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Teitl: Canllawiau ar gyfer y defnydd clinigol diogel o Ddelweddu Atseiniol Magnetig (MRI)

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I'w weithredu gan:

Brif Swyddogion Gweithredol
Ymddiriedolaethau/Byrddau Iechyd Lleol
Cyfarwyddwyr Therapïau a Gwyddor Iechyd
Ymddiriedolaethau/Byrddau Iechyd Lleol
Cyfarwyddwyr Meddygol
Ymddiriedolaethau/Byrddau Iechyd Lleol
Penaethiaid Radioleg a Ffiseg
Ymddiriedolaethau/Byrddau Iechyd Lleol
Arweinwyr Ansawdd a Diogelwch
Ymddiriedolaethau/Byrddau Iechyd Lleol

Angen gweithredu erbyn: 1 Ebrill 2018

Gweler paragraff 3

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Dogfen(nau) amgaeedig: Dim



Ein Cyf: WHC/2018/001

Eich Cyf:

Dyddiad: 5 Chwefror 2018

Annwyl Gydweithwyr,

Canllawiau ar gyfer y defnydd clinigol diogel o offer Ddelweddu Atseiniol Magnetig (MRI)

1. Mae'r Pwyllgor Ymgynghorol Gyddonol Cymru wedi cyhoeddi canllawiau (gweler isod) ar y cymorth gwyddonol ar gyfer delweddu atseiniol magnetig (MRI) yn GIG Cymru mewn ymateb i gyhoeddi adroddiadau canlynol:

- Mae'r Asiantaeth Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd (MHRA) wedi cyhoeddi Canllawiau ar gyfer y defnydd clinigol diogel o offer Ddelweddu Atseiniol Magnetig. I weld y Canllawiau hyn, cliciwch ar y ddolen ganlynol:

<https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imag-ing-equipment-in-clinical-use>

- Hefyd, mae'r Awdurdod Gweithredol Iechyd a Diogelwch wedi cyhoeddi arweiniad ar y Rheoliadau statudol ar gyfer Rheoli Meysydd Electromagnetig yn y Gweithle 2016 sydd ar gael yn:

<http://www.hse.gov.uk/pubns/priced/hsg281.pdf>

2. Mae'r adroddiadau hyn yn gwneud nifer o argymhellion ar gyfer ymarfer ym maes radioleg, ond hoffem dynnu eich sylw'n arbennig at yr argymhellion sy'n dweud y canlynol:

- Dylid cynnal asesiadau risg cyn cyflwyno gwasanaethau MRI newydd neu wasanaethau sydd wedi eu haddasu. Dylai'r asesiadau risg hyn ystyried sefyllfa cleifion a staff sy'n dod i gysylltiad â'r offer delweddu.
- Dylid cynnal archwiliad diogelwch critigol wrth gomisiynu cyfleusterau MRI newydd neu gyfleusterau sydd wedi eu haddasu.
- Dylai Adrannau Radioleg ymgynghori ag Arbenigwr ar Ddiogelwch offer Atseiniol Magnetig i gael cyngor ar yr agweddau peirianyddol, gwyddonol a gweinyddol angenrheidiol sy'n gysylltiedig â diogelwch wrth ddefnyddio offer atseiniol magnetig at ddibenion clinigol. Dylai'r cyngor hwn gynnwys cynllunio'r safle, datblygu fframwaith diogelwch, monitro effeithiolrwydd gweithdrefnau diogelwch lleol, caffael, ymchwilio i ddigwyddiadau negyddol, a chyngor ar archwiliadau cleifion penodol (ee cleifion sydd â dyfeisiau gweithredol sydd wedi eu mewablannu).
- Bydd penodi Arbenigwr Diogelwch ym maes Delweddu Atseiniol Magnetig yn helpu i leihau amrywiadau clinigol drwy deilwra dilyniant o ddelweddu clinigol er mwyn sicrhau bod delweddu o'r ansawdd gorau yn cael eu cynhyrchu.

3. Hoffem argymell yn gryf eich bod yn gweithredu ac yn cefnogi penodiad ffurfiol o Arbenigwr Diogelwch ym maes Delweddu Atseiniol Magnetig sydd â gwybodaeth a phrofiad sylweddol o ffiseg atseiniol fagnetig glinigol.
4. Hoffem ddiolch ichi ymlaen llaw am eich cymorth i weithredu'r fenter hon.

Yn gywir

A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal tail extending to the right.

DR ROB ORFORD
Prif Gynghorydd Gwyddonol (Iechyd)

Welsh Scientific Advisory Committee
Medical Physics and Clinical Engineering Sub-Committee
Radiation Protection Specialist Standing Advisory Group

**GUIDANCE ON SCIENTIFIC SUPPORT
FOR MAGNETIC RESONANCE IMAGING IN
NHS WALES**

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RECORD OF DOCUMENT CHANGES

Version	Issue date	Amendment
1.0	Aug 2016	First issued and presented to Welsh Scientific Advisory Committee
2.0	Jan 2017	Inclusion of changes recommended by Acting Chief Scientific Adviser (Health) including: <ul style="list-style-type: none">• inclusion of advice on how NHS employers in Wales may achieve acceptable levels of scientific support for clinical magnetic resonance imaging;• details of conditions required for employer exemption from regulations governing occupational exposure to electromagnetic fields
2.1	Feb 2017	Minor revision of executive summary and inventory of clinical MRI scanners
2.2	Nov 2017	Final revision

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1. Executive Summary

- 1.1 The Radiation Protection Standing Specialist Advisory Group (RPSSAG) of the Medical Physics and Clinical Engineering Sub-Committee (MPCE-SC) has prepared this document for the Welsh Scientific Advisory Committee (WSAC).

The document is a review of the provision of scientific support for the clinical use of Magnetic Resonance Imaging (MRI) in Wales and has been prepared to inform Welsh Government through the WSAC on potential clinical consequences of maintaining the current level of support and to report on the outcome of a pilot study providing time limited scientific advice.

- 1.2 It is confirmed that no specific scientific support is provided to MRI within NHS Wales. The temporary part time appointment of an MRI physicist provided a range of developmental and safety support to ABMU Health Board with several positive outcomes including the start of an in-situ cardiac pacemaker scanning service, complex pre-scan safety reviews and bespoke scan sequencing.

- 1.3 Review of this ABMU pilot work and appraisal of the current lack of scientific support has led to the following recommendations:

- i. Welsh Government issues guidance, through a quality and safety health circular, to all Chief Executives of Local Health Boards and NHS Trusts outlining the need to appoint or have access to a medical resonance safety expert in line with MHRA¹ recommendations and the advice provided in the latest statutory requirements for governing the control of occupational exposure to electromagnetic fields².
- ii. Local Health Boards and NHS Trusts providing a clinical MRI service should consider the clinical advantages of providing scientific expertise to support this modality.
- iii. Scientific support should be provided either within the current sub-regional radiation protection service structure or alternatively centralised at a single site with all Wales responsibilities.
- iv. In order to provide ongoing resilience in the availability of scientific staff the current Scientific Training Programme for Medical Physics in NHS Wales should be extended to encompass an imaging with non-ionising radiation specialism to attract trainee Clinical Scientists to the Principality.

¹ Medicines and Healthcare Products Regulatory Agency. Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. MHRA. 2015.

² Health and Safety Executive. The Control of Electromagnetic Fields at Work Regulations 2016.

2. Rationale

- 2.1 Over the last decade there has been a significant rise in the number of MRI facilities in Wales (appendix 1) increasing the number of patients scanned (approximately 125000 in 2011³) and the need for scientific support particularly in the performance of risk assessments of patients presenting with MR-conditional implanted devices.
- 2.2 Increasing demand for MRI will have a significant impact on the need for scientific support. Currently the Welsh Health Specialised Services Committee, on behalf of all Health Boards, is co-ordinating the service requirements and commissioning intentions for cardiac MRI diagnostics in Wales with a proposed phased approach over 5 years to achieve optimal numbers. Additionally, with imaging being central to the management of patients with cancer throughout the patient pathway, the use of MRI in cancer diagnosis and radiotherapy treatment planning is rapidly expanding⁴.
- 2.3 Several national and international organisations have reported on their review of the requirements both of staff expertise and services that underpin the safe use and development of clinical MRI. This report examines the gap between the consensus on good practice taken from these reports and the current situation in Wales. It additionally considers the clinical risks that may be associated with current NHS Wales practices.

3. Hazards and Safety Issues

- 3.1 MRI is playing an increasing role in diagnostic healthcare and MR Spectroscopy, a valuable tool in biomedical research, is also beginning to impact on clinical practice. Potential hazards and safety issues arise from each of these clinical activities including:

- Static magnetic field

- Projectiles, rotational forces*

- The potential hazard of the projectile effect of ferromagnetic material in a strong magnetic field is well understood⁵ but remains a serious concern regarding routine and research scanning in MR units. The assessment of the static fringe fields is complex and may influence the ability to position the patient in the scanner. A patient fatality occurred in the USA where the patient has been struck in the head with an oxygen cylinder⁶. This risk is only minimised by the strict and careful management of the MR unit and an understanding of non-linear static field boundaries.

- As well as the attractive force, ferromagnetic objects will also experience a torque that will try to align that object along magnetic field lines. For an implant fixed in the body, the torque will be at a maximum when it is close to the magnet bore opening. Static field problems have been aggravated by the move from 1.5T units to 3T⁷.

- Implantable medical devices*

- The strong static magnetic field can affect implantable medical devices in exposed people (staff, patient or volunteer) which can cause tissue damage and/or damage to the implantable medical device. There have been a number of deaths

³ Estimated throughput of patients in Wales 125000 (based on population based extrapolation of ABMU LHB statistics)

⁴ Schmidt M, et al. Radiotherapy planning using MRI. *Physics in Medicine and Biology*. 2015;60;323-361.

⁵ Health Protection Agency. Protection of Patients and Volunteers Undergoing MRI Procedures. PA 2008 RCE-7. ISBN-978-0-85952-623-5.

⁶ Chaljub G, et al. Projectile cylinder accidents resulting from the presence of ferromagnetic nitrous oxide or oxygen tanks in the MR suite. *American Journal of Roentgenology*. 2001;177;27-30.

⁷ Jerrolds J, Keene S. MRI Safety at 3T versus 1.5T. *The Internet Journal of World Health and Societal Politics*. 2009;6(1).

following the scanning of patients with implanted pacemakers⁸. Patients with novel or complex implantable devices or MR 'conditional' implants require detailed risk assessments prior to scanning. The absence of expert advice can result in either an inappropriate risk assessment or MRI staff conservatively excluding the patient from receiving the required MRI scan.

- Gradient magnetic fields

The safety concerns with the time-varying magnetic field gradients are biological effects; peripheral nerve stimulation, muscle stimulation and acoustic noise⁹.

- Radiofrequency (RF) fields

The main safety issues for RF fields used in MR are thermal heating leading to heat stress and induced current burns and/or contact burns.

4. Legislation and Guidance

4.1 MRI activities are only exempt from occupational exposure limits contained in The Control of Electromagnetic Fields at Work Regulations 2016, provided employers meet the following conditions:

- i. the exposure of employees to electromagnetic fields is as low as reasonable practicable; and
- ii. employees are protected against the health effects and safety risks arising from that exposure.

Condition (i) requires a formal risk assessment and condition (ii) requires the introduction of steps necessary to ensure health and safety of employees including local rules and procedures setting out safe working practices, appropriate staff training, incorporation of safety considerations into the design of the MRI unit, and control of access to the MRI suite including robust screening procedures and labelling of equipment.

4.2 MHRA recommend that, in order to cover all the necessary aspects of safety, employers of clinical units should appoint an MR Safety Expert (MRSE), ideally a state registered physicist with expertise in MRI.

5. Case for Scientific Support

5.1 The purpose of scientific support for MR is to ensure the provision and development of an efficient and high quality clinical service, to provide underpinning MR safety advice with respect to staff and patients, and to collaborate in research and development.

5.2 The main elements of the scientific support are summarised as follows:

- provide the role of MRSE in keeping with MHRA guidelines;
- advise on the development of policies, local rules and procedures setting out safe working practices for employees,
- assist employers meet exemption conditions of The Control of Electromagnetic Fields at Work Regulations 2016;
- advise on selection and procurement of MR and ancillary equipment;
- incorporate safety considerations into the design of the MRI facilities including robust screening procedures and labelling of equipment;

⁸ Irnich W. Pacemaker related Patient Mortality. *Pacing and Clinical Electrophysiology*. 1999;22;9:1279-1283

⁹ U.S. Department of Health and Human Services, Food and Drug Administration, Centre for Devices and Radiological Health; Guidance for Industry and FDA Staff. *Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices*. 2003.

- contribute to optimisation of techniques and procedures;
- advise on quality assurance (acceptance, regular monitoring and maintenance);
- apply specialist scientific knowledge to provide solutions to clinical problems;
- contribute to staff training and delivery of specialist training to support Scientific Training Programme);
- provide prompt response to emergency situations e.g. quench;
- support for advanced imaging techniques including MRS and functional MRI;
- support introduction of new national services (e.g. cardiovascular MRI);
- support departments seeking Imaging Services Accreditation (ISAS);

6. Minimum Staffing Levels for Scientific Support

- 6.1 The Institute of Physics and Engineering in Medicine (IPEM) recommend¹⁰ in hospitals with any MR equipment, minimum staffing levels for Clinical Scientists per scanner with specialist knowledge of MR physics. In stark contrast to other UK countries, no clinical MRI facility in NHS Wales is supported by an appointed MR physicist.
- 6.2 MHRA recommends appointment of an MRSE.

7. Evidence of Clinical Benefit from ABMU Health Board Pilot Study

- 7.1 During 2015/16, in order to address MRI safety concerns and to improve access to MRI for patients presenting with MR-conditional implanted devices, the ABMU Health Board Radiation Protection Service obtained the services of Dr Jonathan Phillips, MRI Physicist and Senior Research Officer in Medical Imaging from Swansea University. This was a temporary 0.2 WTE appointment funded for 12 months through an existing vacancy. The pilot study proved to be successful and provided the following evidence of clinical benefit:
- Development of a novel imaging protocol and establishment of a multidisciplinary safety group for MR scanning of patients with Medtronic MR-conditional pacemakers at Morriston hospital. The work enabled such a patient to be scanned for the first time in the Health Board. Further work will be required to improve access to MRI for patients with other manufacture of pacemaker.
 - Complex risk assessment of thirteen patients presenting with MR-conditional implanted devices resulted in eleven patients being successfully scanned following adoption of recommended adjustments to scanning parameters. Two patients with complex implanted devices were advised to have alternative imaging.
 - Advice provided to Health Board staff following adverse incidents occurring in magnet rooms; one involving a patient with an eye prosthesis containing ferromagnetic material and another involving a patient with a cosmetic eye liner tattoo which had previously not been considered to present any safety issues.
 - Advice provided was used to suitably reassure patients and enabled one to have the intended examination on a lower field strength MR scanner.
 - Establishment of a clinical MR Safety Group to develop the MR safety culture, share good practice and encourage a uniform approach to safety throughout the Health Board.

¹⁰ The Institute of Physics and Engineering in Medicine. Policy Statement: Scientific Safety Advice to Magnetic Resonance Imaging Units that Undertake Human Imaging. IPEM. 2013.

- Performance of MR safety audits in ABMU MR Facilities.

8. Conclusions

- 8.1 MRI is one of the most complex technologies used in modern healthcare. To utilise it optimally, whether it be for diagnostic purposes or research, requires provision of advice based upon advanced specialist knowledge of the physics theory which underpins it. Such knowledge is also required to inform purchasing decisions regarding this expensive technology, as well as in assuring the optimal quality of its initial and ongoing performance.
- 8.2 In addition MRI uses very powerful electromagnetic fields and the complex interactions between these and the soft tissues of the human body, or metal associated with the patient in medical implants, has resulted in deaths and many injuries to both patients and staff. One of the important key roles of MR physics is in the preparation and maintenance of Local Rules which define safe working practices in the high magnetic field environment
- 8.3 The wide role of MR Physics includes: preparation of tender specifications for procurement, critical equipment evaluation, assessment and scoring of tenders, acceptance testing, the provision of specialist diagnostic services, advice to radiologists regarding most appropriate imaging protocols, image artefacts and pulse sequence choice, support and initiation of research programmes and specific projects, quality assurance, teaching on MR theory and safety to all levels of staff, and the maintenance of safe working environments for patients and staff.
- 8.4 The MR physicist also provides and develops MR scientific underpinning for all areas of clinical MRI and specifically multi-modality hybrid imaging, image fusion, high field imaging, functional MRI, and MR planning in radiotherapy.

9. Recommendations

- 9.1 Welsh Government issues guidance on MRI safety through a quality and safety health circular to all Chief Executives of Local Health Boards and NHS Trusts providing a clinical MRI service including the need to appoint a suitably qualified Magnetic Resonance Safety Expert. Guidance to include the following advice to assist employers on achieving acceptable levels of scientific support:
 - inclusion of a workforce element for capital purchases of new MRI equipment;
 - inclusion of funding for an MR physicist in workforce plans.
- 9.2 All Local Health Boards and NHS Trusts providing a clinical MRI should have access to a MR physicist to support development and all necessary aspects of MR safety issues, in accordance with latest MHRA guidelines, including compliance with latest statutory requirements governing the control of occupational exposure from electromagnetic fields;
- 9.3 In order to make effective use of limited resources and to reflect the current provision of physics support for ionising radiation safety within NHS Wales, physics support for MR should be concentrated within the three sub-regional Radiation Protection Services (ABMU and Betsi Cadwaladr Health Boards and Velindre NHS Trust). Alternatively, support for MR could be centralised within a single Service with strong and established links to a University offering MR physics expertise (e.g. ABMU Radiation Protection Service and Swansea University);
- 9.4 The Scientific Training Programme for Medical Physics in Wales provides an Imaging with Non Ionising Radiation specialism in order to attract, select and retain the very best people to MR clinical scientist posts within Wales.

Appendix 1

Inventory Clinical MRI scanners in Wales

NHS Organisation	MRI Scanner				Detail
	0.2T	0.3T	1.5T	3T	
ABM UHB			3	1	2 GE 1.5T, 1 TOSHIBA 1.5T, 1 GE 3.0T
AB UHB			3		3 SIEMENS 1.5T
BC UHB	1		3		1 ESAOTE 0.2T, 1 PHILLIPS 1.5T, 2 SIEMENS 1.5T
C&V UHB			4		4 GE 1.5T
CT UHB			2		1 SIEMENS 1.5T. 1 TOSHIBA 1.5T
HD UHB		1	3		2 GE 1.5T, 1 TOSHIBA 1.5T, 1 HITACHI 0.3T OPEN
PT HB			0		
Vel NHS Trust			1		1 GE 1.5T
PHW NHST			0		
Total	1	1	19	1	All NHS managed scanners
				6	Academic based scanners

Information kindly supplied by Andrew Ward, NHS Wales Shared Services Partnership

KEY

ABM UHB	Abertawe Bro Morgannwg University Health Board
AB UHB	Aneurin Bevan University Health Board
BC UHB	Betsi Cadwaladr University Health Board
C&V UHB	Cardiff & Vale University Health Board
CT UHB	Cwm Taf University Health Board
HD HB	Hywel Dda University Health Board
PT HB	Powys Teaching Health Board
Vel NHST	Velindre NHS Trust
PHW NHST	Public Health Wales NHS Trust

Appendix 2

Definition of MR Safety Expert (MRSE) [European Federation of Organisations For Medical Physics)

Should have the knowledge, skill and competence to provide high level advice on the engineering, scientific and administrative aspects of the safe clinical use of MR devices.

Responsibilities will include:

- the development and continuing evaluation of a safety framework for the MR environment
- the development of local rules and procedures to ensure the safe use of MR equipment
- advice regarding non-routine MR procedures for individual patients and specific patient groups (safety related to implanted devices and tattoos).

The expertise of the MRSE is an important source of

- safety advice regarding the selection and procurement of MR and related equipment
- advice on the design for accommodation and facilities for MR equipment
-

The MRSE would be a valuable member of the multi-disciplinary MR procurement advisory team. Such high level expertise is usually available in large public sector Institutions but it may not be available in every MR facility.

When advice at this level is required in these cases, the expertise could be sourced from a large institution or an independent sector provider.

In the cases of public sector institutions with a number of geographically dispersed MR installations and sites and/or mobiles operated by an independent sector provider, a single MRSE could provide the required expertise.