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Magnetic resonance imaging safety issues including an analysis of recorded incidents within the UK

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1. Introduction

This paper reviews the safety issues and risks associated with exposure to Magnetic resonance imaging (MRI). There is currently a raised awareness concerning the safety of electromagnetic fields (EMFs), which has been partly due to a European Physical Agents Directive on Occupational Exposures to EMFs [1] and an Environmental Health Criteria report from the World Health Organisation Task Force on static EMFs [2]. Within the MRI community itself concerns regarding the safety of magnetic resonance imaging (MRI) had increased over the past decade as indicated by a recent safety review [3]. These concerns coincide with the growing number of MRI scanners installed (Fig. 1), the trend towards higher main magnetic field strengths [4–6] and the widening of the clinical applications for MRI. This paper considers these issues by reviewing the safety issues concerning the static magnetic field, the radiofrequency field and the time-varying EMF gradients. The situation is then analysed by reviewing the number and types of incidents that have been reported within the UK to the adverse incident centre at Medicines and Healthcare products Regulatory Agency (MHRA).

Magnetic resonance imaging (MRI) uses three main components to produce images from inside the body, a high static magnetic field, pulsed radio-frequency (RF) fields and time-varying gradient electromagnetic fields (EMF). The hazards associated with large static magnetic fields are interactions with human tissue and interactions with equipment. For the interactions with human tissue those that affect the ears, blood flow and cardiac cycle are discussed. There is also a brief review of epidemiology studies that have been undertaken by other researchers. For the interactions of static magnetic field with equipment the following issues are discussed; projectiles, implant malfunction, implant movement, monitoring device malfunction and monitoring device movement. The RF issues presented are Specific Absorption Rate (SAR) issues, tissue heating, burns, implant heating and implant interference effects. For the time-varying gradients the main concerns are peripheral nerve stimulation and acoustic noise, alongside potential implant or monitoring device interference. Exposure to the MRI is subject to various guidelines, i.e., for patient exposure to MRI guidelines are given by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) [7], and in an American College of Radiology (ACR) White paper on Magnetic resonance (MR) safety [8,9]. For occupational exposure to EMFs, guidelines were given by ICNIRP in 1994 [10] and in 1998 [11], and by the UK National Radiological Protection Board (NRPB), now part of the Health Protection Agency (HPA), in 2004 [12]. Actual occupational exposure limits have recently been set by the European Union [1]. This paper first reviews the hazards with respect to the main components and then reviews the database of incidents as recorded by the MHRA.

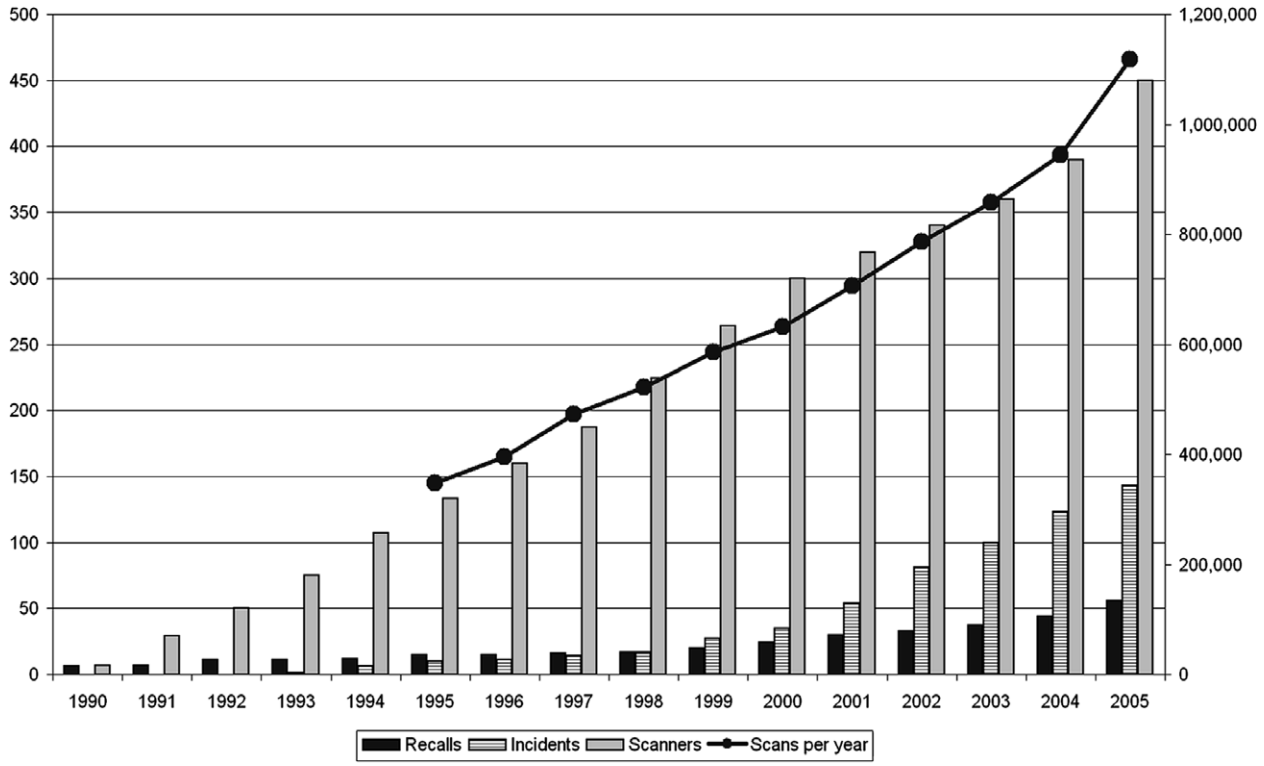

Fig. 1. Chart indicating the growth in installed scanners, number of reported incidents and recalls of MRI components (left hand axis) and the growth in the number of scans (right hand axis) in the UK from 1990 to 2005.

2. Static magnetic fields

2.1. Introduction to static magnetic field exposure

In the presence of high static magnetic fields, the safety issues to be considered are biological and mechanical effects and their resulting exposure issues. The magnets used in clinical MRI range in strength from about 0.2 to 3.0 T. To achieve these field strengths superconducting magnets are mainly used, however, permanent magnets and resistive magnets are utilised in some designs. There are experimental whole body superconducting units that range up to 10 T and for small bore systems the range can be from 4 to 14 T and higher. Many MR systems are designed with a horizontal magnetic field generated by a cylindrical magnet. In these systems, the static field is parallel to the long axis of the patient. Some MRI systems utilise a transverse field magnet and the static magnetic field is normal to the long axis of the patient. The magnetic field experienced by the patient typically is usually limited to the operating field strength of the magnet. However, for some magnet designs there can be areas inside and outside the bore of the magnet that are higher than its operating field strength. There is the patient and occupational exposure to be considered. Gowland [13] has documented the present and future sources of exposure to static fields in MRI and the number of people affected.

2.2. Effects of static magnetic fields on human tissues

The effect of static magnetic fields on human health took on a new highlighted importance for the MRI community after a proposal in a draft European Union (EU) directive [1] to impose a legally enforceable static magnetic field limit for occupational exposure. The limit proposed originated from ICNIRP guidelines [9,10] and was set at 2 T, this raised concerns as it would make it virtually impossible to operate and maintain MRI units installed in Europe. In particular, such a limit would affect the operation of the higher field units of 3 T and above. The static field limit was withdrawn from the published EU directive [1]; however this withdrawal was temporary whilst the effects on static fields on human health were reconsidered on the basis of scientific data. The World Health Organisation (WHO) hosted a Static Field Workshop in Oxford in 2004 which led to the publication of reviews of static field effects on cells [14], living tissues [15], humans [16], animals [17], and an epidemiology review [18]. This work and other work undertaken by the WHO task force on EMFs culminated in an Environmental Health Criteria (EHC) report, 2006 [2]. This EHC report is a detailed and thorough risk assessment of the effects of static magnetic fields.

Schenck [15,19], presents that the fact that the apparent high degree of safety with static field and the very few measurable effects can be attributed to the small value of the magnetic susceptibility of human tissues and to the lack of ferromagnetic components in these tissues. The most reported effects of static magnetic field interactions with human tissues are actually related to movement within the static field. If a charge is moving in a magnetic field it will experience a force that is perpendicular to its direction of velocity and the magnetic field, this is the Lorentz Force. Hence within the human body, respiration, cardiac displacements, and flowing blood or flowing fluid can induce voltages in the body through the Lorentz effect.

Any effects measured tend to occur at field strengths at 4 T and above. In 1992, Schenck et al. [20] observed that there was statistically significant evidence that the sensations of vertigo, nausea and metallic taste were field-dependent and greater at 4 T than at lower fields. Later, Chakeres et al. [21] measured the effect of static field exposure up to 8 T on vital signs which included heart rate, respiratory rate, systolic and diastolic blood pressures, finger pulse oxygenation levels, and core body temperature. The only statistically significant field-dependent effect observed was systolic blood pressure, which resulted in an average increase of 3.6 mmHg in systolic blood pressure at 8 T. In 2005, Saunders [17] reviewed animal studies on the effect of static fields. It was generally found the results from animal studies concurred with those from volunteer human studies and that any measurable effects where only found above about 4 T. Those effects were the induction of flow potentials around the heart and the development of aversive/avoidance behaviour resulting from body movement in such fields. Saunders concluded that there have been far too few animal studies into the effects of static fields. Liu et al. [22] and Crozier and Liu [23] presented mathematical simulation studies detailing the calculation of electric fields induced by body and head motion in high-field MRI. Their simulations show that it is possible to induce electric fields/currents near the level of physiological significance under some circumstances.

Studies detailing neurobehavioural effects have been undertaken. Chakeres et al. [24] conducted a randomized comparison of cognitive function in humans at 0 and 8 T which showed that exposure of the brain to high magnetic fields of up to 8 T does not appear to alter human cognitive performance. De Vocht et al. [25] tested neurobehavioral effects among 17 subjects exposed to high static and gradient magnetic fields from a 1.5 T MRI system. Adverse effects were found for hand coordination and near visual contrast sensitivity. Chakeres and de Vocht [26] reviewed three studies and concluded that the studies did not demonstrate any clinically relevant adverse effects on neuro-cognitive testing from static field exposure. De Vocht et al. [27] investigated the acute neurobehavioral effects of exposure to static magnetic fields. The study assessed exposure-response relations between exposure to magnetic fields and microbehavioural effects, the results found exposure-response relations for visual and auditory working memory, eye-hand coordination speed and visual tracking tasks. However, eye-hand precision, scanning speed, and visual contrast sensitivity were apparently not influenced by the magnetic field strength. De Vocht et al. [28] discuss health

complaints and cognitive performance among employees who experience exposure to static fields in the MRI scanner manufacturing department.

2.3. Static magnetic field interactions with equipment

Most MR incidents can be attributed to the presence of ferromagnetic devices and equipment, including implants, in the MR environment. Any such device will be subjected to the attractive and rotational forces from the static field. In 2004, Colletti [29] reported an incident where the wrong type of oxygen cylinder was brought into the scanner room while a critically ill patient was being monitored. The patient showed reduced oxygen saturation, as the radiographers were removing the patient from the scanner, the patient's physician wheeled in an 80 kg oxygen cylinder. This time the only damage was to the scanner, but in 2001 a boy was killed in the USA following a similar incident. Other incidents can, on the other hand, be attributed to the misuse of devices where their restrictions or limitations have not been properly applied. The effects of the static magnetic field on certain components can cause their malfunction or complete failure. This, in turn, can affect the performance or accuracy of the medical device, possibly compromising patient safety. The following incident of an infusion pump malfunction was described by Leeson-Payne et al. [30]. The static magnetic field caused the pump's motor to operate in reverse, despite relatively normal displays presented to the radiographer. Had it not been for a safety valve in the IV delivery line, blood could have been withdrawn from the patient into the IV bag. Furthermore, a report [31] was published in 1998 about the misuse of a ventilator (which was not approved for MR use), this ventilator delivered inadequate inspiratory pressure when operated in the MR environment. Similarly, some implanted devices that are magnetically, electrically, or mechanically activated may have their function affected by the magnetic field. Examples include some cochlear implants, drug infusion pumps, neurostimulators, ocular prostheses, and cardiac pacemakers.

In the UK, the MHRA has recommended against the use of standard metal detectors for improving MR safety [32]. Metal detectors detect all types of metals therefore their use could lead to a high number of false-alarms. More importantly, standard metal detectors cannot detect very small ferromagnetic materials that may cause injury (small pellets in sand bags), and thus their use could provide a false sense of security. However, specific ferromagnetic detection systems have recently been developed, and have been successful in detecting very small ferromagnetic objects [33]. If the performance observed in the study by Thomas et al. [33] is repeatable and if the devices function as intended and are set to the proper sensitivity, the use of ferromagnetic detection systems could prove to be a beneficial addition to an MR facility's safety practices.

In an effort to minimise incidents, the American Society of Testing and Materials (ASTM) International recently introduced a new device marking system. The ASTM standard, published in August 2005, specified new terminology and symbols (see Fig. 2) for characterizing the suitability of medical devices for use in the MR environment [34].

In addition to patient or staff injuries, incidents often result in damage to expensive equipment. With the current trend and the versatility of MRI, an increasing number of devices and instruments are being used in MR scan rooms: for example, to perform an MRI examination under monitored deep sedation or general anaesthesia, or to conduct interventions under MR guidance. As the amount of equipment used in the MR environment increases, so does the risk of adverse incidents. Moreover, as an increasing number of staff needs to be present in the MR environment, such as surgical staff and other non-MR personnel, the range of individuals who need to be educated about the hazards in the MR environment will need to be expanded beyond the typical MR personnel.

The attractive force on a ferromagnetic object is proportional to the spatial gradient of the magnetic field. The gradient is normally steeper for higher field systems due to the combination of shielding and main field strength. For diagmagnetic or paramagnetic materials the attractive force is also proportional to the field strength. Therefore objects, including implants that have been found to be safe to use in the presence of 1.5 T systems may not be so with the more powerful 3 T systems [35,36].

MRI room and unit design are critical in the prevention of projectile incidents. The ACR White Paper [8,9] advocates the use of zones to reduce the likelihood of ferromagnetic objects being accidentally brought into the scan room and also to decrease the number of people with access to the scan room. In the UK, the MHRA [32] recommends the use of controlled areas within and around the MRI unit to regulate safety. It is optimal if such safety areas can be incorporated into the room design when the MRI unit is in the planning stage before the unit is actually constructed.

As interventional MRI applications increase, new safety issues have to be considered [37]. Interventional MRI is based on the integration of diagnostic and therapeutic

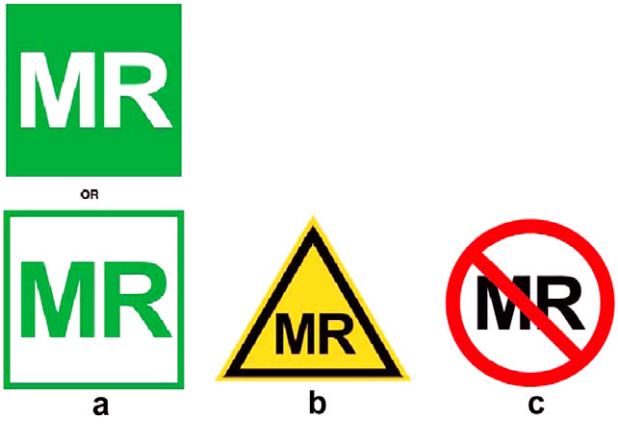

Fig. 2. ASTM terminology [34] for labelling devices (a) MR safe, (b) MR conditional, (c) MR unsafe.

procedures, favoured by the combination of the excellent morphological and functional imaging characteristics of MRI. The spectrum of MR-assisted interventions ranges from biopsies and intra-operative guidance to thermal ablation modalities and vascular interventions.

Interventional guidance implies the use of MRI during the manipulation of needles, catheters by the radiologist or endoscopes, scalpels by the surgeon. Advances in interventional MRI require the development of dedicated MR-compatible equipment, since many instruments used in conventional surgery are made of ferromagnetic material therefore being incompatible for MR-guided interventions, due both to safety concerns and image quality degradation [38–40]. The nonmagnetic form of stainless steel can be used in MR; however, any stainless steel in the imaging volume causes significant image distortion and signal loss. Other materials that are not ferromagnetic, such as titanium alloys (e.g., nitinol), only produce local image distortions and may be used. Theoretically, the ideal material should have similar magnetic susceptibility to the human body. Many plastics, such as Teflon and Plexiglas, have such comparable properties but instruments made of these materials cannot be made sufficiently sharp or stiff for use in surgical interventions and are difficult to visualize in the MRI image and sterilize. Artefacts depending on susceptibility arise in MR images due to incorrect spatial encoding and intravoxel dephasing and therefore hindering the surgeon's view of the region of interest. To overcome this issue, diamagnetic coating or filling of the instruments has been proposed in the literature [41] to compensate for the paramagnetic properties of the instrument. The visibility of equipment also depends on the pulse sequence used. The physics behind the influences of static magnetic field inhomogeneities on MR imaging is well known. Artefacts are generally more pronounced using the gradient echo (GRE) technique than using spin echo (SE) techniques [42]. For example, generation of signal voids in GRE images has been reported in detail in a review article by Reichenbach et al. [43]. Frahm et al. [44] have tested biopsy needles at 0.2 T and 1.5 T showing that artefacts in GRE images on the 0.2 T scanner were clearly less extended than those at the 1.5 T scanner using unchanged imaging parameters.

Lufkin et al. [45] see the operating room of the 21st century containing dedicated interventional MRI units to assist in surgical procedures. As this trend progresses, and MRI is used for guiding and controlling tumour ablation, aspiration cytology, and surgical biopsy of different body parts, the importance of strict local rules will become even more critical.

3. Radiofrequency electromagnetic fields

3.1. Introduction to radiofrequency EMF heating

During MRI procedures, the majority of the radiofrequency (RF) power transmitted is transformed into heat within the patient's tissue as a result of electromagnetic induction and ohmic heating [46]. RF power deposition, leading to tissue heating, is expressed as Specific Absorption Rate (SAR) in W/kg. As an approximation the power deposited in the tissues can be expressed by the following relation assuming that the body can be represented by a uniform sphere of radius r, conductivity σ and density ρ

$$\mathrm{SAR} \propto \frac{r^2 \sigma \theta^2 f_0^2 D}{\rho}, \tag{1}$$

where θ is the RF flip angle which is proportional to the B_1 field strength, f_0 is the transmit frequency, which is proportional to B_0, and D is the duty cycle of the RF pulses.

At field strengths up to about 1.5 T heat is deposited peripherally where it is dissipated more efficiently. At this field strength the ratio of peak to average SAR is about 2.5 based on a homogeneous sphere model [47]. As the RF wavelength decreases at higher fields the ratios of peak to average SAR may also decline whilst these reduced local hot spots may be deeper in the body [48].

Tissue heating can lead to heat stress especially in patients whose thermo-regulatory or cardio-vascular systems are already compromised [46]. There is also a concern with areas of the body that dissipate heat less easily, because of a poor blood supply such as the testis, eyes or the fetus.

3.2. Monitoring and control of radiofrequency EMF heating

The International Electrotechnical Commission (IEC) MR safety standard [49] sets limits both for core temperature increases and maximum absolute temperatures for the head, torso and extremities based on an examination of the available evidence. In common with other hazards a normal operating mode is defined where machine parameters are not expected to present any hazard and a first level operating mode where there is a slight risk of non-serious effect that may cause additional stress to the patient and where medical supervision is required. Above the first level operating mode lies the second level operating mode that presents a significant risk and must not be entered without ethical approval. A system interlock prevents the first level operating mode limits being exceeded.

A maximum core temperature rise of up to 0.5 °C is allowed in the normal operating mode whilst up to 1 °C is allowed in the first level operating mode. According to the IEC [49] all patients can be scanned safely in the normal operating mode whilst the first operating level is appropriate for patients without any thermo-regulatory issues and who are not pregnant. Since it is not practical to monitor patient temperatures directly the SAR parameter represents a convenient surrogate to control these temperature rises.

The IEC standard [49] sets limits for whole body, partial body, head and local (averaged over 10 g) SAR that are implemented in the scanner software. The maximum whole body SAR is 4 W/kg in the first level operating mode. Both

theoretical calculations and experimentation have indicated that this would cause up to a 0.6 °C core body temperature increase over scanning periods of 20–30 min [50,51].

Temperature increases inside the body cannot be measured directly and there has been much interest in estimating temperature or SAR distributions using modelling that uses a realistic patient geometry and takes account of the varying dielectric and conductive properties of the body's tissues [52]. In this way it is possible to predict local hotspots. These may cause local SAR limits to be exceeded before whole body SAR limits are reached [53–55]. The case of the pregnant patient is of particular concern because the fetus is surrounded by a large volume of conductive fluid and because of the sensitivity of the fetus to heat [56]. Recently models of pregnant patient have been developed [54,55] for 64 and 128 MHz exposures in birdcage RF coils. One model has nine versions; one for each month of the gestation [55]. This study suggested that when remaining within the whole body SAR limit for the first level operating mode local SAR limits inside the fetus may be exceeded after five months gestation.

In extreme cases RF power deposition can lead to burns. Burns are normally associated with a relatively high SAR scan and some other contributory factor that acts to concentrate the induced currents and lead to extreme temperature increases.

Inappropriate patient positioning can give rise to a conductive loop formed from the patients own anatomy such as when the hands are clasped or the insides of the thighs or calves are in contact [57]. Avoiding small points of focal skin to skin contact that lead to high resistance is particularly important. The presence of conducting material close to the patient such as the leads for monitoring equipment can also cause temperature hotspots [58]. Taking care with patient positioning and placing sufficient padding between patient and conductor can avoid the possibility of such incidents.

Implanted medical devices with conductive parts can also leads to RF burns. Of particular concern are elongated devices, loops, leads and wires [59]. Such devices may exhibit resonant behaviour leading to extreme heating [60]. RF wavelength resonance effects lead to a great deal of unpredictability. Devices that do not give rise to significant heating at a particular RF wavelength may behave quite differently at a lower or higher RF wavelength because of resonant effects [59].

Scanner whole body SAR values have been used to define safe conditions for scanning patients with certain implants. This approach is problematic however as the parameter is designed to quantify heating in the human body and not in implants [61]. Whether an implant will exhibit heating in the MRI environment depends on multiple factors not accounted for by the patient SAR value including RF wavelength, RF transmit coil type and the position of the implant within the transmitted RF field. As an alternative to using the SAR it has been suggested that the maximum B_1-rms value for each pulse sequence may be defined by the manufacturers [58].

4. Time-varying electromagnetic field gradients

4.1. Nerve and muscle stimulation

The rapidly switched magnetic field gradients used in MRI image formation present the possibility of inadvertent nerve stimulation [62,63]. The time-varying magnetic field ($\mathrm{d}B/\mathrm{d}t$) induces an electric field by Faraday's law of induction and consequently electric currents, in the patient. These induced currents can lead to the depolarisation of nerve or muscle cell membranes and induced action potentials. There is a threshold below which no effects are observed because of the all or nothing nature of action potentials. Furthermore because of the capacitance of the cell membrane the effect is not instantaneous and the probability of an effect depends not only on the magnitude of $\mathrm{d}B/\mathrm{d}t$ but also the duration of the stimulation, which is the ramp time of the gradient pulse. Peripheral Nerve Stimulation (PNS) can range in severity from barely noticeable to extremely painful and there is a wide range in sensitivity amongst human subjects.

Experimental data supports the use of a hyperbolic relationship between pulse duration and stimulation threshold in order to determine $\mathrm{d}B/\mathrm{d}t$ limits [62]. The IEC limits [49] for whole body gradient induced stimulation are given in the Eqs. (2) and (3).

$$\text{Normal mode } \left(\frac{\mathrm{d}B}{\mathrm{d}t}\right)_{\max} = 0.8\mathrm{rb}\left(1+\frac{0.36}{\tau}\right); \tag{2}$$

$$\text{First operating mode } \left(\frac{\mathrm{d}B}{\mathrm{d}t}\right)_{\max} = 1.0\mathrm{rb}\left(1+\frac{0.36}{\tau}\right), \tag{3}$$

where the rheobase $\mathrm{rb} = 20$ T/s and τ is the stimulation time. In the normal mode $\mathrm{d}B/\mathrm{d}t$ values do not exceed 80% of the mean PNS threshold whereas in the first level operating mode they do not exceed 100% of the mean PNS threshold.

The possibility of stimulation is more closely related to the induced electric fields than $\mathrm{d}B/\mathrm{d}t$ and the limits mentioned above may underestimate stimulation thresholds for smaller dedicated gradient coils. Therefore the IEC standard also allows the use of electric field stimulation thresholds. Furthermore the IEC standard also allows for the determination of gradient limits by volunteer studies. The parameters seen at present during MRI only raise the possibility of PNS since the thresholds for cardiac stimulation are much higher. Therefore by protecting against PNS the possibility of cardiac stimulation is excluded.

There are a number of safety issues associated with gradient induced electric currents and implanted medical devices made of conductive materials. Conductive implants will tend to concentrate gradient induced currents in the body particularly in the case of elongated implants, leads or wires [64]. This may increase the possibility of nerve stimulation. Induced currents could also alter the function of an active device such as a pacemaker.

Gradient induced eddy currents flowing inside the implant within the main magnetic field may also lead to

Lorentz forces and torque effects [63]. Considerable vibration has been observed experimentally with well-conducting metallic parts due to the fast alternating torque created as the gradients are switched [65]. The induced torque is proportional to the main field strength and the distance of the implant from the isocentre whilst inversely proportional to the gradient ramp time. Whilst the heating effect of gradient induced currents in tissue is negligible in comparison to the RF power deposition it has been suggested that this torque induced vibration could also cause a heating effect around implants [63].

The EU Physical Agents Directive for EMFs [1] sets occupational limits for exposure to EMF that are intended to be established as legal limits in the member states. The limits for time-varying magnetic fields are expressed as induced current densities to head or trunk and are designed to exclude the possibility of acute neuro-sensory effects over a very wide range of frequencies including those used by the gradient coils in MRI. However, Keevil et al. [66] have expressed concern that because the limits are set two orders of magnitude lower than the PNS threshold, they may prevent staff standing close to the bore during scanning either to carry out interventional procedures or to comfort the patient.

4.2. Acoustic noise generation in MRI

The magnetic field gradients are the major source of noise for a MRI system [67]. Lorentz forces are induced by the passage of electric current through the gradient coils inside the static magnetic field. When current is passed through the conducting windings the forces will either expand or compress the coil mountings in which the windings are embedded. The gradient coil will deform under the squeezing action producing vibrational waves that are transmitted to other structures of the scanner and finally through air to the patients ear. The Lorentz forces are proportional to the current flowing through the coils (and hence the gradient amplitude) and the main magnetic field strength. Apart from direct vibrations of the gradient coils, noise is also electromagnetically induced in other parts of the scanner through leakage gradient magnetic fields causing eddy currents in other conducting parts of the system such as the stainless steel cryostat and RF transmit coil [68,69]. These induced eddy currents themselves give rise to Lorentz forces, vibration and acoustic noise.

A wide-scale survey on acoustic noise levels on commercial MRI systems has shown a broadly linear relationship between worse case acoustic noise in clinical imaging and scanner field strength [70,71]. Noise levels varied from 77.2 dB(A) on a 0.2 T scanner to 118.4 dB(A) on a 3 T system.

In addition to the fact that the Lorentz forces increase with gradient amplitude the acoustic output will generally tend to increase with gradient switching frequency or slew rate. Therefore it is not surprising that pulse sequences that use small field of views, thin slice widths, short TE and TRs and large matrix sizes have increased acoustic noise levels [70].

The frequency spectrum of a MRI pulse sequence appears similar to the Fourier transform of the input gradient waveforms [72]. Typically this consists of a fundamental frequency at the gradient switching frequency and series of harmonics. The prominence of the harmonics is a function of the shape of the gradient waveform. In particular a short rise time (or high slew rate) for a trapezoidal waveform may lead to more prominent harmonics and greater acoustic noise [73].

The Fourier spectrum of the gradient waveform will appear filtered by the gradient frequency response function (FRF) [72]. Measurements of the FRF reveal a complex function of peaks and troughs representing the natural frequencies of the gradient coil and the supporting structures of the scanner generally increasing with frequency. Prominent resonant peaks are present in the FRF which if excited by the gradient waveform lead to much higher noise levels than expected [74].

To protect patients the IEC MRI safety standard specifies that the peak noise in MRI should never exceed 140 dB which is the threshold for instantaneous and permanent acoustic trauma. If the noise level for a sequence can exceed 99 dB(A) then instructions for the use of hearing protection should be included in the operating manual. The figure of 99 dB(A) is derived from the internationally applied 85 dB(A) over 8 h occupational noise exposure limit. An additional 9 dB(A) is added because the exposure is assumed to be once only and an additional 5 dB is added because the exposure time is assumed to be limited to one hour. Noise exposures below 99 dB(A) can however lead to temporary hearing threshold shifts and guidance in the UK is more stringent recommending that hearing protection be offered to all patients unless noise levels can be shown to be well below 85 dB(A) [32]. Staff present in the scan room during imaging will be subject to the national occupational noise exposure regulations and may need to wear hearing protection for interventional procedures particularly at higher field strengths and for extended exposures [75].

Ear plugs and ear muffs have been the mainstay of hearing protection for the patient in MRI. Ear plugs will only be effective if properly fitted into the ear canal. Problems may occur in this regard if patients are left to fit the plugs themselves. Ear defenders may provide more attenuation than ear plugs depending on design. They are also easier to fit. However they may not be used in conjunction with some smaller head and neck RF coils.

Many different methods of noise control have been implemented or suggested [67]. A key issue to be considered is how easily the noise control measure can be integrated into the scanner without impeding the imaging capability of the system such as in the case of radical gradient designs or with the use of heavily optimized pulse sequences. Radical gradient designs [76] have shown the greatest potential for noise reduction at least for EPI sequences of up to 50 dB(A) at 3 T. On the other hand vacuum technology and other forms of isolation [71,77,78] have been successfully implemented in some current MRI systems. These

have resulted in more modest but still significant noise reductions of about 20 dB(A) at 1.5 T.

5. MRI incidents reported in the UK

5.1. Method of incident monitoring

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. The incidents analysed in this paper have been reported to the MHRA. The MHRA is the executive agency of the Department of Health its role [79] to enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe. The MHRA's focal point for the reporting of adverse incidents involving medical devices is the Adverse Incident Centre (AIC). Reports are voluntary from users but manufacturers are required to report serious incidents under the Medical Device Vigilance system [80]. Reports of adverse incidents involving medical devices are investigated and, where appropriate, corrective actions are instigated to reduce the risk of recurrence. Where the result of investigations of those incident reports, or any other information received, has implications for patients or users, the Agency will issue a Medical Device Alert (MDA) advising of hazardous products, potential safety issues or unsafe procedures. In 2005 there were almost 8000 incidents reported to MHRA.

5.2. Analysis of MRI related incidents

In the period January 1990 to November 2006, MHRA received a total of 163 user incident reports and 58 vigilance reports concerning MRI. Fig. 1 shows the cumulative increase in incidents over this period compared to the number of estimated numbers of scanners reference [81] and numbers of scans carried out in England over this period [82]. Fig. 3 shows an analysis of the incidents by type. From this analysis it can be seen that the majority of incidents reported are RF burns followed by incidents involving projectiles. In the following subsections examples of the main type of incidents covering burns, projectiles, cryogen issues, altered device function, foreign metal objects, noise and physiological effects are presented.

5.2.1. RF Burn incidents

The most frequently reported incidents in MRI are RF burns. A sample of cases is discussed here. Case 1 is that of a body loop burn. During scanning an area of red skin developed where skin of thighs were touching, there were no foam pads between thighs. However, the burn did not involve any blistering, pain or soreness being experienced by patient. Case 2 involved blisters appearing under ECG pads that were consistent with RF burns on a paediatric patient undergoing a head and lumbar spine MRI. Case 3 involved reddening of the skin from an underwire bra; a patient attending for an MRI scan of her lumbar spine was asked to remove her under-wired bra prior to the scan.

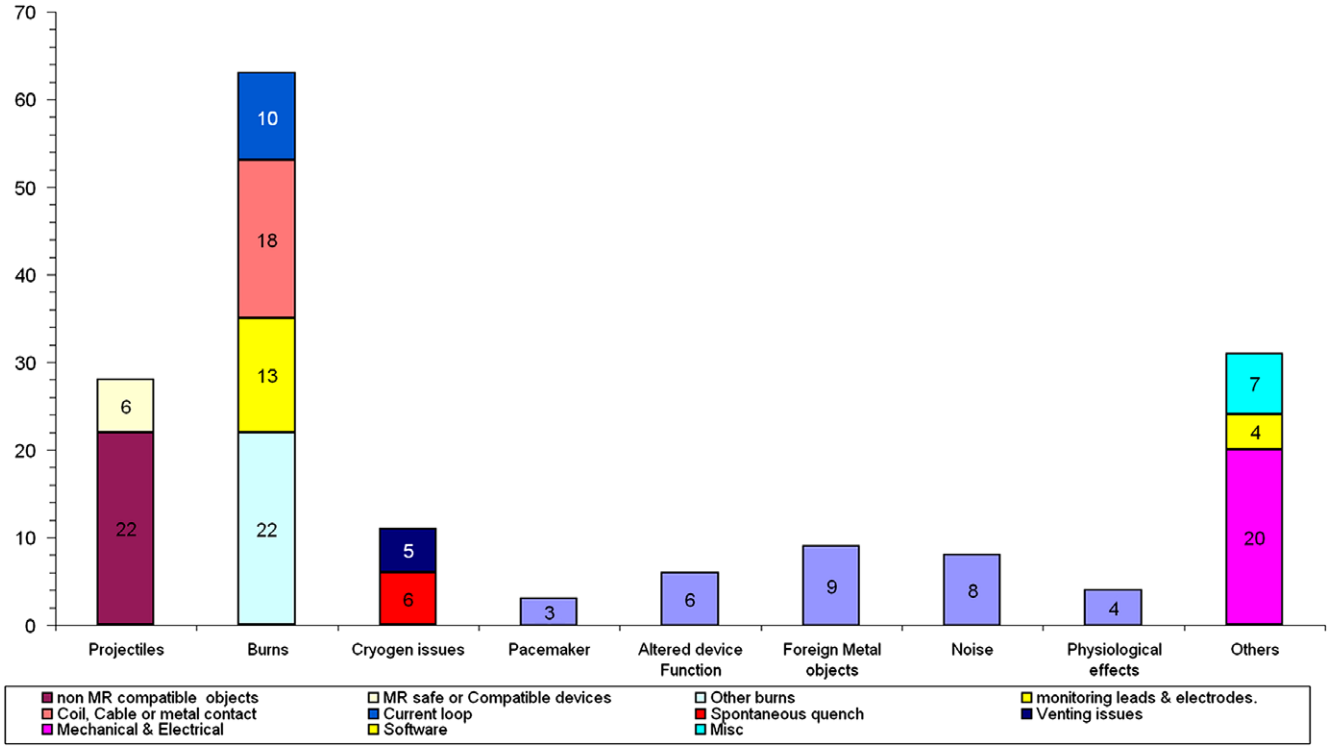

Fig. 3. Analysis of types of incidents involving MRI systems reported from 1990 to 2006.

The patient mentioned that she had attended the department a few weeks previously for a scan of her hip. On this occasion she had not been asked to remove her bra and the next morning she noticed that she had red marks on her skin at the level of the wire. She did not complain of any major problem. Case 4 involved severe facial discomfort, whereby, the patient squeezed the patient buzzer and complained of a lot of discomfort in an area of the face and around the right eye. The patient had heavily made up eyes with eyeliner and mascara. Case 5 involved a tattoo that started to itch during an MRI scan. On removal from the scanner the blue edge dye of the tattoo was seen to be raised. Case 6 involved a patient with bilateral hip replacement two years previous to the MRI scan. An orthopaedic surgeon reviewing the films believed they were a typical Charnley cup and Exeter stem hip replacements. The patient was undergoing a pelvic MR exam and after the third sequence (turbo spin echo, SAR 1.5 W/kg) reported feeling heating in the hip region. The patient who additionally had 100 g Fentanyl patches for pain relief, vomited on being brought out of the scanner, was assessed by a Radiologist and sent to accident and emergency. Case 7 involved a 72 year old male patient with bilateral hip replacement more than ten years previous to the MRI scan. An orthopaedic surgeon reviewing the scans believed these were metal backed polymer cups with Exeter stems. He was also undergoing a pelvic MRI exam and after the third sequence (turbo spin echo, SAR 1.5 W/kg) reported feeling heating in the hip region. The patient felt comfortable again immediately on being brought out of the scanner.

5.2.2. Projectile incidents

It is suspected that the majority of projectile incidents may go unreported. Two examples that have been reported on the incident database involve an MR compatible device and the other a pillow brought in by the patient. Case 8 involved an MRI compatible patient monitor, whereby, after a paediatric general anaesthetic session an experienced MRI radiographer was putting the equipment away and whilst winding the cables to the monitor, the monitor began to drift towards the bore of the magnet. The radiographer attempted to prevent further movement towards the magnet but the combination of the unit weight and magnetic field was too strong and the unit hit the magnet fascia, tipping its stand and wedging the monitor in the magnet bore. On consultation with the manufacturers, they have indicated that there are ferrous materials within the unit and that a warning sticker was on the unit indicating that the unit should not be placed within 9 feet of the bore of the magnet. Enquiries were then made to the supplier of the unit as it was installed by them less than 9 feet from the bore. The supplier stated that they were informed that the safe distance was to ensure accuracy of the monitoring and that there were some ferrous components, but the accuracy would be maintained up to 4 feet away from the bore: at no time was it indicated that the ferrous material was sufficient to lift the monitor into the bore. Case 9 involved an Airstream Bed Pillow which is only available on the domestic market and is not a medical device. It was brought in with a patient from home. The Hospital Trust involved with the incident was to review their MRI safety policy. Furthermore, labelling is now stitched into the pillow stating that it contains springs.

5.2.3. Cryogen related incidents

In a superconducting magnet a quench occurs when there is a sudden loss of superconductivity in the wire of the magnet. The heat generated causes the liquid helium to boil off very rapidly and a large volume of gas is released in a short time and the vent pipe has to be able to carry this flow safely. Most quenches do occur safely, however, very occasionally an issue can arise. If helium gas enters a room the extremely cold temperature of the gas, the significantly increased room pressure, and the displacement of oxygen from the room can all have potentially fatal consequences for anyone in the room. The danger of exposure to cryogenic gases was highlighted by a non-MRI incident in a Medical Research Council (MRC) Unit in Edinburgh in 1999. A member of staff died from asphyxiation whilst working alone in a liquid nitrogen storage room where the venting system had been inadequate. In response to this incident the MRC issued a Code of Practice for Use with Small Scale Liquid Nitrogen Operation [83].

From the MHRA database of MRI incidents, an example is Case 10 where a spontaneous quench of a 3 T magnet occurred whilst the patient was in the scanner bore. The patient reported feeling 'dizzy'. They were removed from scanner bore immediately and suffered no ill effects after the quench. All helium vented safely thought the vent pipe at the back of the unit to the outside air and the oxygen alarm did not register any adverse oxygen concentration in the magnet room. The magnet room door opened easily and the engineer was on site within five minutes, who subsequently replaced the 'burst' disc. In another case, Case 11 involved a site having to remove a scanner from service as the venting pipe had not been designed to the supplier's standards and there was the possibility it would fail in the event of a quench. The scanner was removed from service until the pipe was changed. The installation engineers had used a pipe that was too narrow and had not increased the thickness of the pipe wall to compensate for the increased pressure. This meant that was a potential for rupture and helium leak.

It is worth noting that MRI scanner manufacturers are not usually responsible for the maintenance of quench/venting pipes and do not routinely check them during planned preventive maintenance. The MHRA has issued guidance giving recommendations for annual inspections of all vent piping [84].

5.2.4. Altered device function

The most serious incidents reported involve pacemakers. Case 12 involved a fatality after a patient with Carotid Sinus Syndrome, who was not considered pacemaker dependant, underwent an MRI scan. The pacemaker was

implanted January 1994 and last checked in 1999, the patient had failed to attend clinics since that date. The patient was asked if she had a pacemaker prior to scanning. The patient had two scans and was seen to move during the first, however after the second scan was performed the MRI personnel felt something was wrong. The emergency response team was called to resuscitate the patient but the patient did not recover. Within the incident database, Case 13 demonstrates a case where the device function appeared to be altered by the MRI scanner. The case involved a patient with an implanted drug pump. The patient had the pump implanted in May 2000 and the pump manufacturers state that it is compatible with MRI scanning and this had been checked prior to the scan by a telephone call to the manufacturer's representative from a nurse specialist from the MRI Centre. During the MRI scan the pump infused the full reservoir (12 months worth) of drugs (baclofen, morphine) instantaneously. The scan was stopped immediately, and the patient showed signs of baclofen/morphine overdose and was treated accordingly. The Physicians manual for the pump confirms that the pump is compatible for use in an MRI scan up to 10 T.

5.2.5. Foreign metal object incidents

An example problem caused by foreign metal objects can be demonstrated by Case 14. This involved a patient who was a war-pensioner. In response to the appointment letter, he had sent a letter stating he had no remaining shrapnel in his body. However after his MRI scan, he reported a pain in his hand. The hospital X-rayed his hand which showed metal fragments from a bomb blast. There were no reported residual effects. This newly discovered shrapnel injury is now recorded on his electronic file.

5.2.6. Noise related incidents

Case 15 examines the issue of a patient who suffered hearing loss accompanied by severe unrelenting headaches, ear pains and dizziness after undergoing an MRI scan where they were not given hearing protection. The patient is now consulting an Ear, Nose and Throat (ENT) specialist as a consequence. The Imaging Department Manager stated that, as the system was a 0.5 T MRI system, they felt that the acoustic noise levels were not that high to warrant the use of hearing protection. However, they do offer hearing 'in-the-ear' plugs (soft foam) if the patient would like, but because they use an in-the-bore intercommunication system; they prefer the patient to be able to hear them. The option to use a panic button system is also available, although it seems that it was not used in this case. The scans were lumbar spine images, using four normal spin echo sequences lasting approximately 4 min each. The total time in the scanner was 15 min. The normal acoustic levels in this scanner were around 90 dB(A).

5.2.7. Physiological effects

Very few physiological effects have been reported, Case 16 examines an incident where a patient reported tingling in the arms and numbness in the hands during a scan. The scanner had been operating in the IEC first level mode which is not normally used for lumbar spine. The MRI Centre in question has now amended protocols so as not to use the first level mode as routine.

6. Conclusion

When MRI first emerged as a clinical tool in the 1980s it was hailed as the 'safe' imaging technology as it used non-ionising radiation. Since then, in the intervening decades, society began debating non-ionising EMF radiation, mainly due to the mass public use of mobile phones and the installation of mobile phone masts in communities. During this time, in 1996, WHO began their International EMF project to research and debate the risks associated with EMFs [85]. Furthermore, the European Union began a programme of physical agents directives aimed at the protection of workers against exposure exploitation. MRI uses the frequencies covered by these initiatives and the debate of the 'safety' of MRI took on a new meaning. The MRI community began to hold 'Safety Workshops' and to publish research about MRI safety. What emerged from the analysis of the safety of MRI is, that after the exposure of a large number of patients and staff in over two decades of imaging, the main safety incidents were 'accidents', this is where a safe working practice had not been followed correctly, for example the bringing into the scan room of ferromagnetic objects or allowing the patient to wear something metallic in the scanner, or the patient set up incorrectly, e.g., thigh to thigh contact, allowing body loop current to occur resulting in a burn.

What also is revealed from this exposure of a large number of patients and staff to relatively high static magnetic fields was that below about 4 T there was no evidence of harmful effects and above about 4 T the main effects that could be observed were related to a person moving in the static field, for example metallic taste, dizzy feeling, these effects were transient and soon stopped when the person left the static field or if the person moved slower within the field. Furthermore these affects were not observed in everyone and the precise field strength that this would occur at was dependent on the person. Another effect dependent on the person was peripheral nerve stimulation from the time-varying field gradients. Again this effect is transient and is only experienced by someone within the scanner during a scan. The strength and frequency of the gradients is set far below a level that would cause a harmful effect such as cardiac fibrillation.

From the data presented in this article the most reported safety incidents are those of RF burns, most of these are 'contact' burns, the second most reported events are projectile incidents. The most serious incidents are those where fatalities arise; the one death reported in the UK database was a pacemaker death, where the patient should not have been scanned. This analysis does raise the issue of the training and education of MRI operators/radiographers/MRI

technologists. Examining the incident reports, an on-going programme of safety training is warranted, rather than just an initial training in safety, and would form a critical part of reducing the number of MRI 'accidents'. This is increasingly necessary as the number of higher field systems is growing and the likelihood for projectiles incidents, burns and implant incidents may rise. It must be stated that MRI as a technology is operated by highly trained professionals and, although there are reported incidents, the number is low for the number of scans and patients scanned.

The occupational exposure issue is an important one that needs further clarification, although no evidence has arisen to date, further scientific data needs to be published so that workers can be assured. This issue will become increasingly important as the number of interventional procedures increases. Currently there are only a few units within the UK that undertake such procedures and these tend to be in research units but this practice is likely to spread into general clinical practice as its benefits become established in the peer-reviewed literature.

In conclusion, the majority of the incidents in MRI are related to 'working practice' and if the MRI community establishes educational programmes that enable staff to revisit safety training at regular intervals this could lead to a reduction in incidents. Although currently there is no evidence that occupational exposure within MRI units has any lasting effect, those mentioned within this article were transient effects, such an educational programme could also be invaluable at enabling staff to really understand the MRI system establishing where the stray EMFs are and as such each unit could establish a working practice that minimise occupational exposure where possible.

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