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Summary

New European regulations threaten to reverse pioneering advances in the use of MRI to diagnose disease and treat patients.¹ By 2008, many interventional MR procedures will be illegal, and it may be more difficult to use the most powerful, modern (high field) scanners. Diagnosis and treatment of anaesthetised, frail or anxious patients, and children, will be particularly affected. Patient and staff safety will be put at greater risk from X-rays.

Magnetic Resonance (MR) Imaging has brought huge advances in diagnostics, for example for brain tumours and in the treatment of children born with heart abnormalities. In the emerging field of interventional MRI, therapeutic procedures can be guided using MRI instead of X-rays, eliminating radiation dose and improving performance. New high-field systems allow images to be collected quickly and with greater detail. The UK had a pioneering role in the development of MRI, and continues to be a major player internationally. In 2003, a share of the Nobel Prize for Medicine was awarded to Professor Sir Peter Mansfield of the University of Nottingham.

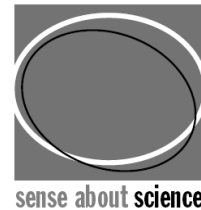
The incorporation into UK law of the 2004 EU Physical Agents Directive, to impose legal limits on electromagnetic field (EMF) exposure, will result in significant restrictions on the use of MRI, for which there is no evidence of harm; it will obstruct plans to reduce X-ray exposure, for which there is long-standing and clear evidence of harm, notably from increased risk of cancers. The Directive, which was drawn up without proper regard for the concerns of the medical community, will lead to real hazards in its efforts to avoid hypothetical risks.

The effects on patient care, particularly in vulnerable groups such as children with heart problems, and on employee safety, are intolerable. The Directive will jeopardise the use of several long-awaited state-of-the-art MR scanners, funded by the UK Government and patient charities, including two interventional systems due to be opened in paediatric units in the near future.²

¹ It is now the method of choice for imaging the brain, often showing tumours and other lesions that are not visible using other techniques. It has a critical role in imaging the spine, joints, heart and abdomen. Functional MRI allows brain function to be mapped out prior to surgery, so that critical structures can be avoided. Cardiac MRI is of growing importance in the treatment of children born with heart abnormalities.

² St Thomas' Hospital funded by the Trust's charity and Great Ormond Street Hospital funded by the British Heart Foundation

Alert: The EU Physical Agents Directive and its impact on MRI



What is the Physical Agents Directive?

In 2004, the European Union adopted the Physical Agents (EMF) Directive (PAD)³ to limit further⁴ all occupational exposure to Electro-Magnetic Fields, including those in medical MR. It must be incorporated into domestic law by Member States by 30 April 2008.

How does it affect MRI?

MRI uses EMF in three frequency ranges, all covered by the PAD: the static magnetic field (0 Hz), time-varying gradient fields (100s-1000s Hz), and the radiofrequency field (10s-100s MHz). The PAD has absolute exposure limits in each case; it will be illegal to exceed these.

Frequency	Exposure limit	Action value for magnetic flux density	Estimated maximum exposure ⁵
0 Hz (static magnetic field)	[2T] *	0.2T	3T (clinical) 7T (research)
500 Hz (magnetic field gradients)	Current density 10 mA ^m - ² to head and trunk	50μT	2,000μT (to head)
10-400 MHz (radiofrequency)	SAR 0.4 Wkg ⁻¹ whole body average, averaged over six minutes	0.2μT	<0.4 Wkg ⁻¹ whole body average

* In its draft stages the PAD included this static field limit, which was then removed. It is possible that a static field limit will be restored in future revision of the Directive or in Member State incorporation.

What does this mean in practical terms?

A static field limit would impact significantly on use of new high-field MR systems in clinical imaging and research. It would make it illegal for a worker to enter the magnet bore, e.g. to clean or maintain the system or to perform experimental work. The gradient limits will prevent workers from standing very close to the bore during imaging, e.g. to carry out an interventional procedure or provide patient care during anaesthesia. The RF limit is averaged over the whole body and so will have little impact for workers.

Why is this necessary?

It isn't! MRI has an excellent safety record, thanks to the combined efforts of manufacturers, expert users and government bodies, working together over many years. According to the PAD, these new limits will protect workers from "known short-term adverse effects on the central nervous system (CNS) occurring instantaneously on exposure to EMF above a well-defined threshold".

Surely if there are effects, we should protect our workers from them?

Yes, but what effects are we talking about? The PAD draws on reports by ICNIRP⁶ and NRPB⁷, which include weak evidence of effects reported at low exposure levels. The adopted limits are based on 'a cautious approach' to avoid biological effects that may or may not be harmful, if they exist at all.

³ Official Journal of the European Union L 159 of 30 April 2004 (and corrigenda L 184 of 24 May 2004)

⁴ Scanners are already designed to IEC safety standards to protect patients, which also has the effect of limiting staff exposure.

⁵ Based on state-of-the-art MR systems.

⁶ International Commission on Non-Ionizing Radiation Protection. Health Physics 1998;74:494-522.

⁷ National Radiological Protection Board. Documents of the NRPB 2004:15(3):1-210.



So are there any established biological effects?

Yes: peripheral nerve stimulation (PNS) is a well-known, but harmless, biological effect due to the changing gradient fields. But the PAD occupational exposure limits are 100 times lower than the threshold for PNS and rely on less well-established phenomena, such as subtle cognitive effects. Evidence for these is sparse, in some cases presented in unpublished form at conferences and in other cases reported only in the 10-100 Hz frequency range. The limits have been extrapolated to higher frequencies even though there are no data to support this. There is no substantial evidence for any *adverse* health effects in the gradient frequency range below the PNS threshold.

What about the static field?

There is evidence that operatives sometimes feel dizzy or sick when moving their heads quickly around a high field magnet. But these effects stop as soon as you stop moving and don't cause any long term effects. It is similar to the experience of a playground ride.

So are there any safety worries?

None at all. The PAD is unnecessary for medical MR and will impede the future of MRI in Europe.

What will be the impact of the PAD in the UK?

It will become illegal to conduct many interventional MR procedures and more difficult to perform scans on anaesthetised, frail or anxious patients and young children. Altering scanners to conform to the PAD is not feasible without compromising performance and extending the duration of scans, which, in a confined space, is already difficult for many patients and presents no benefit to staff. The manufacture of such second-rate scanners would be specific to the small European market and make the costs prohibitive. The European contribution to research and development in MR methodology will seriously decline, especially in the emerging areas of high field and interventional MRI, with consequences for the healthcare of European populations. Most importantly, by denying MR techniques to patients, many cases will involve an X-ray examination instead, exposing both patients and staff to ionising radiation with its well-known health effects, including increased risk of cancer.

Aren't there parallels with the occupational exposure to ionising radiation?

In the case of X-ray imaging, balancing of risk and benefit – not just for the individual, but for society as a whole – allows staff to shoulder some of the risk in view of the benefit to patients: in the case of MRI, there are no known hazards to be balanced against the benefit to patients. The benefits of PAD exposure limits are therefore hypothetical, but the damage to staff and patients will be very real. The Health and Safety Executive has concluded that, 'the benefits [of the Directive]... are very heavily outweighed by the costs'. Why introduce heavy-handed legislation that will throttle diagnostic healthcare, when competent MR professionals have successfully used established guidelines for over 20 years with no ill effects?

What can be done?

Radiologists, and others in the wider clinical and scientific communities, are calling on the UK Government:

- to respond to these serious implications for healthcare and research by pushing for amendment of the Directive to prevent its adverse impact on MRI;
- to consult the MR community before drafting legislation to implement the Directive; and
- to support research into the safety of exposure to MRI, based on both analysis of existing exposure data from clinical MRI and basic research into biological effects.

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