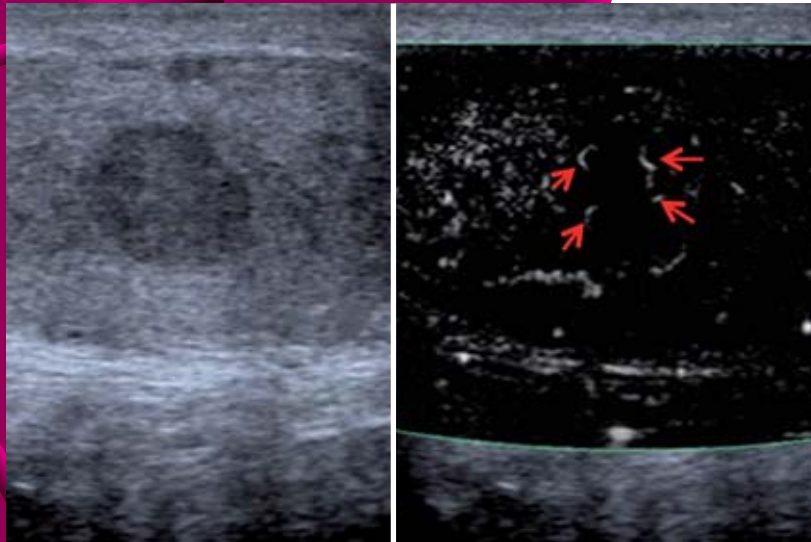
Isidori et al⁵ evaluated 115 impalpable intratesticular lesions and reported the combination of B-mode and CEUS offered a sensitivity of 82% and specificity of 91% in differentiating benign from malignant lesions. Indeterminate enhancement patterns were seen in two metastatic lesions, most likely due to the presence of



▲ **Figure 2:** B-mode image showing multifocal predominantly echopoor masses (red arrows) adjacent to the echogenic mediastinum testis (yellow arrows) seen in both testes on subsequent views; the lesions were present on previous studies and were unchanged. This patient has a known diagnosis of congenital adrenal hyperplasia and in this context the lesions are in keeping with adrenal rests.



◀ **Figure 3:** B-mode image (right) with superimposed CEUS image (left) showing a subtle echopoor intratesticular lesion (red arrows) which is shown to be hypervascular in the arterial phase (yellow arrows) and demonstrated rapid contrast washout in the subsequent later phases (not shown). This patient had a history of cryptorchidism therefore this lesion must be assumed to represent a small testicular germ cell tumour until proven otherwise, although a sex-cord stromal tumour (Leydig or Sertoli cell) could also have this appearance and are frequently hypervascular on contrast ultrasound. This patient went on to have an orchidectomy with a histological diagnosis of a seminoma.



◀ **Figure 4:** B-mode (left) and Superb Micro-vascular Imaging (SMI) (right) images of the same low echogenicity intratesticular lesion as in figure 3. The SMI demonstrates low level intratumoural flow (arrows) that was difficult to appreciate on conventional colour Doppler.

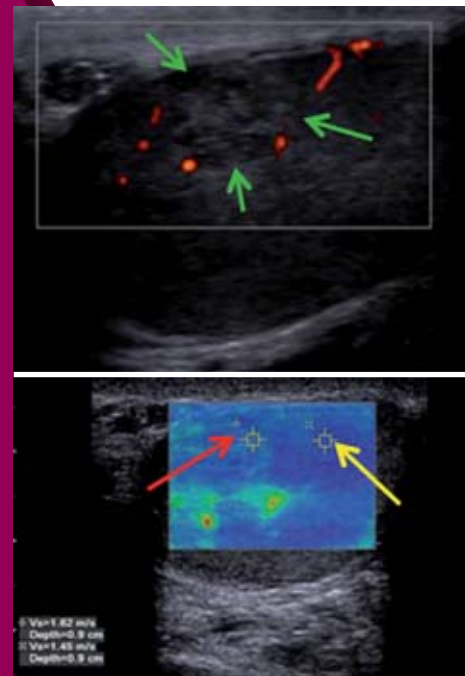
necrosis; and also one case of non-enhancement within a histologically proven malignant embryonal carcinoma.

A new Doppler technique has recently been introduced called Superb Micro-vascular Imaging™ (Toshiba Medical Systems Ltd, Crawley, UK), which permits visualisation of very low flow velocity within small vessels, where flow is not detectable with conventional Doppler techniques. This technique does not require the use of ultrasound contrast media (although it can be used in combination) and we have found it valuable to demonstrate the presence of vascularity within lesions, where flow is not readily identified with colour Doppler interrogation (figure 4); however there is currently limited literature available and further research is required to define its role in characterisation of scrotal masses and whether it is able to replace the need for CEUS.

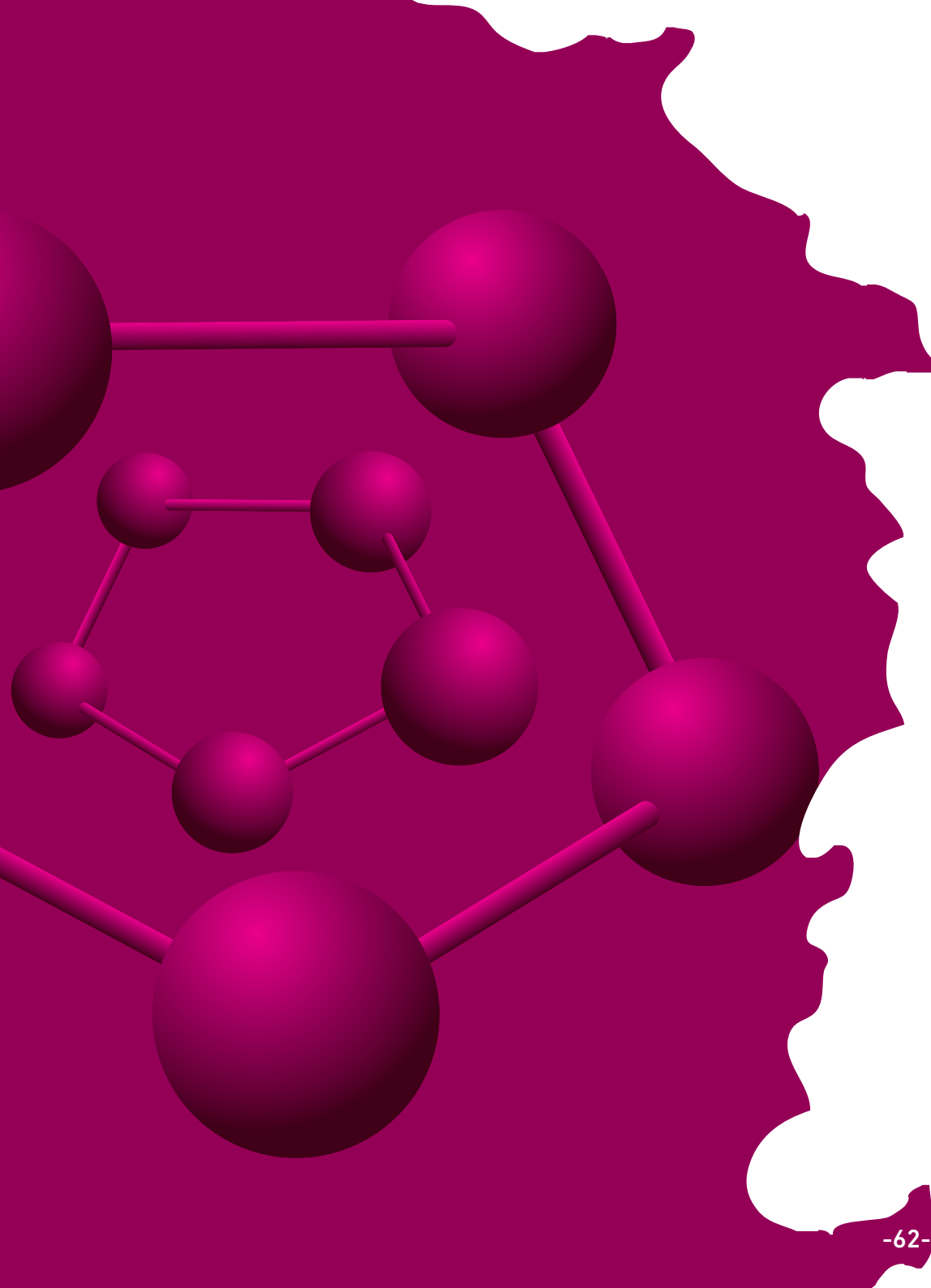
Sonoelastography

Elastography is an ultrasound technique which has shown potential for discriminating between benign and malignant lesions in other organs with the assumption that malignant lesions are stiffer than benign. Elastography is established in evaluating liver parenchyma in diffuse liver disease and focal lesions within the breast, thyroid and prostate, but there are few published data regarding its use in assessing testicular lesions. Elastography is a non-invasive technique based on intrinsic tissue elasticity (and how this is altered by the presence of a pathological process) by measuring the amount of deformation caused by a mechanical stress – essentially measuring the 'stiffness' (figure 5). Strain elastography (SE) uses external tissue compression (usually applied by the operator via the ultrasound transducer) to induce the deformation; the resulting image is usually displayed as a colour map showing regions of different stiffness. Shear wave elastography (SWE) does not require the use of manual compression, but instead relies on a measurement of the speed of propagation of a shear wave which travels laterally through the tissue of interest; SWE is therefore able to produce a quantitative measurement of tissue stiffness. Until recently, neither technique was widely used in assessing testicular lesions, with most current literature based around the use of SE. Both teams conclude that the addition of SE to B-mode ultrasound, in the context of an equivocal lesion, offers a further imaging parameter in characterisation.

A recent study by Aigner et al⁹ evaluated 50 intratesticular lesions with a combination of B-mode, colour Doppler and SE, and quoted a sensitivity of 100%, specificity of 81% and negative predictive value of 100% in diagnosing testicular tumours. Aigner also found 3/50 patients with hard lesions on SE subsequently had benign histology; in particular scarring, infarction or simple cysts may demonstrate increased stiffness (although the diagnosis of cysts should be straightforward on B-mode imaging and therefore not cause diagnostic uncertainty). Goddi et al¹⁰ evaluated 144 lesions in 88 testes and quoted an overall sensitivity of 87.5% and specificity of 98.2%, with an overall accuracy of 95.8% in differentiating benign from malignant lesions, performing best in lesions >11mm in size. Grasso et al¹¹ and Pastore et al¹² were small studies evaluating 41 and 27 testicular lesions respectively and, whilst both studies state elastography can provide additional information for small (<10mm) solid intratesticular lesions, both authors conclude further larger studies are required to establish its role.



▶ **Figure 5 A&B:** Colour Doppler image (A) showing a rounded focal abnormality (green arrows) in the anterior aspect of the testis with no blood flow demonstrated within this small lesion. The shear wave image (B) demonstrates the focal lesion (yellow arrow) has similar shear wave velocities to adjacent normal testis parenchyma (red arrow) and is therefore more likely to be benign. This lesion was managed with serial ultrasound surveillance instead of orchidectomy and has been stable on imaging over an 11 month period so far.



MRI

Although outside the remit of this review, dynamic contrast-enhanced MRI (DC-MRI) also shows potential in characterisation of testicular lesions. MRI offers the advantage of multiplanar and diffusion-weighted imaging, with the addition of dynamic contrast enhancement characteristics displayed by time intensity curves. Using DC-MRI, Tsili et al¹³ evaluated 44 men with 26 intratesticular lesions and found that the 'relative percentages of maximum time to peak' was the statistically significant factor ($p < 0.001$) in predicting malignant versus benign lesions. DC-MRI may have a problem-solving role in managing indeterminate lesions in difficult cases.

Testicular-sparing surgery (TSS)

Despite the lack of randomised controlled trials comparing radical orchidectomy and testis-sparing surgery, TSS is thought to be an effective management option for smaller intratesticular lesions in selected patients³. Previous concerns regarding the risk of incomplete excision, tumour seeding or intraoperative sampling error, have proved to be largely unfounded in recent years, with frozen section examination (FSE) now contributing to a greater diagnostic accuracy, allowing the option to proceed to radical orchidectomy in the same operative procedure as TSS if required. FSE has a quoted 10% false-negative rate but its use in practice varies between centres, with the major limitation being difficulties in histologically differentiating a seminoma from a Leydig cell tumour, despite the differing macroscopic appearances¹⁴. TSS has been shown to be a safe option for treating small TGCT, particularly when postoperative radiotherapy is administered in patients with co-existing carcinoma-in-situ, and may be an attractive treatment option in difficult cases of small malignant tumours, for example in monorchidism or bilateral intratesticular lesions¹⁵. This also means that if TSS is performed on a lesion with a false-negative ultrasound and FSE result, the patient is not disadvantaged. However, the requirement of such surgical and pathological expertise argues the necessity for these procedures to be carried out in specialist centres^{3,14}.

Ultrasound plays a vital role in the preoperative and intraoperative localisation of lesions deemed suitable for TSS. In the postoperative setting, testicular ultrasound is also crucial in assessing for the presence of any residual lesion³. Preoperative percutaneous testicular biopsy is regarded as controversial due to concerns over tumour seeding and scrotal violation. However, some centres routinely perform percutaneous biopsy of equivocal lesions, despite the lack of current evidence or consensus in the role of biopsy technique¹⁶ and biopsy may come to play a crucial role in the future work-up of equivocal testicular lesions.

Interval imaging

There is a current lack of evidence or guidelines as to the role of serial ultrasound as a management strategy for small, incidentally detected intratesticular lesions. Interval ultrasonography could be a potential alternative to surgery or to delay surgical intervention in those lesions with biochemical and imaging features of benignity, particularly where preservation of testicular tissue is crucial. As a pragmatic approach three monthly ultrasound for the first year is often recommended; the need for continuing surveillance of a stable lesion beyond 12-18 months is, as yet, uncertain.

Testicular Microlithiasis (TML)

Testicular microlithiasis is a relatively common incidental finding on scrotal ultrasound with a prevalence of approximately 3% in adult males¹⁷. The general definition of TML is the presence of five or more small, non-shadowing, focal echogenicities within the testis, often occurring bilaterally. The significance and management of TML has been controversial due to the widely documented association of TML with testicular cancer, in particular germ cell tumours¹⁸. This association has led many ultrasound practitioners to recommend ultrasound surveillance in these patients, although there is no consensus on surveillance intervals, duration or patient selection¹⁸. It is probable that the risk of developing TGCT in patients with TML (and no other risk factors for testicular cancer) has been exaggerated and in most patients surveillance ultrasound cannot be justified. New guidance has recently been published, proposing annual ultrasound surveillance only in the presence of additional risk factors such as an atrophic testis, cryptorchidism, a previous history of testicular cancer or family history in a first degree relative¹⁹. TML as an incidental finding in a patient with an impalpable testicular lesion is however, a significant finding, increasing the probability of malignancy.

Conclusion

Advances in scrotal ultrasonography have led to the more frequent detection of incidental small, impalpable and equivocal intratesticular lesions, which are frequently benign on histology. Historically, suspicious and indeterminate lesions have been managed with a radical orchidectomy with the associated psychosocial, endocrinological, sexual and fertility issues affecting, unnecessarily, a large cohort of patients with benign disease. Newer ultrasound techniques such as CEUS and elastography, when added to conventional B-mode ultrasound in a 'multiparametric' examination, can offer the means of better characterising vascularity and inherent stiffness of these lesions, particularly in the context of confirming benignity. Therefore, we advocate the use of multiparametric scrotal ultrasound for evaluating small, impalpable and indeterminate intratesticular lesions, with the aim of reducing the number of radical orchidectomies performed in these patients. Further evidence with surgical, oncological and radiological consensus is required to establish the future roles of serial ultrasound surveillance and percutaneous biopsy of small impalpable testicular lesions. A multidisciplinary discussion between radiologists, urologists and pathologists, with wider availability of TSS at specialist centres, offers the opportunity for improved outcomes in patients with incidentally discovered impalpable testicular lesions.

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CT for all – what’s not to like?

Giles Maskell

We live in a society obsessed with imaging and images. The revolution in digital photography and the growth of social media and other forms of electronic communication have fuelled an explosion in the number of photographic images obtained, published, shared and stored.

The exquisite images of the human body obtained in the course of modern medical imaging retain for now a degree of mystique and are treated with a little more reverence, partly supported by the systems of information governance and confidentiality which pertain in healthcare.

We should not expect this to last. How many 'baby albums' already contain an ultrasonic image of the fetus *in utero*? Images of 'my fracture' are highly prized by teenage acquaintances, so how long can it be before images of 'my pneumonia', 'my hip replacement' and even 'my cancer' are in common currency?

At the same time, clinical management has become ever more reliant on imaging investigations. The number of computed tomography (CT) scans performed in England has increased by an average of 10.3% every year for the past 10 years¹ and the rate of increase shows no sign of slowing. Believe it or not, we still lag behind other developed nations in the numbers of scans we perform so there is plenty of scope for further increase. The most recent comparative figures available from the Organisation for Economic Co-operation and Development (OECD) show the UK undertaking 77 CT scans per thousand population per annum. The OECD average for developed nations is 131 and towards the upper end of the scale, the figure for the USA is 273². Furthermore, there are powerful influences pushing us in the direction of performing more scans. 'Early diagnosis', for example, is a phrase which has captured the imaginations of the public and of politicians particularly in relation to cancer³, and in 2015, early diagnosis basically means more scans.


So what's wrong with that? Is there any reason for us as imaging professionals – or for that matter as tax payers working in a publicly funded healthcare system – to be concerned? Traditionally, our concerns would have centred on the implications of exposure to ionising radiation. We work within a

legal and ethical framework which requires us to ensure that every exposure is justified, because we know from a large body of evidence that there is a risk to health associated with ionising radiation. The magnitude of that risk is usually quoted as increasing the lifetime risk of developing cancer by about 1 in 2000 for a standard CT examination of the torso⁴. Each of us has a lifetime risk of developing cancer of around one in three (going up to one in two according to a recent report⁵) so the increased risk is small for most of us. I would not for a moment suggest that we should ignore the risks, particularly in young people and those who may be at higher than average risk, but this is not the only problem, and not even the biggest problem.

The real problem is that our ability to detect 'abnormalities' on scans has far outstripped our knowledge of what they mean and what to do about them. Modern CT scanners are extremely



Our ability to detect 'abnormalities' on scans has far outstripped our knowledge of what they mean and what to do about them



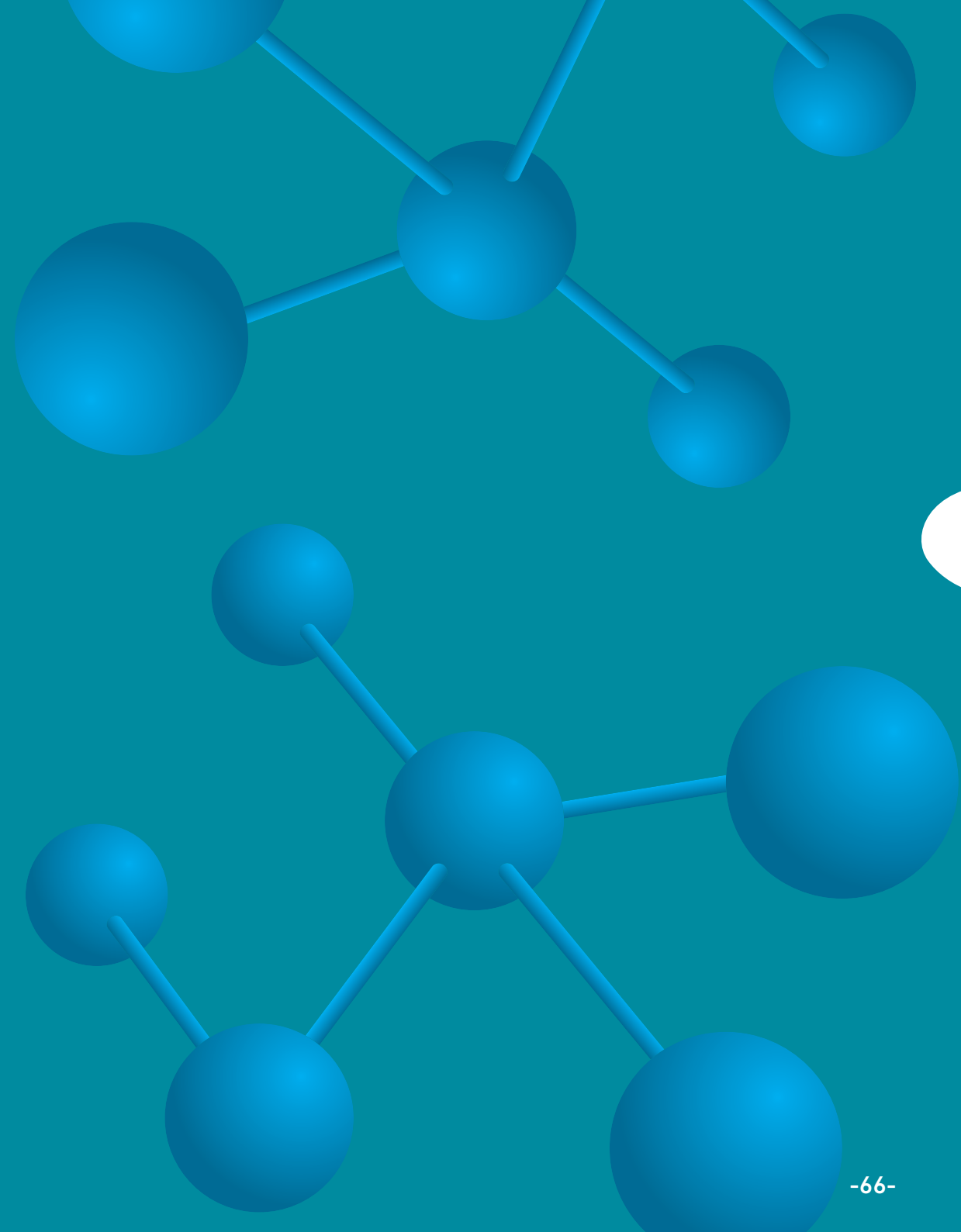
sensitive. Up to 50% of smokers (and plenty of non-smokers) over the age of 50 have at least one small pulmonary nodule detectable on a CT scan. The vast majority of them will be of no significance, but the occasional one will be the first sign of a developing lung cancer. Which one? We have no way of telling, other than to follow up the individual with a further scan, and probably a further scan after that, to make sure that the nodule is not growing.

And what is 'normal' anyway? In the early days of 'well-person CT' in the USA, a radiologist in California was famously quoted as saying proudly that: "We haven't found a normal yet". Every one of us who has reached adulthood will be harbouring something detectable on a scan which could conceivably hold some importance for our future health. A renal cyst, a lung nodule, a fleck of calcification in a coronary artery... the possibilities are many. What do they all mean? For the most part we have no idea except that they almost certainly mean subjecting the individual to further tests, with all the worries and sometimes real physical harm that they will generate. A subtle change on a follow-up scan may lead to a biopsy or even an operation, and all for something which might have had no impact whatsoever on a person's health if left undetected.

Knowing this, why would anyone want to subject themselves to a CT scan? Of course, most of this is not well-known and is certainly not well-understood, even by healthcare professionals. Even for someone not looking to post images of their body on *Facebook* or *Instagram*, the idea of having a scan is quite seductive. It seems to make sense that having a scan must surely be good for you and asking for more medical imaging must surely be a health-seeking behaviour, akin to eating more vegetables or taking exercise. Conceptually it is very difficult to convince people unfamiliar with the intricacies of radiology, that seeking medical imaging could actually be an unhealthy behaviour. There is perhaps a slight similarity with antibiotic usage. Until quite recently, most people would have believed that demanding antibiotic treatment for a sore throat was healthy behaviour, but we are starting to realise that any benefits come at a cost, both to the individual and to society.

It is very important to recognise the difference between on-demand scanning and a screening program. The term 'screening' should be reserved for an organised program of care, integrated with the individual's other healthcare needs, in which the benefits and risks of imaging have been carefully evaluated, and in which structured and detailed information is provided to each participant,

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There are powerful influences pushing us in the direction of performing more scans



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The idea of
having a
scan is quite
seductive

and systematic analysis of the outcomes performed, thus allowing improvements to be made to the program for the benefit of all participants. This is very different from scanning an individual at their request.

Do people not have the right to purchase scans if they want to?

Of course they do. We allow people in our society to do unhealthy things – drink alcohol, smoke tobacco – but rightly we insist that they should be properly informed about the risks beforehand. There will undoubtedly be people who gain from having a CT scan while asymptomatic, but there will be others who lose through harm connected with incidental findings.

Isn't it simply a decision for an individual to take? Why should the rest of us be concerned if one person decides to pay for a scan? The reason why it is an issue for all of us is that when the scan reveals an abnormality, it is highly likely – as we have seen – that further tests will be advised and those are more often than not going to be paid for by the tax-funded National Health Service. So although the individual has paid for the first examination, the three or four further scans which might be needed to confirm the benign nature of a small lung nodule, for example, will often be picked up by the NHS. So in the end we all pay. Moreover, a service which is overburdened with follow-up examinations for incidental findings could result in delays for other patients who might benefit more.

It might seem odd to hear a radiologist suggesting that medical imaging can be harmful. The advantages that imaging has brought to human health are enormous, but those apply for the most part to people with symptoms. I know that I won't convince everybody but my hope is that I'll make a few people think twice – is this really the right thing for me? Do I understand the downside as well as the advantages of having a scan? And perhaps I can encourage those engaged in this practice – radiologists and radiographers – to do their utmost to ensure that people without symptoms, who put themselves forward for CT scans, are as well informed as they possibly can be about the pros and cons of the procedure. The Department of Health in England commissioned a working party to review the evidence and make recommendations as to when self-referred CT examinations can be justified. Their report covers the principal areas of lung, colon and cardiac scanning and makes recommendations in each instance as to the groups of people for whom the potential benefits are such that a CT scan can be justified in the absence of symptoms⁶.

In summary, CT has been one of the outstanding successes of the so-called 'Golden Age' of medical imaging and has brought enormous benefits to patients. We must however, beware of assuming that

the same or equivalent benefits will also accrue when it is applied to people without symptoms. Every healthcare intervention carries risks as well as benefits and the balance is fundamentally different in people who are 'well'. It is part of our duty as imaging professionals to understand that difference as best we can and to be prepared to explain it to patients and the public.

CT for everyone who will benefit? I certainly hope so.

CT for all? Not at the moment, thank you.

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