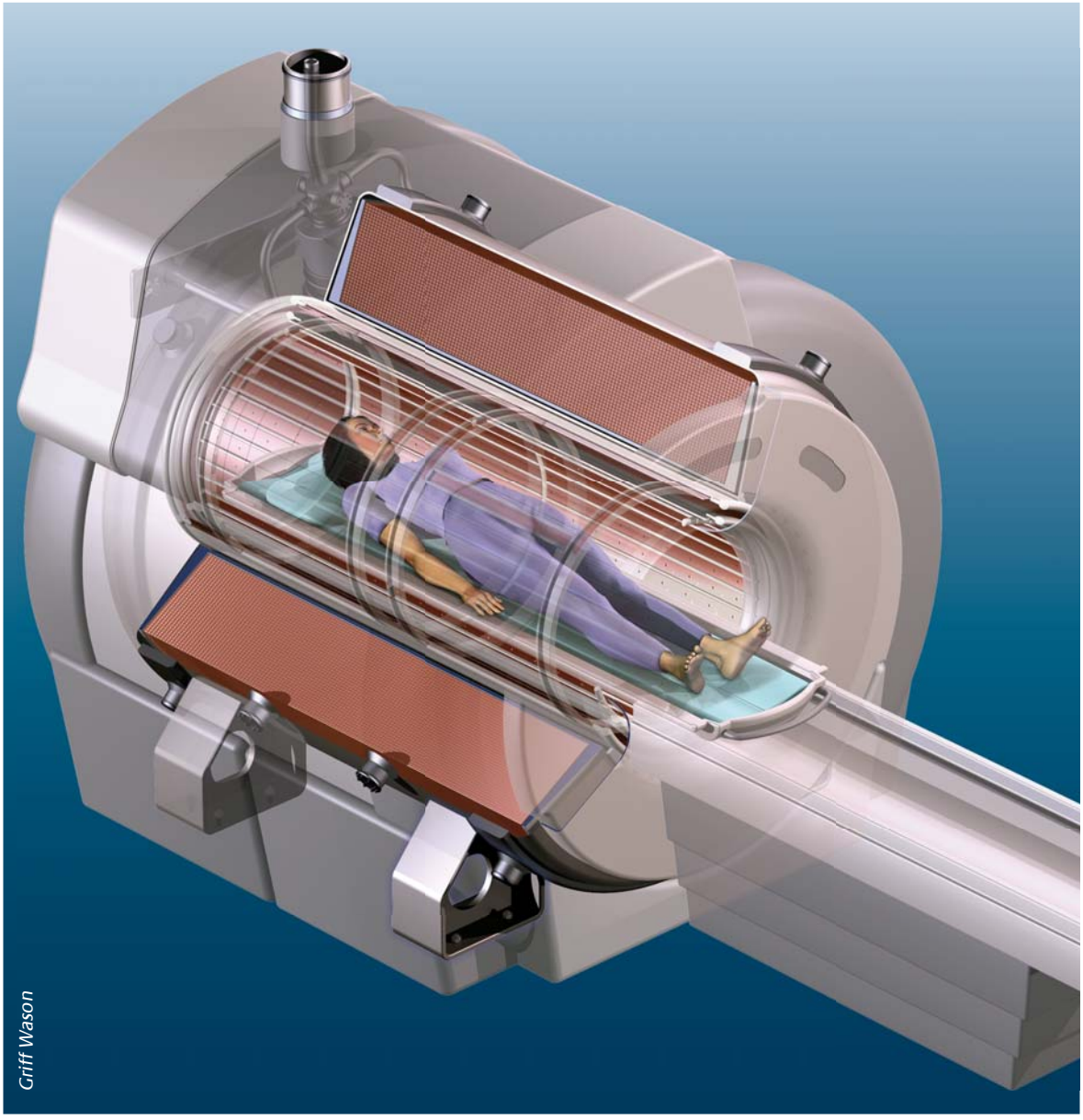
Protection of Patients and Volunteers Undergoing MRI Procedures

Advice from the Health Protection Agency



Griff Wason

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Protection of Patients and Volunteers Undergoing MRI Procedures

Advice from the Health Protection Agency

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Contents

MRI Patients and Volunteers Exposure Group Membership

The review and recommendations set out in this document have been produced by a review group that included staff of the Radiation Protection Division of the Health Protection Agency and invited external experts in the field of MRI technology and its applications.

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Protection of Patients and Volunteers Undergoing MRI Procedures

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Prepared by the MRI Patients and Volunteers Exposure Group

Abstract

This document provides advice on limiting the exposure of patients and volunteers to the static magnetic fields, time-varying electromagnetic fields and acoustic noise from magnetic resonance imaging (MRI). The document also sets out recommendations on best practice and further research needs. The advice provided recognises the clear benefits to individual patients undergoing MRI examinations and more generally, through research involving volunteer exposures, to increasing medical knowledge for the benefit of all.

Previous advice was published in 1991 by the predecessor of the Radiation Protection Division of the Health Protection Agency, the National Radiological Protection Board. More recently, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) has reviewed the scientific evidence relevant to possible adverse health effects from such exposures and published its advice. Recognising the importance of global harmonisation, the advice set out in this document takes account of the ICNIRP review and focuses on the ICNIRP recommendations and particularly on their possible application in the UK.

The review and recommendations set out in this document were produced by staff of the Radiation Protection Division together with invited external experts in the field of MRI technology and its applications. The document has benefited from comments received during a period of public consultation.

This document from the Health Protection Agency reflects understanding and evaluation of the current scientific evidence as presented and referenced here.

Summary

Key points

1 This document provides advice and recommendations on limiting the exposure of patients and volunteers to the static magnetic fields, switched gradient (time-varying) magnetic fields, radiofrequency (RF) fields and acoustic noise from magnetic resonance imaging (MRI). Advances in technology mean that MRI can be routinely used for diagnosis in most areas of the body and in most clinical specialities, and now many scanners in clinical use produce static fields of magnetic flux density 3 tesla (T).

2 The International Commission on Non-Ionizing Radiation Protection (ICNIRP) has reviewed the scientific evidence relevant to possible adverse health effects from such exposures and published its advice in 2004. The Health Protection Agency (HPA) has taken account of this review and, recognising the importance of global harmonisation, has focused on the ICNIRP recommendations and particularly on their possible application in the UK.

3 The biological effects most likely to occur are the production of vertigo-like sensations and these acute effects are associated with movement in the static field. The sensitivity to these effects varies considerably between individuals. Patients and volunteers should be moved slowly into the scanner, to avoid the possibility of vertigo and nausea. Exposure to switched gradient fields induces time-varying electric fields and currents in biological tissues, and exposure limits are based on minimising any uncomfortable or painful sensations caused by the field. Exposure to RF fields can cause heating of the body, hence restrictions are based on limiting body core temperature rises and temperature rises in other parts of the body. Noise levels in scanners can be excessive and hearing protection should be fitted on all patients and volunteers as a matter of course. Manufacturers are also encouraged to consider noise reduction in the design of scanners.

4 In formulating its advice, the HPA has considered the ICNIRP recommendations of 2004 and additional studies published since then. The conclusion is that the ICNIRP exposure limits for static, switched gradient, and RF fields are broadly appropriate. However, somewhat higher exposures to static magnetic fields than those recommended by ICNIRP should be allowed, but only under carefully controlled exposure conditions. The biological basis used by ICNIRP for limiting exposure of patients and volunteers to switched gradient fields is the avoidance of intolerable stimulation of peripheral nerves and muscles. Until further information becomes available, the ICNIRP recommended limits should be followed for switched gradient fields for each operating mode. The ICNIRP recommendations limit patient and volunteer exposures to RF fields by restricting the rise of body and tissue temperatures in order to avoid possible adverse thermal consequences. The ICNIRP guidelines should be

followed for RF fields for each operating mode. However, additionally an upper temperature limit should be specified for the experimental operating mode.

5 The overall health risk assessment for MRI procedures is incomplete and a number of gaps in knowledge are identified. Little is known about the effects of exposure to static fields above 8 T, and increased sensitivity of some people to stimulation by the electric fields induced in the central nervous system (CNS) by switched gradient fields. There are also uncertainties concerning the effects of increased heat loads on infants and pregnant women and on people with impaired thermoregulatory ability as a result of age, disease or the use of medications.

6 The health risk assessment can be improved through additional well-targeted research. Epidemiological investigations are required of cancer risks, pregnancy outcomes and the hearing of children exposed *in utero*. Experimental studies are suggested to investigate the effects of static magnetic fields greater than 8 T on cardiac function and other vital signs; the carcinogenic potential of long-term exposure to static magnetic fields; the effects of exposure on juvenile and adult behaviour; and the responses of the CNS as a result of exposure to switched gradient fields and through movement in static fields. Studies to provide more detailed numerical dosimetry for MRI systems are also recommended, including the development of a thermal model of the fetus.

7 A key element in improving the health risk assessment can come from surveillance of adverse outcomes. If clinically relevant reactions are observed following MRI procedures, and particularly with very high static fields, then it is essential that these are reported to the MRI medical and research community.

8 Finally, all MRI units should draw up local rules which will set out the policies and protocols to be followed to ensure the safety of people in the MRI unit. General advice is provided in the document.

Background

The Health Protection Agency (HPA) has responsibility for advising the government on protection against radiation, chemical and environmental hazards. Such hazards include those associated with exposure to non-ionising radiation, including electromagnetic fields (EMFs). In 1991, the National Radiological Protection Board (NRPB), the predecessor of the HPA Radiation Protection Division, published advice on the protection of patients and volunteers undergoing magnetic resonance imaging (MRI) procedures. Since then, there have been many advances in MRI technology and its applications, and the International Commission on Non-Ionizing Radiation Protection (ICNIRP) published advice on the protection of patients in 2004. Thus, it is appropriate to update the previous NRPB advice and to consider the possible application of the ICNIRP recommendations in the UK.

In developing the advice, the HPA was cognisant of the international standard 'Medical Electrical Equipment – Part 2-33: particular requirements for basic safety and essential performance of magnetic

resonance equipment for medical diagnosis', in which the exposure limits are based on the ICNIRP recommendations. The Medicines and Healthcare products Regulatory Agency (MHRA) has published safety guidelines for MRI equipment in clinical use, an update of previously published advice, and also based on the ICNIRP recommendations.

This document reviews the scientific evidence relevant to possible adverse effects on patients and volunteers undergoing MRI examinations, and provides advice on limiting their exposure.

The review covers published scientific data in the life and physical sciences relevant to possible adverse effects on people of exposure to electromagnetic fields and acoustic noise. In reviewing these data, the focus has been principally on the published review and recommendations from ICNIRP in 2004, and particularly on the adequacy and relevance of that advice, both in respect of the totality of relevant scientific data, including those published since 2004, and in respect of clinical MRI practice and its further development in the UK.

MRI technology

At the end of 2006, it was estimated that there were approximately 500 fixed MRI scanners involved in human imaging, installed at some 350 sites across the UK. Most were in NHS hospitals, about 100 were in private medical centres, and 25 were primarily dedicated to research, of which 20 were in universities or NHS establishments.

Most MRI scanners in clinical use employ superconducting magnets with cylindrical bores and produce static fields of magnetic flux density 1.5 T, although there are now many 3 T scanners in clinical use. A smaller number of ultrahigh field MRI systems are in use in research institutions worldwide and these produce static fields in the range 4.7–9.4 T.

In addition to a static magnetic field, the MRI environment includes time-varying magnetic fields. These are produced by three orthogonal magnetic field gradient coils and radiofrequency (RF) coils. These time-varying fields induce electric fields in the body, causing currents to flow and heating of tissue.

Clinical and research applications

Although traditionally MRI procedures have been associated with imaging the central nervous and musculoskeletal systems, advances in technology – which allow faster and more detailed scanning – now mean that MRI can be routinely used for diagnosis in most areas of the body and in most clinical specialities.

There is also an increasing use of MRI for guidance, monitoring and controlling interventional and intra-operative procedures, in view of its good spatial and temporal resolution, high intrinsic tissue contrast, and its ability to monitor temperature and multiplanar imaging capabilities.

Further, in addition to anatomical imaging, MRI procedures offer the possibility of monitoring tissue function by measurement of flow, diffusion and perfusion, as well as the possibility of using magnetic resonance spectroscopy (MRS) to study biochemistry *in vivo*.

Patient and volunteer exposure

An MRI examination consists of a series of individual scanning sequences, each designed to show anatomy in a particular orientation, or weighted to make different kinds of tissue appear more or less prominent. An individual sequence could be as short as a few seconds or longer than 10 minutes for a very high resolution image. In practice, an examination will be built up from many sequences. To allow adequate planning and preparation of sequences, and to maintain communication with the individual being scanned, there are usually short pauses between each sequence. Most examinations can be completed within approximately 30 minutes. However, some may take up to 90 minutes, but this would usually be when several body areas were being imaged, and may involve periods of time where the patient or volunteer is being moved on and off the table and coils are being changed.

The vast majority of research scans involve similar lengths of examinations, although a few may involve scanning over several hours – for instance, when studying physiological responses over a long period of time.

Patients and volunteers undergoing MRI examinations experience exposure to a static magnetic field, switched gradient (time-varying) magnetic fields, RF fields and acoustic noise.

Static magnetic fields

For each MRI scanner, the nominal strength of the static magnetic field is that produced homogeneously within an imaging region inside the bore of the magnet.

Shielding is commonly used to reduce stray fields outside the magnet. Active shielding, using secondary magnetic coils to cancel out the static magnetic field from the primary, increases the field just inside the bore, such that for most shielded 1.5 T magnets, the static magnetic field at the end of the bore is approximately 2 T. In addition, magnetic field gradients are substantially increased close to the end of the bore.

Switched gradient fields

Gradient pulses are generally trapezoidal, although the particular shape varies with sequence type. The waveforms consist of trains of gradient pulses in which the separation and duration of pulses may vary. Consequently, the waveforms contain components covering a spectrum of frequencies. The gradient waveforms applied in three orthogonal directions are generally different, and their time sequences are complex.

Radiofrequency fields

RF magnetic field exposure is at frequencies of 64 and 128 MHz for 1.5 and 3 T systems, respectively. A smaller number of ultrahigh field MRI systems with static fields in the range 4.7–9.4 T are in use in research institutions worldwide and for these the frequency is in the range 200–400 MHz.

Acoustic noise

The acoustic noise experienced by patients and volunteers is generated by Lorentz forces induced by the interaction between the electric current flowing through the gradient coils and the static magnetic field. As the current is switched, the forces will expand or compress the coil mountings. The gradient coil is deformed producing vibrations that are transmitted to other structures of the scanner and, finally, through the air to the patient or volunteer. Noise is also electromagnetically induced in other parts of the scanner, through gradient magnetic fields causing eddy currents in other conducting parts of the system.

Assessing exposure – computational dosimetry

The role of computational dosimetry is to provide predictions of the electric fields and currents produced inside the body by a known external field or source. It can also be used to predict temperature rises inside the body. The ICNIRP exposure limits place quantitative restrictions on both temperature and temperature rise within the body. However, in practice, the quantity specific energy absorption rate (SAR) is used as a surrogate for temperature, and this is more readily determined either by calculation or by measurement in physical phantoms.

For purposes of calculation, anatomically realistic, numerical models have been developed comprising arrays of numerous small cells. Typically, whole-body examples of these models have a resolution of a few millimetres. However, the application of these models to the dosimetry of MRI is a relatively recent development and there are few published studies.

These anatomically realistic models can account for the selective channelling of electric current through high conductivity tissues which occurs *in vivo*. Recent studies raise the possibility of greater inhomogeneity in the induced electric fields, induced current densities and SARs than was previously recognised. New techniques should be taken as best practice in assessment of compliance for MRI equipment and compatibility of implants.

The SAR is greatly enhanced in the vicinity of metallic implants. This enhancement is sensitive to the geometry of the implant, and to its position and orientation within the body.

Evidence of harm

Epidemiology

There is an absence of published studies of mortality or cancer incidence among either patients or volunteers undergoing MRI procedures. However, there have been many epidemiological studies undertaken on people exposed either to power frequency magnetic fields or to RF fields in non-MRI situations – for example, through their work or in the home. These studies have been extensively reviewed by national and international expert bodies. Taken as a whole, the scientific evidence has not clearly demonstrated adverse health effects, although there is evidence of an association between long-term exposure to residential power frequency magnetic fields and a raised risk of childhood leukaemia.

Biology

In contrast to epidemiology, a large number of laboratory studies have been reported regarding possible health effects.

Static magnetic fields

The biological effects most likely to occur in patients and volunteers undergoing MRI procedures are the production of vertigo-like sensations and these acute effects are associated with movement in the field. The probability of clinically relevant physiological effects or of significant changes in cognitive functions occurring in fields of up to 4 T seems low. In addition, the accumulated experience of MRI procedures in clinical situations, where exposures using fields of 3 T are becoming increasingly common, does not suggest that any obvious detrimental field-related effects occur, especially in the short term.

Much less is known about the effects of fields above 8 T. Similarly, very little is known about the effects of static magnetic fields in excess of a few tesla on growth and behavioural development of fetuses and infants, suggesting some caution is warranted regarding their imaging.

Moving patients slowly into the magnet bore can avoid movement-induced sensory effects. It is clear that sensitivity to these effects varies considerably between individuals, and thresholds for motion-induced vertigo in sensitive people have been estimated to be around 1 T s^{-1} for greater than 1 s.

Switched gradient fields

Exposure to switched gradient fields induces time-varying electric fields and currents in biological tissues. These can cause stimulation of excitable tissues, if of sufficient intensity and appropriate frequency. The rapidly changing fields induced by the high rates of gradient field switching used in MRI systems will preferentially stimulate peripheral nerves. These thresholds are well below those for ventricular fibrillation for induced current pulse widths of less than 3 ms. Hence, limiting exposure of patients and volunteers to switched gradient fields can be based on minimising any uncomfortable or painful sensations caused by the field.

Research has not identified consistent evidence of effects following short-term exposures typical of MRI procedures, although some field-related changes in specific cognitive functions have been reported, and these require further investigation. In addition, some people report increased sensitivity to stimulation by the electric fields induced in the central nervous system by switched gradient fields. These people should be imaged with caution.

Radiofrequency fields

Exposure to RF fields of sufficient intensity can induce heating in biological tissue, while effects in the absence of heating remain controversial. Hence restrictions on exposure to RF fields used in MRI procedures are based on limiting both body core temperature rises and temperature rises in parts of the body.

There are uncertainties concerning the effects of increased heat loads on infants and pregnant women, and on people with impaired thermoregulatory ability as a result of age, disease or the use of medications. These people should be imaged with caution.

Acoustic noise

Although there is little risk of a permanent threshold shift in hearing in those exposed to noise associated with MRI procedures on a one-off or occasional basis, certain scans may exceed the discomfort threshold, particularly for sensitive individuals. Temporary threshold shifts can be induced if patients and volunteers are not adequately protected, which may cause discomfort and be accompanied by other effects such as tinnitus. There is some limited subjective evidence from leisure-related noise exposures and MRI adverse incident reports that permanent effects may be induced in unprotected subjects.

Clinically significant temporary threshold shifts in patients and volunteers undergoing MRI procedures are unlikely in most subjects for noise levels below 85 dB(A), given the relatively low frequencies encountered in MRI, and the typical examination times of less than an hour. However, there are variations in sensitivity between individuals, both in terms of the threshold of discomfort and in terms of the production of temporary threshold shifts. In its 2004 guidance, ICNIRP recommended that patients or volunteers should be given the choice of whether to wear protection if noise levels fall between 80 and 85 dB(A). If followed, this recommendation may inadvertently result in some sensitive patients feeling discomfort or receiving a clinically significant temporary threshold shift, particularly if the examination time is relatively long.

Protection of patients and volunteers

In formulating its advice, the HPA has considered the ICNIRP recommendations of 2004 and additional studies published since then. Some of these used static magnetic fields of around 8 T, and, as in the previous studies, the continued absence of evidence of adverse health effects, is noted. Thus, the HPA advice is to allow somewhat higher exposure to static magnetic fields than those recommended by ICNIRP in 2004, but only under carefully controlled exposure conditions. Importantly, in the case of patients, the decision criteria should include the care of the patient by suitably qualified medical staff, and consideration of the potential benefit for the patient. Volunteer studies are helpful in the development of new MRI techniques and of consequential potential benefit for patients. In such studies, the safety of volunteers is paramount and the studies must be subject to ethics committee approval and carried out with appropriate consideration of the medical circumstances*.

* Following advice from the National Research Ethics Service (NRES), it should be noted that under the Research Governance Framework for Health and Social Care, experimental procedures require ethical review where they are to be carried out in the formal research setting and managed as research. If undertaken outside the research setting, ethical review and research and development approval would not be required, although many NHS organisations have clinical ethics committees that would be an appropriate source of advice. National Institute for Health and Clinical Excellence (NICE) guidance on the interventional procedures programme will apply in such cases.

Recommendations for the protection of patients and volunteers

Static magnetic fields

The values advised by ICNIRP in its 2004 recommendations for static magnetic fields seem overly cautious in the light of the results of recent studies and ongoing and accumulating clinical experience. It is recommended that until further information becomes available, the limits should be relaxed and modified for each operating mode, as follows.

a During routine procedures (termed the *normal operating mode* by ICNIRP), there should be an upper limit for whole-body exposure of 4 T.

b For specific examinations outside the *normal operating mode* and carried out with appropriate consideration of the medical circumstances (*controlled operating mode*), there should be an upper limit for whole-body exposure of 8 T.

c For experimental procedures, also carried out with appropriate consideration of the medical circumstances and for which special ethical approval is required (*experimental operating mode*), there should be a limit above 8 T. No upper limit has been specified, but a progressively cautious approach is suggested for increasingly high magnetic flux densities due to uncertainties regarding possible effects of flow potentials on heart function. In light of these possible effects, it is concluded that patients and volunteers should be exposed to such fields only with appropriate physiological monitoring of pulse rate.

There is a need to ensure that patients and volunteers continue to be moved slowly into the magnet bore, to avoid the possibility of vertigo and nausea. Thresholds for motion-induced vertigo have been estimated to be around 1 T s^{-1} for greater than 1 s. Avoiding these sensations is likely to afford protection against the other effects of induced electric fields and currents that arise as a consequence of motion in a static field.

Switched gradient fields

The biological basis used by ICNIRP for limiting exposure of patients and volunteers to switched gradient fields is the avoidance of intolerable stimulation of peripheral nerves and muscles. It is recommended that, until further information becomes available, the ICNIRP recommended limits should be followed for switched gradient fields for each operating mode.

a During routine procedures (*normal operating mode*), there should be a limit on the rate of change of magnetic flux density (dB/dt) of 80% of the median perception threshold for peripheral nerve stimulation, as defined in the 2004 recommendations of ICNIRP.

b For specific examinations outside the *normal operating mode* and carried out with appropriate consideration of the medical circumstances (*controlled operating mode*), there should be a limit on dB/dt of 100% of the median perception threshold.

ICNIRP provided no explicit guidance for the procedures carried out under the *experimental operating mode*. However, ICNIRP indicated that intolerable stimulation would interfere with an examination and

should be avoided. The lowest percentile for intolerable stimulation equates to approximately 20% above the median perception threshold, and it is suggested that a limit on dB/dt of 120% of the median perception threshold, should apply.

Radiofrequency fields

The 2004 recommendations of ICNIRP limit patient and volunteer exposures to RF fields by restricting the rise of body and tissue temperatures in order to avoid possible adverse thermal consequences. Thus it is recommended that, until further information becomes available, the ICNIRP guidelines should be followed for RF fields for each operating mode. However, additionally an upper temperature limit should be specified for the *experimental operating mode*. Making the conservative assumption that thermoregulatory mechanisms can be ignored, appropriate SAR limits for the *experimental operating mode* could be obtained by scaling the ICNIRP limits on SAR in proportion to the temperature rise. In addition, it is recommended that the correction factors advised by the International Electrotechnical Commission (IEC), in its 2002 technical standards document, are used to adjust whole-body SAR in high ambient temperatures and/or high relative humidity, as follows.

a For routine procedures (*normal operating mode*), there should be a limit of 0.5°C on rise in whole-body temperature, and limits on temperature of 38, 39 and 40°C on the head, trunk and limbs, respectively. This is the preferred mode for normal imaging.

b For specific examinations outside the *normal operating mode* and carried out with appropriate consideration of the medical circumstances (*controlled operating mode*), there should be a limit of 1°C on rise in whole-body temperature, and limits on temperature of 38, 39 and 40°C on the head, trunk and limbs, respectively. Particular consideration should be given to restricting the use of the controlled mode as far as possible for imaging infants, pregnant women, febrile patients and others with impaired thermoregulatory ability or with compromised peripheral circulation.

c For experimental procedures, carried out with appropriate consideration of the medical circumstances and for which special ethical approval is required (*experimental operating mode*), whole-body and local tissue temperatures can exceed those specified for the *controlled operating mode*. It is recommended here that there should be a limit of 2°C on rise in whole-body temperature, and that local tissue temperatures should not exceed 39, 40 and 41°C on the head, trunk and limbs, respectively, in order to avoid tissue damage. These temperatures are unlikely to be exceeded provided that the local SAR (averaged over 10 g) is limited to 15 W kg^{-1} in the head and trunk and 25 W kg^{-1} in the limbs, and the whole-body SAR is limited to 8 W kg^{-1}.

Acoustic noise

Noise levels can exceed 85 dB(A) in almost all commercial MRI scanners, and it is difficult in practice to measure or predict noise levels for each pulse sequence. Therefore, it would be prudent at present, to fit hearing protection on all patients and volunteers as a matter of course. For particularly intense exposures, above 115 dB(A), the use of both ear plugs and ear muffs would be advisable, although it is recognised that the extra attenuation provided may be difficult to quantify.

Summary of proposed limits for static, switched gradient and radiofrequency fields during MRI procedures for patients and volunteers*

			Radiofrequency fields			
				Temperature limits (°C)		
Mode	Static field (T)	Switched gradient fields	Rise in body core temperature (°C)	Head	Trunk	Limbs
Routine operating mode	4	80% median perception threshold	0.5	38	39	40
Controlled operating mode†	8	100% median perception threshold	1	38	39	40
Experimental operating mode	>8	120% median perception threshold	2	39	40	41

* Adherence to a system of working practices involving limiting the speed of motion of patients and volunteers through the field is assumed.

† The use of the *controlled operating mode* should be restricted as far as possible during pregnancy, and for infants, for people with epilepsy or taking drugs that lower seizure activity, and for people with impaired thermoregulatory ability.

As suggested in the ICNIRP recommendations, headphones are superior to other forms of hearing protection; however, manufacturers should be encouraged to provide attenuation data according to the relevant standards so that users can ensure that the protection is adequate at the frequencies of interest. The manufacturers of MRI equipment should also be encouraged to consider the acoustic properties of patient couch mattresses in order to ensure, as far as possible, that the patient or volunteer is mechanically isolated from any vibration in the patient couch.

An important principle of noise control is that the elimination of noise at source is always preferable to reliance upon personal hearing protection that may sometimes fail. The encouragement by ICNIRP of the further development of noise reduction technology, such as quiet gradient coils, is in accord with this principle. It seems reasonable to suggest that if noise reduction measures reduce noise levels to comfortably below 80 dB(A), the requirement for hearing protection may be relaxed.

Other considerations

A key element in improving the health risk assessment can come from surveillance of adverse outcomes. If clinically relevant reactions are observed following MRI procedures, and particularly with very high static fields, then it is essential that these are reported to the MRI medical and research community. This is particularly important in the absence of epidemiological or experimental data.

It is further recommended that all MRI units should draw up a set of local rules which will set out the policies and protocols to be followed to ensure the safety of people in the MRI unit, including patients and volunteers.

Research recommendations

The overall health risk assessment for MRI procedures is incomplete, and needs to be addressed through additional, well-targeted, high quality research. A range of high priority studies is recommended for epidemiology, biology and dosimetry associated with exposures to electromagnetic fields, and for acoustic noise.

Epidemiology

In any future epidemiological studies, particular attention should be given to: characterising exposures accurately and precisely; maximising the study size, possibly by collecting data from several centres using a common protocol; and, when following patients who have undergone an MRI procedure, taking into account the condition that led to the examination.

Noting that there is an absence of studies investigating mortality or cancer incidence among patients or volunteers undergoing MRI procedures, it is recommended that consideration is given to:

a a study investigating cancer risks,

b a follow-up study of pregnancy outcome.

The effect of acoustic noise on fetal hearing is another area of uncertainty. The following is therefore recommended:

c larger follow-up studies investigating the hearing of children exposed *in utero*, involving audiometric testing across a range of frequencies including low and mid-frequencies.

Biology

While many biological studies have been carried out across the spectrum of frequencies associated with MRI, there is a need for further experimental research in specific areas.

Studies are recommended on:

a effects of static magnetic fields greater than 8 T on human and animal cardiac function, and other vital signs,

b responses of the central nervous system to the electric fields and currents induced by exposure to switched gradient fields, and by body movement in the static field gradients,

c carcinogenic potential of long-term exposure of animals to static fields – such studies might be usefully combined with an analysis of immediate and early genomic and proteomic responses,

d effects of prenatal and early postnatal exposure of animals to static magnetic fields above 1 T on juvenile and adult behaviour.

Dosimetry

While much progress has been made in recent years, particularly in the use of anatomical models in investigating electromagnetic field exposure, there remains a need for more detailed numerical dosimetry in some areas relevant to MRI.

Studies are recommended on:

a more detailed numerical dosimetry for MRI systems of 8 T and above using anatomically realistic models and modern dosimetric techniques,

b further research to improve techniques in thermal dosimetry,

c development of a thermal model of the fetus,

d improved estimates of local SAR in anatomically realistic models, and better definition of spatial averaging of induced fields and currents, and SAR,

e induced electric field and current calculations using realistic gradient waveforms.

Best practice in MRI units

General advice on the safety requirements for MRI units is provided in an appendix to this document, recognising that other bodies are involved in providing detailed advice. Achieving best practice with regard to patient, volunteer and staff safety begins at the planning stage with an appropriate design of the MRI unit.

Response to public consultation on the document

An earlier version of this document (Consultation Document) was published for public consultation on 31 October 2007. Six sets of comments were received: these were collated, and a general summary of these and the HPA responses are set out in an appendix to this document.

The comments were generally supportive of the approach taken in preparing the advice, and suggested that all the relevant issues had been covered comprehensively.

1 Introduction

The Health Protection Agency (HPA) has responsibility for advising the government on protection against radiation, chemical and environmental hazards. Such hazards include those associated with exposure to non-ionising radiation, including electromagnetic fields (EMFs). In 1991, the National Radiological Protection Board (NRPB), the predecessor of the HPA Radiation Protection Division, published advice on the protection of patients and volunteers undergoing magnetic resonance imaging (MRI) procedures (NRPB, 1991). Since then, there have been many advances in MRI technology and its applications, and the International Commission on Non-Ionizing Radiation Protection (ICNIRP)* has also published advice on the protection of patients (ICNIRP, 2004). Thus, it is appropriate to update the previous NRPB advice and to consider the possible application of the ICNIRP recommendations in the UK.

In developing the advice, the HPA was cognisant of the international standard 'Medical Electrical Equipment – Part 2-33: particular requirements for basic safety and essential performance of magnetic resonance equipment for medical diagnosis' (IEC, 2002), in which the exposure limits are based on the ICNIRP recommendations. The Medicines and Healthcare products Regulatory Agency (MHRA) has published safety guidelines for MRI equipment in clinical use (MHRA, 2007) – an update of previously published advice (MDA, 2002) and also based on the ICNIRP recommendations.

This document reviews scientific evidence relevant to possible adverse effects on patients and volunteers undergoing MRI examinations, provides advice on limiting the exposure of patients and volunteers, and sets out recommendations on best practice and further research needs. The advice provided does not cover X-ray exposures associated with pre-screening of patients and volunteers for detection of metal fragments. The X-ray procedures should be carried out in compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 (GB Parliament, 2000).

The MRI technique was invented in 1973 and since then its applications in the field of medical diagnosis have burgeoned, and it has become a major medical imaging modality. Although traditionally MRI examinations have been associated with imaging the central nervous and musculoskeletal systems, advances in technology, which allow faster and more detailed scanning, now mean that MRI can be routinely used for diagnosis in most areas of the body and in most clinical specialities.

Over the years, the growth in the number of diagnostic procedures being carried out has reflected the diversity of the use of MRI in medical diagnosis. By the end of 2006, it is estimated that there were approximately 500 fixed installation MRI scanners, at some 350 sites across the UK. In addition, there are mobile private MRI installations in use. There has been a three-fold increase in the number of MRI scans carried out in the NHS over the last decade (DH, 2007).

* ICNIRP is an independent body recognised by the World Health Organization (WHO) that provides advice on the health effects of exposure to non-ionising radiations.

People undergoing an MRI scan are exposed to a range of magnetic fields and to acoustic noise. These exposures are to:

a a static magnetic field,

b time-varying magnetic fields, generated by three orthogonal magnetic field gradient coils that are switched on and off to spatially encode the magnetic resonance signals (switched gradient fields),

c a radiofrequency (RF) field, which is applied to excite the magnetic spin of atomic nuclei within body tissues for image generation,

d acoustic noise, generated by magnetically induced forces that expand and compress components within the MRI unit.

Studies of the effects of exposure to electromagnetic fields have been reviewed by a number of expert panels, including the independent Advisory Group on Non-ionising Radiation (AGNIR). These reviews have been published and are in the public domain (AGNIR, 2001a,b, 2003; IARC, 2002; ICNIRP, 1998; NRPB, 2004a,b; WHO, 2006, 2007). Scientific reviews and recommendations related specifically to the exposure of patients and volunteers were published by the NRPB (1991) and by ICNIRP (2004).

The review and recommendations set out in this document have been produced by staff of the HPA Radiation Protection Division and external experts in the field of MRI technology and its applications. The review and recommendations are concerned primarily with providing information to medical staff and others involved with the exposure of patients and volunteers during MRI procedures, taking into account risk and benefit. The reviewers were aware of the clear benefits to individual patients undergoing MRI examinations and more generally, through research involving volunteer exposures, to increasing medical knowledge to the benefit of all.

The review covers the published scientific data in the life and physical sciences relevant to possible adverse effects on people of exposure to electromagnetic fields and acoustic noise. In reviewing the literature, the focus has been principally on the published review and recommendations of ICNIRP (2004), particularly on the adequacy and relevance of the ICNIRP advice, both in respect of the totality of relevant scientific data, including those published since 2004, and in respect of clinical MRI practice and its further development in the UK.

Clinical judgement is of paramount importance when considering the exposure of patients to clinical MRI for diagnostic purposes. Those taking responsibility for the patient or volunteer during the MRI investigation will be aware of the potential impact of the MRI environment on the well-being of the subject and on the success of the procedure. ICNIRP (2004) advises that the need for an MRI examination and the safety of the patient undergoing such an examination is the responsibility of the medical practitioner caring for the patient. Where MRI examinations form part of a research project, ICNIRP (2004) advises that the project should be guided by ethical considerations. This supports the view expressed by the WHO (2007) that it is mandatory for all volunteer studies to be conducted in full accord with ethical principles, including the provisions of the Helsinki Declaration (WMA, 2004). For further information about ethical review of research in the UK, see the website of the National Research Ethics Service (NRES, 2008).

The ongoing rapid development of MRI technology and equipment continues to bring significant advances in clinical diagnosis, but at the same time patients and volunteers may be exposed to levels of static, switched gradient and RF magnetic fields that have not been fully assessed with regard to their potential to induce adverse health effects. In order to provide flexibility and to allow the cautious development of MRI diagnostic and research techniques, ICNIRP (2004) considered three different exposure conditions, namely those received during routine or specific MRI examinations or during experimental MRI procedures.

a Routine MRI procedures for all patients are termed the *normal operating mode*. This mode was termed the 'uncontrolled level' by the NRPB (1991).

b Specific MRI examinations outside the *normal operating mode* range are termed the *controlled operating mode* and exposures must be carried out with appropriate consideration of the medical circumstances. Here, discomfort and/or adverse effects for some patients may occur, and a clinical decision must be taken to balance such effects against foreseen benefits to the patient. This mode was termed the 'upper level' by the NRPB (1991) which advised against exceeding the maximum values.

c Experimental MRI procedures at levels outside the *controlled operating mode* range are termed the *experimental operating mode*, and are subject to approval by an ethics committee.

ICNIRP provides its advice on the protection of patients and volunteers for each of these three tiers by recommending a series of maximum values for the static magnetic and switched gradient fields and for temperature limits induced in the body by exposure to RF fields.

In carrying out this review, the HPA recognises the many authoritative reviews on possible adverse health effects of electromagnetic fields that have been published and reference is made to these wherever possible. Individual scientific studies are reviewed in this document only when they have not been included in existing reviews or where they are viewed as being particularly relevant and merit further examination.

Chapter 2 of the document considers MRI technology and its various clinical applications. This sets the scene for how MRI works and the fields that need to be considered in respect of patient and volunteer exposure. It includes specific issues such as imaging people with implants, preventing accidents, and emerging techniques and future developments.

Chapter 3 summarises relevant epidemiological studies, covering cancer, reproductive and developmental outcomes, and other health outcomes. The biological evidence for possible adverse effects of MRI exposure on people is reviewed in Chapter 4 and the dosimetric aspects of exposure are covered in Chapter 5. The adverse effects of exposure to acoustic noise are reviewed in Chapter 6 together with aspects of protection.

Recommendations for protection of patients and volunteers are provided in Chapter 7 and Chapter 8 contains recommendations for further research.

Advice on best practice in MRI units is set out in Appendix A, recognising that other bodies are involved in providing detailed advice (IEC, 2002; MHRA, 2007).

The HPA is committed to developing major elements of its formal advice through consultation with partners, stakeholders, members of the public and other interested parties. This document has been developed through a process of consultation with experts in the field of MRI technology, clinical practice and research, and through public consultation. The HPA is grateful to those external experts who contributed to the development of this document. Appendix B summarises the HPA response to comments received during the period of public consultation.

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2 MRI Technology and Medical Applications

The MRI technique was invented in 1973 and has rapidly developed to become a major medical imaging modality which is still growing in its areas of application. This chapter describes the growth of MRI, the range of MRI applications, and the type of electromagnetic field and acoustic noise exposures encountered by patients and volunteers undergoing MRI examinations.

2.1 MRI technology

At the end of 2006 it was estimated that there were approximately 500 fixed MRI scanners involved in human imaging, installed at some 350 sites across the UK; of these, most were in NHS hospitals, about 100 were in private medical centres, and 25 were primarily dedicated to research, of which 20 were in universities or NHS establishments (Price, personal communication, 2007). In addition, there are mobile, private MRI scanners in use across the UK.

Most MRI scanners in clinical use employ superconducting magnets with cylindrical bores and produce static fields of magnetic flux density 1.5 T, although there are now many 3 T scanners in clinical use (see Table 2.1). A smaller number of ultrahigh field MRI systems are in use in research institutions worldwide and these produce static fields in the range 4.7–9.4 T. A whole-body 11.7 T scanner is expected to be installed shortly in France. Cylindrical magnets restrict access to the patient, and can present problems for imaging claustrophobic or obese patients. So-called 'open systems' offer a more patient-friendly environment and provide much easier access to the patient, facilitating, for example, interventional MRI procedures. For technical reasons such systems currently use lower static fields, typically 0.2–1.2 T (Table 2.1). In addition, small scanners dedicated to imaging knees, shoulders, wrists, elbows, hips, hands and feet are available. These use resistive, permanent or superconducting magnets to provide fields up to 1 T, and can be installed in a relatively simply equipped room, rather than requiring a full MRI facility.

In addition to a static magnetic field, the MRI environment includes time-varying magnetic fields, which are produced by the three orthogonal magnetic field gradient coils that are switched on and off to spatially encode the magnetic resonance signals. In general, the faster the imaging sequence, the greater the rate of change of the gradient fields required. These time-varying fields induce electric fields in the body, causing currents to flow. Typically, clinical MRI systems generate gradient fields of around 25–50 mT m^{-1} and slew rates of 100–200 T m^{-1} s^{-1}. Other gradient fields can be as high as 100 mT m^{-1} with slew rates of 800 T m^{-1} s^{-1}.

TABLE 2.1 Breakdown of number of fixed installation MRI scanners by magnetic flux density and bore shape in the UK

	Number of scanners		
Field (T)	**Cylindrical bore**	**Open bore**	**Total**
≤0.35	0	22	22
0.5	19	1	20
0.6	0	3	3
1	58	2	60
1.5	345	0	345
3	35	0	35
>3	2	0	2

The MRI scanner creates a radiofrequency (RF) field (B_1) which is applied at the Larmor frequency to change the orientation of the nuclear magnetism. For protons in a static field of 1.5 T, the frequency is 63.86 MHz. The RF magnetic field induces currents in the body, resulting in tissue heating.

2.2 Clinical applications

2.2.1 Standard imaging

Although traditionally MRI procedures have been associated with imaging the central nervous and musculoskeletal systems, advances in technology, which allow faster and more detailed scanning, now mean that MRI can be routinely used for diagnosis in most areas of the body and in most clinical specialities.

The ability to differentiate grey and white matter and cerebrospinal fluid has made MRI the imaging method of choice in the brain and spine for some time, and MRI is invaluable in improving the diagnosis and treatment planning of brain tumours and spinal cord lesions. Similarly, MRI has allowed more accurate assessment and follow-up of many other neurological conditions, such as multiple sclerosis (Frohman et al, 2003). Excellent soft tissue contrast has also allowed MRI to produce very detailed images of the joints of the body, which is useful in orthopaedics. Cartilage, tendons, muscles, fat, intra-vertebral discs and vessels can all be delineated, as well as bone, aiding the diagnosis of many conditions – for instance, the assessment of lumbar back pain or torn knee ligaments. Pelvic MRI is extremely useful in the diagnosis of gynaecological disease, for evaluation of the prostate, and in the staging and follow-up of rectal cancers. The ability of MRI to help specify lesions makes it very valuable in imaging the breast and the liver.

Magnetic resonance angiography is used to delineate blood vessels in the legs, brain, neck and kidneys, and is now sufficiently robust that in many centres it has replaced invasive, diagnostic X-ray and catheter

angiography. MRI is developing an increasing role in the assessment of cardiac disease, where it is possible to provide useful information about both the anatomy and function of the heart, again with the potential to replace more invasive X-ray catheter techniques. Similarly, magnetic resonance cholangio-pancreatography is able to replace an invasive endoscopic procedure in the diagnosis of some patients with disease of the gall bladder, biliary tree or pancreas.

There is also an increasing use of MRI for guiding, monitoring and controlling interventional and intra-operative procedures. These benefit from its good spatial and temporal resolution, and high intrinsic tissue contrast, and its ability to monitor temperature and its multiplanar imaging capabilities.

Further, in addition to anatomical imaging, MRI procedures offer the possibility of monitoring tissue function by measurement of flow, diffusion and perfusion, as well as the possibility of using magnetic resonance spectroscopy (MRS) to study biochemistry *in vivo*.

The major application of MRI in research is in neurology, where it is used to study normal brain anatomy and function, and this has been the main driver for the installation of dedicated research scanners over the last five years. In particular, the technique of functional MRI (fMRI) is used to map blood flow changes in the brain that reflect cortical responses to activity or stimulation. In the past radioisotope techniques were used in such brain mapping, but MRI has now superseded these in this area. Diffusion MRI sequences are used to map the white matter tracts in the brain, and to study the connections between different parts of the brain.

MRI also has a growing range of applications in biomedical research beyond neurology. This is driven mainly by the flexibility of MRI as a physiological measuring system, which means that several parameters of interest can be measured within a single session (volume, blood flow, dilution, etc). It is also driven by general patient acceptance, which is useful when making repeated measurements.

The range of scanning sequences offered by all manufacturers of clinical MRI systems is now very extensive and allows the use of a whole range of standard and fast imaging techniques; sequences include special packages to study the heart and blood vessels. Some sequences produce particularly high exposures to different types of electromagnetic fields. For instance, applications such as fMRI, cardiac imaging, diffusion imaging and perfusion imaging use echo planar imaging (EPI) techniques in which data for a complete slice are acquired very quickly, typically in less than 100 ms. EPI methods require high performance gradients and slew rates of 200 T m^{-1} s^{-1} are achievable. To be able to encode diffusion, very large gradient fields are applied for short periods leading to large values of switched magnetic field away from the centre of the magnet, although large rates of change of magnetic flux density (dB/dt) are not applied particularly frequently (maybe 30 times per second). Other sequences can involve a relatively high exposure to RF power. This is particularly the case for fast spin echo sequences.

2.2.2 Functional MRI

Functional MRI requires a subject to perform a task or receive a stimulus, so additional equipment is needed in the bore of the scanner (eg goggles to present visual stimuli, buttons to record the person's responses, or a cap to monitor electrical activity in the brain). It is very important that such devices are

safe to use in the MRI environment, and in particular will not cause heating of the subject, either from trailing cables or from transducers placed in direct contact with the person. An example of such additional equipment is that used in transcranial magnetic stimulation (TMS). This involves pulsing a magnetic field (creating dB/dt of 10^4 T s^{-1} for 100 μs) near the head to cause depolarisation of nerve cells within the brain and a temporary 'virtual lesion' which can be used to explore brain function. TMS is performed routinely in research, and now simultaneously with fMRI. Rapidly switching the TMS current in the static field of the MRI scanner will lead to large forces which must be carefully controlled (largely by designing a force-balanced TMS system) if harm is to be avoided.

2.2.3 Contrast agents

Intravenous (iv) contrast agents are administered to many patients routinely to aid diagnosis, and may be delivered either by hand injection or by a pressure injector. The most commonly administered contrast agents are gadolinium-based, but there are also liver-specific and lymph-node-specific agents used in some centres. In addition, to improve image quality of abdominal or pelvic scans, many centres administer anti-spasmodic agents, either as an intramuscular (im) or as an iv injection. Whilst it is uncommon for patients to experience adverse reactions to any of the agents administered in MRI, emergency procedures must be in place to manage any kind of incident (in particular, severe allergic reaction), in addition to basic standards of care for subjecting patients to iv or im injections. In a small number of cases, nephrogenic systemic fibrosis has been associated with the use of particular gadolinium-based MRI contrast agents in patients with severely impaired renal function (Kuo et al, 2007).

2.3 Patient and volunteer exposure

An MRI examination consists of a series of individual scanning sequences, each designed to show anatomy in a particular orientation, or weighted to make different kinds of tissue appear more or less prominent. An individual sequence could be as short as a few seconds, eg a 'single-shot' image, or longer than 10 minutes for a very high resolution image. In practice, an examination will be built up from many sequences. To allow adequate planning and preparation of sequences, and to maintain communication with the individual being scanned, there are usually short pauses between each sequence. Most examinations can be completed within approximately 30 minutes, including, if required, the administration of iv contrast media. However, examinations could take up to an hour, or even up to 90 minutes, but this would usually be when several body areas were being imaged, and may involve periods of time where the patient or volunteer is being moved on and off the table and coils are being changed.

The vast majority of research scans involve similar lengths of examinations, although a few may involve scanning over several hours – for instance, when studying physiological responses over a long period of time.

2.3.1 Typical MRI-related exposures

This section describes the different types of electromagnetic fields and acoustic noise encountered during an MRI scan.

2.3.1.1 Static magnetic fields

For each MRI scanner, the nominal static magnetic field is that produced homogeneously within an imaging region inside the bore of the magnet called the diameter spherical volume (DSV).

Shielding is commonly used to reduce stray fields outside the magnet. Active shielding, using secondary magnetic coils to cancel out the static magnetic field from the primary, increases the field just inside the bore, such that for most shielded 1.5 T magnets, the static magnetic field at the end of the bore is approximately 2 T. In addition, magnetic field gradients are substantially increased close to the end of the bore.

The static magnetic fields produced by an actively shielded 4 T magnet have been described by Liu et al (2003) and Crozier and Liu (2005).

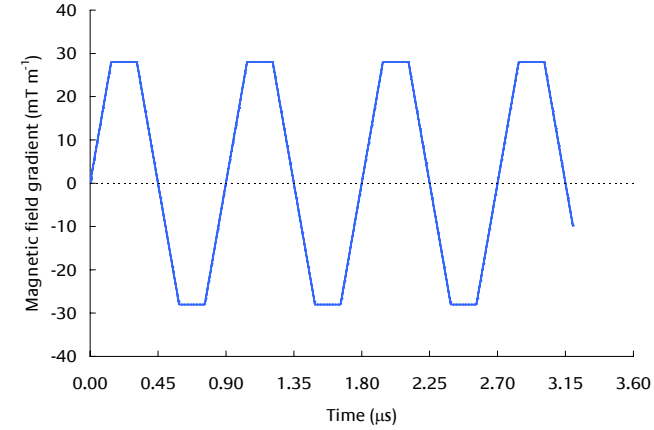
2.3.1.2 Switched gradient fields

Gradient pulses are generally trapezoidal, although the particular shape varies with sequence type. The gradient rise time is typically 200–1000 μs leading to rates of change of the gradient field of 20–150 T m^{-1} s^{-1}. The waveforms consist of trains of gradient pulses in which the separation and duration of pulses may vary. Consequently, the waveforms contain components covering a spectrum of frequencies. The gradient waveforms applied in three orthogonal directions are generally different, and their time sequences are complicated.

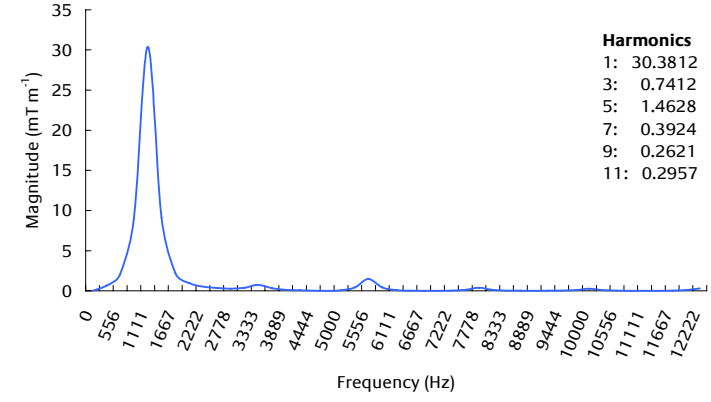
A simulated gradient waveform is shown in Figure 2.1a. This relates to one axis only of a much more complex waveform. This example consists of a train of trapezoidal pulses with alternating polarity, each 0.45 ms in duration, with a slew rate of 200 T m^{-1} s^{-1} and a plateau of 28 mT m^{-1}. The spectral content determined by the Fourier transform of this signal is shown in Figure 2.1b. In this case the dominant spectral component is 1.1 kHz, the fundamental frequency at which the pulses are repeated, and has a magnitude of 30.4 mT m^{-1}. There are also odd harmonic components of generally decreasing amplitude (3.3, 5.5, 7.7 kHz, etc), none of which has a magnitude greater than 5% of the fundamental. The width of the peaks in the spectrum is dependent on the number of cycles in the time-domain sample, in this case four. A greater number of cycles would produce more sharply defined spectral peaks.

2.3.1.3 Radiofrequency fields

The RF magnetic field (B_1) is applied at the Larmor frequency $\omega = \gamma B_0$, where γ is the gyromagnetic ratio. For hydrogen, γ = 42.58 MHz T^{-1} and so for most clinical MRI scanners (with a static field of 1.5 or 3 T), the frequency is approximately 64 or 128 MHz. A smaller number of ultrahigh field MRI systems with static fields in the range 4.7–9.4 T are in use in research institutions worldwide and, for these, B_1 has a frequency in the range 200–400 MHz.



(a)



(b)

FIGURE 2.1 (a) simulated gradient waveform and (b) Fourier transform of waveform

The main transmitter coil is usually a body coil that is integrated into the scanner. In conventional cylindrical bore systems at 1.5 or 3 T, this is usually a birdcage coil designed to achieve a region around the isocentre of the coil in which B_1 is spatially uniform. By driving the coil in quadrature, a circularly polarised B_1 is produced which has the advantage of reducing the RF power deposition in the patient compared with that from coils that produce a linearly polarised field. In open MRI scanners, in which the static field is vertical, a circularly polarised B_1 field is often produced by a pair of planar coils placed above and below the patient or volunteer. In some examinations such as those of the head or knee, other transmitter coils are often used. These require less RF power to be transmitted but this may be at the cost of field uniformity. Problems associated with efficiency and field homogeneity limit the use of birdcage coils in high field and ultrahigh field systems and alternative designs such as transverse electromagnetic (TEM) resonators and arrays are used – see, for example, Vaughan et al (2004), Collins et al (2005) and Ibrahim (2006).

2.3.1.4 Acoustic noise

The acoustic noise experienced by patients and volunteers is generated by Lorentz forces induced by the interaction of the electric current through the gradient coils and the static magnetic field. As the current is switched, the forces will expand or compress the coil mountings. The gradient coil is deformed, producing vibrations that are transmitted to other structures of the scanner and, finally, through the air to the patient or volunteer.

Noise is also induced elsewhere in the scanner, through the gradient magnetic fields causing eddy currents in other conducting parts of the system (Edelstein et al, 2002; Katsunuma et al, 2002).

The Lorentz forces are proportional to the current flowing through the coils (hence the gradient amplitude) and the strength of the main magnetic field. In practice, this means that sequences with high spatial resolution, low repetition times or echo spacing have increased acoustic noise levels (Price et al, 2001).

The frequency spectrum of a magnetic resonance pulse sequence appears similar to the Fourier transform of the input gradient waveforms but filtered by the mechanical gradient frequency response function (Hedeen and Edelstein, 1997). Spectra consist 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 for a trapezoidal waveform may lead to more prominent harmonics and greater acoustic noise (Hennel et al, 1999). Low frequency vibration due to pulse repetition may also be present. Measurements of the frequency response function 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 frequency response function which, if excited by the gradient waveform, lead to much higher noise levels than expected (Price et al, 2004). Access to major resonance frequencies will be blocked by the manufacturers both to avoid excessive acoustic noise and to reduce system vibration that may degrade image quality.

A wide-scale survey on acoustic noise levels on commercial MRI systems has shown a broadly linear relationship between worst-case acoustic noise in terms of absolute sound pressure and scanner flux density (Price et al, 2001, 2003). Typical noise levels increased from 77.2 dB(A) on a 0.2 T scanner to 118.4 dB(A) on a 3 T system, as expected. However, typical noise levels on 1.5 T clinical MRI systems vary from about 80 to 110 dB(A) (Price et al, 2006) depending on sequence type and on the degree of noise reduction technology implemented in the scanner design. Generally, the highest noise levels are associated with ultra-fast gradient echo and echo planar imaging techniques.

Various methods of noise control have been implemented or suggested. Vacuum technology and other forms of isolation (Hedeen and Edelstein, 1997; Katsunama et al, 2002; De Wilde et al, 2005) have been successfully implemented in some commercial MRI systems. Radical gradient designs (Chapman et al, 2003) have been shown to have potential for noise reduction at least for echo planar imaging sequences of up to 50 dB(A) at 3 T. These have resulted in more modest but still significant noise reductions of up to about 20 dB(A) at 1.5 T.

2.4 Special screening considerations

The following sections describe how the different fields used in MRI can interact with implanted medical devices. Medical implants are increasingly important in healthcare and present a challenge to the safe use of MRI. This is because implants with metallic or electrically conductive parts may interact with the switched gradient and/or RF fields used in MRI, causing trauma or burns. Such devices can also experience displacement, rotation and/or translational forces due to interaction with the static field. The function of the implant may also be compromised, which would have serious consequences if it had a life-supporting function.

Medical implants are normally subdivided into passive and active categories. Passive implants include aneurysm clips, coils, stents, wires and orthopaedic devices. Active implants operate electronically – for example, cardiac pacemakers and deep brain stimulators.

A review has highlighted a number of safety incidents related to the scanning of patients with implants in the UK where devices malfunctioned during scanning (De Wilde et al, 2007).

2.4.1 Static magnetic fields

The main safety concern about the static field is the projectile effect, which occurs when ferromagnetic objects are accelerated into the bore of the magnet with potentially lethal effects.

The attractive force on a ferromagnetic object is proportional to the spatial gradient of the magnetic field. This is normally steeper for stronger fields, particularly since active shielding is used to reduce the extent of the stray fields around the scanner. 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 3 T systems. It should also be noted that some novel magnet designs at lower flux densities, such as superconducting open 1 T systems or short-bore 1.5 T systems, may also feature higher spatial gradients than standard cylindrical systems.

The maximum spatial gradient is normally located close to the entrance of the bore in a cylindrical MRI system or close to the edge of the gantry for open MRI systems. Therefore, as a patient is moved into or out of the magnet, they (and any implanted device) pass through the point of maximum attractive force.

Torque effects may also occur and these are maximal in the high uniform field at the centre of the magnet. However, for ferromagnetic objects over the range of fields relevant to MRI (where the ferromagnetic objects are usually magnetically saturated), the torque is generally relatively independent of flux density (ASTM, 2006b).

The safety of an implant is related to the region of the body in which it is situated and this must be taken into account in evaluating safety. In some cases fibrosis is important in knitting the implant into the tissues. In the case of heart valves, displacement forces or torque effects are generally insignificant compared with the forces exerted on the implant from the beating heart. The static magnetic field may

also alter the function of an active implant – for instance, closing the reed switch of a pacemaker. There will also be torques on objects with non-isotropic susceptibilities.

Forces can also act on non-magnetic conducting materials that are moving in a magnetic field (Condon and Hadley, 2000; Robertson et al, 2000). A force will be exerted on conducting objects in a patient being moved into an MRI scanner, or on the objects moving within the patient (eg components of a heart valve).

2.4.2 Switched gradient fields

There are a number of safety issues associated with switched gradient fields. Conductive implants will tend to concentrate currents induced in the body by the gradient field, particularly in the case of elongated implants, leads or wires (Shellock et al, 2004). This may increase the possibility of nerve stimulation. Induced currents can also alter the function of an active device such as a pacemaker.

Gradient-field-induced eddy currents flowing inside the implant within the main magnetic field may also lead to Lorentz forces and torque effects (Nyenhuis and Kamondetdacha, 2005). Considerable vibration has been observed experimentally in objects with highly conductive components, due to the fast alternating torque created as the gradient fields are switched (Graf et al, 2006). The induced torque is proportional to the strength of the main magnetic field and the distance of the implant from the isocentre, whilst inversely proportional to the gradient ramp time.

Whilst the heating effect of gradient-field-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 (Nyenhuis and Kamondetdacha, 2005).

2.4.3 Radiofrequency fields

Implanted medical devices with conductive parts can increase the risk of RF burns. Of particular concern are elongated devices, loops, leads and wires, whether connected to devices or not (Shellock, 2005). Such devices may exhibit resonant behaviour leading to excessive heating, which is difficult to predict. It is important to note that devices that do not give rise to significant heating at a particular wavelength may behave quite differently at a shorter or longer wavelength because of these resonant effects (Shellock, 2005). Heating effects for small, passive implants are generally not significant in respect of patient safety.

Whole-body specific energy absorption rate (SAR) values have been used to define safe conditions for scanning patients with certain implants. However, whole-body SAR is indicative of heating in the human body, not in implants (Nitz et al, 2005). Whether an implant will exhibit heating in the MRI environment depends on a number of factors not accounted for by the patient SAR value, including wavelength, RF transmit coil type and/or the position of the implant within the transmitted RF field.

2.4.4 Screening and testing of implants and foreign bodies

It is essential to identify individuals with implants and foreign bodies, such as metal fragments (Shellock, 2001). Suggested procedures for this are outlined in Appendix A.

Active implants have traditionally been seen as a strict contraindication for MRI scanning. Patients with active implants are scanned at specialist centres using highly specific guidelines for the procedure. However, a number of accidents have occurred where implant manufacturers' guidelines (eg for deep brain stimulators) were not strictly followed.

ASTM International (originally known as the American Society for Testing Materials) has published a series of standards for the testing of implants. These include standards for displacement force, torque, RF heating (passive implants) and image artefact (passive implants) (ASTM, 2001, 2002, 2006a,b).

There is a number of databases of tested implants including one maintained by the Institute of Magnetic Resonance Safety Education and Research (Shellock, 2001).

2.4.5 Medical equipment

Various medical devices are used in the MRI scanning room for patient monitoring, such as electrocardiogram (ECG) and peripheral pulse monitors. Equipment may also be required for life support, such as oxygen bottles, iv stands or anaesthesia systems, and for contrast injection and interventional procedures. Similar safety considerations apply as in the case of implants. Equipment containing ferromagnetic parts can become a projectile when moved close to the scanner. Serious incidents including patient fatalities have occurred when items such as ferromagnetic oxygen bottles have inadvertently been brought into MRI scanning rooms. Monitoring equipment with conductive parts or cables may induce tissue heating when placed on the patient. In addition, any of the fields associated with MRI may alter the function of the device. Care must be taken to ensure that all medical devices used in the MRI environment are completely 'magnetic resonance safe (MR safe)' or safe under certain conditions that are strictly met. For instance, some devices are safe or their function unaffected so long as they are kept a certain distance from the scanner. Generally, cables associated with monitoring equipment should not be looped.

ASTM International has introduced a new device-marking system which specifies new terminology and symbols for characterising the suitability of medical devices (including implants) for use in the MRI environment (ASTM, 2005). This includes the term 'MR conditional' where an implant will be characterised as safe under a set of imaging conditions, eg magnetic field strength, maximum spatial gradient or maximum RF power.

2.5 Emerging techniques and future developments

2.5.1 Interventional MRI

Interventional MRI is an emerging technique that is being used to guide and monitor therapeutic procedures. It has the potential to reduce the use of some X-ray based procedures which can result in ionising radiation exposure of patients and staff. Such MRI units must be managed carefully to prevent accidental injury from the projectile effect: all equipment, such as catheters, surgical instruments and monitoring equipment, is to be MR safe or appropriately MR conditional. Interventional MRI is unlikely to expose patients to particularly high electromagnetic fields relative to other MRI procedures.

Interventional MRI has been used to guide tumour resection in real time (Zimmerman et al, 2001; Hall et al, 2005), and this has led to a reduced rate of tumour recurrence and hence repeat resection. It has been used to guide cardiac catheterisation in special combined units; patients can be transferred between an X-ray catheterisation laboratory and an interventional MRI scanner on a floating table (Razavi et al, 2003). It has also been used to guide high intensity, focused ultrasound therapy (Bohris et al, 1999; Damianou et al, 2004).

2.5.2 Trends in strength of the magnetic field

The clearest trend is the move to stronger fields with the introduction of 3 T installations accelerating and moving into clinical rather than research settings: there are at least two wholly clinical 3 T sites in the UK. This trend has implications for patient safety. Use of high and ultrahigh field systems for structural imaging will increase, particularly in the study of degenerative neurological diseases, high resolution vascular imaging, and detailed monitoring of the effectiveness of anti-angiogenetic and genetic-based drugs for the treatment of cancer. MRI is increasingly being used for physiological and metabolic investigations, and molecular applications such as quantitative imaging of gene expression, marking stem cells and tracking their evolution, or monitoring targeting of malignant cells with targeted contrast agents.

There may be some interest in new low field systems that are more patient friendly, eg superconductive open scanners at 1 T or very-short-bore 1.5 T cylindrical systems, which would normally complement an existing 1.5 T installation. At present these systems are relatively expensive but there are a number of installations in the NHS and the private/charity sector. Low field, open scanners are often used in interventional MRI.

2.5.3 Future developments

The focus on multidisciplinary consideration of patients, compliance with clinical guidelines, and government targets is likely to increase the requirement for more-complete diagnostic information prior to treatments being started, and this will include MRI procedures (RCR, 2002).

Current policies in the delivery of healthcare, such as patient choice and care closer to home, could lead to consideration of new MRI facilities outside a hospital setting – for example, in primary care centres.

Increases in specialised MRI techniques, such as cardiac imaging and interventional procedures, may lead to the emergence of greater numbers of specialised units. Recommendations from advisory bodies, such as the National Institute for Health and Clinical Excellence (NICE) and NHS Quality Improvement Scotland guidance, will continue to influence healthcare provision.

In the light of these drivers and recognising the continuing advances in MRI technology and applications, the number of MRI investigations is likely to continue to increase substantially, as is the emergence of specialised units.

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3 Epidemiological Studies

Particular attention is given in this chapter to studies of static magnetic fields, some of which relate specifically to exposures that result from the use of MRI. However, much of the epidemiological literature on static magnetic fields does not relate to patients and volunteers undergoing MRI procedures, but rather concerns workers at aluminium reduction and chloralkali plants. The static magnetic fields encountered in these workplaces are generally much lower than those in MRI systems. Further, workers at these plants are also exposed to power frequency electromagnetic fields.

In addition to the studies considered here, there have been many epidemiological studies of people exposed either to power frequency magnetic fields or to radiofrequency (RF) fields in non-MRI situations – for example, through their employment or in the home, or through the use of mobile phones. These studies have been reviewed by, for example, AGNIR (2001a,b, 2003), Ahlbom et al (2001), IARC (2002) and the NRPB (2004a,b). Taken as a whole, these studies have not clearly demonstrated adverse health effects, although there is evidence of an association between long-term exposure to residential power frequency magnetic fields and a raised risk of childhood leukaemia (AGNIR, 2001a; IARC, 2002; NRPB, 2004a).

3.1 Cancer

There is no epidemiological literature on cancer risks among patients or volunteers undergoing MRI procedures. Various studies have examined mortality and cancer incidence among workers exposed to static magnetic fields through their employment at aluminium reduction and chloralkali plants (Barregård et al, 1985; Gibbs, 1985; Milham, 1985; Mur et al, 1987; Rønneberg et al, 1999; Spinelli et al, 1991, 2006). Such work is also likely to have involved exposure to a variety of potentially hazardous fumes and aerosols, as well as to power frequency fields, which may confound interpretation. Most of the studies have focused on the risk of brain cancer and leukaemia. Whilst the numbers of observed cases are relatively small, the findings do not point strongly to a risk of leukaemia from static magnetic fields, and there is no consistent evidence for an increased risk of brain tumours or of other types of cancer (Barregård et al, 1985; Rønneberg et al, 1999; Spinelli et al, 1991). For example, Rønneberg et al studied cancer incidence among 2647 male short-term workers (ie workers employed for less than four years) and two cohorts of men employed for at least four years in a Norwegian aluminium smelter (namely, 2888 production workers and 373 maintenance workers). There was no association between exposure to static magnetic fields and cancers of the brain or lymphatic and haematopoietic tissues. Cancer incidence was not elevated in any of the cohorts when compared with the expected incidence calculated based on rates for men in Norway as a whole.

3.2 Reproductive and developmental outcomes

Reproductive and developmental outcomes in relation to the use of MRI have been examined in a number of studies. For example, a cross-sectional postal survey conducted in 1990 examined reproductive health among women employed at most of the clinical MRI facilities in the USA (Evans et al, 1993; Kanal et al, 1993). Based on 287 pregnancies that occurred while working at an MRI unit, as compared with 964 pregnancies that occurred during work in another job, the relative risks for various reproductive outcomes (delayed conception in planned pregnancies, miscarriage, delivery before 39 weeks, low birth weight and sex ratio of babies) were all close to one and none of the differences was statistically significant.

Several studies have looked at children who were examined *in utero* by echo planar imaging. In a three-year follow-up study, Baker et al (1994) found no demonstrable increase in the occurrence of disease or disability (including hearing deficit) that could be related to the imaging. However, this study was based on only 20 children. Myers et al (1998) performed a prospective study of pregnancies in which fetuses were exposed to echo planar imaging, compared with a control group in which there was no such exposure *in utero*. Although the controls were matched on a score for age, parity, ethnic origin, smoking history and postcode, no information was given on other potential confounding factors such as alcohol consumption, diet and socioeconomic status. In addition, the 74 women in the group exposed to MRI were more closely monitored than the control group, which may have affected induction rates and hence the gestational age of delivery. Although the gestational age was lower in the exposed group, the proportion of women delivering prematurely was not significantly different. Further, whilst infant birth weights were significantly lower in the exposed group, the corrected birth weight for gestational age was not significantly different between the exposed and control groups. Clements et al (2000) undertook a paediatric assessment at age 9 months of 20 infants exposed to fields from MRI *in utero* and 32 controls. The method of selection of the subjects is unclear. In particular, the mothers of the control infants had a statistically significantly higher standard of educational attainment. Among infants in the exposed group, gross motor function was advanced and length was slightly decreased relative to the controls, in both instances to a statistically significant degree. Otherwise, however, there was little difference between the two groups in their development or clinical history. Most recently, Kok et al (2004) looked at children, mostly aged between 1 and 3 years, who were exposed to fields of 1.5 T during MRI investigations in the third trimester. No adverse effects on eye or ear functions, or on reproductive outcome, were identified.

There has also been a number of studies of pregnancy outcomes among workers employed at aluminium reduction plants. In contrast to the reported normal sex ratio among babies born to female MRI workers (Evans et al, 1993; Kanal et al, 1993), a study of the offspring of men in Washington State (USA) who worked as carbon setters in aluminium reduction plants reported that the proportion of males was 38.1%, which represented a statistically significant deficit (Milham, 1993). On the other hand, in an analysis of children born in Norway during 1970–93, about 50% of the offspring of fathers who worked in aluminium plants were male (Irgens et al, 1997). However, the corresponding proportion among the offspring of women who worked at these plants was 37%, which was a statistically significant deficit (Irgens et al, 1997).

3.3 Other health outcomes

Moen et al (1995, 1996) examined musculoskeletal symptoms among workers at an aluminium reduction plant in Norway. The first study examined data on musculoskeletal symptoms registered by the occupational health care unit in 1986 and 1991, based on 342 employees exposed to static magnetic fields in the potrooms and a control group of 277 workers who were exposed to background levels (Moen et al, 1995). Rates of symptoms were similar in the two groups, although the power of this study was limited. In the second study, sick leave rates for musculoskeletal disorders over a five-year period were compared among 342 workers exposed to average fields of 8 mT and 222 unexposed controls (Moen et al, 1996). No association was found between exposure and either the number of periods of sick leave per year or the total number of days with sick leave. However, the data on symptoms and associated sick leave used in these two studies may not have been collected in a standardised manner.

3.4 Summary

Overall, the evidence from epidemiological studies indicates no long-term adverse health effects from exposure to static magnetic fields or specifically from MRI; however, the degree of weight that can be placed upon this evidence is limited. Many of the published studies lack statistical power or suffer from other methodological weaknesses, such as a lack of information on exposure levels. In addition, there is an absence of published studies of mortality or cancer incidence among either patients or volunteers undergoing MRI procedures. Further, in the studies conducted on groups exposed to static magnetic fields in non-MRI situations, the fields encountered (usually up to a few tens of millitesla) were generally much lower than those that would normally arise through the use of MRI. IARC (2002) concluded that there was inadequate evidence in people for the carcinogenicity of static magnetic fields.

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4 Biological Studies

Biological studies allow the consequences of exposure to electromagnetic fields to be investigated in a well-controlled and systematic fashion, not only in volunteers but also in a wide range of animal and cell models. Further, these studies allow interaction mechanisms to be identified and investigated.

A large number of laboratory studies have investigated the biological effects of exposure to magnetic fields at various frequencies and intensities. These studies have been reviewed, for example, by AGNIR (2001a, 2003), IARC (2002), the NRPB (2004a,b) and the WHO (2006, 2007). While some subtle effects have been reported, overall these studies have produced no compelling evidence that low level exposures can cause robust and consistent adverse effects.

In this chapter the biological bases used by ICNIRP (2004) for limiting exposure of patients and volunteers during MRI procedures are examined, and the results of more recent laboratory studies using volunteers are considered.

4.1 Static magnetic fields

The biological and health effects of exposure to static magnetic fields have been thoroughly reviewed by the NRPB (2004a), a WHO Task Group (WHO, 2006), and more recently by van Rongen et al (2007) and AGNIR (2008). In addition, the effects of static magnetic fields relevant to human health have been considered at an international ICNIRP/WHO workshop (Leszczynski, 2005; Sienkiewicz, 2005). The information contained in these documents provides a suitable benchmark to judge the relevance and adequacy of the advice from ICNIRP regarding static magnetic fields (ICNIRP, 2004).

ICNIRP recognised that the interaction of static magnetic fields with biological tissues can be characterised as electrodynamic or magnetomechanical in nature. This is entirely consistent with the views expressed by the WHO (2006) and other expert groups. Electrodynamic effects originate through the interaction of magnetic fields with electrolyte flows, leading to the induction of electric potentials and currents. Magnetomechanical phenomena include orientation effects on macromolecular assemblies in fields, and the movement of paramagnetic and ferromagnetic molecular species in strong field gradients. In addition, electronic spin states can be affected which may in turn affect certain classes of electron transfer reactions (radical pair interactions) in living tissues. As a consequence of these interactions, safety issues focus on the effects of induced electric potentials and currents, and on uncertainties concerning other possible adverse effects.

ICNIRP recommended a limit of 2 T for whole-body exposure of patients to static magnetic fields for routine MRI examinations, with an upper limit of 4 T for specific MRI examinations carried out with appropriate consideration of the medical circumstances. Higher flux densities may be used for

experimental MRI procedures, provided risk–benefit analyses are carried out and special ethical approval has been obtained.

These recommendations are based on reports of vertigo at fields greater than 2–4 T (Schenck, 1992) and on electrodynamic interactions with blood flow, particularly around the heart and aorta generating electric flow potentials and a reduction in blood flow (Kinouchi et al, 1996). A series of studies investigating acute effects in volunteers during and shortly after exposure to 8 T static fields reported an absence of effects on heart rate, ECG and blood pressure (Kangarlu et al, 1999), on cognitive function (Chakeres et al, 2003a) and on a variety of physiological parameters, including blood pressure and body temperature (Chakeres et al, 2003b). A significant trend for systolic blood pressure to increase was seen in the last study, but this was only 3.6 mm Hg at 8 T, approximately half the difference seen in moving from a sitting to a supine body position. In addition, vertigo and other sensations were reported during body movement in all three studies. Chakeres et al (2003b) reported that they adopted the working practice of moving patients very slowly into the magnet bore to avoid these effects.

In a further exploration of the effects of motion in a static field gradient, two more recent studies by de Vocht et al (2006, 2007) reported transient and variable effects on the performance of cognitive tasks in subjects who made a series of standardised head movements in close proximity to MRI systems of 3 and 7 T, confirming earlier studies carried out using a 1.5 T system (de Vocht et al, 2003). Transient decrements in the performance of a visual tracking task and an eye–hand coordination task were reported immediately following a standardised series of head movements carried out in static fields of between 600 and 1600 mT, generating rates of change of magnetic field (dB/dt) of up to 300 mT s^{-1} (at 1600 mT). The magnitude of the effect seemed to depend on the time-varying rather than static magnetic field component. These results may have particular implications for staff working in the vicinity of MRI systems.

Glover et al (2007) investigated the sensations and postural responses of volunteers exposed to magnetic fields produced by a 7 T whole-body magnet. Seven out of ten subjects felt sensations of movement (rotation) when they were pushed into the bore of the magnet on a patient couch moving at 0.1 m s^{-1}, giving a peak dB/dt of about 1 T s^{-1}. Two of these subjects indicated that the sensations were severe, and the direction of apparent motion was reversed when they were pushed into the other end of the magnet, or when they turned over (from a supine to a prone position), indicating that the sensation resulted from an effect of the induced current on the neural output of the vestibular system. When the subjects moved their head in the centre of the magnet, nine reported mild or severe vertigo-like effects, of whom two experienced severe nausea. Further, eight subjects reported feelings of dizziness immediately after the end of the test, that persisted for up to 10–30 minutes. It was also found that postural sway was significantly increased for three out of ten subjects standing close to the magnet in a field of around 0.8 T and a field–gradient product of 1 T^2 m^{-1}. In addition, two subjects reported a feeling of 'falling' when standing still near the magnet. This effect, which does not depend on movement, was thought to result from differences in the diamagnetic susceptibility of structures within the vestibular system. More recently, Atkinson et al (2007) reported that exposure to a 9.4 T field during sodium imaging for up to 60 minutes did not significantly affect heart rate, blood pressure, skin temperature or respiration, or have an effect on the cognitive ability of a group of 25 healthy volunteers. However, some of these subjects reported various perceptual and other effects during movement in the field, including vertigo or light-headedness, and a metallic taste.

4.1.1 Conclusions

Although there are gaps in knowledge about the risks associated with exposure to static magnetic fields, the biological effects most likely to occur in patients and volunteers undergoing MRI procedures are the production of vertigo-like sensations and these acute effects are associated with motion or movement through the field. The probability of clinically relevant physiological effects or of significant changes in cognitive functions occurring in fields of up to 4 T seems low. In addition, the accumulated experience of MRI procedures in clinical situations, where exposures using fields of 3 T are becoming increasingly common (as discussed in Chapter 2), does not suggest that any obvious detrimental field-related effects occur, especially in the short term.

Much less is known about the effects of exposure to fields above 8 T. Similarly, very little is known about the effects of static magnetic fields in excess of a few tesla on growth and behavioural development of fetuses and infants, suggesting some caution is warranted regarding their imaging.

Moving patients slowly into the magnet bore can avoid movement-induced sensory effects. It is clear that sensitivity to these effects varies considerably between individuals, and thresholds for motion-induced vertigo in sensitive people have been estimated to be around 1 T s^{-1} for greater than 1 s.

4.2 Switched gradient fields

Many studies have investigated the biological effects of low frequency (less than 100 kHz) time-varying magnetic fields using a wide variety of models, and these results are of relevance to the discussion of the effects of switched gradient fields. These studies have been reviewed by national and international expert groups, including the NIEHS (1999), AGNIR (2001a,b), IARC (2002), ICNIRP (2003) and the WHO (2007). Robust responses have been reported in strong fields that are consistent with the effects of field-induced electric fields on excitable tissues, including the stimulation of peripheral nerves and muscles. Otherwise this research has not identified clear evidence of harm following short-term exposures typical of MRI procedures, although some subtle changes have been observed, particularly in specific cognitive functions, and these require further investigation. In addition, the NRPB (2004a) noted that some people reported increased sensitivity to stimulation by the electric fields induced in the central nervous system (CNS) by switched gradient fields. These included people suffering from or predisposed to epilepsy, and those with a family history of seizure. The use of tricyclic antidepressants, neuroleptic agents and other drugs that lower seizure activity was also thought likely to increase sensitivity.

Three orthogonal magnetic field gradients are rapidly switched on and off and provide spatial information within the magnetic resonance signal from which a two-dimensional image can be reconstructed. These magnetic fields induce electric fields and currents within the body, proportional to the rate of change of the magnetic field (dB/dt) and the inductive loop radius, and can stimulate nerve and muscle tissue.

ICNIRP made recommendations on limiting patient and volunteer exposure to these switched gradient fields – termed time-varying fields by ICNIRP (2004) – based primarily on stimulation of peripheral nerves and muscles, including the heart, by induced electric fields. ICNIRP also considered the possibility of

field-induced changes in the excitability of neurons in the brain, particularly by high rates of change of gradient field. This approach to limit the effects of induced electric fields is consistent with previous MRI guidance from the NRPB (1991) and the FDA (2003).

The effects of induced electric fields on nervous system function have been reviewed by the NRPB (2004a), Saunders and Jefferys (2007) and the WHO (2007). In addition, the effects of weak electric fields in the body were considered at an international NRPB/WHO/ICNIRP workshop (Blakemore et al, 2003; McKinlay and Repacholi, 2003) with particular attention on effects on the CNS.

The responsiveness of nerve and muscle tissue to rapidly pulsed electric stimuli has been well established for many years and is known to depend very much on the properties of the nerve or muscle cell membrane, particularly the membrane time constant, which varies considerably between nerve and muscle fibres. This results from the structure of biological membranes: the thin lipid membrane behaves as a capacitance while the ion channels provide a parallel resistance. An electric field will stimulate the peripheral nerve if the induced membrane depolarisation is above a threshold value sufficient for the opening of the voltage-gated sodium channels to become self-sustaining. Stimulation thresholds rise as the stimulus pulse width decreases below the value of the membrane time constant due to the progressively shorter time available for the accumulation of electric charge on the cell membrane.

A general, somewhat simplified, stimulus strength–duration equation describing this behaviour (Noble and Stein, 1966; Reilly, 1998) is given by

$$I_t = I_{Rh}\left(1 - e^{-t/\tau_m}\right)^{-1} \tag{4.1}$$

where I_t is the threshold current pulse for a given pulse width (t) and I_{Rh} is the minimum asymptotic threshold current (termed the rheobase) for stimulation by pulses much longer than the membrane time constant* (τ_m). The variation in threshold responses for the intermittent induced-current pulses characteristic of gradient field switching are discussed in detail by Reilly (1998). Key factors to take into consideration include the pulse width and the pulse interval, relative to the membrane time constant. In response to sinusoidal stimuli, thresholds rise above a frequency (f_e) proportional to the inverse of the membrane time constant. Conventionally, $f_e = (2\pi\tau_m)^{-1}$, although Reilly (1998), who is frequently cited in this context, used a value of $f_e = (2\tau_m)^{-1}$ derived from a computational model of myelinated nerve fibre excitability, the spatially extended non-linear nodal (SENN) model (Reilly et al, 1985).

In principle, equation 4.1 can be used to determine the approximate stimulus parameters that will result in nerve and muscle excitation during exposure to the fields associated with MRI. However, this neglects various factors including the slow inactivation of sodium ion channels in nerves, termed accommodation, which raises thresholds in response to long stimulus pulse durations (greater than around 50 ms) and low frequencies (less than 10 Hz). An expansion of equation 4.1 to account for accommodation (Hill, 1936; see Noble and Stein, 1966, for further discussion) is given by

$$I_t = I_{Rh}\left(1 - \tau_m/\lambda\right)\left(e^{-t/\lambda} - e^{t/\tau_m}\right)^{-1} \tag{4.2}$$

* The time constant for a tissue τ_m varies according to the way it is derived and might reflect an empirical value rather than that of the membrane time constant (Reilly, 1998).

where λ is the accommodation time constant. For slow rates of accommodation compared to the stimulus pulse width or frequency, equation 4.2 reduces to equation 4.1. Accommodation is therefore likely to be of negligible consequence for the rapidly switched gradient fields of MRI.

Myelinated nerve fibres of the peripheral nervous system are particularly sensitive to electric field stimulation. The fatty myelin sheath increases the nerve fibre length constant, a measure of the resistance of the cell membrane compared to the intracellular and extracellular resistances, so increasing the transmembrane potential that will result from an extracellular electric field gradient. Large diameter (20 μm) peripheral nerve fibres are estimated to have rheobase electric field thresholds of approximately 6 V m^{-1} (Reilly, 1998). In addition, the myelin sheath results in time constants of about 120–150 μs, shorter than those for non-myelinated nerves and muscles, rendering them sensitive to the short pulses and high frequencies characteristic of the switched gradient fields. Myelinated nerve fibres with similar membrane time constants also occur in the white matter of the CNS where they form connections between different regions of the brain or project between the cortex and deep grey matter structures (Wozniak and Lim, 2006). As for most peripheral nerve fibres, they generally have a smaller diameter (5–10 μm), with relatively higher rheobase thresholds estimated to lie around 12–25 V m^{-1} (Reilly, 1998).

Muscle tissue is also electrically excitable, although it is generally less sensitive to electrical stimulation than myelinated nerve tissue. Nevertheless, effects on the heart could be life threatening. Reilly (1998) conservatively estimated the one-percentile threshold for cardiac muscle stimulation (the induction of ectopic beats) to be similar to the median stimulation threshold for large diameter peripheral nerve fibres. However, the relatively long cardiac muscle fibre time constant (3 ms) means that stimulation thresholds for the induction of ectopic beats rise as stimulus pulse widths decrease much below 3 ms (or as sinusoidal stimulus frequencies rise above about 120 Hz), and so will exceed peripheral nerve thresholds under these conditions. Experimental studies by Bourland et al (1999) confirm calculations of a threshold for cardiac stimulation under these conditions some 10–14 times greater than that for peripheral nerve stimulation. Cardiac stimulation *per se* is not necessarily hazardous; ventricular fibrillation is potentially fatal, minimum thresholds exceed those for cardiac excitation by a factor of 50 or more, but this drops to a factor of only 2 if the heart is repeatedly excited during the vulnerable period of the cardiac cycle (Reilly, 1998, 2002).

In practice, the rapidly changing fields induced by the high rates of gradient field switching used in MRI systems preferentially stimulate myelinated nerves of the peripheral nervous system (Nyenhuis et al, 2001). Therefore, the practical physiological limit of exposure to such fields can be based on minimising uncomfortable or intolerable sensations caused by strong perception of the field. Hence perception and pain thresholds resulting from such stimulation have been used to limit exposure (IEC, 2002; FDA, 2003; ICNIRP, 2004).

The IEC (2002) and ICNIRP (2004) recommended a maximum exposure level for switched gradient magnetic fields be set equal to a dB/dt of 80% of the median perception threshold for peripheral nerve stimulation for routine operation, and 100% of the median perception threshold for controlled operation. An averaged variation of the median perception threshold with stimulus duration, which can be approximated by a hyperbolic function, is described by

$$\frac{dB}{dt} = 20\left(1 + 0.36/\tau\right) \tag{4.3}$$

where τ is the effective duration of the induced electrical stimulus in milliseconds, 20 T s^{-1} is the minimum (rheobase) threshold, and 0.36 ms is the stimulus duration, termed the chronaxie, at which the threshold is twice the minimum rheobase value.

At higher flux densities, ICNIRP (2004) noted that intolerable stimulation would interfere with an examination and the patient would receive no benefit. Consequently, ICNIRP recommended that this should be avoided.

These recommendations were based on the studies at Purdue University by Bourland et al (1999), Schaefer et al (2000) and Nyenhuis et al (2001). The studies at Purdue University investigated thresholds for perception and uncomfortable and intolerable sensation in 84 volunteers exposed to switched gradient fields for the *y*-gradient field (anterior–posterior or coronal gradient) and *z*-gradient field (head-to-toe or axial gradient) in which dB/dt pulses (gradient field ramps) of between 50 and 1000 μs, separated by 300 μs intervals, were applied at various intensities. Two volunteers exhibiting ectopic beats were withdrawn from the experiment (Bourland et al, 1999). The pulse separation was sufficiently large to avoid the change in threshold that occurs for closely spaced induced-current pulses, described by Reilly (1998). Significant motor contraction of either abdominal or thoracic skeletal muscle was observed for gradient fields approximately 50% greater than the sensation threshold. Nyenhuis et al (2001) calculated overall population thresholds for each level of sensation and stimulus intensity. They found population median rheobases for perception of 18.8 and 28.8 T s^{-1} for the *y*- and *z*-gradients, respectively, assumed to result from the different maximum inductive loop radii available for each gradient field orientation. In addition, normalising the data to the median sensation threshold for comparison, the rate of change of gradient field needed for the lowest percentile of the study group for uncomfortable stimulation was approximately equal to the median threshold for perception, and the lowest percentile for intolerable stimulation occurred at a dB/dt value approximately 20% above the median perception threshold over this range of stimuli.

The IEC (2002) also allowed an *experimental operating mode* to exceed the *controlled operating mode* values, but provided protection against cardiac stimulation by recommending that

$$\frac{dB}{dt} < 20\left(1 - e^{-t/3}\right)^{-1} \tag{4.4}$$

The NRPB (1991) made a similar recommendation regarding controlled exposures. As described above, for cardiac muscle fibres, thresholds rise as stimulus pulse widths (t) decrease below 3 ms, or as stimulus frequencies rise above about 120 Hz. At frequencies below this value, however, the Purdue University data suggest that protection against cardiac stimulation may be somewhat smaller than originally envisaged by the IEC (2002), which based its assumption on calculations by Reilly (1992, 1998). These indicate that cardiac stimulation rheobase thresholds were approximately 50–70 T s^{-1} for the different gradient fields (and peripheral nerve rheobase thresholds about 40–60 T s^{-1}). Some protection would nevertheless be afforded by the more central location of the heart within the torso compared to peripheral nerves.

There have been no further volunteer studies of perception and pain thresholds since publication of the MRI guidelines by ICNIRP (2004). So et al (2004) used scalar potential finite-difference methods to compute the electric fields induced in a model of the human body by exposure to the switched gradient magnetic fields used in the volunteer study at Purdue University. Peripheral nerve stimulation rheobase thresholds for *y*- and *z*-gradient fields were estimated to lie between 3.8 and 5.8 V m^{-1}, close to the theoretical estimate by Reilly (1998) of about 6 V m^{-1}.

The NRPB (2004a), WHO (2007) and Saunders and Jefferys (2007) discuss in some detail the NRPB/WHO/ICNIRP workshop on weak electric field effects in the body (Blakemore et al, 2003; McKinlay and Repacholi, 2003). In general, these reviews conclude that the integrative properties of the synapses and neural networks of the CNS render it (and therefore its functions) potentially sensitive to the effects of electric fields perhaps as low as 100 mV m^{-1} at 20 Hz. ICNIRP (2004) noted a threshold of about 1 V m^{-1} for this effect.

A consideration of ion-channel kinetics suggested that the threshold for effects on CNS function might remain constant up to around 1 kHz (McKinlay and Repacholi, 2003; NRPB, 2004a; WHO, 2007), although recent *in vitro* data support the view that the long time constants (tens of milliseconds) associated with these effects severely limit their frequency response (Saunders and Jefferys, 2007). There is, however, no evidence available confirming such effects in volunteer studies apart from the well-known induction of phosphenes, the sensation of faint, flickering lights in the periphery of the visual field. Phosphenes are believed to be caused by the induction of weak electric fields in the retina during exposure of the head to low frequency magnetic fields.

4.2.1 Conclusions

It is well established that exposure to switched gradient fields will induce time-varying electric fields and currents in biological tissues. These can cause stimulation of excitable tissues, if of sufficient intensity and appropriate frequency. The rapidly changing fields induced by the high rates of gradient field switching used in MRI systems will preferentially stimulate the myelinated nerves, partly because of their peripheral location in the body. These thresholds are well below those for ventricular fibrillation for induced current pulse widths of less than 3 ms. Hence, limiting exposure of patients and volunteers to switched gradient fields can be based on minimising any uncomfortable or painful sensations caused by the field.

Experimental studies with time-varying fields have not identified consistent evidence of harm following short-term exposures typical of MRI procedures, although some subtle biological effects have been reported. However, people with epilepsy or taking drugs that lower seizure activity may exhibit increased sensitivity to stimulation by the electric fields induced in the CNS, and these people should be imaged with caution.

4.3 Radiofrequency fields

It is well understood that RF energy absorbed by the body results in heating effects due to an increase in molecular rotational and translational kinetic energy. The absorbed heat energy is distributed throughout the body by the circulation of blood and is eventually lost to the external environment. Effects in the absence of heating have been reported but remain controversial (AGNIR, 2003; NRPB 2004a,b).

ICNIRP made recommendations on limiting patient and volunteer exposures to RF fields above 10 MHz by restricting the rise of body and tissue temperatures (ICNIRP, 2004). It is noted that some MRI procedures may use frequencies below this range. These restrictions are intended to avoid the possible health consequences of whole-body heat loads and the localised heating of tissues, including the possibility of unacceptable heating within the embryo and fetus. This approach to limit temperature rises is consistent with previous MRI guidance from the NRPB (1991) and the FDA (2003) and with the recommendations of the IEC (2002).

ICNIRP recommended that the RF-induced rise in core body temperature of a person being scanned in the *normal operating mode* be restricted to 0.5°C, and that in the *controlled operating mode* the temperature rise should be restricted to 1°C. In the *experimental operating mode*, ICNIRP allowed the whole-body temperature to rise in excess of 1°C. During pregnancy, ICNIRP further recommended that exposure duration be reduced to a minimum, and that only the normal operating mode be used. ICNIRP also noted that fever was generally assumed to increase susceptibility to exogenous sources of heat such as RF fields.

With regard to localised tissue temperature, there is general agreement that adverse health effects will be avoided with a margin of safety if tissues of the head are restricted to a maximum of 38°C, tissues of the trunk to a maximum of 39°C, and tissues of the limbs to a maximum of 40°C. ICNIRP recommended that local tissue temperature be restricted to these maximum values in both the *normal* and *controlled operating modes* but allowed these temperatures to be exceeded in the *experimental operating mode*.

The recommendations by ICNIRP are based on an established literature concerning adverse temperature levels in humans; these have been discussed at a WHO workshop (Goldstein et al, 2003; Kheifets et al, 2003). Cardiovascular responses to heat, which are central to body temperature regulation, have been reviewed by Donaldson et al (2003) and Adair and Black (2003). ICNIRP noted in particular the studies of RF heating of volunteers by MRI systems (Shellock et al, 1989, 1994) and the mathematical modelling of human thermoregulatory responses to RF-induced heat load of 4 W kg^{-1} (Adair and Berglund, 1986, 1989, 1992). Overall, there is a consensus among the reviews that in most cases adverse health effects will not occur if any increase in core temperature does not exceed 1°C.

With regard to RF-induced hyperthermia during pregnancy, ICNIRP noted that developmental defects, particularly neural tube and facial defects, had been seen in a number of different animal species when maternal temperatures were raised by about 1.5–2.0°C above normal core body temperature for up to an hour or so (Edwards et al, 2003). Such defects had also been reported in children whose mothers had experienced prolonged or repeated hyperthermia during pregnancy (Chambers et al, 1998). Further, ICNIRP noted that fetal temperatures were normally 0.5°C higher than that of the mother (Schröder and Power, 1997) and recommended limits on body temperature rises of 0.5°C in infants and pregnant

women. People with cardiac and/or circulatory impairment were considered compromised in their ability to dissipate heat (Adair and Berglund, 1989, 1992; summarised by Adair and Black, 2003) and were also included in this group. These authors also estimated the impact of elevated environmental temperatures and relative humidity on body temperature in compromised patients undergoing an MRI scan. Correction factors by which whole-body SAR should be lowered in environments that exceed 24°C and/or 60% relative humidity have been incorporated in the IEC standard (IEC, 2002).

The restrictions recommended by ICNIRP on localised temperature rises in body tissues were based on data derived from experimental studies of heat-induced tissue damage. These studies, reviewed at the WHO workshop by Dewhirst et al (2003) and Sharma and Hoopes (2003), had been carried out largely in order to develop hyperthermia as an adjunct to other therapies in the treatment of cancer. The results were variable, but in many cases, cell loss and/or tissue lesions occurred when temperatures exceeded 40–42°C or so for periods of more than about an hour; the CNS, including the blood–brain barrier, and the testes seemed the most sensitive tissues. ICNIRP concluded that these data supported a previous recommendation by Athey and Czerski (1988) that adverse effects will be avoided with a margin of safety if temperatures in the head are less than 38°C, temperatures in the trunk less than 39°C, and temperatures in the limbs less than 40°C.

Since publication of the MRI guidelines by ICNIRP in 2004, the effects of RF-induced heating have been reviewed by the NRPB (2004a,b). Although supportive of the position adopted by ICNIRP, the NRPB noted the vulnerability of older people to prolonged heat stress. This is particularly true if they are dehydrated. The NRPB also suggested that the lens of the eye should be treated as potentially heat-sensitive tissue. ICNIRP suggested that when the eye is in the field of a small local coil used for RF transmission, care should be taken to ensure that the temperature rise is limited to 1°C. Kussman et al (2004) highlighted the need for caution regarding RF intensive cardiac MRI examinations of anaesthetised children with compromised ability to regulate body temperature on account of congenital heart disease.

4.3.1 Conclusions

Exposure to RF fields of sufficient intensity can induce heating in biological tissue, while effects in the absence of heating remain controversial. Hence restrictions on exposure to RF fields used in MRI procedures are based on limiting both whole-body core temperature rises and temperature rises in parts of the body in order to avoid possible adverse responses or thermal injuries.

At present, upper values have not been specified by ICNIRP for the rise of core body temperature and for the maximum local temperatures in the head, trunk, and extremities during MRI procedures performed under the *experimental operating mode*. This potentially might allow scans to be run where temperatures rise to thermally damaging levels. Temperatures should be limited to values that allow for the increased absorption of RF energy, but still offer an adequate margin of protection against adverse thermal effects.

There are uncertainties concerning the effects of increased heat loads on infants and pregnant women, and on people with impaired thermoregulatory ability as a result of age, disease or the use of medications. These people should be imaged with caution.

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5 Dosimetric Studies

The role of computational dosimetry is to provide predictions of the electric fields and currents produced inside the body by a known external field or source. It can also be used to predict temperature rises inside the body. In its recommendations ICNIRP (2004) placed limits on both temperature and temperature rise within the body. However, in practice, the SAR is used as a surrogate for temperature, and this is more readily determined by calculation. ICNIRP made little reference to dosimetric calculations for static magnetic fields or for gradient fields, because few studies were available in these areas.

All modern dosimetric techniques start with the construction of a mathematical model of the anatomy. This is composed of an array of numerous small cells, which may form either a regular structured grid of cuboids (voxels) or a more general unstructured grid containing other polyhedra. The size of these cells is determined by a compromise between the level of accuracy and detail required in the computed field and the limitations of the available computer hardware and software. Typical whole-body voxel models usually have a resolution of a few millimetres.

Each computational cell is assumed to be homogeneous and assigned a single tissue type. The electrical and thermal properties have been tabulated for many tissues, and these are used as input to the calculation of electromagnetic fields and temperature. Some of the parameters (particularly thermal parameters such as blood perfusion rates) are not known with complete certainty. This must be taken into account in estimating the uncertainty in dosimetric results.

The application of anatomically realistic models to the dosimetry of MRI is a relatively recent development, and few such studies were available when ICNIRP produced its recommendations (ICNIRP, 2004). Recent dosimetric studies are reviewed here, firstly to provide examples of techniques which should be used in assessing compliance, and secondly to predict which exposure scenarios are most likely to exceed relevant biological thresholds.

5.1 Static magnetic fields

The static magnetic field generated by MRI scanners can be associated with induced currents, or paramagnetic or diamagnetic effects within the body which may result in biological effects (Section 4.1).

Computational studies have been performed to calculate induced electric fields and currents in the body (see, for example, Crozier and Liu, 2005). They have also been used to predict the effects of electric flow potentials on heart function (Holden, 2005). A number of approaches are available, which include the method of moments, finite-element and finite-difference time-domain (FDTD) techniques (Barnes and Greenebaum, 2007). These techniques commonly use anatomically correct voxel models of the human body (Dimbylow, 1997; Caputa et al, 2002). Each approach has its advantages and disadvantages when used to predict field intensities in different tissue types. For example, the finite-element method is more

suited to irregular mesh generation but may not be computationally tractable when used with high resolution human voxel models.

In its recommendations ICNIRP made little reference to dosimetric calculations in the area of static magnetic fields, possibly as only a small amount of published information existed on this subject at the time (ICNIRP, 2004). The work of Kinouchi et al (1996) was mentioned, in which calculated current densities induced in and around the aorta by the flow of blood in a person exposed to a magnetic field of 5 T were found to be about 10% of the normal maximal cardiac current densities, well below the estimated threshold for cardiac stimulation (Reilly,1998). In addition, Kinouchi et al found that magnetohydrodynamic forces reduced the flow of blood by around 1% at 5 T, well within the normal range of variation. Recent calculations by Holden (2005) suggested that thresholds for changes in cardiac pacemaker rate or the initiation of ectopic beats in the heart would be greater than 8 T. Other recent publications are predominantly concerned with the effects of motion in a static field.

Liu et al (2003a) used a quasi-static finite-difference method to calculate induced electric fields and currents in the body due to patient movement and 'head-shake' (movement of the head in a traverse direction) whilst inside an MRI system. The electric field values induced in a human voxel model were calculated using an electric scalar potential, derived from a finite-difference approximation method (Liu et al, 2003b). Although the original spatial resolution of the voxel model was 2 mm, this was re-scaled to a coarser 6 mm resolution for the purposes of calculation. A 4 T static field generated by a compact, symmetrical, actively shielded magnet was studied by Crozier and colleagues (Crozier et al, 2001; Zhao et al, 2001). The inhomogeneous fields produced at the ends of the magnet provided probable locations for the induction of fields within the body. The peak current density in one voxel was 220 mA m^{-2} for a patient moving in this scanner. The authors cited a threshold-induced current density for peripheral nerve stimulation of 480 mA m^{-2}, quoting Kangarlu and Robitaille (2000) and, through extrapolation of field values and velocities, predicted that this level would be reached for a velocity of 0.8 m s^{-1} in a 7 T magnet.

Generally, however, minimum threshold values for peripheral nerve stimulation are estimated to lie around 1 A m^{-2}, or about 6 V m^{-1} (see, for example, Reilly, 1998). It is important to note that these thresholds vary with stimulus parameters such as pulse width or stimulus frequency (see Section 4.2), and therefore must be extrapolated appropriately between different electrical stimuli. The minimum values cited above refer to thresholds for pulses longer than about 150 μs and frequencies below about 1 kHz. For frequencies below about 10 Hz, or for long (greater than 50 ms) pulses, accommodation decreases nerve excitability, raising thresholds (see Section 4.2). Peripheral nerve stimulation thresholds when moving slowly into the bore of the magnet are therefore likely to be higher than the values cited above.

A further study by Crozier and Liu (2005) calculated electric field values induced in a voxel model when moving at various positions around the magnet of an MRI system. For this investigation, the MRI magnet, anatomical model and numerical method remained the same as in Liu et al (2003a). Calculations predicted higher induced electric fields and current densities for movement at 0.5 m s^{-1} at positions near the end of the magnet. The largest induced electric field value near the surface of the body was in line with that of the Liu and Crozier (2004) study at 2.0 V m^{-1}, peaking at 3.1 V m^{-1} within the chest. In this context typical head translational and rotational frequencies associated with walking are around 0.5–5 Hz

(Grossman et al, 1988; Pozzo et al, 1990). Such low frequencies are also likely to be typical of body movement, and suggest that peripheral nerve stimulation thresholds may be somewhat higher than the values cited by Crozier and colleagues.

5.1.1 Conclusions

There are few published computational studies related to the static fields generated by MRI scanners. An area which has been examined is the effect of electric flow potentials on heart function. The calculations indicate that thresholds for changes in cardiac pacemaker rate or the initiation of ectopic beats in the heart would be greater than 8 T.

Additionally, calculations of induced fields and currents due to movement in a static field have been performed for MRI systems. These studies predict that movement in a large magnetic field could induce the required current density for peripheral nerve stimulation, although in this work it is possible that minimum threshold values for peripheral nerve stimulation have been overestimated.

5.2 Switched gradient fields

Peripheral nerve stimulation associated with gradient fields is well documented. In accordance with theoretical models of nervous stimulation, effects are expected to be dependent on the induced electric field, and therefore (by Faraday's law of induction) on the rate of change of the magnetic field (dB/dt). Models of stimulation in long straight nerves predict that the relevant parameter is the gradient of the electric field rather than its absolute magnitude. However, it is not clear which is the more relevant quantity *in vivo* where there is a combination of straight and curved nerve sections together with terminations.

By the very nature of gradient coils, dB/dt is not spatially uniform. Indeed, at the centre of the coil it is zero. The standard definition of dB/dt, specified by the IEC, is to use the maximal value measured on a radius of 0.2 m from the axis of the magnet (IEC, 2002).

Peripheral nerve stimulation occurs when dB/dt exceeds threshold values, which vary with the stimulus parameters. As discussed in Chapter 2, gradient field rise times are typically 200–1000 μs. The magnitude of the induced electric field depends on the type, orientation and position of the coil and therefore, for a given stimulus, thresholds vary between coils. The lowest threshold magnetic fields are found for the *y*-gradient coils because the magnetic field in the *y*-direction (corresponding to the anterior–posterior direction through the body) traverses the greatest cross-section and largest current loops in the body, inducing the highest electric field.

The IEC (2002) and ICNIRP (2004) recommended, for each mode of operation, a maximum exposure level for switched gradient fields expressed in terms of dB/dt and specified as a fraction of the median perception threshold for peripheral nerve stimulation. This threshold is based on observed biological effects and determined by volunteer studies. Therefore these guidelines are not reliant upon the adequacy of the dosimetric studies which have been performed for gradient fields.

At the switching frequency of the gradient fields the electromagnetic field may be considered quasi-static (ie the displacement current may be neglected). Further, the relative magnetic permeability of all the human tissues is approximately one. From these two observations it follows that the human body does not significantly perturb the magnetic field. The magnetic field or associated vector potential may therefore be calculated from the geometry of the coils using the Biot-Savart law. The electric field strength can be derived from the vector potential together with a scalar potential calculated from, for example, finite-difference or finite-element methods (So et al, 2004). The FDTD method was originally developed for application at much higher frequencies, but modified versions have been applied to MRI (Zhao et al, 2002; Liu and Crozier, 2004).

The dosimetry of gradient fields is complicated by a number of factors. In realistic MRI scanning sequences, all three gradient coils are activated simultaneously. While several coils are active, the vector sum of all field contributions must be used when comparing the electric field to the stimulation threshold.

Analytical solutions using homogeneous cylindrical models have been used to estimate the electric fields (While and Forbes, 2004). Such solutions can give some insight into the mechanism of interaction between the field and the body. Predicted electric fields for realistic gradient sequences were around 10 V m^{-1}. This exceeds the reported threshold for peripheral nerve stimulation. However, this model involves great simplification of the anatomy and also of the electrical properties (assumed zero or infinite conductivity).

Numerical models using realistic anatomical data can be used to relate the electric field inside the body to dB/dt. In this way the thresholds of peripheral nerve stimulation, measured in terms of dB/dt, can be converted to electric field values. Independent numerical studies using realistic anatomical models (Liu et al, 2003c; So et al, 2004) have derived thresholds of about 4–6 V m^{-1}. These electric field thresholds are more or less independent of coil orientation, although the measured dB/dt thresholds are not. This is to be expected, since the underlying nerve physiology is isotropic, and demonstrates that the differences in dB/dt thresholds are indeed due to dosimetric factors, namely the sizes of the respective current loops. In a study by Nyenhuis et al (2001), somewhat lower electric field values were derived (around 2 V m^{-1}).The discrepancy can most probably be explained by the use of a homogeneous phantom in the earlier study. In a realistic anatomical model, and *in vivo*, the channelling of currents through high conductivity tissues causes higher peak electric fields.

So et al (2004) reported that the highest electric fields were found in the spine when using z-gradient coils, but in the skin and fat when using x- and y-coils. Bencsik et al (2007) used the 'HUGO' phantom which has hands clasped together. In the case of the y-coil the maximum electric field was found near the hands, due to the large current loop formed through the arms. After scaling to a slew rate of 100 T m^{-1} s^{-1}, Bencsik et al (2007) found their predicted electric fields to be in reasonable agreement with those of So et al (2004) but somewhat larger than those found by the FDTD method (Zhao et al, 2002; Liu et al, 2003c; Mao et al, 2006).

With respect to cardiac stimulation, Liu et al (2003b) have calculated the induced electric fields for a gradient coil with a slew rate of 100 T m^{-1} s^{-1}. These are about a factor of 30 lower than those required for the production of an action potential in healthy heart. This effect is very dependent on induced current pulse width. However, the thresholds may be lower in patients with certain abnormal cardiac conditions.

Induced fields and currents may be enhanced close to a metallic implant, particularly if the implant has the form of a long wire or a loop of sufficient size (Nyenhuis et al, 2005). For example, fields have been computed using a finite-difference model of a spinal fusion stimulator (Buechler et al, 1997). When a switched gradient field was applied perpendicularly to the plane of the U-shaped wire implant, the electric fields at the bare ends of the wire were enhanced by a factor of 20. For a bare wire the computed enhancement factor was 90, and for a cut wire 200. In all cases the enhanced electric fields were restricted to within a few diameters of the bare portion of the wire.

5.2.1 Conclusions

Numerical techniques have been developed which relate dB/dt to the distribution of electric fields within anatomically realistic models. For gradient fields at the threshold for peripheral nerve stimulation, recent studies predict electric fields of a few volts per metre. This is fairly consistent with the available theoretical models of nerve stimulation.

However, it is still not clear what characteristic of the electromagnetic field is most relevant to predicting the occurrence of peripheral nerve stimulation. Numerical dosimetry cannot predict with confidence the precise location of stimulation.

A sharp metallic implant can enhance the induced electric fields in its vicinity. However, this is unlikely to cause stimulation unless a bare wire end is located extremely close to a nerve.

5.3 Radiofrequency fields

Several types of RF transmitter coil are in common use. Examination of deep tissues is commonly performed using a volume coil which encloses the torso, head or limb – for example, birdcage, TEM or microstrip coils. Examinations of superficial tissues may use a surface coil which does not completely enclose any part of the body. A phased array is composed of a number of independent radiating elements, for which the input amplitudes and phases are chosen to synthesise the desired field pattern.

The most commonly used target for *in vivo* MRI is the hydrogen (^{1}H) nucleus, which has a Larmor frequency of 42.58 MHz for a static magnetic field of 1 T (see Section 2.3.1.3). In the discussion that follows, the frequency is given with, where appropriate, the corresponding static magnetic flux density B_0 in parentheses. At fields over 3 T, the wavelength of the RF field is comparable to the size of body parts such as the head. In this case resonance effects lead to increased inhomogeneity in the field pattern, ie 'hotspots'.

ICNIRP recommended restrictions both on the body core temperature and on the maximum local tissue temperature, as discussed in Chapter 4 (ICNIRP, 2004). To ensure compliance with these limits there are corresponding restrictions on whole-body and local SAR, respectively. The relationship of core temperature to whole-body SAR is predicted by compartmental models, such as that of Adair and Berglund (1986), which have been validated by volunteer experiments. The status of thermophysiological modelling was reviewed by ICNIRP, and this provides an adequate basis for the ICNIRP restrictions on

whole-body SAR. The derived limits on local SAR were described by ICNIRP as being based on published experimental studies concerning temperature rise and on theoretical simulations.

The studies cited by ICNIRP (2004) include Brix et al (2002) and Yeung and Atalar (2001), which apply a Green's function technique to roughly predict the maximum temperature rise. These techniques can give generic upper bounds on temperature rise provided that the SAR distribution is known. The highest temperature rises per unit SAR are expected in low perfusion tissues such as adipose tissue. According to Brix et al, a local SAR of 4 W kg^{-1} results in a steady-state temperature rise of about 2°C, the IEC limit for an examination of the torso (IEC, 2002). In addition, the limits on local SAR in the extremities are supported by empirical data describing the relationship between absorbed power and local temperatures in the hand and wrist (Sienkiewicz et al, 1988).

Since the publication of the ICNIRP guidelines in 2004, there has been considerable progress in computation of the relationship between local SAR and tissue temperature, with the development and increasing use of anatomically realistic models.

Calculations of SAR in anatomically realistic human models are performed, for example, using FDTD or finite-element methods. In the FDTD method the computational cell size must be no greater than one-tenth of the wavelength, otherwise an accurate result cannot be obtained (similar considerations apply to the finite-element method). The cell size must also be small enough to model thin layers such as the skin. However, if the cells are too small, the total number of cells required may be too great to allow practical computation. Thus, in computational dosimetry it is important to strike a balance between accuracy and computational efficiency. FDTD calculations using a human head phantom with various resolutions in a volume imaging coil (Collins and Smith, 2003) indicate that local and average SAR in the head may be calculated with reasonable accuracy using a resolution of 5 mm.

The relationship between local SAR and temperature rise is usually modelled using the bioheat equation (Pennes, 1948). This is a partial differential equation which can be solved by FDTD or finite-element methods similar to those applied in the SAR computation. However, the physiological parameters involved in the bioheat equation, and the validity of the equation itself, are subject to a greater level of uncertainty than is present in the SAR computation.

FDTD calculations of SAR have been performed for the head in a birdcage coil (Collins and Smith, 2001). These show that local (1 g) SAR limits will be exceeded before average SAR limits. This demonstrates the importance of accurate methods for the prediction of local SAR. Subsequent calculations of SAR and temperature rise (Collins et al, 2004) have suggested that the temperature in the brain is unlikely to rise by more than 1°C provided the SAR averaged over the head does not exceed the IEC limit for normal mode operation, 3.2 W kg^{-1}. Temperature rises in other parts of the head, however, may reach 2–3°C. If a surface coil is driven so as to reach the IEC limit on head-averaged SAR, the temperature might rise by 1.8°C in the posterior cerebellum. However, it should be noted that surface coils are not generally driven at such high powers, since they are designed to excite a small region only. Nguyen et al (2004) calculated SAR and temperature in the head with a birdcage coil at frequencies from 64 MHz (1.5 T) up to 500 MHz (11.9 T). Each simulation was scaled to produce a 90° flip angle in a 3 ms pulse. Temperature rises were less than 1°C, with the exception of the simulation at 300 MHz (7 T), where there

appears to be a resonance phenomenon. The largest temperature rises were often found in the eye, which is particularly sensitive due to its low blood perfusion rates.

The IEC (2002) and ICNIRP (2004) pointed out that when the eye is in the field of a small local transmit coil, care should be taken to ensure that the temperature rise is limited to 1°C. No guidance was given on suitable dosimetric techniques to accomplish this. However, several thermal models of the eye have been constructed to evaluate the safety of mobile communication handsets – see, for example, Hirata (2005), Flyckt et al (2007) and Wainwright (2007). These models suggest that the temperature rise in the eye should not exceed about 1.7°C provided that the local SAR in the eye is limited to 10 W kg^{-1}. Results of the same order may be expected if the models are applied to an MRI examination with a local RF transmit coil.

Computations have also been performed using a birdcage body coil loaded with different people (Liu W et al, 2003). For 128 MHz (3 T) exposure of one subject, the maximum local SAR (1 cm^3 averaged) was calculated as 38.45 W kg^{-1} and the whole-body average as 1.46 W kg^{-1}. This implies a ratio of 25 between the two values. Smaller ratios were found at 64 MHz (1.5 T) and also for a smaller subject. It was suggested that the effect of subject size may be due to the larger electric fields in the vicinity of the coils, or to the inductive loop size (Faraday's law). Zhai et al (2004) have demonstrated that the use of a homogeneous FDTD body model overestimates the whole-body SAR and underestimates the local SAR generated by a birdcage body coil. For the model exposed at 128 MHz (3 T), the local SAR and whole-body SAR were, respectively, 10 and 0.8 W kg^{-1}, implying a ratio of 12.5. This again implies that restrictions on local SAR will be exceeded before those on whole-body SAR.

The FDTD method has also been applied to predict SAR and temperature distributions in the leg due to a butterfly decoupling coil at 64 MHz (1.5 T) (Hand et al, 1999). When the total power absorbed in the leg was 2 W, the maximum temperature rise was 1.3°C. Reasonable agreement was obtained with skin surface temperature measurements using fibre-optic probes. At 8 W, measurements diverged from predictions, probably because of thermoregulatory responses which were neglected in the implementation of the bioheat equation. The same butterfly coil was driven so as to produce a constant RF magnetic field B_1 at different frequencies from 64 MHz (1.5 T) up to 213 MHz (5 T). It was found that the SAR and temperature rise increased significantly with frequency f, being approximately proportional to $f^{2.3}$ over this range (Hand et al, 2000). This is to be expected, since at higher frequencies a larger driving voltage must be applied to produce the same B_1 field.

Theory predicts that local SAR hotspots are likely to occur in high field (high frequency) MRI systems or when transmit/receive surface coils are in use. Kangarlu et al (2003) have used fluoroptic thermometry to measure temperatures in a human equivalent phantom head (ground turkey breast) in a volume head coil at 8 T. Moderate temperature rises were measured, ranging up to 0.7°C for an SAR of 4 W kg^{-1}. This is probably a conservative estimate, since the physical phantom lacked the blood flow and other thermoregulatory mechanisms of a living person.

5.3.1 Coil optimisation for SAR reduction

The reduction of SAR, which is desirable for patient safety, is not necessarily inconsistent with high image quality. Indeed, it has been observed that excessive inhomogeneity in the RF magnetic field B_1 increases the power required for a given spin excitation and consequently decreases the signal to noise ratio (SNR) (Kangarlu et al, 2005).

The use of multiple transmit coils ('parallel transmission') may potentially be applied for SAR reduction (Katscher and Börnert, 2006). It has been suggested that an optimised phased array transceiver for chest imaging can improve homogeneity of the B_1 field, thus maintaining high image quality while reducing local SAR hotspots (Li et al, 2005).

For volume coils, one important design criterion is a fairly uniform distribution of B_1. However, this does not ensure uniformity of the electric field, particularly near the coils themselves. This is very sensitive to the exact coil design – for example, the arrangement of the capacitors. Wang and Shen (2006) calculated the SAR, SNR and B_1 for three types of volume head coil, namely birdcage, TEM and microstrip, using a homogeneous head phantom. All three coils were driven so as to produce a 90° flip angle in the centre of the phantom after a 5 ms pulse at 300 MHz (7 T). Nevertheless, Wang and Shen found that the microstrip coil had substantially lower average and local SAR than the others, because the electric field is largely confined to the gap between the microstrip and ground plane.

5.3.2 Implants and monitoring equipment

The SAR may be greatly enhanced in the vicinity of elongated metallic structures such as implanted leads (Nyenhuis et al, 2005). Adverse clinical outcomes have been reported in several cases where MRI examinations have been performed on patients with deep brain stimulation (DBS) systems. Implanted cardioverter defibrillators are presently contraindicated, since measured temperature rises *in vivo* in animal models and in saline phantoms have been reported to reach several tens of degrees. While some authors have suggested that these devices may be MR safe (see, for example, Roguin et al, 2004), this question remains open. The ratio of temperature rise to whole-body SAR is expected to be dependent on how the lead is positioned in relation to the landmark. Nyenhuis et al (2005) also noted that the small hotspots at the bare ends of a wire will have a thermal time constant which is much shorter than the six-minute averaging time used in the ICNIRP guidelines (ICNIRP, 2004). Therefore, for consideration of implant heating a shorter averaging time may be appropriate.

It has been noted that the whole-body averaged SAR is not a good predictor of temperature rise in the vicinity of thin wire implants (Nitz et al, 2005). In particular, if a straight or helical wire is insulated along its length and the ends left bare, the current will be concentrated, causing a very high local SAR at the ends. Another situation of concern may occur if the wire dimensions are such as to induce resonance; in this case heating would occur along the length of the wire, rather than at the ends. This would occur at the higher frequencies associated with the higher field MRI scanners. The SAR may be greatly enhanced close to passive metallic implants such as cardiovascular stents.

In an experimental study using a 24 cm wire in a saline gel phantom, an 8.6°C temperature rise was produced at the bare ends when the SAR was normalised to 4 W kg^{-1} whole-body average (Bassen et al, 2006). Computational dosimetry using the FDTD method is difficult because of the contrast between the size of the RF coil (around 1 m) and the thickness of the wires (less than 1 mm); this may require graded meshing techniques.

The currents close to a straight wire may be calculated by the method of moments (Park et al, 2005). Temperature rises predicted for a DBS lead in a saline phantom showed good agreement with measurement (Nyenhuis et al, 2005). For a long (40 cm) lead in a worst-case layout, the temperature rise was measured to reach 30°C at the electrode, corresponding to an SAR of 1 W kg^{-1} at the landmark.

Baker et al (2004) exposed a phantom with a DBS implant in two different 64 MHz (1.5 T) MRI systems and found a 90-fold difference in the resulting temperature rise per unit SAR. Thus recommendations for implant safety based on the average SAR seem to be very specific to a particular equipment model. The differences may be due both to hardware (coil) design and to the software used to estimate the SAR. However, the experimental study of Bhidayasiri et al (2005) did not find temperature rises in excess of 2.1°C, so these authors have concluded that imaging a DBS patient is safe under the particular conditions of their study. Rezai et al (2004) have stressed the importance of following the implant manufacturer's recommendations punctiliously and not attempting to extrapolate the safety information to other MRI system configurations or imaging modes.

Metallic implants can distort the fields of a MRI scanner and thus impede imaging in the vicinity of the implant. Some implants (eg certain stents) incorporate resonators which enhance the magnetic field to allow post-implantation imaging. These resonators, however, also absorb energy and enhance the SAR in their vicinity. For a whole-body SAR of 4 W kg^{-1} (which is the limit for the *normal operating mode*, see Chapter 7), temperature rises above 5°C were predicted (Busch et al, 2005, 2006) under a few conditions, namely for implants occupying a large volume and for damaged devices which contain high resistance hotspots. Experimental and theoretical work suggests that large orthopaedic implants might cause significant heating in some circumstances (Muranaka et al, 2006).

In view of the sensitivity of the electric field to the precise details of coil design, the SAR close to an implant should be verified for the particular coil design using the FDTD method. The worst-case situations should be validated experimentally (Nitz et al, 2005). It may be possible to mitigate heating by simple design changes to the implant (see, for example, Gray et al, 2005). In some circumstances fibre-optic components can replace metallic parts in an implant (Greatbatch et al, 2002).

In some circumstances, electroencephalogram (EEG) leads may be used inside the scanner – for example, in conjunction with functional MRI to study brain function. In such cases care must be taken to avoid burns to the skin. In addition, several computational studies have indicated the presence of enhanced local and whole-head SAR in the presence of EEG leads. As in the case of implanted devices, the problem is that the SAR estimates provided at the operator's console do not take into account such enhancement. At 128 MHz (3 T) there may be a five-fold increase in whole-head SAR (Angelone et al, 2004). It has been reported that a temperature rise of 3.4°C was obtained after 30 minutes near the electrode in a head phantom, while the local SAR reported for the 300 MHz (7 T) MRI machine was 12 W kg^{-1} (Angelone et al, 2006).

5.3.3 Pregnancy

Few dosimetric studies have yet considered exposure of the fetus to electromagnetic fields. Most have used highly simplified geometrical models of the fetus – see, for example, Fleming and Joyner (1992) and Kainz et al (2003). Neither have these studies addressed the specific case of MRI procedures.

However, a recent paper (Hand et al, 2006) used the finite-integration technique to predict the SAR for a pregnant patient (28 weeks' gestation) in a birdcage body coil at 64 MHz (1.5 T) and 128 MHz (3 T). In this scenario the local (10 g) SAR in the fetus was 55–65% that in the mother. As in other studies, it was found that the ICNIRP limit on the local SAR would be exceeded before the whole-body limit (ICNIRP, 2004). The ratio of the SAR averaged over 10 g to that averaged over the whole body was 8–8.5, compared with a ratio of 5 between the two corresponding ICNIRP limits.

Wu et al (2006) used the FDTD method to study the SAR and temperature for various gestational ages. An MRI-derived model of the fetus and surrounding tissues was linearly scaled, and placed within a homogeneous female phantom. The shape of the mother's body surface was modified, and the fetus and uterus were scaled, to generate a model for each month of pregnancy. At the normal mode whole-body SAR limit, 2 W kg^{-1}, the local SAR in the mother's body exceeded the ICNIRP restriction. For the 64 and 128 MHz birdcage coils at 4 W kg^{-1}, the ICNIRP restrictions on the local SAR and temperature in the fetus (10 W kg^{-1} and 38°C) were approached or exceeded. At 64 MHz (1.5 T) the restrictions were exceeded from the fourth or fifth month onward. At 128 MHz (3 T), the field has a lower penetration depth. In this case the restrictions were approached, but not exceeded, in the last few months only.

5.3.4 Conclusions

Modern dosimetry using anatomically realistic models can account for the channelling of electric current through high conductivity tissues which occurs *in vivo*. Recent studies therefore raise the possibility of greater inhomogeneity in the SAR and current density than was accounted for in the studies reviewed by ICNIRP (2004).

Recent developments in dosimetry do not invalidate the ICNIRP recommendations, which were based on well-verified experimental results and basic physiological mechanisms. However, the new techniques should be taken as best practice in assessment of compliance for MRI equipment and compatibility of implants.

Calculations of SAR have shown that the local SAR distribution may be highly inhomogeneous, and sensitive to the coil design, frequency and body part exposed. In some circumstances the local SAR will exceed the ICNIRP limits before the whole- or partial-body SAR. It is necessary to take particular account of the local SAR distribution when designing control software.

Recent dosimetry suggests that the ICNIRP restrictions on local SAR and temperature may be approached or exceeded in the fetus during scans at the whole-body SAR limit for the controlled operating mode.

The SAR is greatly enhanced in the vicinity of metallic implants, particularly those with sharp points or edges such as leads. This enhancement is sensitive to the geometry of the implant and its location and orientation within the body.

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6 Acoustic Noise

6.1 Review of effects

Switched gradient fields are the primary source of acoustic noise associated with MRI procedures and ICNIRP (2004) states that this exposure to noise represents a potential risk to patients on systems operating above 0.5 T. A recommendation is made that hearing protection is offered to patients (and workers) when a noise level of 80 dB(A) is exceeded and that hearing protection is always worn at levels exceeding 85 dB(A), consistent with the action values in the Control of Noise at Work Regulations 2005 (GB Parliament, 2005). However, it should be noted that in the occupational regulations the action values are noise levels averaged over the working day or week. These time-averaged limits are not considered appropriate for patients and volunteers undergoing MRI procedures since the aim is not only to exclude the possibility of permanent hearing damage but also to provide protection against the discomfort that can be caused by the relatively short, but intense noise exposures they may experience. When time-averaged, these exposures may very well fall below the occupational limits.

It should further be noted that while it is generally the case that acoustic noise will increase at higher flux densities, systems at and below 0.5 T are capable of producing noise levels well in excess of 80 dB(A), (Price et al, 2006).

The risks of excessive noise exposure are well documented with regard to occupational and public exposures not associated with MRI (WHO, 1999, 2001).

6.1.1 Discomfort and stress

Excessive noise may cause immediate discomfort and stress. The threshold for discomfort in normal individuals is around 120 dB in the range 1–5 kHz (Flindell, 1998). However, those individuals suffering from auditory recruitment or hyperacusis may be discomforted by noise levels very much lower (Anari et al, 1999).

Noise is a stressor which can cause anxiety and changes in pulse and respiration rate (Bies and Hansen, 2003). It has been identified as one factor amongst others, such as temperature and claustrophobia, in heightening anxiety amongst patients undergoing MRI procedures (Quirk et al, 1989).

6.1.2 Temporary threshold shift

A short period of exposure to excessive noise with no protection can produce a temporary threshold shift in the sensitivity of hearing. This loss of sensitivity may be appreciated as a dulling in hearing at the end of the exposure and may be accompanied in some cases by tinnitus. Once the noise ceases, hearing may

recover to normal. However, if the noise exposure is especially severe or if it is continually repeated, particularly before a full recovery has occurred, there may be a permanent threshold shift.

The production of temporary threshold shifts in MRI has been demonstrated and almost certainly at noise levels lower than the 100 dB(A) sound pressure level that ICNIRP (2004) has suggested. Brummett et al (1988) measured the hearing of 24 patients before and after MRI on a 0.35 T system. Sound pressure levels were not measured as part of this study nor were pulse sequence types recorded. However, measurements by Hurwitz et al (1989) on the same model of scanner indicated that noise levels for gradient echo sequences, probably the loudest sequence used on such a system at that time, would have been around 93 dB(A). Pure tone audiometric thresholds were measured at a range of frequencies from 0.25 to 8 kHz. Fourteen patients were scanned without hearing protection. Six of these patients suffered a threshold loss greater than 15 dB at least at one frequency. Of the patients scanned with hearing protection, only one suffered a temporary threshold shift. All threshold changes returned to within 10 dB of the baseline within ten minutes.

This study may be contrasted to one carried out by Wagner et al (2003). In this, 123 patients were subjected to audiometric tests before and after MRI. All patients wore ear plugs and were also protected by the foam lateral head coil supports pushed against each ear. Out of 173 ears tested an elevation of audiometric threshold by 10 dB or greater in at least one measured frequency was found in 14 ears. Three ears showed either a threshold elevation greater than 10 dB at more than one frequency or an elevation greater than 15 dB at one frequency. However, 23 ears showed an improvement in hearing threshold. Of these, 14 ears showed a threshold improvement of 10 dB or greater at one frequency and nine ears showed a 10 dB threshold improvement at two or more frequencies or a 15 dB improvement at one frequency. Therefore the authors concluded that no significant temporary threshold shifts were measured.

Data from non-MRI exposures indicate that a clinically significant threshold shift (greater than 10 dB) may be avoided in most cases if noise levels are kept below 80 dB(A). Miller (1974) presented hypothetical curves for the growth and recovery of threshold shift after various single and continuous exposures to noise centred near 4 kHz. The hearing system is generally regarded as most sensitive to damage to sound around this frequency. These hypothetical curves were for average, normal hearing, young adults, and were based on data available at the time. The threshold shift was estimated at 4 kHz and measured two minutes after the end of the exposure. The data indicated that measurable temporary threshold shifts could be caused by noise exposures as low as 61 dB(A) if the exposure was extended to many hours. However, noise levels below 81 dB(A) did not appear to result in a threshold shift greater than 5 dB if the exposure was restricted to about an hour. At 86 dB(A) the threshold shift reached 10 dB after 30 minutes and 15 dB after 45 minutes.

Mills et al (1979) performed experiments on individuals using octave band noise centred at 0.5, 1, 2 and 4 kHz. The lower three frequencies are relevant in terms of the frequency spectrum associated with the acoustic noise associated with MRI procedures. The results showed that the sensitivity to threshold shift was lower as the test frequency was decreased. In the case of each frequency maximum threshold shifts (in terms of group medians) were negligible (less than 5 dB) for exposures below 80 dB(A) when the duration was less than an hour. A noise level of 86 dB(A) at 1 kHz was capable of producing a median threshold shift greater than 5 dB after about an hour.

6.1.3 Permanent threshold shifts and subjective effects

The threshold of instantaneous and permanent acoustic trauma normally associated with exposure to impulsive noise is 140 dB in adults. Commercial MRI systems in compliance with the IEC standard cannot produce a peak sound pressure greater than 140 dB (IEC, 2002). The highest noise levels recorded in the literature on a commercial MRI system were a continuous equivalent level of 128 dB and peak sound pressure of 138 dB for echo planar imaging at 3 T (Prieto et al, 1998).

Children may have a lower threshold and maximum peak noise levels of 120 dB are advised (Prasher, 2003). It is generally accepted that a noise level of 75 dB(A) will not give rise to a permanent threshold shift, however long the exposure (Prasher, 2003). Robinson et al (1994) stated that noise exposures of 85 dB(A) over many years may result in some effect but that it can only be demonstrated statistically in studies of large groups, not in individuals.

Therefore between 75 and 140 dB the risk of permanent noise-induced hearing loss is related to the intensity and duration of exposure. The energy equivalence principle is in widespread use in the estimation of noise hazard (WHO, 2001). A 3 dB(A) trading rule has been widely accepted. This means that an 85 dB(A) exposure averaged over an 8-hour working day is equivalent to a 30-minute exposure to 97 dB(A).

Given the normally limited exposure time involved, the potential risk to patients and volunteers undergoing MRI procedures is unlikely to involve the production of a permanent threshold shift.

Studies of people exposed to intense, continuous noise at music concerts where noise levels may reach 120 dB(A) (Clark, 1991) suggest that subjective effects not reflected in audiometric threshold tests, such as tinnitus and hypersensitivity, may occur and these effects may be permanent even after a single exposure (Schmuzigert et al, 2006).

De Wilde et al (2007) reported the case of a patient who suffered hearing loss accompanied by severe, unrelenting headaches, ear pains and dizziness after undergoing an MRI scan on a 0.5 T system without being given hearing protection. It had been assumed that noise levels would not be hazardous for a system at this flux density.

6.2 Hearing protection

Personal hearing protection in the form of ear plugs and ear muffs is a form of passive noise control based on absorption. 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 muffs may provide more attenuation than ear plugs depending on design. They are also easier to fit. However, they may be found uncomfortable to use in conjunction with some smaller head radiofrequency (RF) coils. Specially designed ear plugs and ear muffs are commercially available for babies and children.

For some clinical applications such as breath-hold scanning, good communication between the patient and radiographer is essential. MRI equipment manufacturers provide earphones for this purpose that attenuate the acoustic noise whilst allowing communication with staff.

The protection provided by personal hearing protectors is frequency dependent with generally less protection afforded at low frequencies. Typically up to 35 dB of protection is afforded at the frequencies of interest in MRI. The most accurate, standardised method of determining the effectiveness of hearing protection in use in Europe, involves the use of assumed protection values (HSE, 2005). Assumed protection values are determined by hearing protection manufacturers through audiometric measurements on a population of normal subjects. The effectiveness of protection to a particular noise frequency spectrum is then determined by performing an octave band frequency analysis of the noise and subtracting the assumed protection value for each band. The noise in each band is A-weighted and summed to give the effective noise level to the ear.

Ear plugs and ear muffs can be worn together if the noise is very intense, generally providing up to 6 dB of attenuation above the most effective form of protection when worn alone (HSE, 2005). However, measured attenuation data on the use of various plugs and muffs in combination are not generally available.

For noise exposures above 115 dB(A) (assuming 35 dB(A) of attenuation for ear plugs or ear muffs when used alone), using both in combination would be required to reduce noise at the ear to below 80 dB(A).

6.3 Fetal exposures

The existing evidence on the effect of noise (from non-magnetic resonance sources) on the fetus was reviewed by Hepper and Shahidullah (1994a) for the Health and Safety Executive. The issue of the noise exposures of pregnant patients during MRI was reviewed by De Wilde et al (2005).

6.3.1 Development of fetal hearing

The outer, middle and inner ear of the fetus appear anatomically fully formed by the 20th week of gestation enabling the fetus to begin to detect sounds (Pujol et al, 1990). The responsiveness of the fetus to auditory stimuli has been evaluated between 19 and 35 weeks of gestation (Hepper and Shahidullah, 1994b). This has shown that the fetus responds to low frequency sounds first. An initial response was elicited at 20 weeks to a 500 Hz pure tone. The range of frequencies capable of eliciting a response first expanded downwards to 250 Hz and 100 Hz and then upwards to 1000 Hz and 3000 Hz. As the pregnancy developed there was a marked reduction of 20–30 dB in the sound intensity level required to elicit a response.

6.3.2 Sound transmission to the fetus

Transmission of sound to the fetal inner ear will involve very different mechanisms to those after birth (Sohmer and Freeman, 2001). There is evidence from human, animal and non-biological phantom studies that exogenous noise reaching the fetus is effectively low-pass filtered by maternal tissues and fluids surrounding the fetal head (Richards et al, 1992; Hepper and Shahidullah, 1994a; Gerhardt

and Abrams, 1996, 2000; Lecanuet et al, 1998). Richards et al placed a hydrophone in the uterus of nine pregnant women and exposed them to sounds of varying frequencies. At low frequencies (0.125 kHz) there was a small mean enhancement of sound pressure levels (3.7 dB), whilst attenuation increased at higher frequencies to 10 dB at 4 kHz.

Noise transmission to the fetus from MRI has been modelled using a hydrophone in a male volunteer's stomach (Glover et al, 1995). An attenuation of at least 30 dB in acoustic intensity was measured across the frequencies of interest by assuming the abdomen had the acoustic impedance of water. The use of sound intensity level rather than sound pressure level will tend to give a larger apparent attenuation because of the large difference in acoustic impedance between air and water. It was also found that the patient couch mattress played an important role in mechanically isolating the volunteer from vibration in the patient couch. Performing the experiment with the volunteer placed directly on the couch increased sound intensity levels by about 10 dB.

6.4 Animal studies of intense noise exposure

Animal studies have provided evidence for fetal hearing damage from intense noise exposures (Gerhardt et al, 1999). Pregnant ewes carrying fetuses at 111 days gestational age (dGA) were exposed to three 16-hour sessions of broadband noise exposure at 120 dB. At 137 dGA the animals were slaughtered and the fetal cochlears harvested. Scanning electron micrographs showed damage to inner and outer hair cells in comparison with an unexposed control group. Damage included missing or distorted stereocilia, phalangeal scarring and cytoplasm ballooning out of the hair cells. It was most severe at the apical turn of the cochlear. The middle turn had received some damage whilst the basal turn was apparently undamaged. This pattern of damage is quite different to that seen in mammals (including humans) after birth. Hearing damage appears towards the basal end of the basilar membrane where higher frequencies are detected.

It has also been suggested from studies of altrical animals after birth, that there is a critical period of auditory development where the risks of fetal hearing damage from noise are greater (discussed by Hepper and Shahidullah, 1994a, and by Pierson, 1996).

6.5 Occupational exposures of pregnant women

Two studies have examined the hearing of children whose mothers were exposed to high noise levels occupationally during pregnancy (Daniel and Laciak, 1982; Lalande et al, 1986). Both studies identified a small degree of hearing loss in some subjects. Lalande et al concluded that prenatal noise exposure to sound pressure levels between 85 and 95 dB increased the risk of hearing damage in children by a factor of three compared to prenatal exposure levels of up to 85 dB. There was some evidence of damage to low frequency hearing in children whose mothers were exposed to noise with a significant low frequency component (although what was meant by low frequency was not defined by the authors). The studies in question have been criticised for various methodological errors including lack of adequate controls and retrospective noise evaluations (Hepper and Shahidullah, 1994a; Pierson, 1996; Etzel et al, 1997).

6.6 Effects on reproductive outcomes

Etzel et al (1997) reviewed the hazards of noise to the fetus and the newborn. They concluded there was some evidence of shortened gestation and decreased birth weight from excessive noise exposure during pregnancy. The evidence was from a small number of studies all associated with extended occupational or public exposures. Hepper and Shahidullah (1994a) concluded that any effect on reproductive outcomes from noise is probably indirect due to its role as a stressor on the mother and that reducing this stress through the provision of suitable hearing protection may reduce the risks.

6.7 Follow-up studies after MRI

Three follow-up studies of children exposed to MRI *in utero* have been published that included hearing tests (Baker et al, 1994; Clements et al, 2000; Kok et al, 2004) (see Section 3.2). Baker et al performed a 3-year follow-up study of children imaged *in utero* at between 20 and 40 weeks' gestation with echo planar imaging. Out of 18 children, 2 failed their 8-month distraction test. The expected failure rate is 7%.

Clements et al performed a prospective case-controlled observational study of infants exposed to echo planar imaging *in utero* after 20 weeks' gestation. A hearing distraction test was performed as part of a detailed paediatric assessment at 9 months of age. Out of the 19 infants tested, 1 failed compared with 4 out of 28 in the control group.

Kok et al examined 35 children exposed to MRI in the third trimester of pregnancy. No adverse effect on hearing was identified, although the nature of the tests was not described.

Although no effects on hearing could be identified, the small sample sizes make it difficult to draw any definite conclusions from the studies. Qualitative hearing tests performed such as the distraction test may not be sufficient to rule out mild hearing loss.

6.8 Summary

Although there is little risk of a permanent threshold shift in hearing in those exposed to acoustic noise associated with MRI procedures on a one-off or occasional basis, certain scans may exceed the discomfort threshold, particularly for sensitive individuals. Temporary threshold shifts can be induced if patients and volunteers are not adequately protected, which may cause discomfort and be accompanied by other effects such as tinnitus. There is some limited subjective evidence from leisure-related noise exposures and MRI adverse incident reports that permanent effects may be induced in unprotected subjects.

Clinically significant temporary threshold shifts in patients and volunteers undergoing MRI are unlikely in most subjects for noise levels below 85 dB(A), given the relatively low frequencies encountered in MRI, and the typical examination times of less than an hour. However, there are variations in sensitivity between individuals, in terms of both the threshold of discomfort and the production of temporary threshold shifts. ICNIRP recommended giving patients or volunteers the choice of whether to wear

protection if noise levels fall between 80 and 85 dB(A). If followed, this recommendation may inadvertently result in some sensitive patients feeling discomfort or receiving a clinically significant temporary threshold shift, particularly if the examination time is relatively long.

6.9 References

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7 Protection of Patients and Volunteers

7.1 General advice

In formulating its advice, the HPA has considered the ICNIRP recommendations (ICNIRP, 2004) and additional studies published since then. Some of these used static magnetic fields of around 8 T, and, as in the previous studies, the continued absence of evidence of adverse health effects, is noted. Thus, the HPA advice is to allow somewhat higher exposure to static magnetic fields than those recommended by ICNIRP in 2004, but only under carefully controlled exposure conditions. Importantly, in the case of patients, the decision criteria should include the care of the patient by suitably qualified medical staff, and consideration of the potential benefit for the patient. Volunteer studies are helpful in the development of new MRI techniques and consequently of potential benefit for patients. The safety of volunteers is paramount and such studies must be subject to ethics committee approval and carried out with appropriate consideration of the medical circumstances*.

Appropriate consideration of the medical circumstances will vary depending on the subject's situation and the type of scanning to be undertaken and will be influenced by various factors, including the physical proximity of the MRI unit to any acute medical facilities and/or appropriate medical expertise. The nature of the appropriate consideration of medical circumstances should form part of the MRI unit's local rules, or be outlined in the ethics submission, if appropriate.

For example, when scanning apparently healthy volunteers, it may be sufficient simply to include questions on the normal MRI safety screening form to allow the exclusion of people with risk factors such as impaired thermoregulation (eg including pyrexia or conditions leading to poor circulation). In other circumstances, a medically qualified person may need to be present in the MRI unit, or provision may need to be made for medical help to be summoned in an appropriate time frame.

In arriving at the following recommendations, the HPA was cognisant of the clear benefits to individual patients undergoing MRI examinations and more generally, through research involving volunteer exposures, to increasing medical knowledge.

* Following advice from the National Research Ethics Service (NRES), it should be noted that under the Research Governance Framework for Health and Social Care, experimental procedures require ethical review where they are to be carried out in the formal research setting and managed as research. If undertaken outside the research setting, ethical review and research and development approval would not be required, although many NHS organisations have clinical ethics committees that would be an appropriate source of advice. National Institute for Health and Clinical Excellence (NICE) guidance on the interventional procedures programme will apply in such cases.

Clinical judgement is of paramount importance when considering the exposure of patients to clinical MRI for diagnostic purposes; the need for an MRI examination and the provision of appropriate and accurate clinical information about the patient is the responsibility of a medical practitioner. Once a person attends an MRI unit, responsibility for their safety due to the MRI environment is taken by authorised staff in the unit.

Where MRI examinations form part of a research project, the health and safety of volunteers should be managed strictly in accordance with the research protocol and the terms of ethical approval by a relevant body. The UK body that oversees research ethics issues is the National Research Ethics Service (NRES, 2008). The person with overall responsibility for conduct of the research should provide relevant information to the ethics committee, sufficient for the committee to reach a judgement. This might include information about impairment in thermoregulation and about sensitivity to electric fields in the central nervous system, together with any other parameters relevant to the safety and well-being of the patients and volunteers. It is acknowledged that the risks associated with ultrahigh field exposures cannot be quantified at present with precision. Further information about ethical review of research in the UK can be obtained from the NRES website (NRES, 2008).

After reviewing the scientific evidence, the rationale adopted by ICNIRP for limiting exposures of patients and volunteers to static magnetic fields, switched gradient fields and radiofrequency (RF) fields during MRI procedures remains appropriate and justified. However, for static magnetic fields, the recommended limits indicate a particularly cautious approach and impact on the ability to perform routine clinical MRI using high field scanners.

The three tiered approach proposed by ICNIRP affords adequate levels of protection to patients and volunteers as well as providing no hindrance to routine clinical imaging. Additionally, it provides flexibility for research and for the further development of diagnostic procedures.

People with epilepsy or taking drugs that lower seizure activity may exhibit increased sensitivity to stimulation by the electric fields induced in the central nervous system, and these people should be imaged with caution. Similarly, very little is known about the effects of static magnetic fields in excess of a few tesla on growth and behavioural development of fetuses and infants, suggesting some caution is warranted regarding their imaging. There are uncertainties concerning the effects of increased heat loads on infants and pregnant women, and on people with impaired thermoregulatory ability as a result of age, disease or the use of medications. These people should be imaged with caution.

A summary of the proposed limits for static, switched gradient and RF fields during MRI procedures for patients and volunteers is given in Table 7.1.

TABLE 7.1 Summary of proposed limits for static, switched gradient and radiofrequency fields during MRI procedures for patients and volunteers* (where values are modified from those in ICNIRP (2004), the values suggested by ICNIRP are given in italics, in parentheses)

			Radiofrequency fields			
				Temperature limits (°C)		
Mode	Static field (T)	Switched gradient fields‡	Rise in body core temperature (°C)	Head	Trunk	Limbs
Routine operating mode	4 *(2)*	80% median perception threshold	0.5	38	39	40
Controlled operating mode†	8 *(4)*	100% median perception threshold	1	38	39	40
Experimental operating mode	>8 *(>4)*	120% median perception threshold (avoid intolerable stimulation)	2 *(>1)*	39 *(>38)*	40 *(>39)*	41 *(>40)*

* Adherence to a system of working practices involving limiting the speed of motion of patients and volunteers through the field is assumed.

† The use of the *controlled operating mode* should be restricted as far as possible during pregnancy, and for infants, for people with epilepsy or taking drugs that lower seizure activity, and for people with impaired thermoregulatory ability.

‡ Indicative perception thresholds are provided by Nyenhuis et al (2001).

7.2 Static magnetic fields

The values advised by ICNIRP for static magnetic fields seem overly cautious in the light of the results of recent studies and ongoing and accumulating clinical experience. It is recommended that until further information becomes available, the limits should be relaxed and modified for each operating mode, as follows.

a During routine procedures (termed the *normal operating mode* by ICNIRP) there should be an upper limit for whole-body exposure of 4 T.

b For specific examinations outside the *normal operating mode* and carried out with appropriate consideration of the medical circumstances (*controlled operating mode*), there should be an upper limit for whole-body exposure of 8 T.

c For experimental procedures also carried out with appropriate consideration of the medical circumstances, and for which special ethical approval is required (*experimental operating mode*), there should be a limit above 8 T. No upper limit has been specified, but a progressively cautious approach is suggested for increasingly high magnetic flux densities due to uncertainties regarding possible effects of flow potentials on heart function. In light of these possible effects, it is concluded that patients and volunteers should be exposed to such fields only with appropriate physiological monitoring of pulse rate.

There is a need to ensure that patients and volunteers continue to be moved slowly into the magnet bore, to avoid the possibility of vertigo and nausea. Thresholds for motion-induced vertigo have been estimated to be around 1 T s^{-1} for greater than 1 s. Avoiding these sensations is likely to afford protection against the other effects of induced electric fields and currents that arise as a consequence of motion in a static field.

7.3 Switched gradient fields

The biological basis used by ICNIRP for limiting exposure of patients and volunteers to switched gradient fields is the avoidance of intolerable stimulation of peripheral nerves and muscles. It is recommended that, until further information becomes available, ICNIRP limits should be followed for switched gradient fields for each operating mode.

a During routine procedures (*normal operating mode*), there should be a limit on the rate of change of the magnetic field (dB/dt) of 80% of the median perception threshold for peripheral nerve stimulation, as defined by equation 1 in the ICNIRP recommendations*.

b For specific examinations outside the *normal operating mode* and carried out with appropriate consideration of the medical circumstances (*controlled operating mode*), there should be a limit on dB/dt of 100% of the median perception threshold, as defined by equation 1 in the ICNIRP recommendations.

ICNIRP provided no explicit guidance for the procedures carried out under the *experimental operating mode*. However, ICNIRP indicated that intolerable stimulation would interfere with an examination and should be avoided. The lowest percentile for intolerable stimulation equates to approximately 20% above the median perception threshold, and it is suggested that a limit on dB/dt of 120% of the median perception threshold, as defined by equation 1, should apply.

7.4 Radiofrequency fields

ICNIRP limited patient and volunteer exposures to RF fields by restricting the rise of body and tissue temperatures in order to avoid possible adverse thermal consequences. Thus it is recommended that, until further information becomes available, the ICNIRP guidelines should be followed for RF fields for each operating mode. However, in addition an upper temperature limit should be specified for the *experimental operating mode*. Making the conservative assumption that thermoregulatory mechanisms can be ignored, appropriate SAR limits for the *experimental operating mode* could be obtained by scaling the ICNIRP limits on SAR in proportion to the temperature rise. In addition, it is recommended that the correction factors advised by the IEC (2002) are used to adjust the whole-body SAR in high ambient temperatures and/or high relative humidity, as follows.

* The median perception threshold is described by $dB/dt = 20(1 + 0.36/\tau)$ T s^{-1}, where τ is the effective duration of the induced electrical stimulus in milliseconds (ICNIRP, 2004).

a During routine procedures (*normal operating mode*), there should be a limit of 0.5°C on rise in whole-body temperature, and limits on temperature of 38, 39 and 40°C on the head, trunk and limbs, respectively. This is the preferred mode for normal imaging.

b For specific examinations outside the *normal operating mode* and carried out with appropriate consideration of the medical circumstances (*controlled operating mode*), there should be a limit of 1°C on rise in whole-body temperature, and limits on temperature of 38, 39 and 40°C on the head, trunk and limbs, respectively. Particular consideration should be given to restricting the use of the controlled mode as far as possible for imaging infants, pregnant women, febrile patients and others with impaired thermoregulatory ability or with compromised peripheral circulation.

c For experimental procedures, carried out with appropriate consideration of the medical circumstances and for which special ethical approval is required (*experimental operating mode*), whole-body and local tissue temperatures can exceed those specified for the *controlled operating mode*. It is recommended here that there should be a limit of 2°C on rise in whole-body temperature, and that local tissue temperatures should not exceed 39, 40 and 41°C on the head, trunk and limbs, respectively, in order to avoid tissue damage. These temperatures are unlikely to be exceeded provided that the local SAR (averaged over 10 g) is limited to 15 W kg^{-1} in the head and trunk and 25 W kg^{-1} in the limbs, and the whole-body SAR is limited to 8 W kg^{-1}.

7.5 Acoustic noise

Noise levels can exceed 85 dB(A) in almost all commercial MRI scanners, and it is difficult in practice to measure or predict noise levels for each pulse sequence. Therefore, it would be prudent at present, to fit hearing protection on all patients and volunteers as a matter of course. Hearing protection should be selected that reduces the noise at the ear drum to below 85 dB(A). For particularly intense exposures, above 115 dB(A), the use of both ear plugs and ear muffs would be advisable, although it is recognised that the extra attenuation provided may be difficult to quantify.

As suggested by ICNIRP, headphones are superior to other forms of hearing protection; however, manufacturers should be encouraged to provide attenuation data according to the relevant standards so that users can ensure that the protection is adequate at the frequencies of interest. The manufacturers of MRI equipment should also be encouraged to consider the acoustic properties of patient couch mattresses, in order to ensure, as far as possible, that the patient or volunteer is mechanically isolated from any vibration in the patient couch.

An important principle of noise control is that the elimination of noise at source is always preferable to reliance upon personal hearing protection that may sometimes fail (HSE, 1998). The encouragement by ICNIRP of the further development of noise reduction technology, such as quiet gradient coils, is in accord with this principle. It seems reasonable to suggest that if noise reduction measures reduce noise levels to comfortably below 80 dB(A), the requirement for hearing protection may be relaxed.

7.6 Other considerations

A key element in improving the health risk assessment can come from surveillance of adverse outcomes. If clinically relevant reactions are observed following MRI procedures, and particularly with very high static fields, then it is essential that these are reported to the MRI medical and research community. This is particularly important in the absence of epidemiological or experimental data.

It is further recommended that all MRI units should draw up a set of local rules which will set out the policies and protocols to be followed to ensure the safety of people in the MRI unit, including patients and volunteers. Advice on this is given in Appendix A.

7.7 References

ICNIRP (2004). Medical magnetic resonance (MR) procedures: protection of patients. *Health Phys,* **87**(2), 197–216.

IEC (2002). Medical Electrical Equipment. Part 2-33: particular requirements for basic safety and essential performance of magnetic resonance equipment for medical diagnosis. IEC 60601-2-33:2002. Geneva, International Electrotechnical Commission.

NRES (2008). National Research Ethics Service, www.nres.npsa.nhs.uk/ (accessed March 2008).

Nyenhuis JA, Bourland JD, Kildishev AV and Schaefer DJ (2001). Health effects and safety of intense MRI gradient fields. In Magnetic Resonance Procedures: Health Effects and Safety (FG Shellock, Ed). Boca Raton, CRC, pp 31–52.

8 Research Recommendations

The overall health risk assessment for MRI procedures is incomplete, and needs to be addressed through additional well-targeted, high quality research. A range of high priority studies are recommended for epidemiology, biology and dosimetry associated with exposures to electromagnetic fields, and for acoustic noise.

The recommendations for static magnetic fields are consistent with and extend those suggested by the WHO (2006) and by an international ICNIRP/WHO workshop which considered the effects of static magnetic fields relevant to human health (summarised by Sienkiewicz, 2005). In addition, the recommendation for switched gradient fields parallels a similar recommendation made by an international NRPB/WHO/ICNIRP workshop which considered the effects of weak electric fields on the functions of the central nervous system (Saunders, 2003).

8.1 Epidemiology

Overall, while the epidemiological evidence does not suggest that any long-term adverse health effects would be associated with MRI procedures, the weight that can be placed on this evidence is limited. Importantly, there is an absence of studies investigating mortality or cancer incidence among patients or volunteers undergoing MRI procedures. Information concerning non-cancer health outcomes may also be of merit, due to the paucity of relevant data, but would be allocated a lower priority. In any future epidemiological studies, particular attention should be given to: characterising exposures accurately and precisely; maximising the study size, possibly by collecting data from several centres using a common protocol; and, when following patients who have undergone an MRI procedure, taking into account the condition that led to the examination.

It is recommended that consideration is given to carrying out the following studies.

a A study investigating cancer risks

Rationale There is an absence of studies investigating cancer incidence among patients or volunteers undergoing MRI procedures and this would complement experimental studies of the carcinogenic potential of exposure to static magnetic fields (see Section 8.2).

b A follow-up study of pregnancy outcomes

Rationale This is desirable in view of the increasing numbers of women undergoing MRI procedures during pregnancy.

The effect of acoustic noise on fetal hearing is another area of uncertainty. Evidence for fetal hearing damage comes from animal studies with intense noise of exposure durations far longer than would be

used in MRI procedures, or from methodically weak studies of occupational exposures in people. However, there is a coincidence between the suggested susceptibility of the fetus to low frequency hearing damage and the frequencies encountered in MRI. This warrants further investigation. In particular, the following is therefore recommended.

c Larger follow-up studies investigating the hearing of children exposed *in utero*, involving audiometric testing across a range of frequencies including low and mid-frequencies

Rationale This will provide a firmer basis for the assessment of hearing in people following fetal exposure.

8.2 Biology

8.2.1 Human laboratory studies

a Further studies of the effects of static magnetic fields greater than 8 T on human cardiac function and other vital signs

Rationale Flow potentials and an increased resistance to blood flow occur in blood vessels of people exposed to strong magnetic fields, but it is not clear at what flux density these effects might be of physiological significance. Theoretical calculation and volunteer studies indicate that adverse effects do not occur at fields up to 8 T. However, the development and use of MRI systems using higher flux densities depend on adequate knowledge of possible adverse health reactions.

b Further studies of the responses of the central nervous system to the electric fields and currents induced by exposure to switched gradient fields, and by body movement in the static field gradients, particularly around the magnet bore

Rationale There is evidence that induced electric fields and currents contribute to the sensations of vertigo, nausea and phosphenes, during movement, and to peripheral nerve stimulation during exposure to the switched gradient fields. In addition, there are uncertainties regarding effects on cognitive processes. There is a need to characterise more completely these effects and the conditions under which they arise.

8.2.2 Animal laboratory studies

a Exploratory studies of the possible effects of very intense fields on cardiac function in animals

Rationale These studies would usefully supplement volunteer studies of possible cardiac effects during exposure to intense static magnetic fields. Although there are data suggesting that exposure of animals to fields of around 8 T does not produce arrhythmias, it would be useful to explore the effects of considerably higher fields, say of up to 20 T.

b Long-term animal studies to investigate the carcinogenic potential of exposure to static fields – such studies might be usefully combined with an analysis of immediate and early genomic and proteomic responses

Rationale There are at present no long-term studies assessing the potential carcinogenicity of exposure to the high static magnetic fields associated with MRI. In the absence of epidemiological data, such fields therefore remain unclassifiable with regard to their carcinogenicity.

c Further studies of the effects of prenatal and early postnatal exposure to static magnetic fields above 1 T on juvenile and adult behaviour

Rationale There is a need to supplement existing studies concerning possible effects on reproduction and development with experimental studies on exposure to fields above 1 T; the assessment of neurotoxicity is a particularly sensitive assay of possible teratogenesis.

8.3 Dosimetry

a More detailed numerical dosimetry for MRI systems of 8 T and above using anatomically realistic models and modern dosimetric techniques

Rationale At present, there are few published computational dosimetry studies related to static fields in and around MRI systems. In the future, the demand to carry out MRI at higher flux densities looks likely to continue. Because of this, there is a requirement, in line with expected research into biological effects in ultrahigh fields of 8 T and above, to perform the corresponding computational studies for these new MRI systems. In particular, there is a need to model the effects of electric flow potentials on heart function. The accurate calculation of induced electric fields and currents in the body at these higher flux densities is also required.

b Further research to improve techniques in thermal dosimetry

Rationale It would be desirable to use temperature rise, rather than the SAR, as the primary quantity for compliance assessment. In particular, this would allow attention to be focused on tissues and organs which are most prone to temperature rise, and avoid overly conservative SAR restrictions on other tissues. However, thermal dosimetry is not yet sufficiently well established to enable the routine calculation of temperature in compliance assessment. The relationship between local SAR and temperature rise is based on the Pennes bioheat equation, which is no longer strictly applicable when the body core temperature is significantly modified or thermoregulatory mechanisms are activated. The thermal parameters necessary for temperature calculation are well known for the most common tissues, but no comprehensive and agreed database exists.

c Development of a thermal model of the fetus

Rationale Work in support of protection of the fetus during MRI procedures must have high priority. An adequate model of the thermal behaviour of the fetus should address all significant mechanisms of heat exchange with the mother, including counter-current heat exchange in the placenta and convection of the amniotic fluid.

d Improved estimates of local SAR in anatomically realistic models, and better definition of spatial averaging of induced fields and currents, and SAR

Rationale Recent dosimetric studies suggest that the local (10 g averaged) SAR may exceed the whole- or partial-body SAR by a substantial factor. Further, the definition of local SAR is sensitive to the procedure chosen for averaging. Further modelling should be carried out to determine the required safety factors to be applied in the machine control software for MRI systems.

e Induced electric field and current calculations using realistic gradient waveforms

Rationale Much of the work on this topic has used assumed gradient waveform characteristics, such as a train of bipolar trapezoids, applied in only one direction. Real systems involve different waveforms being applied simultaneously to each set of gradient coils and the character of each waveform is more complicated than simple trapezoids. Induced electric fields and currents in the body should be calculated using measured gradient fields for a range of systems, and summing together the contributions of all orthogonal field components in the time domain.

8.4 References

Saunders RD (2003). Rapporteur report: weak field interactions in the central nervous system. In Proceedings International Workshop on Weak Electric Field Effects in the Body, NRPB, Chilton, March 2003. *Radiat Prot Dosim,* **106**(4), 357–61.

Sienkiewicz Z (2005). Rapporteur report: implications for guidelines. In Proceedings International Workshop on Effects of Static Magnetic Fields Relevant to Human Health, NRPB, Chilton, April 2004. *Prog Biophys Mol Biol*, **87**(2–3), 289–320.

WHO (2006). Static Fields. Environmental Health Criteria 232. Geneva, World Health Organization. Available at www.who.int (accessed March 2008).

Glossary

Accommodation (of nerve) The property of a nerve by which it adjusts to a slowly increasing level of stimulus, so that its threshold of excitation is greater than it would be were the stimulus level to have risen more rapidly.

Acoustic impedance A frequency-dependent property of a material defined as the product of its density and acoustic velocity.

Action potential (nerve impulse or 'spike') A sudden, brief reversal of the local membrane electric potential that occurs once a threshold depolarisation has been exceeded and which quickly propagates down a nerve axon conveying 'digitally' encoded information.

Adverse health effect A biological effect which has a detrimental effect on mental, physical and/or general well-being of exposed people, either in the short-term or in the long-term.

Attenuation The reduction in amplitude and intensity of a signal, usually measured in units of decibels per unit length of medium (dB m^{-1}) and represented by the attenuation coefficient of the medium in question.

Auditory recruitment An auditory impairment caused by damage to the cochlear cells, resulting in an inability to hear quiet sounds while louder sounds may be painful.

B_1 The term used to describe the RF field which is used to excite the spin system and tilt its magnetisation into a direction perpendicular to the direction of the main magnetic field. The RF field is applied at the Larmor frequency, ie a resonance condition.

B_0 The term used to describe the static magnetic field in an MRI scanner, the field used to align the magnetic moments or spin system along the long axis of the magnet bore.

Biological effect A measurable change in a biological system in response, for example, to an electromagnetic field.

Birdcage coil A type of volume coil consisting of a number of wires running along the z-direction, arranged to give a cosine current variation around the circumference of the coil. The coil consists of parallel spaced conductors (rungs) on the surface of a cylinder, and end conductors in the form of an end cap and a ring or a pair of end rings transverse to the rungs.

Blood–brain barrier The mechanism whereby the circulating blood is kept separate from the tissue fluids surrounding the brain cells. It is a semi-permeable membrane allowing solutions to pass through it but excluding solid particles and large molecules.

Body coil The coil that is generally permanently installed in a scanner to transmit and receive the RF signal. If local receive-only coils are used – for instance, to study the head – then the body coil serves as the transmit coil.

Case–control study An epidemiological study in which people who have developed a health outcome (cases) are identified, and their earlier exposure to putative causes is compared with that of controls who have not developed the health outcome.

Central nervous system The cells, such as neurons and glial cells, of the brain and spinal cord. It includes the retina, which is formed as an outgrowth of the forebrain.

Chronaxie The stimulus duration at which the threshold for stimulation is twice the rheobase value.

Cohort (cohort study) An investigation involving the identification of a group of individuals (the cohort) about whom certain exposure information is collected, and the ascertainment of occurrence of diseases at later times. For each individual, information on prior exposure can be related to subsequent disease experience. Cohort studies may be conducted prospectively or retrospectively.

Computational dosimetry The method used to provide predictions of the fields and currents produced inside the body by a known external field or source.

Confounding Misleading findings due to the failure to take account of one or more variables that are correlated with the exposure of interest and, independently, are related to the disease under investigation. A confounding variable can lead to a false conclusion about whether or not there is a causal relationship between exposure and disease.

Contrast agent A substance administered to the subject to increase the image contrast between different tissues, thus improving the delineation of the target tissue.

Core (or deep) body temperature The 'average' temperature of tissues deep within the body, which is normally regulated around a 'set point' value of approximately 37.5±0.5°C, as distinct from, for example, the temperatures of the skin and peripheral tissues of the limbs, which are more labile.

Cross-sectional study A descriptive study in which disease and exposure status are measured simultaneously in a given population.

Decibel (dB) The dimensionless logarithmic unit expressing the magnitude of a physical quantity as a ratio relative to a specified or implied reference level. Sound pressure level is a logarithmic measure of the root mean square (rms) sound pressure relative to a reference value of 20 micropascals. The suffix A or (A) denotes the so-called 'A-weighting' which is used to account for the variation in perceived loudness according to the frequencies present in the noise.

Depolarisation A decrease in the value of a cell membrane potential from its normal resting value conventionally described as around −70 mV, the inside of the cell being negative compared to the outside.

Diamagnetism The magnetisation of a substance which exists only in the presence of an externally applied magnetic field, and in a direction which opposes the external field (see *magnetic susceptibility*).

Diameter spherical volume (DSV) The region inside the bore where the applied polarising magnetic field B_0 is controlled to be highly homogeneous, and the imaging gradients are highly linear.

Diastole The period of relaxation of heart muscle, following contraction (systole).

Diffusion MRI A technique that produces *in vivo* images of biological tissues weighted with the local microstructural characteristics of water diffusion.

Dosimetry Evaluation of the absorbed dose or dose rate by an object in an electric, magnetic or electromagnetic field.

Echo planar imaging (EPI) A gradient echo technique that uses ultra-fast switching of the imaging gradients to allow the acquisition of an image in less than 100 ms.

Ectopic (heart) beats The term applied to extra heart beats, representing the most common disturbance of heart rhythm.

Eddy currents Electric currents induced in the magnet housing and other conducting objects within the magnet bore, when the currents through the gradient coils are turned on and off. Eddy currents can cause image distortion and loss of signal.

Electric field strength (E) The force on a stationary unit of positive charge when placed in an electric field. The magnitude of the electric field vector (unit V m^{-1}).

Epidemiology Study of the distribution of disease in populations and of the factors that influence this distribution.

Fast spin echo sequence A sequence that acquires an image very quickly by using many RF pulses, also known as turbo spin echo.

Ferromagnetism The phenomenon by which a material, such as iron, becomes magnetised when placed in an external magnetic field, and remains magnetised when it is no longer in the field (see *magnetic susceptibility*).

Fibrillation (ventricular) The loss of organised, synchronous contractions of the ventricle.

Flip angle (excitation pulse, pulse angle) The angle by which magnetisation is tilted when a spin system is excited by an RF pulse. The angle can be varied by changing the shape, strength and duration of the excitation pulse applied.

Fourier transform Mathematical operation needed to reconstruct MRI images from raw data.

Frequency The number of cycles per second of a periodically varying quantity. Frequency has the unit hertz (Hz).

Functional MRI (fMRI) A technique used to map blood flow changes in the brain that reflect cortical responses to activity or stimulation.

Gene expression The production of a functional protein or an RNA molecule from genetic information (genes) encoded by DNA.

Gradient A spatial variation in the amplitude of the B_0 field to allow spatial encoding of information contained in the emitted RF signal. The gradients are generated by three orthogonal coils, placed in the bore of the scanner, that will create field variations along the x-, y- and z-axes of the scanner. The z-axis corresponds to the longitudinal axis of the patient, the x-axis to the transverse direction, and the y-axis to the anterior–posterior direction.

Gradient echo (GRE) sequence A type of MRI sequence that uses RF pulses, but which is more sensitive to magnetic field inhomogeneities than spin echo imaging, leading to signal drop out and image distortion. An advantage is this type of sequence can generally produce a shorter scan time.

Interventional MRI (iMRI) In this procedure the images produced by an MRI scanner are used to guide an invasive procedure intraoperatively and/or interactively. It normally requires the use of an 'open bore' magnet which permits the operating staff better access to patients during the operation.

Isocentre The geometric centre of the main magnetic field of an MRI scanner.

Larmor frequency The frequency at which spins precess about a magnetic field. The precession or resonance frequency is proportional to the strength of the magnetic field applied.

Lorentz force The force exerted on a charged particle in an electromagnetic field. The particle will experience a force due to electric field and, if it is moving, due to the magnetic field as well.

Magnetic flux density (*B*) The amount of magnetic flux per unit area of a cross-section, perpendicular to the direction of the flux. It is the product of the magnetic field strength and the permeability of the medium, and has the unit tesla (T).

Magnetic susceptibility A measure of the extent to which a tissue or substance becomes magnetised when placed in an external magnetic field.

Magnetic resonance angiography An MRI technique that uses sequences providing good vessel-tissue contrast for generating images of blood vessels.

Magnetic resonance spectroscopy (MRS) A non-invasive means of obtaining metabolic information based on the detection of signal from molecules containing hydrogen, phosphorus, sodium and other nuclei. The technique offers unique biochemical information from various organs and tissues and is therefore increasingly applied to improve tissue characterisation in normal and pathological states.

Membrane (transmembrane) potential The electric potential difference (voltage) across a cell's membrane.

Microstrip A concept used in the design of RF surface coils for high field MRI/MRS systems.

Neural network A group of interacting neurons.

Paramagnetism The magnetisation which occurs only in the presence of an externally applied magnetic field and in the direction of the applied field (see *magnetic susceptibility*).

Perfusion The amount of blood flowing through the vessels of a specific organ.

Peripheral nervous system The part of the nervous system that mainly deals with the voluntary and conscious aspects of neural control such as voluntary muscle (motor) contraction and sensations such as those of warmth or pressure. The cell bodies lie within the spinal cord, but the peripheral nerves (axons) terminate on muscle fibres or in specialised sensory receptors throughout the body.

Phalangeal scars The sites of hair cell degeneration where supporting cells seal the luminal surface.

Phase The angle by which a rotating magnetic vector of a precessing spin in the x–y-plane differs from that of a second vector.

Phosphene The perception of flickering light in the periphery of the visual field induced by non-visual means such as a transretinal electric current.

Prospective study An epidemiological study in which data on exposures and disease outcome are collected as the events occur (*cf* retrospective study). Some cohort studies are conducted prospectively.

Pulse sequence A pulse sequence is a pre-selected set of defined RF and gradient pulses, usually repeated many times during an MRI scan, wherein the time interval between pulses and the amplitude and shape of the gradient waveforms will control magnetic resonance signal reception and affect the characteristics of the scan. The sequence is controlled by computer programs that control all hardware aspects of the MRI measurement process.

Quench The sudden loss of superconductivity in an MRI system, with the consequent breakdown of the static magnetic field.

Relative risk The ratio of the disease rate in the group under study to that in a comparison group, with adjustment for confounding factors such as age, if necessary.

Retrospective study An epidemiological study in which data on exposures and disease outcome are collected some time after the event (*cf* prospective study). Examples include case–control studies and some cohort studies.

Rheobase The minimal electric current duration that results in an action potential or the contraction of a muscle. In the case of a nerve or single muscle cell, rheobase is half the current that needs to be applied for the duration of chronaxie to result in an action potential or muscle twitch.

Rise time A parameter that describes the performance of a gradient field. It is the time it takes to reach maximum gradient amplitude.

Shielding The reduction of stray magnetic fields outside the magnet, either actively by the use of secondary coils or passively by the use of ferromagnetic materials.

Signal to noise ratio (SNR) A measure of image quality expressed as the relationship between signal intensity and image noise.

Slew rate The parameter that describes the rate of change of a gradient amplitude, defined as the maximum gradient strength divided by the rise time.

Specific energy absorption rate (SAR) The rate of absorption of electromagnetic energy per unit body mass, usually expressed in watts per kilogram.

Spin The feature of a particle that relates to its ability to undergo nuclear magnetic resonance. A fundamental property of almost all elementary particles (protons, neutrons and electrons).

Spin echo (SE) sequence The most widely used pulse sequence in routine clinical MRI. The sequence consists of an excitation pulse with a flip angle of exactly 90° which is followed by a 180° RF pulse for refocusing the spins after the dephasing caused by transverse relaxation has occurred. The sequence is robust and insensitive to magnetic field and gradient inhomogeneities, but is limited by a long scan time.

Statistical power The probability that, with a specified degree of confidence, an underlying effect of a given magnitude will be detected in a study. A study with low power might not detect a potentially important difference in disease risk.

Statistically significant result A finding that would arise only rarely (usually less than one in twenty times) in the absence of an underlying effect.

Stereocilia (inner ear) Mechanosensing organelles of hair cells, which respond to fluid motion or fluid pressure changes in numerous types of animals for various functions, primarily hearing.

Surface coil An RF coil specifically designed for localised body regions; it provides improved signal to noise ratios by limiting the spatial extent of the excitation or reception.

Synapse A junction between two neurons, or between a neuron and a muscle fibre, that allows the transmission of electrical information, usually by means of a chemical transmitter (neurotransmitter) released from the presynaptic terminal of one neuron on to the closely juxtaposed post-synaptic terminal of the other.

Transcranial magnetic stimulation (TMS) A technique used to investigate brain function involving the pulsing of magnetic fields close to the head.

Transverse electromagnetic (TEM) coils TEM coils consist of parallel spaced conductors (sometimes called 'rungs') and a coupled cylindrical RF screen providing current return paths. Resonance modes of TEM coils are typically rung-to-screen, although some rung-to-rung resonance modes may also be supported.

Vestibular system Balance organs of the inner ear.

Voltage-gated ion channel Cell membrane proteins that allow the passage of particular ion species across the cell membrane in response to the opening of a molecular 'gate' which is steeply sensitive to the transmembrane voltage. They are associated with electrical excitability.

Volume coil An RF coil that surrounds either the whole body, or one specific region, such as the head or a knee. Volume coils have a better RF field homogeneity than surface coils, extending over a large area. For large volume imaging, the same coil may transmit and receive, or separate coils may be used in which case the volume coil may be used as the transmitter and a smaller coil used as the receiver.

Appendix A

Best Practice in MRI Units

Achieving best practice with regard to patient, volunteer and staff safety begins at the planning stage, with an appropriate design of an MRI unit. The following advice is intended for those concerned with the installation of new MRI facilities.

General advice on the safety requirements for MRI units is provided by the Medicines and Healthcare products Regulatory Agency (MHRA, 2007) and it is suggested that this document is referred to for more detailed advice on best practice. The American College of Radiology has also provided useful guidance on site design for MRI units (ACR, 2007).

In general, the physical layout of the site should act to reinforce best practice by staff, minimising as far as possible the potential for human error and consequential accident.

Consideration must be given to achieving a well-designed outer controlled area within the unit that not only encloses the 0.5 mT isocontour but also prevents unauthorised access. This is achieved through physical demarcation of the area with access to authorised personnel only.

In particular, it should not be possible to enter the scanner room directly from an uncontrolled area. Therefore the outer controlled area should include the area outside the scanner room, in front of the scanner room door even if the 0.5 mT isocontour does not extend there. A safe area should be defined outside the scanner room to which patients can be moved for emergency treatment if required.

Careful planning of the layout of the unit will both facilitate best practice and improve the working environment. The design of the site as a whole should promote the smooth flow of patients and staff through the unit. Outside the controlled area, adequate space should be provided for all the required activities and needs within the unit. This includes a private area for patient screening and discussion, patient changing rooms and secure quarantine facilities for unsafe items brought into the unit by patients or staff. A holding area for screened and changed patients may also be required that does not allow patients to leave the unit and then re-enter with unsafe items.

All MRI units should draw up a set of local rules, which will set out the policies and protocols to be followed to ensure the safety of all people entering the MRI environment, whether staff, patients, volunteers, carers or other members of the general public. These local rules will vary from one unit to another, but should be based on published advice. Useful sources of reference are provided at the end of this appendix.

In general, the local rules should state that the day-to-day responsibility for safety in the MRI unit will be held by the MRI responsible person, who should consult with MRI advisers in drawing up local rules. Access to the MRI controlled area should only be given to authorised persons, a list of whom should be

held by the MRI responsible person. Access to the controlled area should be physically restricted by means such as self-locking doors with coded locks, so that unauthorised persons are unable to gain access to the controlled area without the supervision of an authorised person.

Before any individual enters the controlled area, adequate screening should take place to ensure that it is safe for them to enter that area. This should usually take the form of a written questionnaire and suggested examples are available, eg on the British Association of MR Radiographers website at www.bamrr.org (BAMRR, 2007).

Screening should also determine whether there is any possibility of pregnancy, with consideration then given on whether it is appropriate for that individual to enter the MRI environment or undergo a scan. More detailed advice on screening is provided by the MHRA (2007). For those being scanned, it is useful to find out whether there are any medical conditions that might increase risk in the MRI environment, eg hypertension, poor circulation, diabetes or epilepsy.

Extra care must be taken to screen any individuals who are unconscious, or otherwise incapable of adequately completing a safety checklist, using physical examination and the help of relatives, referring clinicians, patients' notes etc, as available.

All loose ferromagnetic items, eg coins and keys, must be removed from a person before they enter the controlled area, and items that can be damaged by the magnetic field, eg credit cards and watches, should also be removed. In addition, it must be ensured that no aspect of an individual's clothing, eg zips or buckles, could pose a risk, either through being subject to heating effects, or to causing artefacts on the images.

It is necessary also to establish whether individuals have any implanted devices or materials, whose operation, position or temperature could be affected by the magnetic field, eg pacemakers, aneurysm clips, stents, clips, shunts, wires or joint replacements. Before an individual can enter the controlled area, the exact nature of any such devices must be determined and then reference made to published data, eg manufacturers' websites or safety websites on MRI, to determine whether these devices are MR safe, MR conditional or MR unsafe.

The maintenance of safety with regard to scanning people with implants requires great diligence to obtain accurate information about the behaviour of particular devices in the MRI environment. New devices are continuing to come into use whilst scanning conditions are also changing, as is the case with the trend towards higher field systems. Generic rules, eg 'all aneurysm clips are safe now', are to be avoided in favour of a case-by-case approach. The safety of an implant is related to the area of the body in which it is located and this must be taken into account in evaluating safety. In the case of heart valves, displacement forces or torque effects may be insignificant compared to the forces exerted on the implant from the beating heart. In some cases fibrosis is important in knitting the implant into the tissues. Therefore, scanning may not be advisable until a sufficient period has elapsed after implantation.

It is also important to determine whether an individual has any history of a penetrating injury from metal, particularly in the eyes. If appropriate, further investigations such as X-rays may be required to confirm whether any fragments remain, in order to avoid potential injury to the individual from movement or

heating of such fragments. The X-ray procedures should be carried out in compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 (GB Parliament, 2000).

When positioning individuals for MRI procedures, care must be taken to minimise risk of burns. Burns can occur if a conductive loop pathway is created, eg by hands/thighs/calves touching together. Burns can also occur if metallic objects are in close proximity to the person. All monitoring devices, including coil leads, ECG leads and oxygen monitor probes, in particular, must be MR safe or MR conditional, and appropriate foam insulation should be placed between the skin and these types of items. It is particularly important that the conditions under which any device has been tested are understood so that it can be used safely and appropriately, especially with the trend towards higher field systems.

Individuals should be weighed accurately before being scanned, since this may be required for input to the MRI system to estimate and restrict the SAR levels to which they will be exposed, so as to avoid any excessive heating. Where available, bore lighting and ventilation should be adjusted to an individual's comfort and regular communication should then be maintained to ensure that the individual remains at a comfortable temperature, either through adjustment of covers and bore ventilation, or by introducing breaks in scanning. If possible, protocols should be set up so that sequences delivering higher SAR are not all consecutive. An emergency call button should be provided so that patients can contact staff immediately during scanning, if required.

These precautions are particularly important for certain vulnerable groups such as children, pregnant women, febrile patients and those with a compromised thermoregulatory response.

Since it is difficult to be sure of the noise levels that an individual will be exposed to during their scan, all individuals being scanned should be given hearing protection, including those who are unconscious or under general anaesthetic. Ear plugs and ear muffs have been the mainstay of hearing protection for the patient in MRI providing up to 35 dB of attenuation at the frequencies of interest. 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. Depending on design, ear muffs may provide more attenuation than ear plugs. They are also easier to fit. However, they may not be suitable for use in conjunction with some smaller head radiofrequency (RF) coils.

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Appendix B

Response to Public Consultation on the Document

An earlier version of this document (Consultation Document) was published for public consultation on 31 October 2007. The HPA thanks all those who provided comments. Six sets of comments were received: these were collated, and a general summary of these and the HPA responses are set out below.

The comments were generally supportive of the approach taken in preparing the advice, and suggested that all the relevant issues had been covered comprehensively.

The HPA noted the request for guidance on the use of X-rays in MRI scans used for research purposes – for instance, in protocols involving peri-orbital X-rays to detect foreign bodies. Detailed advice on this was considered to be beyond the direct scope of the document. However, it was recognised to be an important safety issue and so it is now stated in the document that any such procedures must be carried out in compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 (GB Parliament, 2000).

It was acknowledged that the term 'medical supervision', used in various contexts in the Consultation Document, needed to be clarified in relation to advice on MRI safety procedures in patient and volunteer settings. The medical circumstances will vary depending on the subject's situation and the type of scanning to be undertaken and will be influenced by various factors, including the physical proximity of the MRI unit to any acute medical facilities and/or appropriate medical expertise. The nature of the appropriate consideration of medical circumstances should form part of the MRI unit's local rules, or be outlined in the ethics submission, if appropriate. For example, when scanning apparently healthy volunteers, it may be sufficient simply to include questions on the normal MRI safety screening form to allow exclusion of those with risk factors such as impaired thermoregulation (eg including pyrexia or conditions leading to poor circulation). In other circumstances, a medically qualified person may need to be present in the MRI unit, or provision may need to be made for medical help to be summoned in an appropriate time frame. A note to this effect has been included in the document.

The HPA is grateful for comments which helped to improve the overall technical content of the document, in particular in the section covering MRI technology and medical applications. A number of comments were received on imaging issues associated with high field systems. Any related safety issues were considered to have been covered adequately in various places in the document.

Requests for references to other technical standard and advice documents were noted. In developing the advice, the HPA was cognisant of the international standard 'Medical Electrical Equipment – Part 2-33: particular requirements for basic safety and essential performance of magnetic resonance equipment for medical diagnosis' (IEC, 2002), in which the exposure limits are based on the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP, 2004). The Medicines and Healthcare products Regulatory Agency (MHRA) has published safety guidelines for MRI equipment in

clinical use (MHRA, 2007) – an update of previously published advice (MDA, 2002) and also based on the ICNIRP recommendations. A note to this effect has been included in the document.

Comments were received about the roles of various bodies with responsibilities for ethical review within and outside research settings in the UK. A general reference has been included in the document to the National Research Ethics Service (NRES, 2008), which can provide more information on this subject.

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