

Institution: The University of Nottingham
Unit of Assessment: 9
Title of case study: Regulatory Framework for Electromagnetic Field Exposure Limits for Magnetic Resonance Imaging
<p>1. Summary of the impact</p> <p>Our research on the physiological effects of the electromagnetic fields generated in magnetic resonance imaging (MRI) has been used by: (i) the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the UK Health Protection Agency (HPA) in establishing advisory limits and action values in their published regulatory guidelines; (ii) the EU Commission as part of the evidential basis in their decision to derogate MRI from the scope of the Physical Agents Directive 2004/40/EC. These decisions have enabled the continued operation of MR scanners across Europe, safeguarding the access to MRI for 500 million people. The economic benefits arising from the manufacture of MRI equipment were also secured. Our work has thus resulted in impact on public policy, the economy and healthcare.</p>
<p>2. Underpinning research</p> <p>Exposure to high magnetic fields can lead human subjects to experience sensations such as magnetic field-induced vertigo, metallic taste and visual disturbance. Our research has provided advances in the fundamental understanding of the relevant underlying physiological processes, and was also motivated by a need to determine the possible impact on patients and operators when stationary, or moving, in and around magnetic resonance (MR) scanners. The development of high field MR scanners (3T since 1991, and 7T since 2005) in Nottingham provided a major stimulus for this work since physiological effects, such as magnetic field-induced vertigo, have been suggested as a barrier to the operation of high-field scanners. As we describe below, our research has been used by ICNIRP in establishing guidelines for occupational exposure to static and low frequency magnetic fields, and has helped to demonstrate that the Physical Agents Directive 2004/40/EC, which would have drastically disrupted the use of MRI in Europe, was overly proscriptive and based on incorrect application of theoretical models.</p> <p>Our research has involved theory, computational modelling and experimental studies and builds on our expertise in electromagnetism, electronics and electrophysiology. Since 1993 this work has involved three members of academic staff (<i>Glover, Gowland and Bowtell</i>) and has been funded by three EPSRC project grants (i-iii), an EPSRC/MRC Programme Grant on ultra-high field (7T) MRI (iv) and a Joint Infrastructure Fund award (v) that funded the development of the UK's first 7T scanner in Nottingham.</p> <p>Below we describe the key elements of our investigations [1-5], organised according to the frequency range of the applied magnetic fields.</p> <ul style="list-style-type: none"> • Static Magnetic Fields <p>We have demonstrated that exposure to static magnetic fields in and around MR scanners, including low frequency movements of the body in these fields, can produce measureable effects on the vestibular, visual and taste systems. Such exposure can lead to postural sway, feelings of vertigo, metallic taste and magneto-phosphenes. We characterised the field regimes (rate of change of field and total field change) which produce vertigo and metallic taste effects [1,3], and identified the magnetic susceptibility of the otoliths and induced currents acting on the vestibular afferent nerves as candidate mechanisms for magnetic field-induced vertigo [1].</p> <ul style="list-style-type: none"> • Time-Varying Magnetic Fields (0-100 kHz) <p>At frequencies of the order of kHz the currents induced in the human body by time-varying magnetic fields may cause peripheral nerve stimulation (PNS). Numerical simulations were used to characterise the spatial distributions of the electric fields induced in the body by time-varying magnetic field gradients and to compare the applied magnetic fields (which can be readily measured) with the induced current density, which is used in regulatory guidelines, but cannot easily be measured [2]. In addition, we demonstrated the ability to measure very low frequency surface electric fields in a human subject exposed to the magnetic fields of an MR scanner [4]. We also attempted to repeat and extend small studies from the literature, upon which much of the regulatory position was founded. In particular, we conducted experiments to measure the effects of the time-varying magnetic fields used in MRI on visual acuity and visual evoked potentials [5].</p>

3. References to the research

(*denotes paper which best describes quality of research)

- 1) ***P.M. Glover, I. Cavin, W. Qian, R. Bowtell, P.A. Gowland**, *'Magnetic-field-induced vertigo: A theoretical and experimental investigation'*, *Bioelectromagnetics* **28**, 349 (2007).
DOI: 10.1002/bem.20316
- 2) ***M. Bencsik, R. Bowtell, R.M. Bowley**, *'Electric fields induced in the human body by time-varying magnetic field gradients in MRI: numerical calculations and correlation analysis'*, *Phys. Med. Biol.* **52**, 2337 (2007).
DOI:10.1088/0031-9155/52/9/001
- 3) **I. Cavin, P. Glover, R. Bowtell, P. Gowland**, *'Thresholds for perceiving metallic taste at high magnetic field'*, *Journal of Magnetic Resonance Imaging* **26**, 1357 (2007).
DOI: 10.1002/jmri.21153
- 4) ***P.M. Glover and R. Bowtell**, *'Measurement of electric fields induced in a human subject due to natural movements in static magnetic fields or exposure to alternating magnetic field gradients'*, *Phys. Med. Biol.* **53**, 361 (2008).
DOI:10.1088/0031-9155/53/2/005
- 5) **P.M. Glover, S. Eldeghaidy, T.R. Mistry, P.A. Gowland** *'Measurement of visual evoked potential during and after periods of pulsed magnetic field exposure'*, *Journal of Magnetic Resonance Imaging* **26**, 1353 (2007).
DOI: 10.1002/jmri.21155
- 6) **P. Mansfield and P.R. Harvey**, *'Limits to neural stimulation in echo-planar imaging'*, *Magnetic Res. Med.* **29**, 746 (1993).
DOI: 10.1002/mrm.1910290606

Funding

- i. *'Nerve stimulation due to rapidly switched magnetic field gradients in MRI'*, PI: Bowtell, EPSRC GR/R07899/01, (Nov 2000 – Nov 2003) £177,953
- ii. *'Forward & inverse analysis of electromagnetic fields for MRI using computational mechanics techniques'*, PI: Jones, EPSRC GR/T22445/01, (Feb 2005 - Jan 2008) £208,925
- iii. *'Measurement and modelling of electric fields induced in the human body by temporally changing magnetic fields'*, PI: Glover, EPSRC EP/G062692/1, (Oct 2009 - Dec 2012) £377,840
- iv. *'Functional neuroimaging at ultra-high magnetic field'*, PI: Morris, MRC/EPSC, Programme Grant G9, (Jan 2005 - Dec 2009) £1.8M
- v. *'An ultra-high field facility for functional magnetic resonance'*, PI: Morris, Joint Infrastructure Fund, (Jan 2001 - Dec 2005) £2.33M

4. Details of the impact

The adoption of guidelines based on our research was stimulated by the publication by the EU Commission of the Physical Agents Directive 2004/40/EC in 2004. The aim of this Directive was to harmonise European legislation and establish a formal legal framework for electromagnetic field (EMF) exposure of workers, which would have been based on the guidelines issued by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) in 1998 [Health Physics 74 (4):494-522; 1998]. The Exposure Limit Value (a current density of 10 mA m⁻²) relating to exposure to magnetic fields in the frequency range 0-100 kHz, which was proposed in the Directive, would have rendered many common MRI procedures illegal in Europe (as detailed in a report by the UK Health and Safety Executive (HSE) [A]). The Directive would consequently have had a severe, negative impact on patients, health professionals, and scanner manufacturers.

However, this Exposure Limit Value was based on the extrapolation of old or very limited data. Through the programme of research described above, we produced a body of work which updated, and/or contradicted, the data on which the proposed EU limits were based. Our research thus provided a platform for a lobbying process (described below, and in the Institute of Physics report "MRI and the Physical Agents (EMF) Directive", November 2008). In 2009, this lobbying resulted in the relaxation of the ICNIRP static field exposure guidelines for MRI (described in a draft report of which *Gowland* is a co-author) and later produced a derogation of MRI from the scope of the 2004 EU directive.

The Nottingham group used their research to influence the UK government to lobby for changes in the proposed EU guidelines. A letter sent by Nottingham MRI physicists *Gowland* and *Morris* (with

four other leading members of the UK MRI community) to Dr. Strather of the National Radiological Protection Board (NPRB) in June 2003 [B] drew attention to the unreliability of the, then, ICNIRP guidelines, and the impact on MRI of adopting the guidelines proposed by the EU. Subsequently, the lobbying was channelled through the Institute of Physics and Engineering in Medicine (IPEM) with Prof. Stephen Keevil (now IPEM President) playing a central role in publicising the issue through the national media (article in the Guardian [C]) with support from *Sense about Science*, an independent charitable trust. These activities led to a meeting with Lord Hunt (2005, then Minister of State at the Department for Work and Pensions) and an inquiry by the House of Commons Science and Technology Committee (to which Keevil, *Gowland* and others provided evidence [D]). This committee produced a report in June 2006 [D], which was critical of the HSE, the UK Health Protection Agency (HPA), ICNIRP and the European Commission. In 2007, the Alliance for MRI was formed and presented an HSE-commissioned report [A], which draws upon our research [6], in Brussels. Subsequently, a new Directive 2008/46/EC was adopted (23rd April 2008). This postponed the transposition deadline of Directive 2004/40/EC to 30th April 2012. ICNIRP then re-evaluated the relevant underlying science, drawing extensively on our work [1-5], and introduced new guidelines. On the 29th June 2013 Directive 2004/40/EC was repealed and a new directive 2013/35/EU, based on guidelines from ICNIRP, in turn based on our research, became official EU law.

4.1 Evidence for the Impact of our research

4.1.1 Impact on Public Policy: Changing Underpinning Legal Frameworks

- The recommended action limits for low frequency magnetic field exposure in our published work [1,4], have been incorporated into guidelines by: ICNIRP (2009) [E]; the HPA (2008) [F]; and the British Standards Institute and International Electrotechnical Commission (2008) [G]. These recommended limits have global reach since ICNIRP is formally recognised by the World Health Organisation. In addition, *Gowland* was invited to join (March 2013) the ICNIRP Scientific Expert Group (SEG), contributing her expertise in MRI.
- The ICNIRP guidelines, based in part on our research, have been incorporated within the legal framework for EMF exposure in Europe (population circa 500M). Workers in the EU who may be exposed to high magnetic fields will thus benefit from a more robust understanding of the effects of occupational electromagnetic field exposure.
- The role and importance of Nottingham research in providing the scientific basis for lobbying UK and EU government organisations is confirmed by IPEM President-elect, Prof. Stephen Keevil who states, [H]

'The work of the Nottingham group has made a tremendous contribution to the body of science underpinning negotiations about the EU EMF Directive, and particularly has helped MRI practitioners in their attempts to mitigate the adverse impact of this legislation on MRI in clinical practice and research. In an area where there are significant gaps in the literature, leading to assumptions and suppositions with little evidence to support them, this work has been very significant in our negotiations with the European Commission and has also had a major influence on the International Commission on Non-Ionising Radiation Protection (ICNIRP). It is of lasting significance to the MRI community in Europe and beyond.'

References to the media coverage, Prof. Keevil's appearances at the European and UK Parliaments, the House of Commons Science and Technology Committee's report 'Watching the Directives' (dated June 2006 and highlighting the impact on MRI), and an HSE paper identifying the agreed actions in the light of the House of Commons report are also provided [C,D,F].

4.1.2 Impact on Health and Economy

The revision of the original guidelines in the EU 2004/40/EC Directive based on the Nottingham work has mitigated a number of effects. The beneficiaries of these are:

- Patients undergoing MRI: if the Directive had proceeded as originally planned, high-field ($\geq 3\text{T}$) MRI would have ceased until major and costly scanner redesigns could have been implemented, and the use of 1.5T MRI would have been limited [I]. This would have had particular impact on: patients suffering from neurological disease, cancer and other serious

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conditions where MRI is the leading, and sometimes only, relevant non-invasive diagnostic technique; patients requiring constant monitoring by staff during scanning – this includes patients under anaesthesia and paediatric patients for whom alternative modalities, such as X-ray Computed Tomography (CT), have clear associated risks (there are 500 lifetime deaths associated with the 600,000 paediatric CT scans performed annually in the UK); patients for whom interventional MRI has replaced more invasive alternative procedures. Overall the European population has retained the full health benefits of mid- and high-field MRI as a consequence of the relaxation of the original EU directive, a process in which our research and lobbying played a critical role.

- The National Health Service (NHS): in 2011 the NHS had 304 MRI scanners with an average cost of £895k per scanner [National Audit Office, “Managing High Value Capital Equipment in the NHS” (2011)]. The EU Directive would have either introduced major constraints on the use of this equipment, or significant modification costs to make their use legal. Estimating the resulting financial cost is problematic, but the overall scale of investment in MRI by the NHS is ~£270M (see above) so that modification costs, or reduced use, even in the range of 5-10% would have had a significant impact on health budgets and/or delivery of healthcare.
- European Manufacturers of MRI scanners: the Directive would have required radical modifications to equipment and working practice to avoid exposure of workers involved in the manufacture, operation and servicing of equipment for no scientific or clinical benefit. In 2007 the UK MRI industry supported ~ 4000 jobs and a value-added contribution to GDP of £195M [J]. Since companies outside Europe, notably those in the USA, would not have been governed by the guidelines, this would have endangered the viability of European industry and reduced global competition.

5. Sources to corroborate the impact (available on request)

- A. Health and Safety Executive, “Assessment of Electromagnetic Fields around Magnetic Resonance Imaging (MRI) equipment”, Research Report RR570, (2007).
- B. Letter from *Morris, Gowland* et al. to Dr. Strather of the NPRB (June 2003).
- C. “EU limits may lead to big cuts in MRI scans”, *The Guardian*, September 2005.
- D. House of Commons Science and Technology Committee, “Watching the Directives: Scientific Advice on the EU Physical Agents (Electromagnetic Fields) Directive”, HC 1030, 29th June 2006.[please see Ev47, Ev67, Ev69, Ev70].
- E. ICNIRP publication, “Guidelines on Limits of Exposure to Static Magnetic Fields”, *Health Physics*, 96(4), 504-514, 2009.
- F. Health Protection Agency, “Static Magnetic Fields: Report of the Independent Advisory Group on Non-ionizing Radiation”, 2008. See references on pages 32, 49, 50, 65, 115, 116.
- G. British Standards Institute and International Electrotechnical Commission, “Medical Electrical Equipment — Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis”.
- H. Letter from Prof. Stephen Keevil, IPEM president (President Elect at the time the letter was dated, President from September 2013).
- I. SF Keevil, W Gedroyc, P Gowland, DLG Hill, MO Leach, CN Ludman, K McLeish, DW McRobbie, RS Razavi, IR Young. Electromagnetic field exposure limitation and the future of MRI. *British Journal of Radiology* 78 (935): 973-975 2005.
- J. Oxford Economics, “The economic impact of physics research in the UK: a case study approach”, December 2009 [see page 24].