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Deeson.

### Editorial



ight years ago I began editing *Imaging & Oncology* with the expectation that, if luck were with me, I might produce two issues. Instead, thanks to fine contributions from dedicated professionals within and beyond the UK, I've
managed eight issues comprising nearly 90 thought-provoking articles. It's time now, however, for a new editor to bring fresh insights and a different perspective but in the meantime please enjoy this last collection from me.

Neoteric concepts and, undoubtedly, game-changing developments are all in here, including evaluations of MRIlinac, proton beam therapy, molecular therapy and the exciting potential of electron spin imaging. What is particularly inspiring is that both MRI-linac and proton beam therapy techniques, due to their ability to fine tune radiation dose delivery, offer real advantages to children and young adults with cancer. Further compelling ideas and evidence to benefit patients can be found in articles discussing population-based healthcare, the merits of upright MRI and radiographer-led discharge. Of course, radiographer-led discharge also has the bonus of bringing increased autonomy and job satisfaction to those radiographers involved as well as potential financial savings for trusts.

As litigation involving radiology escalates, Weston gives a timely insight into the role of the expert witness. McNulty discusses surprising discrepancies in radiographer education across Europe. Having seen surveys from the European Society of Radiology and spoken to some of my radiologist friends from overseas I suspect that programmes are also quite variable for radiology training. It would be good to have a submission on this topic for next year's issue.

I'm particularly grateful to two bold sonographers from the Netherlands who have described novel ultrasound practice from a Dutch perspective, and to Gillian Thompson, a therapeutic radiographer, who has vividly illustrated the life-changing aftermath of a cancer diagnosis. Where else would you get such diversity in one issue?

Warmest wishes to the next editor who I'm sure will advance and strengthen this unique publication. And sincere thanks to Audrey Paterson, OBE, who gave me invaluable advice in the early days and, more recently, to Charlotte Beardmore, the current SCoR Director of Professional Policy, who has also provided rock solid support and guidance in the post-Audrey era. Finally, I'm very grateful to the Advisory Board for their helpful comments, and to Mel and Doug at the Deeson Group for their kindness, patience and professionalism. Without doubt, the last eight years have been for me not just a massive educational experience but also an absolute pleasure. Thank you.

Hazel Edwards, Editor • hazeledwards@sor.org

### Foreword



s President of the Society and College of Radiographers it's a real privilege to be asked to be involved with writing contributions for various publications whether it's a professional guidance document or a blog or an article in *Synergy News*. Writing for *Imaging & Oncology* is no exception. Since the first issue in 2005, the professions and the health service provision, whether it's within the NHS or the growing private sector, have seen many changes including increases in demand and huge advances in technology. The increase in research in this country is outstanding and makes us the leading light to which others across Europe look, to allow their own practice to flourish and grow.

Over the last 12 years in which this publication has been produced, under the guidance of the managing editors Professor Audrey Paterson OBE and more recently over the last eight years, Hazel Edwards, I am sure it has encouraged many or at least some of the developments in practice that we have seen. So, I must thank Audrey and Hazel for their unstinting work in producing an inspirational publication which has again been launched at UKRC/UKRO in June.

As I have been writing this column, I have had a chance to review forewords by Presidents in previous editions of *Imaging and Oncology*, and they have mentioned very importantly those changes in healthcare that we face, and the various government initiatives and documents which set out goals for the health service. It's essential that we should have a clear focus and that our patients should be at the centre of what we do; that the care we give should be both compassionate and timely. We should allow timely diagnosis using the resources in imaging and reporting of those images, whether by radiologist or radiographer, to facilitate the planning and treatment of patients to give the best of outcomes. On my travels across the country over the recent months, and I am sure those months which follow, I have seen this in practice. I have been amazed at the depth and breadth of practice across all levels and areas of practice in both imaging and therapy, and the radiographers out there should be congratulated.

Our professions are acutely aware of the need for efficiency and for cost-cutting, but we still need to move forward and it is quite clear from the pieces of work included in this year's publication, that we are moving forward. Despite some differences of opinion of late around professional roles, as a group we must pull together so we do our best for the patients we serve.

So, as I close this foreword, I recommend this edition with enthusiasm and I am sure we will continue to work together developing and sharing our knowledge, and pushing forward the professions involved in imaging and oncology.

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Steve Herring, President The Society and College of Radiographers

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### Proton Radiotherapy: Important Clinical and Technical Aspects for UK Patients

Charles Fong, Paul Sanghera, Andrew Hartley, Jason Cashmore, Dan Ford, Stuart Green

Proton radiotherapy (PRT) is becoming a mainstream treatment modality, with new facilities opening at a substantial rate worldwide.

#### Background

This article follows the excellent description of the physics and clinical aspects of PRT by Carl Rowbottom featured in this publication in 2011<sup>1</sup>. Here we will review basic principles of dose deposition and then focus on

- a) The emerging evidence from clinical studies comparing PRT with the most modern forms of intensity modulated radiation therapy (IMRT).
- b) Developments in proton-computed tomography to deliver improved dose conformality and truly adaptive proton therapy.

We will conclude with an overview of the developing PRT facilities in the UK.

#### Some basics and technical aspects of proton therapy

The principal dosimetric advantage of PRT comes from the finite range of protons in tissue and the Bragg profile of dose versus depth. This is illustrated in Figure 1

for pristine and modulated beams compared with the typical depth-dose curve for a therapeutic energy x-ray beam. The shaded area is indicative of the saving in total energy deposited (termed *integral dose*) for particle beam treatments compared with those delivered with high energy x-rays.

The exact depth of the Bragg peak in a patient is subject to some uncertainty (typically around  $\pm 3.5\%$  or  $\pm 7$ mm at 20cm depth) which means that target volumes need to be adapted (ie enlarged) to accommodate this. Current practice in PRT mitigates

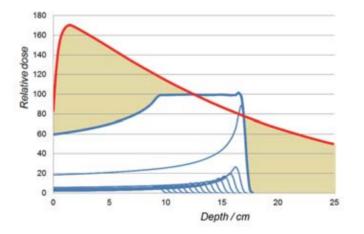


Figure 1: Depth dose curves for 6MV x-rays (red), pristine and modulated protons (blue), illustrating the reduction in integral dose (shaded) which is possible with proton radiotherapy.

range uncertainty by utilising the lateral beam edge to reliably reduce doses to critical healthy tissues that are close to the high dose or target volume. At depths beyond around 15cm, the steepness or sharpness of these lateral edges will always be worse for PRT than for x-ray radiotherapy because of the physics of proton interactions and multiple Coulomb scattering, which tends to blur the beam-edge at depth. The lateral edge of proton beams at shallow depths can be more or less steep than for x-ray beams, depending on the beam delivery approach and the available nozzle design. Critical parameters are:

a) The availability of collimation.

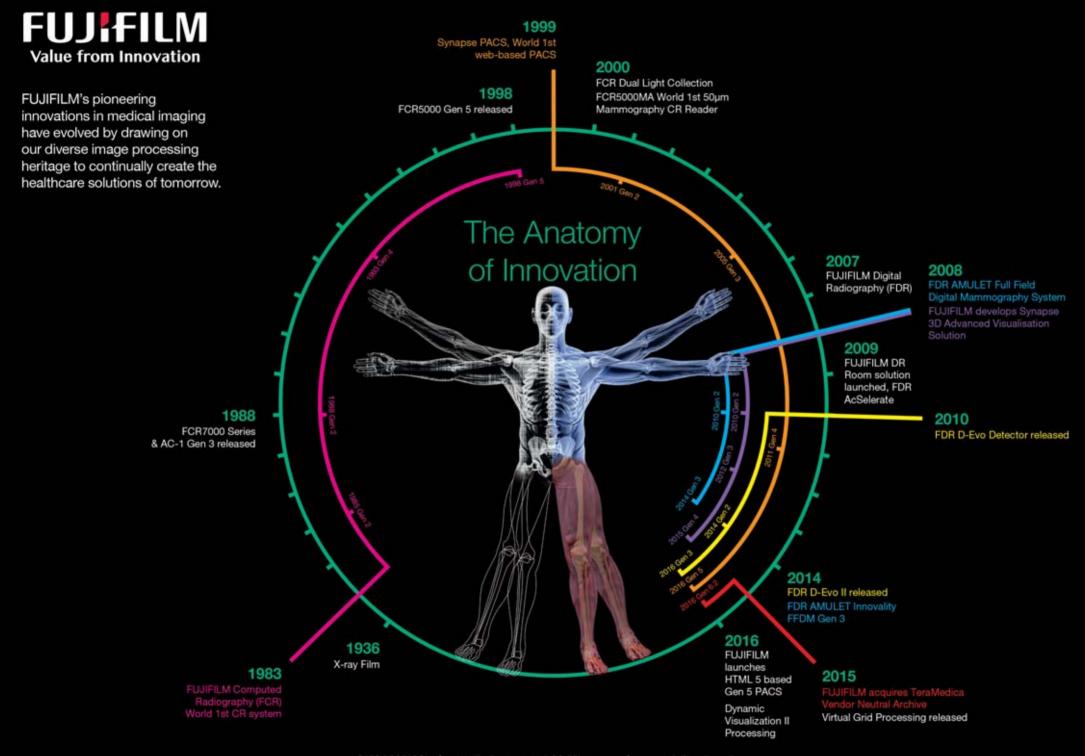
- b) The size of the pencil beam spot for scanned proton beam delivery.
- c) The distance that the beam travels between the final vacuum window of the nozzle and the patient.

These characteristics of proton energy deposition combine to mean that with current technology, compared to x-ray radiotherapy, similar dose conformality can be achieved around the tumour/target volume, but at reduced (sometimes considerably reduced) overall or integral dose.

#### **Clinical data**

Comparative proton treatment planning data have been followed by mainly small, retrospective treatment outcome reports from paediatric, skull base, paraspinal, and head and neck sites, where the dosimetric benefits of protons were felt to be most likely to translate into clinical benefits.

The potential for toxicity and radiationinduced malignancy reduction is attractive for children and young adults



#### Children and young adults

Due to reduced integral dose, the greatest benefit over IMRT is likely to be for paediatric cancers. The potential reduction in late effects and second malignancies in craniospinal irradiation (CSI) of paediatric medulloblastoma has resulted in this indication becoming an illustration of the advantages of proton therapy. Example treatment plans for modern IMRT and PRT for CSI are shown in Figure 2.

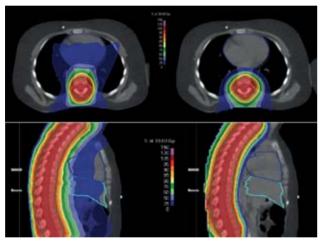


Figure 2: Illustrative treatment plans for the spinal section of a paediatric CSI plan. The plans on the left are IMRT and on the right are proton plans.

The upper axial slices of Figure 2 are at the level of the heart. In both axial and sagittal planes, there is a clear reduction in integral dose for the proton plans on the right compared to the IMRT plans on the left. A single arm phase II study using PRT for CSI showed equivalent long term disease control and favourable toxicity profiles<sup>2</sup>. PRT for CSI is also considered cost-effective through the reduction in late morbidity.

A phase II study in childhood rhabdomyosarcoma has also demonstrated favourable efficacy and toxicity for PRT compared to historic IMRT data<sup>3-5</sup>. Furthermore, only 15% of patients on PRT received  $\geq$ 16Gy to the hypothalamus, compared to 30% in the IMRT group<sup>3</sup>. Reduction in dose to the pituitary-hypothalamic axis should result in long term clinical benefits<sup>6</sup>.



Modelling studies suggest that for children and younger adults with high likelihood of long-term cancer survivorship, a lower risk of radiation-related second malignancies is expected for PRT as the much-reduced integral dose outweighs the slightly increased risk, secondary to neutron interactions. Several case-matched series of photon versus proton therapy have alluded to a reduced risk of second malignancies in these patients<sup>7</sup>. In the absence of long-term clinical validation, the potential for toxicity and radiation-induced malignancy reduction is attractive for children and young adults. Both groups are extensively included within the NHS overseas PRT programme<sup>8</sup>.

#### Skull base and head and neck

For adults there has been considerable interest in the potential for PRT to improve local control (LC) through dose escalation in complex anatomical sites. Significant experience has been gained in the treatment of patients with skull base chordomas and chondrosarcomas, given their relative radioresistance and proximity to critical organs. Five year LC rates of up to 81% (chordoma) and 94% (chondrosarcoma) with acceptable toxicity have been reported<sup>9</sup>. These outcomes exceed results with historic photon therapy and NHS patients are able to access PRT through the overseas programme. However, this reflects the use of maximal surgical resection in combination with PRT in an experienced setting. Dose escalation adjacent to critical organs is also possible with modern photon therapy. For example, five year LC rates of 65% (chordoma) and 88% (chondrosarcoma) have been reported using image guided IMRT<sup>10</sup>. The risk of brainstem toxicity dictates the need for maximum resection away from this critical structure, regardless of technique. Paediatric PRT brainstem necrosis has been highlighted recently<sup>11</sup>. It remains unclear whether photon and proton dose constraints are interchangeable, further complicating comparisons. The uncertainty of the relative biological effectiveness at the end of the proton beam may be one of several factors

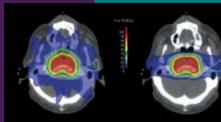
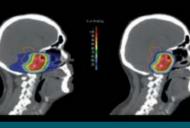


Figure 3: Illustrative IMRT and proton plans for a skullbase tumour site.



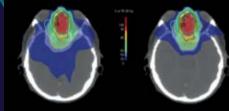
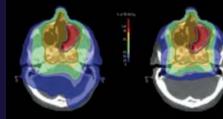


Figure 4: Example axial slices of treatment plans for a sino-nasal tumour illustrating a reduction in integral dose to brain from proton plans (right) with similar coverage of the planning target volume.



#### The ideal solution for accurate planning and for online adaptation of treatment is to image with proton-CT

influencing toxicity rates.

Figure 3 indicates the achievable dose distributions from modern rotational IMRT delivery, compared with a parallel-opposed configuration of intensity modulated proton fields. Similar conformality of the high dose region is achieved with substantially reduced dose-bath from the proton plans (right of Figure 3).

Sino-nasal malignancies have been considered for PRT due to treatment related morbidity and poor outcomes in some histological subtypes. A meta-analysis of 41 noncomparative studies of photon therapy versus charged particle therapy (predominantly PRT) reported the superiority of PRT over IMRT in terms of five year disease-free survival (72% vs 50% respectively, p 0.045) and locoregional control (81% vs 64%, p= 0.011)<sup>12</sup>. However, due to the heterogeneity of pathological, patient and treatment factors it remains difficult to draw firm conclusions. Multicentre cohort studies stratified by histology, extent of surgery and use of chemotherapy are required.

Nasopharyngeal carcinomas are geometrically complex and require high doses close to critical structures. High LC rates are achieved with image guided IMRT, although morbidity still remains significant. A case-matched retrospective analysis of 30 patients compared intensity modulated proton therapy (IMPT) with IMRT. The main clinical benefit was that fewer patients in the IMPT group required feeding tubes. The most likely advantage of PRT over IMRT is toxicity reduction through reduced dose to normal tissue away from the target volume. Oropharyngeal cancer has risen in incidence due to human papilloma virus. The high morbidity with standard therapy in this curable disease has also prompted interest in PRT. Small patient-reported outcome studies have suggested reduced gastrostomy tube dependence and improved taste/appetite<sup>1314</sup>. An ongoing phase III trial may help to determine the actual level of benefit. The dosimetric advantages in selected cases are easy to see, however these patients are particularly vulnerable to changes in anatomy and this poses a greater technical challenge to PRT than rotational IMRT. To date, many programmes have included patient participation in an aggressive nutrition programme to minimise risk of such anatomy changes.

#### Other clinical sites

The first reported phase III randomised trial of PRT versus IMRT was performed in the setting of locally advanced (stage II-IIIb) non-small cell lung cancer. Here, 57 patients received passively scattered PRT and 90 patients received IMRT. Patients were eligible for randomisation only if both plans satisfied normal tissue constraints at the same prescription dose. No statistical differences were identified in the incidence of grade  $\geq$ 3 pneumonitis or LC<sup>15</sup>.

Despite being a frequently treated tumour site for PRT, randomised controlled data demonstrating an improvement in the therapeutic ratio for prostate cancer are not available. This, combined with the current costs of PRT, makes it unlikely to be routinely commissioned for prostate cancer in the near future.

#### **Ongoing clinical studies**

As of mid-2016, there are around 120 active clinical trials involving PRT. Only five phase III trials will directly compare PRT with photon therapy (breast, lung, low/intermediate-risk prostate, oesophagus and oropharynx sites). Only three phase III studies will assess PRT with carbon ion therapy for chordoma and chondrosarcoma sites. Another three phase III trials (lung, glioblastoma) have recently closed recruitment.

The majority of these studies remain observational and therefore will not provide the highest level of evidence. Dutch investigators have recommended the use of models of normal tissue complication probability to select patients more likely to gain from PRT<sup>16</sup>. However, clinical validation for these models remains challenging. An alternative is to design randomised trials, selecting patients predicted to have a greater gain on the basis of such modelling. Designing such studies will require clinical equipoise. It may be in the interest of socialised healthcare systems to undertake such trials to justify expenditure. Clinical validation of improved outcomes for rare cancers will remain reliant upon well-conducted prospective phase II/cohort studies.

#### Progress update on key technology aspects: Focus on proton-CT

As noted above, the exact depth of the Bragg peak in a patient is subject to some uncertainty and the largest component of this uncertainty relates to the current necessity to derive a map of proton stopping powers from planning x-ray CT images. Direct measurement of proton stopping powers would substantially reduce this uncertainty. Proton-CT imaging offers this possibility.

In addition, the defined range of proton beams makes them much more sensitive to anatomy changes than x-ray beams, so the need to routinely adapt proton treatments during the course is much greater than for rotational IMRT treatments. On-gantry x-ray cone-beam CT is considered 'new' technology in PRT and while this offers capability to monitor patient anatomy on a daily basis, the ideal solution for accurate planning and for online adaptation of treatment is to image with proton-CT. The UK is fortunate to have one of the leading teams developing these approaches in the PRaVDA consortium<sup>17,18</sup>. This research aims to deliver reduced proton range uncertainty (down to around  $\pm$ 1% from  $\pm$ 3.5%) and the capability to achieve an efficient pathway for daily adaptive proton radiotherapy.

The basic components of a proton-CT system are shown in Figure 5. This utilises

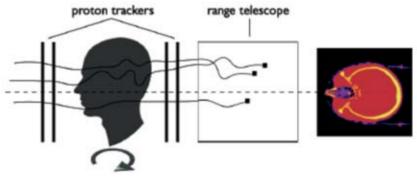
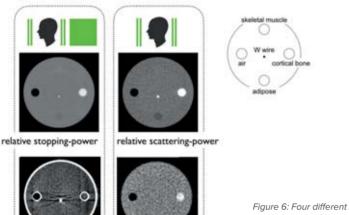


Figure 5: basic geometry of proton-CT.

'tracker' modules to identify the position and direction of protons entering and leaving the patient, and a further 'range telescope' to measure the residual proton energy. Knowing the incoming and exit energies, and the proton path through the patient, allows reconstruction of a 'proton-CT' image set based on the tracking of many (around 100 million) individual protons delivered from many angles. In its standard mode (as illustrated) the proton-CT image set is essentially a map of proton stopping-powers so is directly required for treatment planning.

The PRaVDA consortium is developing further imaging modes, as illustrated in

relative straggling-power



relative attenuating power PRaVDA team.

Figure 6, where other tissue properties are imaged. Some of these modes (Figure 6, right) require only the tracker modules and so can potentially be delivered by a much simpler imaging system. A focus on imaging the relative stopping-power (Figure 6, top left) automatically gathers the data required to deliver all of the image modes shown in this figure.

While the principle of proton-CT is established, there is still much work to be done and investment to be found to deliver this in a clinically usable form. Only then will the potential benefits in terms of improved planning accuracy and daily treatment adaptation be realised.

#### Update on UK provision of proton radiotherapy

The UK is now embarking on a rapid and large-scale investment in proton radiotherapy. This involves NHS investment with two centres (six NHS treatment rooms) and private sector investment of at least three and possibly considerably more rooms for treatment of private patients. It is notable that, to date, all proposed UK facilities involve scanned proton beam delivery and will have access to CT image guidance within the treatment room. These are significant advances from the

## The UK is now embarking on a rapid and large-scale investment in proton radiotherapy

technologies available elsewhere in the world.

The development of the NHS centre at The Christie Hospital, Manchester, features three NHS treatment rooms and a research room, and is on course for first patient treatments in mid-2018. The centre at University College London Hospital, also with three NHS treatment rooms, will possibly open during 2020. Both centres will use Varian technology (Varian Medical Systems, Palo Alto, California, USA) with full 360 degree gantry delivery capability. NHS England policy is that designation for NHS tariff will be limited to these two centres for the foreseeable time. While they become established, overseas referrals will continue for selected patients.

In the private sector, at least six centres are currently being developed around the country with some likely to be offering treatment by 2018. Combining both NHS and private sector developments in the next five years, it is possible that the UK will have 10-15 proton radiotherapy treatment rooms. If fully utilised these would represent around 4-6% of total radiotherapy treatment capacity for England. The level of demand for proton radiotherapy in the private sector remains to be demonstrated.

#### Summary

The capability of PRT to deliver high quality treatment at reduced integral dose may bring benefits to many patients. Reasonable clinical evidence and arguments exist for paediatric patients. For adults with certain tumours in the head and neck region, dosimetric studies suggest advantages, however clinical data are lacking. Technological developments such as proton-CT could play an important role in maximising clinical outcomes from PRT. Routine use of PRT may challenge the ability to confirm the margin of clinical benefit through research. Establishing this margin of benefit is particularly important for socialised healthcare systems where increased expenditure in one area can lead to reductions in another.

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Jason Cashmore is Consultant Clinical Scientist and leads the treatment planning team at UHB who plan around 3500 patient treatments per year. Jason's research with Elekta laid the foundations for the use of flattening filter free radiotherapy in the Versa HD<sup>TM</sup> machines.

Dan Ford is a Consultant Clinical Oncologist and is Clinical Service Lead for Oncology at UHB. Dan treats paediatric patients and also patients with urological malignancies. He is a member of the NHS panel that considers patients for proton treatment overseas.

Stuart Green is Consultant Clinical Scientist, Director of Medical Physics at UHB and former President of the British Institute of Radiology. He is currently engaged in research on proton-CT imaging as part of the PRaVDA consortium and Chairs the IPEM group developing a dosimetry code of practice for proton therapy in the UK.

All are members of the Hall-Edwards Radiotherapy Research Group.

### Advances in Molecular Radiotherapy for Thyroid Cancer

Jonathan Wadsley

Molecular radiotherapy refers to the delivery of radiation to a tissue (usually malignant) via the interaction of a radiopharmaceutical with molecular receptors in that tissue. The treatment may be delivered orally, intravenously, or selectively, for example by direct infusion into the hepatic artery to target the liver.

here are significant advantages in delivering a high dose of radiation to the target tissue whilst sparing normal tissues. However, treatment is complicated by the fact that the radiopharmaceutical remains within the patient and this can create significant radiation protection issues, depending on the particular characteristics of the radioactive isotope being employed. Delivery of treatment requires a highly skilled multidisciplinary team including a medical physics expert, nuclear medicine technologist, oncologist or nuclear medicine physician and in some cases, an interventional radiologist if the treatment is to be delivered selectively.

#### Thyroid cancer and radioiodine

One of the most common applications of molecular radiotherapy is in the treatment of thyroid disease. Thyroid cell membranes harbour a protein known as the sodium iodide symporter (NIS) which pumps iodine into thyroid cells. Very few other cell types express NIS making radioactive iodine (RAI) an ideal targeted therapy for thyroid cells.

Whilst RAI has applications in the treatment of benign thyroid disease, this review will concentrate on developments in RAI therapy in thyroid cancer. Thyroid cancer is the most common endocrine malignancy with an incidence of around 3500 new cases per year in the UK. Women are more commonly affected than men and incidence peaks between the ages 30-50. For most patients the prognosis is very good, in part due to the efficacy of RAI therapy.

RAI has been used as a treatment for thyroid cancer since the 1940s. Compared with other cancer therapies it is relatively cheap and is readily available, although due to its short half life it does not have a shelf life and has to be ordered individually for each patient. It has numerous applications, including the ablation of the normal thyroid remnant following thyroidectomy, adjuvant therapy to reduce the risk of recurrence following surgery for early stage disease, and therapy for metastatic disease. In some cases of metastatic disease, in particular in younger patients with lung metastases, RAI can be curative.

Until recently, national and international guidelines have recommended that most patients with thyroid cancer receive RAI therapy following total thyroidectomy. Typically patients have been treated with an empirical activity of 3.7-7.4GBq I131. This particular isotope has a physical half-life of eight days and emits  $\beta$  and  $\gamma$  radiation. Patients



As new molecular targets are identified novel technologies will be developed, exploiting the possibility of delivering high doses of radiation specifically to tumour cells

have therefore typically been nursed in isolation for two to four days post therapy to comply with radiation protection legislation. In order for RAI to be optimally taken up by thyroid or thyroid cancer cells, levels of thyroid stimulating hormone (TSH) need to be high. Historically, this has been achieved by withdrawing the patient's thyroid hormone replacement for two to four weeks prior to therapy, leading the pituitary gland to produce TSH. Whilst effective, this approach adversely affects quality of life, often leaving patients with marked symptoms of hypothyroidism, in particular fatigue.

Whilst RAI is known to be a very effective treatment for some patients with metastatic disease, leading to durable response and in some cases cure, in earlier stage disease the evidence base for treatment is much less strong. Overall survival following optimal surgery is known to be extremely high for the majority of these patients and is unlikely to be improved by RAI. RAI may reduce the likelihood of local recurrence. This does however come at the cost of some toxicity, including the symptoms of hypothyroidism around the time of treatment and a small risk of inducing a second malignancy – an excess lifetime risk estimated to be in the order of 0.5%<sup>1</sup>.

These concerns have led to the testing of new approaches to treatment with RAI. In 2012 two randomised trials were reported<sup>2,3</sup> testing the use of a lower activity of I131 (1.1GBq compared with previous standard 3.7GBq) and the use of a recombinant TSH rather than thyroid hormone withdrawal in preparation for ablation therapy for patients who had undergone total thyroidectomy for relatively low risk disease. Both studies demonstrated non-inferior ablation success rates, defined by a clear I131 uptake scan and low stimulated thyroglobulin measurement at six months post therapy for the lower activity of I131 and use of recombinant TSH.

The advantages of lower radiation exposure likely to reduce the second malignancy risk, and reduced effects on quality of life for the use of recombinant TSH when compared with thyroid hormone withdrawal, have led to recent guidelines recommending these approaches are adopted for this patient population<sup>4</sup> and rapid adoption by many UK centres. An added benefit of the use of recombinant TSH is that renal clearance of I131 is more rapid than in patients managed with thyroid hormone withdrawal. This, along with the use of a lower activity of I131, makes day case therapy feasible as radiation levels fall to limits safe for discharge within a few hours of treatment. This significantly improves patient experience and reduces healthcare costs. Patient selection for day case treatment remains important and some patients, for example those with young children at home, may still require a short hospital stay.

Furthermore, a new project, the IoN trial (EUDRACT No 2011-000144-21), is investigating whether a group of patients can be identified who are at low risk of recurrence and can avoid RAI ablation therapy altogether. Patients with low risk completely resected thyroid cancer are randomised to RAI ablation followed by TSH suppression therapy or to TSH suppression therapy alone, thus testing whether RAI can be omitted in this group. The primary endpoint for the study is the five year disease free survival rate.

Whilst RAI is often a very effective treatment for patients with metastatic thyroid cancer, a proportion of cancers will either not respond to radioiodine, or will initially respond but then become resistant to further treatment. This situation is known as radioiodine refractory differentiated thyroid cancer (RR-DTC). Whilst this only occurs in a small minority of patients, for these patients prognosis is poor when compared with the majority of thyroid cancer patients, with 10 year survival of around 10%. Until recently there has been no effective treatment for this group of patients. Phase 3 trials of the tyrosine kinase inhibitors Sorafenib<sup>5</sup> and Lenvatinib<sup>6</sup> have demonstrated improved progression free survival, but this comes at the cost of significant ongoing toxicity. Novel therapies are required.

Since RAI is such an effective treatment for thyroid cancer cells that are iodine avid, numerous attempts have been made to re-stimulate RAI uptake in RR-DTC. Historically, a number of approaches have been tested, including lithium therapy<sup>7</sup>, long known to have effects on iodine metabolism in the thyroid, and redifferentiation therapy with retinoids<sup>8</sup>. Although small preliminary studies appeared promising, further investigation has not demonstrated benefit from either of these approaches.



Recent developments in the understanding of the cellular and molecular changes resulting in RAI resistance have however, led to new approaches. It is known that activating mutations in elements of the MAP kinase signalling pathway can result in loss of expression of NIS in thyroid cancer cells. Laboratory work in iodine refractory thyroid cell lines has shown that inhibitors of elements of the pathway such as MEK, can lead to re-expression of NIS in these cells. This laboratory work led to a single centre pilot study in patients with RR-DTC<sup>9</sup>. Patients underwent a baseline I124 positron emission tomography (PET) scan and were treated with Selumetinib, an oral MEK inhibitor, for four weeks. A further I124 PET scan was performed to determine whether there had been any change in the degree of iodine uptake. In 12 of 20 patients studied, increased iodine uptake was demonstrated. In eight of these it was sufficient to consider further RAI therapy. All eight patients achieved either a radiological response or disease stabilisation.

Whilst very interesting, these findings need replicating in a larger, multicentre study, and a number of outstanding questions remain. The SELIMETRY trial (EUDRACT No

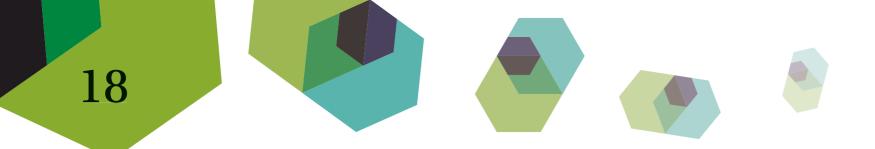
It is critical that we have a clearer understanding of the dose delivered both to tumour and to organs at risk 2015-002269-47) will run in eight UK centres, aiming to enrol 60 patients with RR-DTC. Patients will be treated in a similar manner to the pilot study, although I123 SPECT/CT rather than I124 PET will be used to assess iodine uptake pre- and post-Selumetinib. An important aspect of this trial is the collection of standardised dosimetry measurements to allow calculation of absorbed dose to target lesions in patients receiving I131 therapy. It is anticipated that this may allow a threshold lesional absorbed dose to be established; the minimum absorbed dose required to see a response to treatment. This may in turn lead to better selection of patients for treatment, and potentially individualisation of therapy, with prescription of a higher administered activity if it is determined that this will be required to achieve the necessary absorbed dose.

Dosimetry has been a much neglected area in molecular radiotherapy. In thyroid cancer and many other applications, typically an empirical activity is administered, in some cases adjusted for body weight or body surface area. Usually no attempt is made to quantify the absorbed dose to the target. Studies have shown that this can vary greatly between patients even when the same absorbed dose is administered. One study investigating absorbed dose to thyroid remnant showed that for a fixed activity administration absorbed dose to the thyroid remnant varied from 1.2-540Gy<sup>10</sup>. Since response to therapy is very likely to be determined by absorbed dose delivered to the target, it is critical that we have a clearer understanding of the dose delivered, both to tumour and to organs at risk. This has led to calls for further development of dosimetry techniques for molecular radiotherapy<sup>1112</sup>.

Dosimetry for molecular radiotherapy is not straightforward, requiring serial measurements, and imaging and sophisticated software to model the cumulative dose delivered over time. Whilst time consuming, these techniques are now available. It is hoped that the SELIMETRY trial, having established a network of centres capable of standardised dosimetry for I131 therapy, will lead the way in further research in this area.

#### Other applications of molecular radiotherapy

In recent years a number of new applications of molecular radiotherapy have been shown to be beneficial in a range of different cancers, including bowel and prostate. Radium-223, an alpha-emitter, has been shown to reduce skeletal-related events and improve overall survival in patients with metastatic prostate cancer<sup>13</sup>. In neuroendocrine tumours, peptide receptor radiotherapy (PRRT) using Lutetium-177 labelled Dotatate



has been shown to significantly improve progression free survival in patients with progressive disease<sup>14</sup>. In colorectal cancer, selective internal radiotherapy (SIRT), using Yttrium-90 labelled microspheres delivered directly to the liver via the hepatic artery, has been shown to improve progression free survival in patients with liver only metastases<sup>15</sup>. In all of these areas further research is ongoing, investigating expanded indications and optimisation of therapy, including work on dosimetry. It is likely that applications of molecular therapy will continue to grow in the future as its potential is more fully explored and realised. New applications will be established for existing technologies and as new molecular targets are identified, novel technologies will be developed, exploiting the possibility of delivering high doses of radiation specifically to tumour cells.

#### Summary

Molecular radiotherapy has been used in the treatment of cancer for many years. In the treatment of thyroid cancer, recent developments have led to better selection of patients for treatment, improved convenience and tolerability of treatment for those who do receive it. Ongoing research is investigating ways to overcome resistance to radioactive iodine in more advanced disease.

Recently, numerous other therapies have demonstrated benefit across a range of cancers. Further research is needed to investigate the wider application of these therapies, and to optimise the existing indications, in particular by improving dosimetry so that we know what absorbed dose is being delivered to the target.

It is likely that in the future, molecular radiotherapy will have an important role to play in improving the treatment outcomes of an even wider range of cancers.

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MRI Guided Radiotherapy: A Short SWOT Analysis

Marcel van Herk, Alan McWilliam, Michael Dubec, Corinne Faivre-Finn, Ananya Choudhury

Combining magnetic resonance imaging (MRI) guidance with external beam radiotherapy is an exciting prospect and is currently generating much research. A simple PubMed search on 'MRI linac' retrieved 116 relevant publications, of which 40 were abstracts. MR imaging used to guide radiotherapy from a linear accelerator, offers a new and potentially more accurate method of treatment for certain cancers. But just what is so exciting about this combination? In this opinion piece, we will try to separate hype from fact by applying the simple SWOT (strengths, weaknesses, opportunities and threats) analysis to MRI guided radiotherapy.

everal types of MRI guided radiotherapy equipment are under development or have become clinically available recently. Two devices seem to be the most advanced in their development; first, the MRIdian® system (ViewRay, Oakwood Village, Ohio, USA) has been in clinical use for a few years. Its original design used three cobalt sources each with a multileaf collimator, combined within a 0.3 T MRI with a split magnet system. The company has announced that a linear accelerator (linac) based version of the system will become available this year<sup>1</sup>. Second, the Elekta/Philips Atlantic system (Elekta Instrument AB, Stockholm, Sweden) consists of a seven megavolt linac that rotates around a closed bore 1.5 T MRI<sup>2</sup>. The latter device is currently being installed in Manchester (Figure 1) as well as in other consortium sites. The radiation is delivered through the magnet, which has gaps in the gradient coils but not in its enclosure and superconducting coil. A team at the University of Alberta has been developing a rotating magnet solution and has just initiated commercialisation<sup>3</sup>. Finally, the Australian MRI linac project is active, though so far it has mostly been focused on research testing different magnet orientations<sup>4</sup>. Given the important role this development may play in radiotherapy research and clinical application, we will provide a short SWOT analysis to inform readers what to expect of such systems.

#### **Strengths**

**Improved image quality.** The major advantage of MRI over x-ray based image guidance technology is the greatly improved soft-tissue contrast<sup>2</sup> (Figure 2). This has the greatest advantage in the lower abdomen and pelvis, where cone beam computed tomography

With an integrated MRI, adding an imaging sequence for response monitoring is just a matter of keeping the patient on the treatment table a bit longer 21



Figure 1: The MRI linac system being constructed in Manchester is nearing completion. The patient is placed in the bore of a 1.5T MRI, and the linear accelerator is rotating around the magnet. From a patient perspective, the linac is invisible, and imaging and radiation delivery can occur simultaneously.

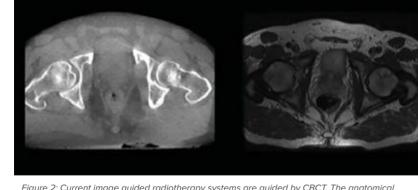
(CBCT), the current mainstream image guidance solution that MRI seeks to replace, is hampered by the low tissue contrast and artefacts introduced by organ motion. In addition, MRI has shown potential for identification of involved lymph nodes<sup>5</sup>. Another advantage of MRI is its speed; a single slice of MRI data can be acquired in a fraction of a second. This means that motion blurring is reduced, which is especially important for anatomy affected by respiratory and cardiac motion as well as bowel motility. Four dimensional (4D) CBCT imaging options have been available to reduce motion blurring but these introduce artefacts of their own. However, even though single slice MRI is sub-second, motion will still affect image contents between slices, so appropriate motion handling is still required for MRI guidance in anatomical regions with significant motion (>1cm). Possible solutions are 4D image reconstruction based on image sorting or modelling or undersampled motion compensation techniques<sup>6,7</sup>.

Beam-on images. MRI guided radiotherapy equipment allows the acquisition of MR images beam-on as opposed to pre- or post-beam CBCT images acquired on standard linacs. This will allow close monitoring of tumour and organs at risk of motion during delivery. This supports exception gating, eg when a patient is coughing, repetitive gating for respiration, and potentially tumour tracking. One of the potential applications of MRI guided radiotherapy is the safer delivery of hypofractionated treatments, including extreme hypofractionation (eg single fraction stereotactic ablative radiotherapy to the prostate) facilitated by the accurate localisation of the tumours and organs at risk during the delivery of a radiotherapy fraction. In such situations, beam-on imaging will be crucial as intra-fraction motion will less likely be 'washed out' by subsequent fractions. However, random motion of less than 1cm range is likely to have a very limited effect on dose delivery due to inherent unsharpness of the dose distributions<sup>8</sup>.

On-board functional imaging. The availability of on-board functional imaging is important for studies into response monitoring<sup>9</sup>. Even though it is possible to regularly acquire MRI or PET scans out of room, the logistics make this a daunting exercise in a typical radiotherapy department. With an integrated MRI, adding an imaging sequence for response monitoring is just a matter of keeping the patient on the treatment table a bit longer. Logistically and medically, repetitive use of contrast will be a problem. Therefore, diffusion weighted imaging (DWI) is currently the most interesting functional

Figure 2: Current image guided radiotherapy systems are guided by CBCT. The anatomical contrast such systems provide is quite low in the pelvis and lower abdomen. a: (left) CBCT of a patient with prostate cancer. b:(right) MRI of a similar patient on a 1.5T MRI, representative of the image quality of the upcoming MRI linac systems.

The technique lends itself well to radiation sensitive patients, eq children



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MRI sequence for this purpose<sup>9</sup>. Based on such images, large scale data mining may identify methods to modify treatment early on, eg initiate dose escalation but only for those patients it would benefit. Repeated imaging can also quantify early shrinkage of tumour and/or lymph nodes, which may be predictive of tumour control and can therefore be used as an incentive to modify the therapy dose.

Avoids exposure to imaging dose. In contrast to the use of CBCT guidance, MRI guidance avoids exposure to diagnostic radiation. Therefore, the technique lends itself well to radiation sensitive patients (paediatrics) and those who need continued monitoring using many scans. The possible high frequency of imaging is also well suited to accurate dose accumulation<sup>10</sup> and intra-fraction plan adaptation<sup>11</sup>. However, in our view, deformable image registration is not yet accurate or reliable enough to allow clinical decision making on such results. In particular, anatomy mapping of homogeneous organs, hollow organs and sliding tissues, have high degrees of uncertainty. Incorrect mapping could result in incorrect compensation of cold and hot spots, leading to under- or over-dosage.

#### Weaknesses

Besides the high purchasing cost of MRI guided radiotherapy devices, there are several other limitations that need recognition and that will drive the research direction in the coming years.

**Fraction times.** Due to the possibility and often necessity of online replanning (as table movement is often restricted), the throughput of MRI guided irradiation is currently low. Fraction times on the MRIdian system have been reported of up to one hour. This is due to several reasons; first the need for recontouring, which can be initiated by deformable registration but still requires frequent editing by a radiation oncologist. However, by limiting the editing to a few centimetres around the planning target volume, the editing time can be reduced with limited effect on plan quality<sup>12</sup>. Also, a method for automatic contour propagation quality assurance (QA) has been proposed that can indicate which contours need special attention by validating the consistency once they have been propagated 'full circle'<sup>13</sup>. The internal anatomy of a patient can change over time such as the development or movement of gas pockets, which must be defined for each fraction.

Other time consuming activities are patient specific plan QA (eg by independent dose calculation<sup>14</sup>), and long dose delivery due to the low dose rate of current machines.

Deformable registration accuracy. Image registration is widely used in radiotherapy, eg for image guidance and target volume delineation. Registration systems need to achieve a compromise between image similarity and smoothness of the deformation, attempting to find the 'smallest' deformation that still optimises the image similarity. This compromise is achieved by tuning parameters. An important caveat of deformable image registration is the inadequacy of visual validation to provide a final verdict on the registration accuracy, as completely different deformable registrations can result in identical images. This can be highly detrimental for dose accumulation which forms an important part of several adaptive workflows. Another unresolved issue is that registration performance is poor around sliding tissues and anatomical changes in the patient, and specific care should be taken with clinical decisions which depend on dose summation around such regions.

**Magnetic field.** The interaction of the magnetic field with the secondary electrons liberated by the treatment beam causes (predictable) dose deviations, in particular around low density structures such as air cavities (electron return effect) or in detectors. This effect has consequences for calibration, plan optimisation and adaptive radiotherapy. Special care must be paid to the performance of dosimeters used for calibration<sup>15,16</sup>. For adaptive radiotherapy, the current consensus is that plans can best be optimised with transient air pockets (rectum, sinus cavities) artificially filled during planning, such that the planning system does not try to compensate for the dose displacement, avoiding hot and cold spots when the cavities are closed<sup>17</sup>. Also, MRI safety must be considered, which imposes new constraints on the layout of the radiotherapy department and workflows. Finally, MRI linacs are designed to ensure that the magnetic field will have a minimal effect on the linear accelerator but the stability of these measures is so far unknown. It is therefore possible that these systems may need more frequent maintenance.

**Small bore size.** An MRI linac resembles a large bore MRI device but has a much smaller patient space than a conventional linac. Patient access will be limited during treatment and patients that are claustrophobic may be unable to have treatment. Not related

MRI guided treatments represent a fantastic research opportunity and many of the early adopters are contributing to the literature

to patient treatment, but an issue nevertheless, is that calibration equipment must be especially adapted to fit the small bore and deal with the magnetic field. Furthermore, measuring systems that are under development have limitations, eg in the beam area that can be scanned.

Geometrical deformation and MRI linac calibration. Since MRI systems define the anatomical locations by modulating the magnetic field, correct correspondence between MRI origin and radiation isocentre is purely defined electronically and will need to be quality assured regularly. Machine motion such as gantry rotation may be an additional factor affecting the images<sup>18</sup>. In addition, it is not guaranteed that all MRI sequences will provide correct anatomical localisation. A good example is water-fat shift which is known to cause registration inaccuracies. Also, fluctuations in the magnetic field, eg due to



external influences, may cause geometrical inaccuracies. Finally, metal implants in the patients could make MRI guidance unfeasible or unsafe, while active implants may be affected by the magnetic field or the radiofrequency signals.

#### **Opportunities**

Newly developed workflows. With a radically new treatment machine, workflows can be redefined and there is now a lot of focus on daily adaptive replanning. Obviously this allows optimisation of geometrical accuracy, although the workflows are not very practical in their current implementation, reducing patient throughput. Because of the good image quality, guidance can be performed on structures that were previously invisible. A good example is the potential to guide on individual lymph nodes, which may lead to a game change in defining elective nodal irradiation. **Extreme hypofractionation.** The improved geometrical accuracy in combination with the possibility to adapt treatment on the fly, and monitor for motion during delivery, gives for the first time, the ability to safely perform extreme hypofractionation in areas with organ motion, ie outside the brain<sup>19</sup>. Clinical trials are being designed to test these approaches in anatomy where brachytherapy was used before (eg prostate).

**Research.** MRI guided treatments represent a fantastic research opportunity and many of the early adopters are contributing to the literature. There is however, a risk that the large volume of MRI based research will reduce research on other aspects of radiotherapy, eg target definition, especially when the high accuracy of MRI guidance has been realised. However, since MRI traditionally has been developed for diagnostic purposes, there is a great opportunity to develop novel MRI sequences and methods especially tailored for radiotherapy. One of the major challenges in the field of MRI guided radiotherapy will be to demonstrate the benefit in terms of local control, toxicity or survival, compared to standard CT guided radiotherapy.

#### Threats

**Workflow and software development.** MRI guidance workflows depend on software and workflows that are not yet well developed. For instance, 4D CT is widely used in radiotherapy planning of abdominal tumours, yet 4D MRI so far has only been available for research applications. Poor image registration may affect dose accumulation and invalidate adaptive workflows, leading to underdosing of the tumour and overdosing of organs at risk. In the new workflows, geometrical accuracy of guidance is improved which changes the balance between different error sources, ie tumour delineation accuracy will almost certainly be the weakest link. This may lead to overconfidence in the total chain of accuracy and may lead to incorrect margin definition, leading to local recurrences. Such a situation has been documented when marker based image guidance was first introduced<sup>20</sup>.

**Fraction times.** Long fraction times lead to an increased likelihood of intra-fraction motion. Particularly problematic could be organ motion in the period between initial imaging and acceptance of the adapted plan. If organ deformation or global patient motion occurs, the plan may no longer be acceptable even before treatment

commences. This in turn, would lead to the necessity of creating a new plan, extending fraction time even more.

**Sub-optimal patient selection.** New technology is attractive, but incorrect evaluation of its strengths and weaknesses may lead to incorrect patient selection, ie patients that are not significantly benefiting from the technology occupying time slots due to, for example, commercial pressures. This situation has occurred before with proton therapy, where many patients with prostate cancer were treated without evidence of benefit over photon therapy.

Staffing. Currently MRI guided systems are operated by teams of physicians, therapists, radiographers and physicists, because of the diverse and complex tasks to be performed in order to deliver the treatment. This is in stark contrast to CBCT guided therapy which is, at least in Europe, performed by therapists only. Combined with the limitations of access due to MRI safety issues this situation could lead to staff shortages. Ultimately, we should work towards a situation where therapists are capable of performing the entire workflow.

#### Conclusion

Although we have highlighted several issues yet to be resolved, MRI guided radiotherapy is a promising and exciting technology that may be a real game changer in the treatment of many tumour sites. However, the proof of the pudding is in the eating, and extensive clinical evidence is needed to demonstrate the benefits of this technology<sup>21</sup>.

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### Up Close and Personal with the Breast Cancer Pathway – A View From the Other Side of the Fence

Gillian Thompson

I trained as a therapeutic radiographer between 1990-1993 and worked clinically until 2002, when I moved into higher education, teaching radiotherapy and oncology. Over the years, I had probably treated thousands of patients with breast cancer and thought I had a relatively wide range of knowledge and experience, which I keenly passed on to my students. That was until I was diagnosed with breast cancer at the age of 43. Now, having been through the breast cancer pathway myself, I realise I didn't know half as much as I gave myself credit for.

his article will explore some of the issues faced by being on the other side of the fence. One of the main things I have learned is that no two people with a diagnosis of cancer feel the same, no two patients have the same experience and you can't really compare like for like. We are non-standard and non-conforming specimens. While 'cancer patients' may all have similar underlying emotions we deal with our problems differently. I will describe some of those commonalities and differences, and how my own experience has led to my having increased empathy.

#### The newly diagnosed patient

Nothing can quite prepare you for the day a doctor tells you the lump they thought was very unlikely to be anything sinister actually is something sinister. I remember feeling rushed through the breast screening pathway at break-neck speed, barely having time for the news to sink in. Then having a plethora of information to absorb, but not knowing quite where to start. I was assigned a wonderful breast care nurse who handed me a neat little file with any irrelevant information scribbled out and she talked me through the options. I asked how long I would need off work; nine months to a year I was told. Ridiculous! Of course I wouldn't, or so I thought.

In February 2015, I was diagnosed with a 2cm ER+/PR-/HER2+ stage 2 grade 2 ductal



carcinoma with disease in two out of 10 lymph nodes. In other words, the primary tumour tested positive for oestrogen receptors, negative for progesterone receptors and positive for HER2 protein receptors (Human Epidermal Growth factor 2). The plan was a wide local excision and axillary clearance followed by six cycles of FEC-T chemo; three cycles each of fluorouracil, epirubicin and cyclophosphamide then three cycles of docetaxel followed by 20 fractions of radiotherapy, 18 cycles of trastuzumab (brand name Herceptin®) and 10 years of tamoxifen. Easy when you say it fast but on closer inspection I found this a very daunting care plan. The research started in earnest. Of course I understood the radiotherapy side of things but I knew little about chemotherapy regimens and their associated side effects. Surgery went very well, the tumour was removed successfully, fluid was drained, the swelling started to recede and the scars were neat.

During recovery, when I first met a fellow patient for coffee and a chat, and some 'recommended' peer support, I found I was rather lost for words as she had undergone a mastectomy. Since I hadn't had one myself I could not begin to imagine how she felt losing a breast – my sympathy was genuine but my empathy wasn't. In my opinion, most therapeutic radiographers do not particularly focus on the kind of surgery a patient has, other than whether it is a mastectomy or breast conserving surgery. Surgical options remain a void in my knowledge of the breast cancer pathway and I make no apology for that; I was too busy working through the information that was relevant to me that I completely shut off from the rest. There will always be patients who find that knowledge is power while conversely others find it unnerving. I think that whether patients embrace or shut off from knowledge, both groups are demonstrating a form of self-preservation.

Nothing can quite prepare you for the day a doctor tells you the lump they thought was very unlikely to be anything sinister actually is something sinister

#### **Conflicts of interest?**

Fast forward from February 2015 to April 2015 and the surgical scars are healing nicely. The chemotherapy is about to begin but first there is a 'booking-in' appointment at the chemotherapy unit, which involves explaining the procedures and side effects, going over my medical history and answering guestions about ongoing symptoms and any allergies. Another perfectly competent healthcare professional goes through my medical history and explains what will happen next, but as soon as she asks me what I do for a living and I tell her I teach radiotherapy and oncology, she seems to go into panic-mode, feeling like she's being assessed by someone who knows more than her. I strongly reassure her that I know very little about chemotherapy and I want it explained to me from the beginning as if I knew nothing. Similarly, when I started my radiotherapy treatment I wasn't given the 'chat' that all patients get. I assumed that they felt I knew it all anyway and it would be patronising to go through information I teach to students on a daily basis. However, guidelines and recommendations change. For example, the local skin care protocol to reduce skin reactions had been changed from aqueous to QV™ cream (Crawford Healthcare, Knutsford, Cheshire, UK), which is a lanolin-free moisturiser. However, it is not one of the recommended creams in current skin care guidelines<sup>1</sup>, which conclude that, overall, the evidence base is not strong enough to either support or refute the use of any particular product for topical application. I met other ladies in a similar position to me through various forums and support networks, and it became apparent that across the UK, that advice to patients regarding skin care during radiotherapy was mixed. At first, I would put forward my professional view explaining the difference between local protocols and guidelines from national organisations. However, in the end it became an arduous task trying to appease a large group, so I held back from offering any advice at all - the exact opposite of what I had been trained to do and this saddened me.

#### Managing side effects

Radiographers play a vital role in the diagnosis and treatment of patients with cancer<sup>2</sup> and so they are well placed to provide information and support, but in order for this to be effective they need to be aware of the potential issues patients may be facing. I thought that with all my years of clinical experience, I had a good level of knowledge of what a patient with breast cancer may be experiencing when they attend for treatment. Having breast cancer is a chronic condition rather than an acute illness, and I think this is a fundamental aspect which may often be overlooked by some radiographers

Naively, I thought that as radiotherapy is given post-operatively then they do not have cancer any more as it has been surgically removed. Right? Wrong. Having breast cancer is a chronic condition rather than an acute illness, and I think this is a fundamental aspect which may often be overlooked by some radiographers.

Chemotherapy brings its own side effects – some you are warned about and some you are not. I was told I would lose my hair from day 17 of cycle 1 onwards, and this was pretty accurate. I was told I would be very nauseous and that was also true. However, nobody told me about 'chemo-brain' and how my brain would feel like it had turned to jelly and I would be incapable of holding a thought in my head for longer than three seconds. Nobody told me that my nails would suffer and I would lose toenails, which would be replaced by a version of gnarly hardened skin rather than actual nail, or that this would lead to repeated infections and ingrown toenails which would require long term podiatrist care. Or that my fingernails would continue to split and flake and be virtually useless as nails. It seems that not everybody suffers these side effects, but they were happening to me, therefore they were important.

#### Peer support

After diagnosis, I was encouraged to engage with and meet different women in the same situation. In fact, hospital waiting rooms are full of posters about support groups and meet-ups and coffee mornings, enough to keep you fully occupied on your good days. In this era of social media you can meet other patients at the touch of a screen or the click of a mouse. Being 43 years old when I was diagnosed meant I qualified as a 'younger' breast cancer patient, and was directed towards a Facebook group

called Younger Breast Cancer Network (YBCN) set up by a patient who was frustrated at the lack of support for younger women and the issues they face, including body image and fertility. I met women online in a closed private group who were at all stages of the breast cancer pathway – some were newly diagnosed, some were starting chemotherapy, some were starting radiotherapy, some were having reconstructive surgery. Nothing was off limits and you could ask a question or offer a virtual hug or just use the group to rant about how angry you were. Anger is a common emotion in people with cancer, as well as feelings of helplessness. This group became my lifeline because they just 'got it'; they knew how it felt because they had been through it themselves and had true empathy.

I made particularly good friends with a woman (A) who lived quite near me. We would meet for coffee regularly and stay in touch by text and we quickly became close. Just before Christmas 2015, we had a regional coffee meeting and were joined by another local woman (B) who told us she was having treatment for secondary breast cancer as her original disease had spread to her lungs, liver, brain and bone. This is where it starts to get tricky – you get so much from your peers who have empathy with your situation, but what happens when the news isn't good? Now my friend (A) has also been diagnosed with brain and lung metastases and has recently completed palliative radiotherapy to her head and chest less than a year after finishing primary treatment.

In addition to YBCN, I joined the Where Now? course at the local Maggie's Centre<sup>3</sup> after treatment had finished, which is a seven week structured programme dealing with the issues faced by patients at the end of their active treatment, such as exercise and nutrition. I grew very close to the rest of the women in the group. One of them died two weeks ago. That unfortunately, is the reality of making friends with fellow patients; you take the rough with the smooth. It is hard not to feel guilty about the fact that you remain well(ish) when others are facing a shorter life, but the support you get from them means you create a special bond that you can only really understand through experience. Therapeutic radiographers like myself and other health professionals may be deeply sympathetic in such circumstances, but of course a new dimension is added when you are the one affected. Family and friends are a constant source of love and support but peer support is another arena entirely – you don't have to pretend to be strong in front of your peers. They have been through diagnosis and treatment just like you, they fear recurrence just like you, and they understand the lingering side effects just like you.

They have been through diagnosis and treatment just like you, they fear recurrence just like you, and they understand the lingering side effects just like you

#### After treatment

My experience is that when treatment finishes (if indeed it ever really does) you are expected to rejoice and celebrate, but the reality is that this is the point at which you are least willing to celebrate. You are not sure what exactly you're celebrating and, perhaps surprisingly, you can be at your lowest point mentally, physically and emotionally. This feeling has been described as 'being pushed off a cliff' as you are sent off into the big bad world again and expected to find your new niche as the 'new you', damaged but grateful to be alive. You go back to work, you apologise for your failings, you make excuses for the menopausal side effects, and you try not to catch yourself in the mirror too often. However, you continue because that is the only way to go, forward. You need to find your way back to normality but what you don't always realise is that you have to find your 'new normal'<sup>4</sup>.

It is just over a year since I finished chemotherapy and radiotherapy, and I still don't feel able to celebrate just yet, but hopefully that day will come. I miss my treatment buddies as we don't get to see enough of each other – we have to join in with real life again. I returned to work in March 2016 while still undergoing Herceptin treatment which consisted of 18 intra-muscular injections into the thigh every three weeks. The side effects were manageable enough to allow me to go back to work – but I did need that year off after all.

While the physical scars of cancer may fade and the hair may grow back and the hot flushes may settle down, you certainly don't come out of it the other side unscathed. It has been likened to a form of post-traumatic stress disorder<sup>5</sup> and some patients report anxiety issues for many years. One thing that has kept me going throughout the last 18 months has been my desire for learning, and I've learned so much from my journey through cancer which I could never have gleaned from articles, texts or indeed any kind of academic setting. It is a harsh lesson for anyone to learn, but I'm determined to use it to enhance my practice as a professional and to enhance the patient experience.

#### Summary

As a therapeutic radiographer I had always worked hard to make a difference to my patients, and give them the appropriate support and care needed and expected but now, as a cancer survivor myself, I can offer a new dimension of care that simply wasn't possible before. This is the way forward for me as I continue my life and career as a

#### Nobody told me about 'chemo-brain' and that it would make me incapable of holding a thought in my head for longer than three seconds

health professional. I said at the start of this article, no two people experiencing cancer are the same and certainly 'one size' does not fit all. However, my personal experience of the cancer pathway, and the friendships forged as a consequence, now give me greater insight, empathy and understanding when serving my patients.

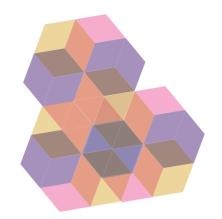
I am in a much stronger position to support them and their families when they attend for treatment, and I can try to teach my students to do the same. I feel better equipped to educate people about the benefits of peer support and the issues faced by patients going through the cancer pathway. When a patient attends for radiotherapy they may be facing myriad emotional and physical issues of which we as healthcare professionals are simply not aware – so my message is clear – don't assume you know what they are going through, and don't assume that when they say they are 'fine' they are fine. The reality is probably quite different.

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Gillian Thompson is a Therapeutic Radiographer who qualified in 1993 and moved into higher education at Sheffield Hallam University in 2002, becoming a Professional Development Facilitator/Senior Lecturer in Radiotherapy and Oncology. In 2015 she was treated for breast cancer and subsequently joined the Patient & Public Liaison Group at the Society and College of Radiographers.

If you wish to learn more about the work of the Society of Radiographers' Patient and Public Liaison Group please visit http://sor.org/about-radiography/patient-and-public-and-liaison-group 33



### Radiographer-Led Discharge: What are We Waiting for?

Morag Howard

Radiographer-led discharge (RLD) by appropriately trained radiographers is an advanced practice that facilitates the discharge of patients with minor musculoskeletal (MSK) injuries directly from the imaging department<sup>1,2,3</sup>. This in effect, cuts out 'the middle man' and negates the need for this category of patient to return to the emergency department (ED) to await further consultation and discharge. Return visits, often with lengthy delays, can be frustrating for both health professionals and patients alike, where the majority of diagnostic imaging examinations undertaken are normal and the patient requires minimal or no treatment<sup>2</sup>. he first published study in relation to RLD dates back a decade ago to 2007. However, despite this extended scope of radiographic practice showing positive benefits for patients sustaining minor injuries in terms of waiting times and streamlining of the care pathway<sup>2,3</sup>, there is little evidence to suggest it is being widely adopted in the UK.

The purpose of this commentary is to share the experiences of RLD in a community hospital site in rural North East Scotland. It is believed that this is the only hospital in the North of Scotland where the practice of RLD exists, despite a Scottish Government recommendation that the involvement of radiographers is optimised in patient discharge processes to support compliance with the four hour ED waiting time initiative<sup>4</sup>.

#### The patient pathway before RLD

EDs and minor injuries units (MIUs) in the community hospital setting in North East Scotland are nurse-led with the support of local general practitioners (GPs). Additional support utilising the national picture archiving and communications system (PACS) is provided by the nearest regional trauma centre through the use of telemedicine or clinical decision support, which is solely a telephone advice service. All of these hospitals offer diagnostic imaging facilities with a radiographer commenting system, providing a preliminary diagnostic opinion for referrers. However, these tend to be available only during daytime working hours. Traditionally, patients who had sustained a minor MSK injury and been referred for imaging experienced increased waiting times due to the nature of the patient pathway (Figure 1). In addition, local hospital protocol dictated that this category of patient must have their diagnostic image reviewed by

### A pertinent feature of this service is the application of interprofessional working

either a GP (who may not be on-site) or an ED physician from the regional trauma centre, regardless of the written opinion of the radiographer. This invariably meant a significant waiting time for the patient.

#### The introduction of RLD in the community

Continuous audit of commenting performance by the community radiographers in North East Scotland and a programme of continuing professional development in image interpretation equates to a highly skilled workforce, who provide consistently accurate preliminary opinions on image appearances, thus enabling appropriate patient management. One highly experienced and motivated community-based radiographer undertook a short training course in minor injury assessment and discharge, in addition to an appendicular skeleton reporting module at a Scottish university. With support from radiologists, radiography management, locality management and the community hospital ED team, it was decided to pilot RLD on that site to examine the feasibility of the practice in relation to the patient pathway.

A collaborative radiographer-led discharge protocol was developed by the radiographer, ED consultant from the regional trauma centre, minor injury nurses and GPs. The protocol shaped a scope of practice which permitted the discharge of patients with minor MSK injuries of the ankle, foot, wrist, hand and elbow directly from the imaging department, but only when a written radiographer comment was provided to confirm that there was no acute bone or joint injury seen on the radiograph. Restrictions on individuals eligible for RLD were infants under the age of two, the presence of open wounds, a pre-existing bone or joint injury or comorbidities such as diabetes or immunosuppression.

A pertinent feature of this RLD service is the application of interprofessional working practices to provide an optimal patient-centred approach to the care pathway. The discharging radiographer works closely with the minor injuries nurses to establish a holistic treatment pathway which is individual to each patient and showcases an









Inclusion of clinical assessment skills in undergraduate curricula may breed a new type of graduate radiographer



innovative use of radiographer-led discharge skills where there is direct influence on the patient's treatment pathway. This approach works well in a community hospital likely due to a generally slower pace of patient throughput than in larger trauma centres and, anecdotally, stronger interprofessional relationships that seem to exist within a smaller workplace.

#### The pilot study

A pilot study to investigate the feasibility of RLD in a community hospital was undertaken over a period of six months, with the results of this study to be disseminated in a profession specific peer reviewed journal. During the study period the radiographer, when on duty, discharged all patients who fell (no pun intended) within the RLD protocol. Following an individualised patient treatment plan, the radiographer offered selfmanagement advice, answered any questions the patient may have had in relation to their injury and undertook simple treatments such as buddy strapping of digits and the administration of inflatable walking boots for ankle sprains. Furthermore, the practice of RLD freed up the GPs and minor injuries nurses to undertake other more urgent duties within the hospital.

To explore the impact of RLD in terms of the patient pathway, the arrival time of the patient to the ED and the time of discharge were recorded. This enabled comparisons to be made between the usual clinician-patient discharge method and RLD in patients with minor MSK injuries.

#### Impact of RLD

In line with other published evidence, this small scale pilot study found that the mean patient discharge time utilising RLD was significantly reduced (10-100%). Delays in telemedicine consultations from the busy regional trauma centre and GPs arriving onsite from home visits are believed to account for the favourable discharge times using RLD. Perhaps the most important finding was that no patients re-attended the ED with the same injury after RLD. It could be suggested that the radiographer empowered the patients to self-manage their injury effectively with unambiguous treatment advice. A further study is warranted to examine patients' perspectives of RLD in an attempt to explore patient experience and satisfaction.

In this community hospital RLD is popular with both GPs and minor injuries

nurses, due to the positive benefits in shortening the patient journey and by freeing up practitioners' time. As such, RLD has been formally adopted on this site and is being continually audited to ensure best practice. This action supports the Scottish Government's 2020 vision for health policy that advocates that hospital attendees are treated and discharged to their home as promptly as possible<sup>5</sup>.

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#### Potential barriers to RLD

Radiographers themselves, particularly those with extensive ED experience, may be ambivalent to the practice of RLD, mainly due to concerns relating to adequate recompense for increased responsibilities and potential litigation from patients<sup>1</sup>. This may indicate a lack of confidence relating to the skillset required to enable radiographer-led patient examination and discharge. However, Snaith and Lancaster in 2008 stated that 'clinical assessment skills are not an optional extra, but are a requirement of radiographic practice'<sup>6</sup>. Furthermore, the Health and Care Professions Council's Standards of Proficiency for diagnostic radiographers state a requirement for registrants to possess knowledge of patient assessment and have the ability to distinguish normal from abnormal appearances on images<sup>7</sup>, both of which are necessary for RLD. Perhaps ultimately, the inclusion of clinical assessment skills in undergraduate curricula may breed a new type of graduate radiographer, who embraces RLD due to inherent proficiency in patient consultations and assessment of injuries including subsequent image appearances. In the meantime, the development of short focused postgraduate courses may support radiographers wishing to undertake RLD. Alternatively, radiographers may access courses such as the Minor Injury Nurse Treatment Service programme<sup>6</sup> in Lanarkshire.

With particular reference to Scotland with its diverse geographical landscape, barriers to radiographer role extension exist in terms of access to postgraduate education and backfill provision<sup>8</sup>. It is also disheartening that the radiological support for radiographer role extension that was found to be present a decade ago<sup>9</sup>, appears to have diminished. According to subsequent Scottish studies, the radiography workforce perceives radiologists to be resistant to the evolving role of the radiographer<sup>8,10</sup>. Further research to ascertain the reasons behind this apparent change of radiological attitude would be beneficial to the radiography profession, as this 'old alliance' could work better collaboratively to shape the diagnostic pathway for patients.



#### The future of RLD

Radiographer-led discharge in the community hospital setting is sustainable and supports a reduction in ED waiting times in line with national targets. In addition, the care pathway in patients with minor MSK injuries can be streamlined thus enhancing the overall patient experience. Perhaps the most notable finding is that patient reattendance and possibly recall rates in ED can potentially be reduced, due to an accurate initial diagnosis being made by radiographers following imaging. However despite the potential benefits to service delivery, the practice of RLD does not appear to be widely employed across the UK. The reasons behind this lack of implementation are unclear but one may be an uncertainty around which budget should fund the service. Further reasons may be unearthed by exploring attitudes of radiography staff and management, as well as ED health professionals. Finally, and perhaps most importantly, patients' opinions should be heard since they are often drivers of change in today's patient-focused NHS. Previous studies in relation to RLD have been small scale and so to fully assess the potential impact of this practice on EDs, larger UK-wide studies should be undertaken.

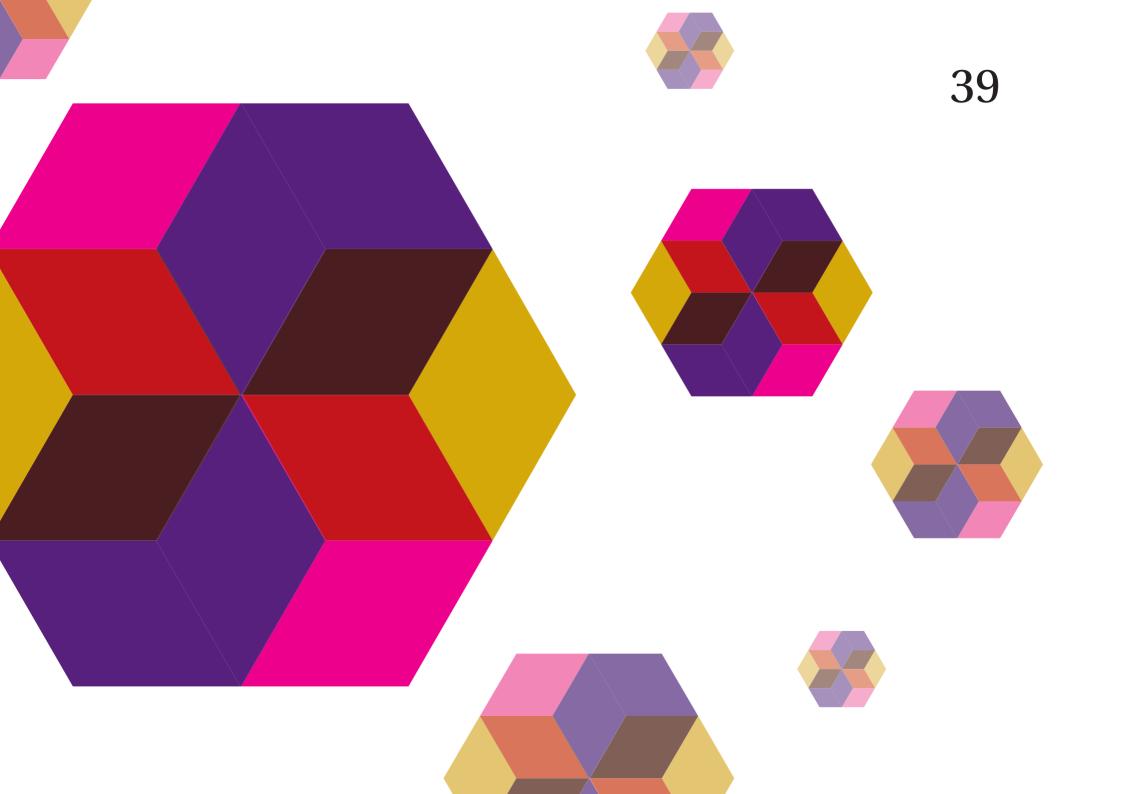
Furthermore, it is imperative that discharging radiographers are equipped with the necessary image interpretation skills, as well as proficiency in assessment and discharge through specialist training, and that radiology/ED managers support the progression of RLD in terms of finance, education and backfill. Radiographers undertaking RLD also need to be confident in their abilities to diagnose normality on images and possess the communication skills required to effectively disseminate the diagnostic findings and treatment advice to patients. It could be suggested that these skills relate to advanced practice, which comes hand-in-hand with added responsibilities and is therefore an attractive proposition for highly motivated individuals.

So, can the practice of RLD be driven forward? RLD promotes patient-centred care as well as interprofessional working practices. Therefore, if the service is to thrive, collaboration is needed between different health professions. Service providers can learn from sites where successful models of RLD are established. Additionally, education providers may help drive RLD by offering postgraduate training and by including assessment and discharge skills in undergraduate curricula. This would equip graduate radiographers from the very start of their career who are intent on maintaining and practising these skills. For RLD to become an extension of current practice service providers, radiographers, educational institutions and professional bodies need to work together and pave the way by providing strong leadership and guidance to the radiography profession.

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# Open Magnetic Resonance Imaging – Thinking Outside the Tunnel

Debbie Horne, Mel Jones, Andy Morris, Alan Breen

Open, upright magnetic resonance imaging (MRI) was first introduced by FONAR (FONAR Corporation, Melville, New York, USA) in the mid 1990s, but has recently received attention in the press and at meetings of the imaging community following the introduction of a new generation of upright systems.

> he use of open, upright MRI has expanded slowly in the UK and Southern Europe and it is rarely, if ever, found on National Health Service (NHS) sites. Its intricacies are traditionally of little interest to most radiologists, some of whom seem sceptical of its value. However, these scanners do have their supporters, mainly for the additional findings they can reveal and the special

patient circumstances they can accommodate, even though research has so far failed to consolidate any particular diagnostic benefit.

Up to 10% of the population are claustrophobic at some point during their lives<sup>1</sup> and specific research into claustrophobia in MRI has concluded that on average 1.2 to 2.3% of MRI examinations are abandoned due to patient anxiety but may be as high as 15% in some centres<sup>2.3</sup>. Based on NHS figures for MRI activity in 2013-14<sup>4</sup> this would equate to

at least 32,892 patients failing to complete or even start their MRI scan. With an increase in MRI referrals of about 12% per year<sup>4</sup> this figure is growing, which suggests there is viability to a service that, as well as being able to provide upright scanning, may also accommodate the majority of these claustrophobic patients.

Here, we discuss an open, upright scanner service which, like most others in the UK, operates in the private sector. Our facility is unusual in that it is operated by a higher education institution that is also a charity and not a for-profit business. We believe that this has helped us to take a fairly impartial view of the role of open, upright MRI in patient care.

#### **Procurement**

Setting up a completely new MRI unit in a non-NHS establishment came with a long list of challenges that needed to be overcome, to ensure that a safe and appropriate service was created.

In the first instance, it was necessary to persuade the governors of the Anglo-European College of Chiropractic (AECC) that it would be a good idea to spend a vast amount of money on a project that was far removed from anything they had done before, and in a field in which they had no experience. They approved the project for three main reasons: The first was to enhance the College's undergraduate, postgraduate and research provision, the second to fulfil an unmet health need in the local area and the third to bring to reality an innovation that would both serve the objectives of the charity and be financially sustainable.

The AECC is a higher education college in Bournemouth whose graduates (chiropractors) are publicly regulated. Missing in the facilities available to them as

The business case for installing yet another MRI scanner in the Bournemouth and Poole area was initially unconvincing

practitioners, but gradually becoming more accessible (if not always affordable), were MRI services. Learning to use MRI in a way that would prepare them to meet the required standard of safety and governance was therefore desirable. The College already had plain radiography and diagnostic ultrasound, and had just constructed a new outpatient clinic, in which there was room to extend further. It had also developed an innovative application of fluoroscopy, which allows the mechanics of spinal linkages to be measured. This was a main pillar of its research and collaboration profile and would be enhanced by the addition of MRI. 41

The business case for installing yet another MRI scanner in the Bournemouth and Poole area was initially unconvincing. There were already eight MRI scanners both private and NHS within a six mile radius of the AECC – and it was difficult to see how the College could attract local referrals with so much choice. Whilst the machine's purchase would be through charitable funds, once installed it would need to become self-sufficient, so it was necessary to have clear objectives about the MRI service we were hoping to offer and how we would differentiate ourselves in an already crowded local market. The solution appeared when the prospect of an open, upright magnet presented itself.

Apart from providing an affordable self-pay service to musculoskeletal (MSK) patients of local practitioners, an open, upright scanner could accommodate patients who would never otherwise receive MRI. These include patients with severe claustrophobia, certain deformities and conditions that would prevent them from lying flat. However, there was an important trade-off. Lower field scanners are limited for some purposes and the college environment is not suitable to support administering intravenous contrast, so careful consideration was needed around whether such a scanner would be economically viable. However, the majority of MRI referrals are for MSK conditions and the added capability of upright scanning ensured that if the correct machine could be found, the benefits of an

open, upright scanner should outweigh the disadvantages in terms of sustainability.

In addition, choosing an open, upright scanner would allow the College to have a unique MRI service, not only in the local area, but in the whole South-West of England. At the time of tendering for the system, there were only two manufacturers who were able to offer MRI that might fulfil the College's clinical and research requirements. A small team was put together, including a radiologist and a senior MRI radiographer, to assess the machines and provide the College with guidance on which system might best suit their needs.

The Paramed 0.5T open, upright MRI system (Paramed Medical Systems, Genoa, Italy) was eventually selected, its unique design lending itself well to the positional spinal scanning research the AECC was already conducting, with the potential for further development of these studies. Therefore an extension was built onto the College's dedicated chiropractic clinic and in April 2014, the 26 tonne magnet was lowered into the pit that would house it. The magnet design is superconducting but it is a closed system so there is no loss of helium once the system is set up.

The table design facilitates positional scanning of the patient from completely upright (for weight-bearing lumbar or thoracic spines) to semi-recumbent (for brain and cervical spine imaging in claustrophobic patients) to completely supine (Figure 1). The table can also be lowered to allow weight-bearing imaging of the knee or removed totally from the scanner bore to image the lumbar spine with the patient standing. The spine coil design also facilitates the upright and positional scanning as it is flexible, and can be positioned close to the patient, even if there is a significant curvature.

The College employed a radiographer with extensive experience in MRI and research to set up and run the department. Eighteen months into the project a second senior MRI radiographer joined the team. Four local radiologists came on-board to provide reporting services, and a picture archiving and communications system (PACS) with voice recognition was installed to ensure best quality viewing capabilities, reporting facilities and image storage. The unit also organised connection to the Image Exchange Portal to ensure efficient image transfer to hospitals to provide streamlined and effective continuity of patient care.

The operational remit for this project was exceedingly varied and there was a requirement to ensure that the role of MRI within the College was clearly established, and that all correct procedures were adhered to by the chiropractors when utilising the

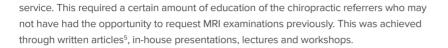
### So far we have not failed to perform an MRI scan on any of our patients

#### Table 1

#### To be able to scan patients:

- With claustrophobia (without resorting to sedation).
- With deformities that prevent them from fitting into a tunnel scanner (eg contractures, severe kyphosis).
- Who cannot lie flat for physiological reasons (eg cardiorespiratory/ oesophageal reflux/hiatus hernias/dizziness).
- Whose diagnosis needs a scan with loading or non-orthogonal positioning.





#### Analysis of service

The College has been providing the service for well over two years now and several aspects are worth specific attention. An open, upright scanner is much less intimidating and with the capability to be flexible in our method of scanning, we have been able to detect significant pathology that might not have been identified otherwise in many of these patients. We have found large disc prolapses, spinal stenosis and even spinal tumours in patients who, due to claustrophobia, were unable to tolerate conventional MRI. An open scanner is a safer option than sedation on a conventional scanner. Also, the ability to scan sitting or in flexion/extension can detect instability not apparent on a supine conventional scan.

Being situated in a chiropractic college, the referral base is very different from an NHS hospital. About 50% of patients are referred by chiropractors from the College and surrounding areas who would not normally have access to MRI. Also, now that the facility is more widely known, an increasing number of patients are being referred by hospital spinal surgeons and rheumatologists. In addition, general practitioners make referrals for a number of reasons; some may not be able to refer to NHS hospitals for scans, some may have difficulty obtaining a timely scan even if they may request MRI directly, and others may struggle to get a timely consultant referral. Necessarily, the scans are private but the cost has been set at an affordable level. Many NHS hospitals are now funding referrals for claustrophobes or patients especially suited to this scanner.

All scans are reported by practising NHS consultant radiologists from local hospitals in their spare time, to ensure reporting quality is equivalent to the standard within the NHS. Image quality is satisfactory and diagnostic although the images do appear a little different from what is seen on a more powerful 1.5T scanner. The image sequences may often be different using the Dixon technique<sup>67</sup> but this does have the advantage of providing four sets of images, including a form of fat suppression.

An NHS hospital is unlikely to buy an open low field MR scanner as it cannot perform all the more technical scans including cardiac, abdominal, vascular and diffusion weighted studies. However, there is clearly a need for an open scanner in every geographical region for claustrophobic patients and to detect MSK-related instability. The types of patients seen and the longer scan times required by the 0.5T magnet, means that we are in the enviable position of being able to allow much longer time slots for each individual compared to those allocated commonly within the NHS. Many of our patients have failed to complete MRI in conventional scanners or have refused to even attempt a scan. Accordingly, we give patients long appointments (our shortest appointment slot is 60 minutes) so we can spend time putting them at ease, fully explaining the examination and discussing the best and most comfortable way to scan them. Good communication is vital and by conveying a sense of calm and relaxation, we aim to allay their anxiety from the outset<sup>8</sup>.

Previous studies assessing the advantages of using open configuration MRI have documented the improved tolerance of patients for this type of MRI<sup>9</sup> and in our own experience so far, we have not failed to perform an MRI scan on any of our patients. In order to get the best quality images, we prefer to achieve our anatomical imaging in the supine position, but within reason we can be flexible depending on an individual's needs.

#### How often is upright scanning useful?

Aside from the obvious benefits of having an open scanning facility, the College was also very interested in assessing whether there were significant imaging differences between supine and weight-bearing lumbar spine studies. Many patients present with pain experienced only when sitting or standing, or indeed when in flexion or extension, so did scanning them in the position of pain demonstrate pathology differently? By retrospectively assessing our positional scanning over a seven month period initially we were able to make some interesting comparisons.

Discussion of the merits of open, upright scanners centre around the premise that weight-bearing scanning is frequently decisive for diagnosis. However, the principles of good clinical governance suggest that selection and justification are more likely to be deciding factors. The same is true for open and/or upright scanning, which tends to be requested for patients with special requirements and not as a replacement for general MRI. A sample of these requirements is listed in Table 1. Between 40-45 % of our referrals for open, upright scans have been because of claustrophobia. While sedation is an option for some patients and encouragement and reassurance works for others, when MRI is necessary, it is necessary and should not be delayed if an open, upright scanner is the

only way available to achieve it. In addition, many spinal patients who are referred for open, upright scanning are elderly and reclined sitting is a common scanning posture. Age sometimes results in severe kyphosis, where the spine cannot be imaged in a conventional scanner to investigate the cause (Figure 2).

#### Nerve root pain

Most patients referred for weight-bearing lumbar or cervical spine scans have suspected neural compression, either due to segmental alignment or stenotic lesions. In a small case series we conducted in 2015 and 2016 (N=45) about 60% of these patients showed nothing different in terms of stenosis between lying and weight-bearing scans. In the rest, compression was more common in the weight-bearing position and less frequent lying down (Figure 3).

Neural disruption was more common than malalignment, but sometimes both were present. Figure 4 shows an example of this as L3 nerve root compression that is apparent only on weight-bearing lumbar extension, partially due to the bulging disc and partially to the retro-position of the vertebra.

Such cases might benefit from the investigation through enhanced conservative management in the light of the findings, making upright scanning a potentially useful tool for chiropractors, osteopaths and physiotherapists working in the community, while referral by surgeons and rheumatologists for upright scanning for suspected nerve compression is perhaps more often made due to claustrophobia or deformity.

#### Conclusion

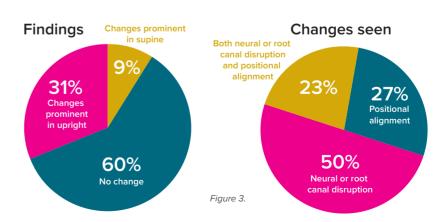
Open, upright scanning is an invaluable and innovative imaging modality for key groups of patients who may otherwise not benefit from MRI diagnosis. Ours is a truly patient focused service whilst at the same time being cost effective and accessible. The current hardware, software and physical limitations of this kind of system mean that it is unlikely to expand into the more complex fields of MRI. However, it is clear that open, upright scanning has a useful place in the MRI community and, as research continues into the benefits of postural scanning, there will undoubtedly be new applications identified for which this scanner is uniquely suited.



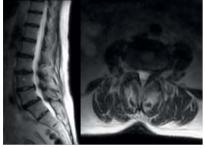
Figure 1: Bournemouth open, upright MRI scanner with table in the upright position and flexible spine coil in situ.

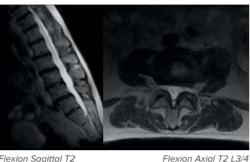


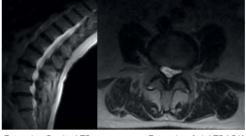
Figure 2: Example of a weightbearing sagittal T2 sequence on a patient with severe kyphosis.











Supine Saaittal T2

Supine Axial T2 L3/4 Flexion Sagittal T2

Extension Saaittal T2

Extension Axial T2 L3/4

Figure 4: Example of nerve root compression that becomes more severe in weight-bearing extension and lessens in weight-bearing flexion.

Debbie Horne is a Senior MRI Radiographer who qualified in Ipswich in 1988. She has over 20 years' experience of MRI in Swindon and Salisbury (NHS) and was a volunteer providing MRI services to athletes at the London 2012 Olympics. Debbie assisted with the initial procurement choice of the Paramed MRI and eventually joined the team at the Bournemouth Open Upright MRI in 2015.

Mel Jones qualified as a Radiographer in 1996, commenced MRI training in 2002 and went on to gain an MSc in Magnetic Resonance Imaging. Since then Mel has managed NHS and private MRI departments, as well as a research MRI unit for Oxford University (Acute Vascular Imaging Centre). She came to the AECC in 2014 as Superintendent MRI Radiographer to set up the Bournemouth Open Upright MRI.

Andy Morris trained in Medicine and Radiology at Liverpool Medical School and has been a Consultant Radiologist at Salisbury District Hospital since 1984. He has had a special interest in musculoskeletal imaging and MRI for over 20 years and was a key investigator in the research and development of the AECC's quantitative fluoroscopy systems.

Alan Breen is Professor of Musculoskeletal Research at the AECC as well as in the Faculty of Science and Technology at Bournemouth University. His specialty is the intrinsic biomechanics of the spine, which has been the focus of many research projects and a substantial proportion of his 112 journal publications and over 240 conference papers. Alan is also Clinical Director for Special Imaging at the AECC, with responsibility for quantitative fluoroscopy and MRI services, having led the procurement of the first upright MRI scanner at a chiropractic college.

### Compression was more common in the weight-bearing position

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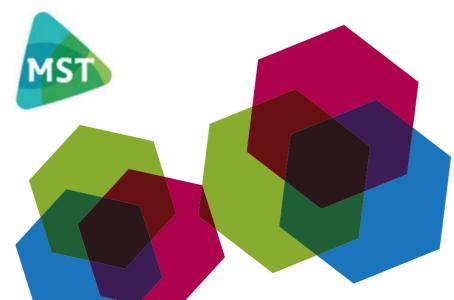
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# Ultrasound Practice in Enschede: Our Journey

Wendy Visscher, Melissa Bax

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With more than 600 beds, Medisch Spectrum Twente (MST) is a large, non-academic hospital in Enschede, located in the East of the Netherlands. The core mission of MST is to promote health in the region by providing top quality secondary and tertiary care.



n addition to high quality general clinical care, MST also offers a number of services that are usually provided only by academic hospitals, including liver surgery (radiofrequency ablation) and neurosurgery. The hospital's 30 clinics, including ultrasound and radiology, are spread over four locations. The radiology department has 24 examination rooms and performs 188,000 examinations and treatments each year, of which roughly 33,000 are ultrasound. Radiology has 145 employees, including 12 sonographers, who have been responsible for ultrasound and reporting in MST for the past 22 years.

MST has a unique approach to ultrasound examinations in the Netherlands. Until 1998, ultrasound functioned as a separate department in the MST hospital. The sonographers performed ultrasound examinations in the fields of cardiology, gynaecology and general ultrasound, under the supervision of the corresponding medical specialists, ie cardiologists, gynaecologists and radiologists. General ultrasound comprised abdominal, vascular and musculoskeletal studies. The sonographers were trained on the job and had no radiological or radiographic background.

The turning point came in 1994, when the ultrasound department received a mediocre assessment from the Dutch Society of Radiology, making it evident that some changes had to be made. One of the radiologists, together with one of the sonographers, decided to focus on abdominal ultrasound. They made an agreement to perform all the ultrasound examinations together for a period of three months to see how they could complement each other. The sonographer had mastered the technique and was able to perform a high quality examination, while the radiologist applied



Figure 1: The Medisch Spectrum Twente hospital, Enschede.

One of the outcomes of the collaboration between the radiologist and sonographer was that the person performing the examination must produce the report



the clinical reasoning from his medical background. The big question was: Could they optimise quality?

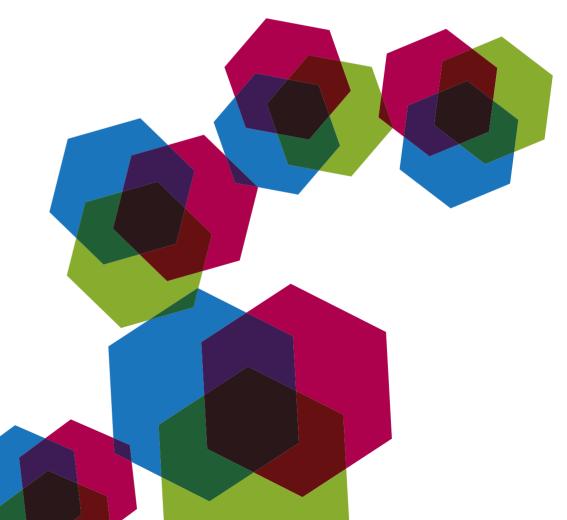
All cases were analysed together, to determine whether or not the posed clinical questions were answerable with ultrasound. Various pathological conditions were discussed alongside images retrieved from learning resources, including textbooks and web-based medical sites. By communicating together and discussing their findings, they could achieve an accurate diagnosis and produce a report. In the previous situation, the radiologist did the reporting based on the images saved by the sonographer. One of the outcomes of the collaboration between the radiologist and sonographer was that the person performing the examination must produce the report. This practice is recommended by organisations in the United Kingdom<sup>1</sup>. The sonographer's reports were sent to the radiologist for validation and, occasionally, further discussion.

The positive results yielded from the sonographer-radiologist collaboration meant that the initial trial period of three months was extended to six months. The number of examinations rose sharply due to quality improvement and increased consumer confidence, which in turn led to an increase in staff. This method for developing clinical reasoning in the first sonographer was also applied to new sonographers.

With increasing knowledge and expertise in specific fields, it became clear that it was no longer possible for sonographers to continue practising in all three clinical areas, as they had done previously. The ultrasound department had to change and sonographers were faced with the difficult task of choosing a subspecialty of either general, cardiac or gynaecological work at the expense of the other two.

After the quality improvement in abdominal ultrasound, vascular ultrasound followed in 1996 and musculoskeletal in 1997. In the early days, the less involved radiologists found it difficult to see the technical knowledge and expertise of the sonographers surpass their own. In addition, the reporting had formerly been a task only for the radiologist. The quality of an ultrasound examination was now no longer dependent on an individual radiologist, but was based on collaboration between sonographer and radiologist.

Today, sonographers are no longer trained on the job without a radiographic background. Now, the vast majority of sonographers at our hospital are radiographers who have specialised in ultrasound, which mirrors the situation in the United Kingdom. Other hospitals have shown interest in our way of working, our internal training programme, and how it improves patient safety



#### Standards and policies 2017

#### Professional association NVMBR

The association Nederlandse Vereninging Medische Beeldvorming en Radiotherapie (NVMBR) (Dutch Association of Medical Imaging and Radiotherapy) consists of several sections, one of which is ultrasound. This section comprises approximately eight people who are responsible for drafting, revising and implementing policies of the NVMBR within the field of ultrasound, and for providing training opportunities.

The NVMBR opened a quality register for advanced practitioners (AP) in ultrasound in 2015, which is voluntary and linked to the Paramedic Quality Register for diagnostic radiographers. They have drawn up a document describing the defining competencies necessary for an AP in ultrasound. It is an addition to the existing profession of the diagnostic radiographer. The definition according to the NVMBR of an AP in ultrasound is as follows:

'The AP in ultrasound performs the ultrasound examination within his/her area of expertise independently, and assesses and reports his/her findings orally or in writing. During the examination, he/she continuously takes into account the technical and physical aspects of ultrasound, in order to be able to accurately demonstrate the state or function of the body part, organ system or foetus, continuously adapting the examination according to the findings'<sup>2</sup>.

#### Nederlandse Vereniging voor Radiologie (NVvR); (Radiological Society of the Netherlands)

The NVvR Ultrasound Working Group has developed a consensus on the implementation of ultrasound. This consists of a pair of documents: A process description for radiologists and a position on the role of sonographers. This policy was established in June 2015 and describes the process from performing the examination up to, and including, the report. For ultrasound, there is a policy concerning the use of sonographers in clinical practice. This policy was written on behalf of the board of the NVvR and devised by means of a commission, which provided the following requirement: A sonographer could carry out protocolled examinations and answer unambiguous clinical questions on their own, with a high level of independency<sup>3</sup>.

#### Current method in MST

The current work involves the subspecialties: abdominal, musculoskeletal and vascular ultrasound. A contract of at least 24 hours per week is required in order to maintain the appropriate level of competence. The sonographers work solely within ultrasound and do not work with any of the other imaging modalities in the radiology department. A disadvantage is that the group is vulnerable in the event of illness and absenteeism; individual lists of patients are booked for each sonographer, which need covering in the event of sickness. In the absence of national guidance on ultrasound examinations, the full range of examinations undertaken at MST are defined by local protocols, as are other responsibilities and supervision by the radiologist.

Ultrasound examinations are carried out independently by the sonographers with one radiologist always available for advice and supervision as required. All sonographers at MST must embark on a specific postgraduate degree in ultrasound and follow an internal training programme for two years. We have drafted a document describing the sonographer training programme, which offers structure for the training period. This document is used by new employees, stating which goals are to be achieved and when. The aim is for the trainee to eventually operate at the same level of independence as the already established sonographers.

#### The three main phases of this internal training are:

- Performing ultrasound examinations under the guidance of an experienced and qualified sonographer.
- Performing independent ultrasound examinations; conferring on every examination with the supervising radiologist.
- Performing ultrasound examinations independently, with independent reporting.



#### Essential elements of the MST ultrasound service

#### **Clinical reasoning**

During the examination sonographers will ask the patient questions, a valuable source of information which can be combined with the medical information listed on the original referral. One tool used is the VALTIS, a structured method for taking a patient history.

#### VALTIS stands for:

- V (Voorgeschiedenis) History: Is there a relevant history?
- A (Aard van de klacht) Nature of the complaint: For example, is there pain and/or swelling?
- L (Lokalisatie) Localisation: Where is the complaint?
- T (Tijd) Time: How long has the patient had the complaint
- I (Intensiteit) Intensity: How severe is the complaint?
- **S** (Samenhang) Consistency: Are there other symptoms that may be related to the complaint?

A history taken with this method can also easily be passed on to the radiologist following the examination<sup>4</sup>.

#### **Quality and safety**

Ultrasound is seen as a safe and non-invasive examination modality and has been used successfully in patient diagnosis for many years. The applications are extensive and growing. To take full advantage of the technological advances it is important to ensure the safety of the patient. An important risk factor for mistakes, according to inspection reports, are untrained users<sup>5</sup>. In this context, the covenant: 'Safe application of medical technology in a hospital,' was drafted and signed by the association of hospitals and university medical centres. The agreement focuses on the safe use of medical technology in hospitals. This means a safe product, in the hands of a trained user, and performed in a safe environment<sup>6,7</sup>. Therefore, every employee should undergo a training period before working independently on a new ultrasound device. In addition, according to MST protocol, the sonographers should be assessed on their capabilities on each unit every three years.

### An important risk factor for mistakes, according to inspection reports, are untrained users

The Independent Working Group on Infection Prevention (WIP) has written a directive on hygiene requirements in ultrasound. The guideline describes hygiene measures specific to performing ultrasound examinations<sup>8</sup>.

The Dutch Institute for Accreditation in Healthcare (NIAZ) develops standards and evaluates healthcare institutions. They assess whether hospitals are able to provide an acceptable level of quality of care in a reproducible manner. NIAZ also prepared a set of standards for diagnostic imaging, including ultrasound<sup>9</sup>.

#### Reporting

Sonographers use structured reporting for safety, reproducibility and legal purposes<sup>10</sup>. The reports are reviewed and signed by the supervising radiologist<sup>11</sup>.

In order to maintain a high clinical quality in ultrasound, to demonstrate our capabilities to our clients and patients, and to meet the requirement of the NVvR, we need to show consistent quality and value. Our registration as advanced practitioners in ultrasound with the NVMBR is one of the ways in which we do this.

The ultrasound department in MST strives continuously to improve and optimise processes. One way is by giving clinically-oriented classes and continual training, both in the Netherlands and abroad. The sonographers have to complete a Yellow Belt in 'Lean' training, and at the moment a few sonographers are following the more advanced Green Belt training. This training will give sonographers tools for improving current processes according to the Lean principles. The Lean principle focuses primarily on eliminating activities that do not add value to the patient/client<sup>12</sup>. For example, in April 2015 a protocol change took place at the request of the orthopaedic surgeons who wanted infants with suspected hip dysplasia scanned earlier than previously. The sonographers involved are compiling a database and auditing the new service, so that consequences from this change may be investigated and understood.

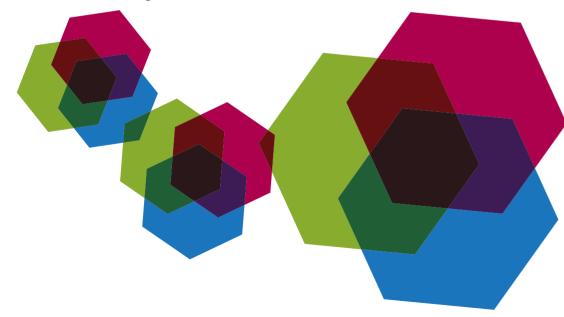
#### Conclusion

We are one of the few hospitals in the Netherlands where radiographers who have specialised in ultrasound work only in ultrasound. Other hospitals have shown interest in our way of working, our internal training programme, and how it improves patient safety.

The quality of an ultrasound examination is largely determined by the knowledge and skill of the sonographer but they are not medical doctors. However, by following a postgraduate ultrasound training programme and the two year internal training, MST provides a very good basis for clinical reasoning and scanning skills/expertise. The scanning skills of the sonographer and the involvement of the radiologist both support continual improvement in ultrasound services at our clinic.

#### Acknowledgement

We wish to thank Herma Hemelt-Vaanholt, Antione van Straalen, Kwame Aviane, Marieke Hazewinkel, Laura Westerik-Scholten and Donald Bouman for their help in writing this article.



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Both Wendy Visscher and Melissa Bax have worked at MST for approximately 11 years, first as radiographers then for the last six or seven years as sonographers. Both practise general, vascular and musculoskeletal ultrasound.

# **Triple Value Imaging**

Sir Muir Gray

Imaging professions can be proud of the part they have played in the healthcare revolution over the past 20 years. They, and the industries they worked with, have been at the forefront of not only developing high quality interventions but also developing services that ensure that quality is maintained, measured and improved throughout the NHS. However, the paradigm is shifting from the model that has dominated the NHS for the last two decades, namely evidence-based decision making and quality improvement, to one that focuses on value.

or the last 20 years, there has been a drive to reduce cost, or to put it in another way to increase productivity by reducing the mean cost of a radiology investigation, be it a chest x-ray, ultrasound or magnetic resonance imaging (MRI). This has to continue, as indeed does the drive to improve quality and safety. Low quality care is of low value but high quality care may not necessarily be of high value.

The NHS RightCare Programme<sup>1</sup> is focused on increasing value to meet rising need and demand in the decade to come, in which there is unlikely to be a commensurate increase in the funding for the NHS, so it is vitally important to focus on value and to shift resources from lower value activity to higher value activity. But what does the word *value* mean?

#### Productivity, efficiency and value

Productivity is a classic economic term meaning outputs over resources, for example the cost of a lumbar spine MRI or the cost of a hip replacement or even the percentage of knee operations that are done as day case operations. In 1966, Avedis Donabedian introduced the concept of quality into healthcare. He emphasised that as well as thinking about inputs and outputs, the economists' classic terms, it was essential to think about outcomes, namely what was the result for the patient, and therefore for the population, of a particular intervention. Efficiency therefore is measured by relating the outcomes to the resources used.

It is important to point out that in the literature of North America, where there is a growing number of articles about 'value based payments', the term value is used to mean the outcomes related to the resources used to treat the patients. However, in the NHS, outcomes over resources is termed efficiency and is not the same as value,

Overuse of healthcare is now recognised internationally as a major issue

because in the NHS we need to consider not only the patients who are treated but also underuse and overuse:

- Underuse the people in need within the population who are not being referred or being investigated or treated, which is sometimes related to their social class, so may be a problem of equity as well as efficiency
- Overuse the people getting diagnostic tests or treatment, which are of little or no value to them because it represents an overuse of the health service.

In NHS RightCare therefore, the term 'value' is a broader concept than the terms of efficiency and productivity, the average cost of an x-ray or MRI or CT scan, as described in the Venn diagram (Figure 1)

### Understanding overuse and underuse and unwarranted variation

The need for clinicians to focus on the populations they serve as well as the patients they see was first described by Professor Jack Wennberg<sup>2</sup>. He studied variation in New England in the 1990s and showed large differences in healthcare between cities, counties and states. Some of this can be explained by variation in need but much of it he termed unwarranted, namely it could not be justified by variation in need or by the explicit choices or preferences of the individuals and the populations being served. He published the *Dartmouth Atlas of Variation in 1999* and in this he wrote about overuse and underuse.

Overuse of healthcare is now recognised internationally as a major issue which always wastes resources and sometimes results in harm. In January 2017, *The Lancet* published seven papers in overuse and underuse, and the need for higher value healthcare.

Overuse wastes resources in that it consumes resources that could be used for other patients and, as stated in a recent report from the Academy of Medical Royal Colleges,

Utilisation Value Are the right people being treated or is there either 1. harm from over diagnosis or 2. inequity from underuse?

Outcome for patients treated / costs

Productivity Outputs / costs

Figure 1: The relationship between utilisation value, efficiency and productivity in healthcare.

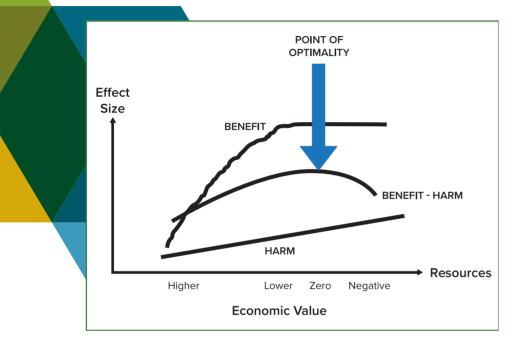


Figure 2: Donabedian's optimality curve<sup>5</sup>.



with the Royal College of Radiologists centrally involved, a waste of resources does not mean that the taxpayers' money has been wasted. It means that other patients' treatment has been delayed or denied<sup>3</sup>. Overuse is therefore a key issue and we need to think about its relevance to imaging.

#### Unwarranted variation and imaging

The NHS RightCare Programme introduced Atlases of Variation based on Jack Wennberg's wonderful Dartmouth Atlas of Variation. Two atlases have been produced on variation in diagnostic services which show marked differences.

Such a range of performance cannot be explained by variation in need and is therefore classified as unwarranted variation and although the imaging that has been done is of high quality it will not all be of high value for the population served. Furthermore it is not caused by consumer demand but by a style of practice on the supplier side of the equation<sup>2,4</sup>.

Increasingly we will be looking to the imaging professions not only to think about quality but also to think about value particularly to prevent harm.

#### The harm from over diagnosis

In the news section of a United States journal ten years ago, an American radiologist wrote about the problems of incidentalomas or as he wrote 'an incidental Oh My' namely things that are seen that would not have been seen with older equipment, leading to referral and perhaps extra investigations or treatments which carry a risk and a cost. It is vitally important that we start thinking about this. It is also very important to appreciate another of Donabedian's great initiatives and innovations, his optimality curve (Figure 2).

In 1980, Donabedian published his classic book on quality and included this diagram which is vitally important for everyone in imaging<sup>5</sup>. It shows that as you increase the amount of resources the benefits flatten off but the harm increases in a straight line. Quality changes the relative position but not the shape of these curves and with imaging growing at least 10% per annum, we have to ask what is the added value of the last 10% of the increase and are there some aspects of imaging where added value is starting to decrease? Imaging professionals must take time to analyse which factors are driving low value imaging. The answer is, of course, complex and multifactorial.

#### Moving to triple value

The value discussed above is the value from the utilisation of resources but there are two other aspects of value – allocative and personal.

#### Allocative value

Allocative value and allocative efficiency are generated by the allocation of resources. For example, we spend about seven billion pounds on cancer, three billion pounds on eyes and vision and five billion pounds on respiratory disease every year in the UK. At a local level, the same pattern of spending is monitored by what we call programme budgeting information, which can be seen in the Commissioning for Value Packs available online and on the NHS England website<sup>6</sup>. What is striking is the variation between one population and the other. For example, there is a 1.9-fold variation in spend on cancer and a 1.9-fold variation in spend on mental health with no apparent reason. This is unwarranted variation in expenditure.

Now, at the Clinical Commissioning Groups (CCG) level, no allocation decision is made about imaging as a whole but increasingly there will be an examination of the amount spent on imaging for a population, or within the cancer programme budget the amount spent on imaging, compared with the amount spent on chemotherapy or radiotherapy or surgery. The professionals involved in imaging should be thinking about their budget in terms of not just how much they can get from the hospital budget, but also how much is being spent on imaging in their population and how that compares with expenditure on imaging in other similar populations. The NHS RightCare Programme produces Commissioning for Value Packs which allow CCGs to compare themselves with the nine most similar CCGs in demographic terms. This has not been done yet but will happen.

#### Personal value

Finally, we need to think about the concept of personal value. How would the individual value an investigation such as MRI? Increasingly, we are asking patients to rate what difference a treatment has made to the problem that is bothering them most. What if we were to ask every patient what difference the imaging examination had made? This of course, brings up the need to define outcome and the outcome of imaging is often complicated because it is often used to make or confirm a diagnosis or on other

With imaging growing at least 10% per annum, we have to ask what is the added value of the last 10% of the increase? 55

occasions to exclude a diagnosis, or indeed to reassure an anxious clinician.

However, the issue of the personal value individuals attach to any intervention including a diagnostic intervention, will become increasingly important in the decade to come because the collection of outcome data will become routine; people will be asked questions such as: 'How well did this intervention help you cope with the problem that was bothering you most?'

#### Population based and personalised imaging

Imaging services, like all other health services, face the challenge of increasing demand without an increase in resources. Furthermore, because of a failure to understand the value that radiologists, radiographers and physicists bring, there is a move among provider chief executives to think that services can be outsourced.

They do not realise the difference between an image and a test. Those companies that simply offer cheaper images, without the knowledge that radiologists bring to convert those images into tests of high value for populations and individuals, will increase costs in the longer term, although there may be short term reductions in costs. Commissioners are relatively unsympathetic because they rarely see the detail of what is happening within healthcare organisations, although there may be a significant increase in referral because of a change in clinical practice style without additional resources being made available within the provider organisation. This represents a major challenge to the professions.

#### Summary

In all countries, need and demand will increase faster than the resources available. All societies will have to make decisions about the amount of resources invested in, for example, the programme budget for people with musculoskeletal disease or the programme for people with cancer. Within the musculoskeletal programme budget of about £110 million per million population, how much should be spent on rheumatoid and how much on back pain or hip pain? Within each of these budgets, professionals will need to ask how much should be spent on imaging. In addition, imaging services will need to ask if the balance of their activity between different patient groups or different imaging modalities is optimal. Should resources be shifted from ultrasound to CT, or vice versa? These will be the key questions of the next decade. Commissioners are relatively unsympathetic because they rarely see the detail of what is happening within healthcare organisations

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Sir Muir Gray entered the Public Health Service by joining the City of Oxford Health Department in 1972 after qualifying in medicine in Glasgow. He is now working with both NHS England and Public Health England to bring about a transformation of care, with the aim of increasing value for both populations and individuals, and has published a series of 'How To' handbooks including *How to Get Better Value Healthcare, How To Build Healthcare Systems* and *How To Create the Right Healthcare Culture.* 



# Litigation in Radiology: A Personal Perspective

Mike Weston

We live in an increasingly litigious culture and the rising number of medico-legal claims reflect this. Unfortunately, radiology is one of the areas of healthcare most liable to claims of medical negligence<sup>1</sup>. When a claim is made, an important part of the preparation and decisionmaking in the legal process is to draw on the opinions of an experienced professional – the expert witness.

> his is my personal perspective as an expert witness. In little more than three years I have been asked to comment on 100 cases which fall within my expertise, and appeared in court on two occasions. This article discusses the practicalities of being involved in medico-legal work and also aims to draw out some messages from the cases to inform one's everyday radiological practice.

#### How do the lawyers find expert witnesses?

If you do not wish to engage in medico-legal report writing, then have no fear, you can just say no if a lawyer approaches you. Equally, even though you may be a willing

'expert', a case offered may not be within your scope or there may be a conflict of interest if you know individuals involved. Sometimes lawyers ask professional bodies for advice since some hold a database<sup>2</sup> or lawyers may have been given your name by another expert, as someone who has expertise in the area required. It helps to have a reputation for your radiological practice either in your local hospital setting or in the wider national sphere from publications, presentations, college work or guidance publications. Alternatively, you can register with an organisation such as 'Action against Medical Accidents'<sup>3</sup> or 'The Medico-Legal Experts Practice'<sup>4</sup> as having an interest in writing reports.

#### What does it involve?

It is becoming less common for the solicitors to send you a large box containing numerous lever-arch files of copy notes and correspondence. Information governance has led to many of them either sending all the material on an encrypted disc or to providing you access to a password protected website. Even so, the images are still mostly sent to you on an encrypted disc.

The lawyer in the letter of instruction will direct you to answer certain radiological aspects of the case. However, they invariably send you far more information and papers than you need and add the proviso that you should not confine yourself just to their questions. They are hoping, of course, that you may identify some other avenue of attack or defence they or their clinical experts have not thought of.

It is important to have defined the fee scale and the deadline for your report before you start. Solicitors may ask to defer payment of your fee until the case is concluded. I have never favoured this, preferring the 'bird in the hand is worth two in the bush' approach.

### One common theme is a failure to properly compare any scan findings with previous radiology

#### The report

A medico-legal report requires several sections and needs to be clearly laid out. It helps to number paragraphs for ease of future reference. The report is a 'medical report to the court' and should be impartial in its approach regardless of whether you have been hired by the claimant or the defence<sup>5</sup>. It should contain your qualifications and credentials; the instruction from the lawyer; a list of the materials you have reviewed; your observations; your opinion; and a conclusion. Finally, there must be a coda to say that you understand your duty to the court and a statement of truth: 'I confirm that I have made clear which facts and matters in this report are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.' If you have used any references, they must be listed and a copy attached.

#### What happens next?

Lawyers seem to work to a different timescale than the rest of us. There will be long periods when you may hear nothing, followed by a frantic request for an immediate response to supplementary questions or to comment on some other expert's report or the response from the other side. If the case continues and both sides have provided a radiological report, then the court may require you to communicate with your counterpart and produce a joint statement. The lawyers for both sides will agree a schedule of questions for the two radiology experts to work to. The joint statement will need to define the areas on which you both agree and on those you do not, with the reasons why. Occasionally, it may be possible when you review the images together, to convince your counterpart that your view is the correct one. Your instructing lawyer will be delighted if this happens.

If a case proceeds further, it is usual for a court date to be set. This may be a long time in the future. In the meantime, you may be asked to have a case conference with all

the involved parties for your side. This is usually by telephone rather than face-to-face. There is often a very impressive barrister who will lead the conference. They will test out your evidence by asking you questions and posing alternate interpretations. It is always friendly and courteous. Sometimes it is done with the intent of showing to the claimant or the defendant who will be present at the conference (depending on which side you have reported for) that their position is untenable.

My experience is that the lawyers prefer not to go to court as the outcome can be unpredictable. Cases are either dropped or settled before the date for a court appearance. In this respect, lawyers value a sensible medico-legal opinion as they do not wish to waste time and money by pursuing a hopeless cause.

A court appearance can be stressful but mostly it is a fascinating view into another world. There is a new tendency to 'hot-tub' the two opposing radiological experts so that you are both on the stand together being asked questions by two sets of barristers. Like all presentations, it is best if you can speak clearly and concisely and be authoritative in your opinion.

#### Some terms that may be used

**Breach of duty** – This is a view that the care that has been provided has fallen below an acceptable standard. Radiologically, for instance, it is not enough to say that something has been missed on a scan but also to affirm that the majority of competent radiologists or imaging practitioners would have detected it. In this respect, it is very useful to be able to show the images to several colleagues to see if they detect the abnormality. Clearly, how you present the information to them needs to be carefully done so that bias is reduced.

**Causation** – Did the breach of duty lead to the harm described? It is possible for a lesion to have been missed on a scan and yet for that to have made no difference to the outcome for the patient.

**Quanta** – If breach of duty has been proved and it has been shown that this caused the harm described, then the amount of monetary redress has to be calculated. This is known as quanta. The imaging expert is not often involved with this area but can be.

In the absence of a relevant image the discussion will centre around the protocol that was in force at the time of the event

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Table 1: Clinical areas for alleged negligence	Number of cases	
Obstetrics	23	
Early pregnancy	9	
Gynaecology	32	
Pelvic sepsis/drains and surgical complications	17	
Staging of malignancy	7	
Urological	5	
Testicular	3	
Miscellaneous	4	
Total	100	

Table 2: Obstetric conditions for alleged negligence	Number of cases	
Heart	8	
Neural tube	2	
Posterior urethral valves	2	
Limb	1	
Hydrops	1	
Cord knot	1	
Pelviureteric junction obstruction	1	
Cystic fibrosis	1	
Agenesis of corpus callosum	1	
Holoprosencephaly	1	
Akinesia	1	
Caudal regression	1	
Osteogenesis imperfecta	1	
Down's syndrome	1	
Total	23	

#### My cases

The types of cases which require my opinion are a reflection of my own expertise and clearly a chest radiologist or some other expert will deal with a completely different mix (Table 1). Obstetric cases invariably relate to whether a condition should have been detected before birth, mostly at a mid-trimester anatomy scan (Table 2). Usually, the claimants are the parents and often sue for 'wrongful birth', ie they claim they would have terminated the pregnancy had the abnormality been detected and explained to then prenatally. The majority of obstetric cases comprise heart defects.

There is a tension between what a properly provided screening service is expected to detect and the individual case. It is not enough to say that since serious heart defects are only detected 50% of the time, that it was reasonable to have missed a heart defect.

The recorded antenatal images are valuable. They help to show the quality of the scan that has been done, the machine settings used, any patient factors reducing the image quality and the length of time taken (between the first and last image). Sometimes there are pertinent images of the missed abnormality, for instance, is that a cavum septum pellucidum or a high riding third ventricle in agenesis of the corpus callosum? However, more often than not, there will not be an image as, if there were, the condition would not have been missed.

In the absence of a relevant image, the discussion will centre around the protocol that was in force at the time of the event, whether the sonographer adhered to it and the governance of the service.

A sonographer stating that the scan was 'difficult' but yet ticking that all the structures were seen, does not help. The lawyer will argue that if the sonographer was unable to see the required structures properly, they should have arranged a rescan according to their local protocol. The introduction of the NHS Fetal Anomaly Screening Programme (NHS FASP) protocol has been useful<sup>6</sup>. It has provided a nationally agreed framework against which lawyers will measure local practice. Trusts need to be clear whether they are following NHS FASP or their own modified protocol. For instance, the NHS FASP does not require the number of bones in the lower limbs to be counted but one hospital concerned had a more stringent protocol saying that they should be. So, when an absent fibula was missed, the sonographer was found to have fallen below the accepted standard of care.

Agency sonographers who move from one hospital to another need to have had proper induction so that they understand all the protocols that are in force. Trusts are



vicariously liable for the outside agencies that they utilise.

Lastly, for obstetrics, it is not all bad news. Sometimes it is the case that the claimant has not understood that some conditions may not manifest until after the mid-trimester anatomy scan. Posterior urethral valves fall into this category.

#### Early pregnancy scans

The main area of contention is the diagnosis of ectopic pregnancy. Usually, the ultrasound scan is not the focus of the case as the clinical management of the presentation as a whole is under consideration. However, despite clear guidance from the National Institute for Health and Care Excellence (NICE)<sup>7</sup> there are still instances of sonographers giving inappropriate reassurance that the findings are of a complete miscarriage in women presenting with bleeding when they have no prior scans to enable them to know. There are also cases of repeat scans being arranged well outside the times recommended by the NICE, so it is important that local protocols are kept up to date and adhered to by staff.

#### **Gynaecological diagnosis**

There are cases of delayed diagnosis where the images may show that the diagnosis should have been made on an earlier scan, there are cases where the imaging findings have been misinterpreted and there are cases where there has been an overcall on imaging leading to unnecessary surgery or complications. Simple misses on imaging are uncommon as the sole cause of complaint. The cases tend to be more complex. One common theme is a failure to properly compare any scan findings with previous radiology. Fibroids, particularly in the postmenopausal age group, are an example; if the reporter doesn't compare with previous imaging they will not notice there has been rapid growth.

Sometimes the imaging is not under criticism but the scans need to be reassessed in order to give credence to some other line of argument being advanced by the clinical experts.

#### Pelvic sepsis/drains and surgical complications

Here, the issues are usually about whether the clinical team should have involved radiology in the management. So, the radiology is not under criticism but may offer evidence to help decide the case. These cases fall into three main types: Should the

diagnosis of sepsis have been realised earlier; should a drainage have been done; and was the surgeon at fault? An example might be a woman who has undergone surgery for prolapse and the question might be: Does the radiology show evidence of obturator nerve damage or, in another woman, has the fixation to the sacrum caused a discitis?

#### Urological diagnosis and testicular tumours

My experience of testicular tumour cases is that the radiologist or sonographer is not under criticism. The action is usually against the clinician who saw the man sometime before the diagnosis was made. Was it appropriate for them to have diagnosed an epididymal cyst and not referred them for ultrasound and is an epididymal cyst visible on the scan when the testicular tumour is eventually found?

Other urological cases have similar diagnostic issues as those found in gynaecological diagnosis. Overcall is also a source of litigation. For example, diagnosing a ureteric calculus on CT scan when it isn't may lead to inappropriate ureteroscopy and ureteric damage.

#### **Malignancy staging**

The question is either to affirm what the radiological staging was and inform the case regarding the clinical issues or to be asked to extrapolate back in time and say what the staging might have been if the disease had been diagnosed earlier. The latter is fraught with difficulty and it may be impossible to say. Overcall can be an issue here as in other areas. One case involved a man with a bladder cancer. The staging CT scan done soon after the transurethral resection of bladder tumour reported 'smokiness' in the perivesical fat and diagnosed local spread of tumour. The multidisciplinary review rightly recognised this as an unreliable sign and disregarded it when making their management plan. When later on he had an aggressive pelvic recurrence of his tumour and died, his widow read the original CT report and sued the hospital for mismanagement.

#### **Personal view**

It is clear that many of the cases I have seen involve ultrasound and sonographers as well as radiologists. Styles of reporting vary<sup>8</sup> but sonographers are more likely to use caveats than radiologists<sup>9</sup>. Those who believe in wrapping their thoughts up in words of prevarication or evasion as a way of protecting themselves from litigation are misguided<sup>10</sup>. I have talked about 'difficult' ultrasound scans above. The word is unhelpful. It is better to be explicit if you have not been able to see something. Phrases using words such as 'no obvious' or 'no gross' abnormality do not protect you if it turns out you have missed a lesion. Saying that something 'cannot be excluded' is a poor way of thinking. For instance, if you think the diagnosis includes malignancy, say so explicitly.

There will always be a need for expert witnesses. It is inevitable in an imperfect world that things will go wrong or be missed. In addition, inappropriate claims where there is no fault may be made perhaps due to a lack of understanding, and these also require advice from expert witnesses. People will use the legal system to obtain answers that they feel have not been forthcoming from the complaints system or from the team that had been looking after them or their relative. The better and more open a hospital complaints and liaison service is, the less likely that the legal system will be turned to.

Finally, I think that my own practice of radiology has benefited from taking part in medico-legal report writing. It has helped to see where others have run in to trouble. Sometimes, one realises the aphorism, 'but for the grace of God, there go I' is very true.

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# Educating Europe's Radiographers: Current Challenges and Future Directions

### Jonathan McNulty

Rapid technological developments and the desire for more comprehensive and accurate diagnosis and therapies, place significant pressures on healthcare systems. It is therefore essential that working practices within diagnostic imaging and radiation oncology are flexible and streamlined to ensure we get the most out of the technologies available to us, which in turn, should optimise patient experience.

n medical imaging the rollout of molecular imaging, national screening programmes and national stroke programmes, with imaging and interventional radiology at their core, have led to significant growth in workload predictions. The Royal College of Radiologists (RCR) (UK) has projected growth of up to 50% in the number of medical imaging examinations in England between now and 2022<sup>1</sup>. This includes staggering growth predictions of over 180% for magnetic resonance imaging (MRI) and over 135% for computed tomography (CT) studies. Another recent analysis has suggested that the demand for radiotherapy services across Europe will grow by 16% by 2025, with the highest growth estimated for prostate cancer at 24%<sup>2</sup>. On a country by country basis, Albania, Cyprus, Iceland, Ireland, Luxembourg, Malta, Norway, Switzerland and the Netherlands are all estimated to demonstrate growth in radiotherapy courses in excess of 25%.

In order to meet these demands over the next decade and to ensure the delivery of high quality, patient-centred care, we must ensure that we have a highly trained, multiprofessional workforce. With radiology and radiation oncology becoming more complex, it is not possible for individual radiographers, radiologists and radiation oncologists to maintain high levels of expertise across all specialist areas. Subspecialisation is not a new concept for radiographers (across all three recognised branches: medical imaging, nuclear medicine and therapeutic)<sup>3</sup>, radiologists<sup>4</sup>, and radiation oncology staff<sup>5</sup>; and we are all aware of the exponential growth in medical imaging and radiation oncology. This demands innovation and radical changes in the education and training of the professions from entry level to the profession, usually at Level 6 (Bachelors) of the European Qualifications Framework (EQF)<sup>6,7</sup>, through to Level 8 (Doctoral). On top of this, we have the situation whereby in many countries such as my own country, Ireland, and the UK, there are significant shortages of radiographers (diagnostic and therapeutic) due to the growth identified above, whereas other countries report insufficient vacancies for their graduates.

The recent NHS Benchmarking Network *Radiology Benchmarking National Report* (2016) reported radiographer vacancies at 11%, sonographer vacancies at 22%, and consultant radiologist vacancies at 15%<sup>8</sup>. This contrasts with the lack of vacancies in countries such as France, Greece, Italy, the Netherlands, Norway, Poland and Spain, identified by national radiography societies in the European Federation of Radiographer Societies (EFRS) Member Societies Survey 2015<sup>9</sup>. Similar variability is seen across Europe for radiology, as evidenced in two recent RCR publications, which highlight the extremes of less than nine radiologists per 100,000 population in countries such as Ireland and the UK to over 17 radiologists per 100,000 population in countries such as Austria, France, Greece, Italy and Sweden<sup>110</sup>. In many of the countries with lower population densities of radiographers and radiologists, high vacancy rates, together with a lack of focused investment, and insufficient trainees would appear to be key factors which present a clear and present danger to the future of medical imaging.

#### **Radiography education: Current status**

Data gathered by the EFRS in 2015 from the 41 educational institutions that form the EFRS Educational Wing, were subsequently published in *Radiography* early last year, and highlighted the variability in radiography education across Europe<sup>11,12</sup>. Of the 46 unique radiography programmes offered, the majority of institutions (n=26; 63.4%) offered a combined medical imaging, radiotherapy and nuclear medicine programme. A dedicated medical imaging programme was offered by 14 institutions (34.2%) and a dedicated nuclear medicine programme by just three institutions (6.5%). Only one offered a dedicated radiotherapy programme. This study also gathered data on the total duration of these programmes and interestingly, while some institutions offer a dedicated programme over four years, others offer combined programmes in just three years. Another point of interest arising from the recent EFRS survey<sup>11</sup> is the extremes

One must ask how the competences of graduates of a programme with only 500 hours of clinical activity compare to those with over 1500 hours of clinical activity

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in the total amount of practical experience gained in a clinical environment. While 55% of programmes included over 60 ECTS (European Credit Transfer and Accumulation System) credits of clinical activity (the equivalent of a full academic year in terms of credit load), two programmes included 21 to 30 ECTS of clinical activity and one less than 20 ECTS of clinical activity. For all students undertaking professional programmes, the value of real world clinical exposure and hands-on experience is indisputable. Thus one must ask how the competences of graduates of a programme with only 500 hours of clinical activity compare to those with over 1500 hours of clinical activity. This is not just an issue at the European level, as in some countries significant variation in the total clinical hours are evident between programmes. Of the programmes included in the EFRS survey, approximately 10% have not yet adopted the Bologna (Bachelor) cycle for the education of radiographers and are offering programmes at EQF Level 5<sup>12</sup>.

Post-graduate education is another key consideration in terms of ensuring the workforce is fit for purpose, prepared for future demands over the next decade, and can deliver high quality, patient-centred care. However, only 39% of educational institutions currently offer Masters programmes for radiographers. Those countries which indicated at the time of the survey that they offered dedicated Masters programmes for radiographers were Austria, Finland, Ireland, Italy, Malta, the Netherlands, Norway, Portugal, Slovenia, Sweden and the UK. At doctoral level, only 14.6% offer programmes for radiographers, which is of concern<sup>12</sup>. These institutions were located in Ireland, Italy, Malta, Norway and the UK. As was the case with the EFRS *EQF Level 6 Benchmarking Document for Radiographers* (2014)<sup>6</sup>, it is anticipated that the recently published EFRS *EQF Level 7 Benchmarking Document for Radiographers* across Europe while also facilitating the enhancement of existing programmes.

#### Changing patterns of education

While there is some evidence of harmonisation of radiography education and the profession across Europe, it could be argued that the variability in radiography programmes across Europe is growing. In many countries, we have a mix of programmes ranging from two to four years in duration and in a few countries, we have a mix of combined medical imaging, radiotherapy and nuclear medicine programmes, alongside dedicated medical imaging, radiotherapy or nuclear medicine programmes

of the same duration. This raises the question as to if and how the first-post competences of the respective graduates would compare between programmes for each of the three branches of radiography. In the UK, the introduction of accelerated graduate entry/pre-registration MSc programmes now means that entry to the profession is possible after two years of study. At the same time, Bachelors programmes of both three and four years in duration are offered, which suggest a large variation in course content. However, the rigours of accreditation by the Health and Care Professions Council (HCPC) and the College of Radiographers, across the 25 UK universities offering radiography programmes, provide some degree of reassurance about the quality of entry-level competences of the graduates. More recent developments related to dedicated, two year ultrasound programmes and the introduction of apprenticeship programmes in diagnostic radiography, therapy and ultrasound, further add to the debate.

In my own country, Ireland, with the expansion of radiography education to meet service needs, we may shortly see a similar pattern to that of the UK (but on a much smaller scale) with a mix of graduate entry/pre-registration MSc and BSc programmes. In Malta, a significant change occurred in radiography education with the move from a four year BSc (Honours) Diagnostic Radiography programme to a new four year BSc (Honours) programme, combining diagnostic and therapy in 2010, as part of the national investment in oncology services and the opening of a new national oncology centre. This change was replicated in Portugal, where there was a national move away from institutions offering separate medical imaging, nuclear medicine and radiotherapy programmes, each four years in duration, to combined programmes of the same duration. One could argue that this goes against the need for innovative approaches to radiography education, including possible sub-specialisation, to meet future demands in medical imaging and radiation oncology.

We also have the situation of the 10% of programmes across Europe, based on the EFRS data<sup>12</sup> which are likely an underestimate, that do not have EQF Level 6/Bachelors level programmes available, yet work across all branches of the profession. All of the above present significant challenges in making one of the four freedoms enjoyed by European citizens, namely free movement of the workforce, achievable within radiography.

All of this raises numerous questions about the amount of time dedicated to the specific branches within combined programmes; the competences required for entry

At doctoral level, only 14.6% offer programmes for radiographers, which is of concern to the profession and to work in the specific branches of the profession; and the scope of practice of those graduating from combined programmes versus dedicated programmes. This body of work is something the EFRS aims to investigate in more detail this year.

#### Role development, role extension and advanced practice

While the aforementioned variability in the programmes allowing entry into the profession across Europe will naturally lead to some variability in scopes of practice, it also contributes to the variability in role development, extension, and advanced practice. Numerous factors have helped radiographers in the UK become the front-runners in expanding their scope of professional practice<sup>14,15</sup>. Indeed, the global overview of the changing roles of radiographers and the level of role advancement identified by Cowling in 2008<sup>14</sup> has not really changed over the past nine years, with the UK sitting at Level 1 (countries which have implemented an effective system of role advancement), followed by countries such as Australia, Canada, Japan, South Africa and New Zealand, together with a growing number of European countries sitting at Level 2 (countries where the driving forces are the same but implementation has not yet happened to any great degree). Thus, the majority of European countries remain at Level 3 (countries which have made moves towards having formal recognition for their profession, with role development being their next step) despite 90% of EFRS national societies stating that they actively promote and support radiographer role development<sup>9</sup>.

Drivers required for the adoption of extended scopes of practice for radiographers are well documented with growing service needs, as discussed in the opening paragraphs of this article, being the most important driving factor<sup>15-17</sup>. In order for health systems and service providers to keep up with the exponential growth in diagnostic imaging and radiation oncology, the scope of practice of radiographers must be carefully considered and appropriate structures developed sooner rather than later. Using reporting as an example, in the UK, such structures have led to 21% of all reporting now being performed by advanced practice radiographers and sonographers<sup>8</sup>. There is a growing evidence base which highlights the value of high quality radiographer reporting on service delivery, patient care and clinical outcomes, whilst also freeing up radiologists to apply themselves to more complex tasks driven by the exponential growth in medical imaging, however, the topic also remains controversial even in the UK<sup>18,19</sup>. It is also

important to acknowledge that radiographer advanced roles is not a 'one size fits all' solution as highlighted by Henderson et al<sup>20</sup>.

There is a vital role for national champions for such initiatives, both from radiology and radiography, for progress to be possible<sup>21,22</sup>. Such a team approach is echoed across the literature on advanced practice<sup>17,23,32</sup>. The transition from practitioner to advanced practitioner also requires significant investment at the individual, service and organisational level if it is to succeed and become firmly embedded within healthcare practice<sup>15</sup>. To achieve this status, additional knowledge, skills and expertise are required, ideally at EQF Level 7 (Masters level) together with clinical education and training<sup>13,23,33</sup>. The benefits to radiographers and to patients evidenced in the literature for reporting are also evident in areas such as breast imaging, gastrointestinal imaging, interventional procedures and radiotherapy. The journal *Radiography* continues to host much of the evidence relating to advanced practice and was one of the main motivations for the EFRS to identify it as their official journal.

#### Summary

High educational standards for radiographers are of the utmost importance. They will help ensure our profession is fit for purpose, future-proofed, ready to streamline our work practices to optimise the patient experience, and to optimise the use of the technologies at our disposal. At the same time, these standards must be flexible enough to facilitate advanced practice across diagnostic imaging and radiation oncology. As the umbrella organisation for 39 national radiographer societies and 57 educational institutions, representing over 100,000 radiographers and over 8000 radiography students across Europe, the EFRS has a role in raising the profile of the radiography profession and of radiography education amidst the diversity.

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# Electron Spin Resonance Imaging: A Roadmap for the Future

Malcolm Sperrin

Diagnostic imaging is a mainstay of healthcare and has been for decades. It takes many forms which rely on different characteristics of tissue from which contrast is derived, and this reveals why there are different imaging modalities. For instance, a fracture can be considered to be a discontinuity in the bone and hence the contrast needs to be based on some factor of the tissue that changes as a result of this discontinuity – in this example, the linear attenuation coefficient of the tissue itself.

he last major imaging modality to enter common usage was magnetic resonance imaging (MRI) in the 1980s, although hybrid imaging and some very specialist diagnostic options have been developed more recently. However, there is an increasing demand for greater information about tissue properties that extends beyond the currently available mainstream alternatives. Most imaging is used to identify anatomical boundaries such as bone or organ edges; nuclear medicine is an exception in that it images function which is derived from radioisotope uptake. However, none of these techniques will enable the imaging of the presence of chemical species such as might be useful for drug trials investigating the identification of metabolic pathways.

MRI relies on the magnetic properties of the proton as a constituent of the water molecule. There are two possible energy states that can be occupied by the proton and the energy difference between these two states can be utilised to create an energy surplus. The rate of decay of this energy differs between tissue types and hence can be used as the basis of contrast in the MR image. The contrast is therefore a map of the density of these protons and the local environment into which the energy is released.

Conceptually, a parallel imaging option exists with electrons, whereby the spin properties of the electrons are utilised as the basis for contrast. Similarly to protons, the electrons have two spin states which, in the presence of a magnetic field, have different energies. The transition from one state to the other is associated with photons in the microwave part of the electromagnetic spectrum: For a 0.35T field this equates to 10GHz. By comparison a 0.35T MRI system has an associated radiofrequency of 15MHz.

A parallel imaging option exists with electrons, whereby the spin properties of the electrons are utilised as the basis for contrast

Electron spin resonance (ESR) has been used for many years for analytical purposes such as chemical analysis, and in this respect is again similar to proton magnetic resonance where an option exists for MR spectroscopy. There are additional considerations at the quantum mechanical level which lead to a modification of the energy of the splitting, but the important point to be made is that electron spin resonance can be used for imaging and spectroscopic purposes.

ESR has traditionally been associated with poor sensitivity due, in part, to the methods used to detect the emitted electromagnetic energy. Coils, similar in nature to those used for MRI, are used but these typically require a spin difference of upwards of 10<sup>9</sup> spins in a one second window, in order to create a signal of usable quality. Bearing in mind the volume required to contain this number of spins, the resolution of traditional ESR systems is quite poor; one commercial system having a resolution of 25µm or 40lp/mm. Whilst this may seem to be very good in contrast to current imaging resolutions from more familiar modalities, it is only just comparable to animal cell sizes and therefore may not be ideal for the detailed imaging that is being sought, especially in relation to chemical pathways. A reasonable working estimate is that the imaging system resolution should be one order of magnitude better than the detail being looked at.

The resolution can be improved by more elaborate detectors but this is in turn associated with limited applicability, especially for imaging applications. For spectroscopic applications, where samples may be very small, techniques have been developed that require a spin difference of fewer than 10 to give rise to a meaningful signal.

#### Potential benefits of ESR

Because ESR relies on electron rather than nuclear spin, it raises the possibility of using ESR to image chemical pathways. There is an absolute need for unpaired electron spins

since paired spins have opposing magnetic quantum numbers and hence cancel each other out. Biologically, this is very significant since the primary location of unpaired spins in the natural state is in ligands which occur as part of reactive pathways; ligands are themselves highly reactive but can be used to reveal local tissue chemistry of relevance to understanding diseases and their progression. This therefore, becomes of great consequence where the mechanism of drug action is being investigated or where there is some aspect of the tissue that requires study, such as tumour growth where ligands are considered to be relevant to the in-vivo processes.

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It is useful at this point to highlight the nature of a ligand. In applications being discussed in this paper, a ligand forms a complex with a biomolecule to serve a biological purpose and this simple definition provides insight into why a technique that depends upon their presence for image contrast is of considerable potential. It is the presence of unpaired spins in such ligands that permits ESR as an imaging option.

The information to be gained using this technique extends beyond the simple splitting associated with the electron spins in the magnetic field. The magnetic properties of the unpaired electrons will interact with the magnetic properties of the nearby nucleus; this is termed hyperfine splitting and its manifestation is as slightly modified energy levels. The precise degree of modification will depend on the nucleus concerned and hence analysis of the hyperfine splitting permits elucidation of the chemical environment. This permits the study of drug actions since, as the drug in question penetrates into a volume, the chemical environment will change with a consequential perturbation of the hyperfine splitting. This at least has the potential to resolve drug actions at cellular scales.

ESR microscopy has been developed that operates in a manner similar to MRI where pulses are used to excite the sample and T2 values are derived from the associated decay of the emitted signal. This does require fast switching of gradients in order to obtain acceptable resolution but again, there is a significant challenge related to the detector characteristics such as sensitivity and decay time. An early ESR 'microscope'

It has also been shown that ESR can be used as a tool for measuring oxygen concentration

was used to create images of acceptable contrast, but with resolution still poor in comparison to that required. It is therefore necessary to make significant improvements in hardware design, such as resonators which generate the appropriate electromagnetic field, detectors and gradient coils.

There is clearly a significant difference in the ability to perform in-vitro and in-vivo studies. Whilst laboratory use of ESR for chemical analysis is very useful, the major development would be to use ESR for image generation in humans where it can contribute toward the management of key conditions. Imaging has been conducted on live mice using a spin probe comprising a nitroxide radical administered orally and which enabled the generation of planar and 3D images. The images clearly demonstrated anatomy but also temporal variations, as the radicals were distributed throughout the mouse due to absorption thus revealing function.

Imaging of the passage of chemical species across the blood-brain barrier is of great significance in that it can reveal the presence of tissue changes but also it can provide insight into drug pathways relevant to the staging or treatment of conditions such as cancer. Imaging of the passage of nitroxide radicals has been conducted in rats which permitted the change over time of the radical to be determined. This study confirmed the hypothesis that the decay of the radical could be determined, from which the chemical concentration half-life could in turn be calculated with good reproducibility. This clearly revealed the potential benefit of the technique in that it provided spatial and temporal resolution and reproducibility, all of which are essential for a meaningful diagnostic option.

The use of nitroxide radicals has been shown to provide information on the passage of ligands across the blood-brain barrier but the use of a single spin probe is revealing in its own right. The imaging technique does rely on chemical processes and hence alternatives are desirable which may follow different metabolic pathways and lead to greater understanding. One alternative has been identified as the nicotine acetylcholine receptor ligand, which distributes widely throughout the central and peripheral nervous system and is known to mediate a variety of brain functions. This in turn, leads to further possibilities for the delivery of nitroxide ligands to the brain based on carrier molecules. This does introduce the possibility of targeted imaging and raises the potential benefits that ESR may bring that goes way beyond anything currently offered in 'conventional' imaging such as contrast based upon chemical pathways, or hybrid imaging, which brings together anatomical and chemical environments.

In addition to the imaging of ligands in the region of the blood-brain barrier, it has also been shown that ESR can be used as a tool for measuring oxygen concentration. This is of importance since oxygen transport is vital to tissue viability, but oxygen use is often accelerated in the vicinity of enhanced metabolism, such as in the growth of tumour cells. The uptake of oxygen to cancer spheroids, which are multicellular 3D models used to mimic cancer sites, is assessed by the use of a spin probe in a crystallographic packing form. In the presence of paramagnetic oxygen at typical tissue concentrations, the combination of these two species results in line broadening that is proportional to oxygen concentration. This permits the construction of a concentration map with a resolution of around 20µm, or similar to a typical animal cell dimension.

#### Potential barriers to the use of ESR

The use of ESR as a tool for imaging chemical pathways is now well established, but problems still exist that relate to its use as a routine option. Generation of the magnetic field and design of the detectors are both challenging, especially where large volumes are to be imaged. Devices are currently commercially available although the spectroscopic market is dominant.

Risk is always a concern for any modality to which a human is exposed. Some functional information can be obtained using the familiar modalities of nuclear medicine or its variants, such as positron emission tomography (PET). Whist of proven utility, PET does present a radiation risk as well as being dependent on the injection of short-lived isotopes bound on to a carrier drug; usually <sup>18</sup>F-FDG (18 Flourine-flourodeoxyglucose) which is a glucose analogue. This does permit the identification of regions of enhanced metabolism, but it is of very poor resolution and does not currently permit the range of drug-related pathway imaging offered by ESR.

It would be hasty to assume that ESR presents no risk. The magnetic field by itself precludes its use on patients with implants, and the use of electromagnetic fields and switched gradients are both known to present hazards either by tissue heating or nerve stimulation and hence, as with MRI, careful risk assessments must be made before use. However, such risks are conceptually the same as those with MRI although the different radiofrequencies used may generate resonances in tissue that need to be identified and understood before the safety of the technique can be properly established.

This becomes of great consequence where the mechanism of drug action is being investigated or where there is some aspect of the tissue that requires study, such as tumour growth

#### The future

The future of ESR will depend upon many factors. Whilst the majority of imaging is used to identify anatomical boundaries, there is an increasing need to image function. This may be to provide evidence of tumour boundaries, but it may also be required to investigate the mechanism of distribution of new drug agents, in particular where the action of the drug is intended for local administration such as to cross the blood-brain barrier or the targeting of specific lesions.

There is also the question of cost. This is of vital consequence to a health service that is already financially challenged, although the additional information that the imaging option generates may well reduce costs elsewhere in the patient pathway. This is because drugs would become more targeted and hence the underlying condition may become more susceptible to remedy, with a consequential reduction in ongoing costs such as for hospital stays.

As with any new therapeutic or diagnostic option, there needs to be a clear benefit to the intended patient outcome. This benefit manifests itself both in terms of additional information, which can be used to manage a condition but also in the cost-benefit balance. One major application may lie in the more precise determination of regions of enhanced metabolic activity surrounding a tumour volume, with the consequential increase in accuracy of treatment volume. Apart from making a treatment more targeted, this could also reduce the damage to surrounding healthy tissue.

Also of consideration is the capital necessary to locate such an ESR system. It is envisaged that the size would be comparable to a conventional MRI system, with staff being trained and operating in a similar manner to MR. Broadly speaking, it is the basis of the image contrast that differs and it is reasonable to assume that the necessary training relates to the operation of a new device rather than a completely new technique. Such complex techniques are likely to be initially found in medical research centres before being rolled out to routine users but the information generated by ESR is of great utility. As with MRI, technical scientific staff are likely to work alongside imaging staff in order to maximise the benefits of the service.

Whilst the currently available technology is not sufficient to make ESR a routinely available option, the rapid pace of improvement in software and hardware is likely to enable the transfer of ESR as an imaging option from research facility to healthcare provider in the next few years.



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