MRI directive threatens the care of Europe's cancer patients

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If EU Physical Agents (EMF) Directive 2004/40/EC goes through in its current form, hospitals may have to stop using MRI or open themselves to the risk of being sued by employees. Campaigners are now hopeful of a last-minute reprieve.

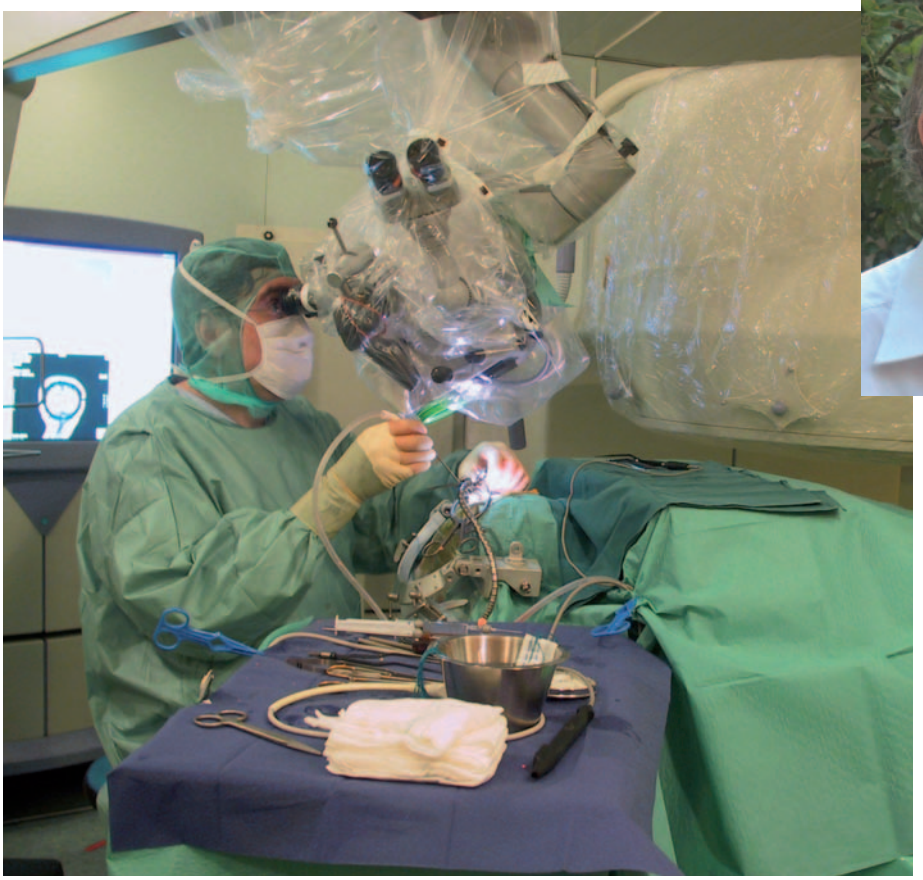
Radiologists, other doctors, medical researchers, patient groups and industry are calling for urgent action to postpone the implementation of an EU directive that threatens the future of magnetic resonance imaging (MRI).

They are concerned that if action is not taken now either to delay implementation of the directive or to suspend the parts of the directive that affect MRI, then the use of MRI in the diagnosis and treatment of patients and for research purposes will effectively cease in Europe and patients' lives will be lost. This would affect some eight million patient examinations a year, and halt research that uses MRI to investigate the brain, heart disease, cancer and a number of other conditions and diseases. The value of the investment by health services in MRI equipment would be reduced and the industries that design and manufacture the magnets would suffer.

Politicians at national and European level have begun to accept there may be a problem with the directive and the European Commission has requested an independent expert group to analyse the implications of the directive on the clinical use of MRI. However, this analysis will not be completed before autumn of this year, by which time campaigners fear it will be too late to make any changes. EU Member States have to implement the directive by April 2008, and the process of amending a directive and having the amendments approved by the European Council can take up to a year.

However, a meeting in March with the EU commissioner responsible for the directive has raised hopes that officials may, at last, be listening to the storm of protest from the medical profession and that implementation of the directive may be delayed.

MRI is one of the great success stories of the past 30 years in biomedical research; according to industry estimates, it has benefited more than 500 million patients worldwide since it was first developed. British physicist Peter Mansfield shared the 2003 Nobel Prize in Physiology or Medicine with Paul Lauterbur in the US for the work he did in developing MRI so that it could produce images of the body.



Life saver. Frank Boeye *(above)* survived a brain tumour with minimal damage, because his surgeons were able to work with MRI guidance. *(Left)* This interventional MRI theatre at Oulu University Hospital in Finland uses a resistive low-field (0.23T) MRI scanner with a vertical magnetic field, which takes only six minutes to turn on, making it possible to shut it down for long periods during the surgery, thereby minimising exposure for the surgical team. If the EU directive is adopted unamended, experts believe many procedures would become impossible

Picture courtesy of Jani Katisko, Oulu University Hospital, Oulu, Finland

Since the 1970s MRI has become an increasingly useful tool for the diagnosis, treatment and research of a number of diseases or conditions, including cancer. It uses strong magnetic fields and radio waves to produce detailed images of the inner workings of the body. Unlike a CT scanner, it does not use ionising radiation and, therefore, has none of the harmful effects associated with X-rays.

The EU Physical Agents (EMF) Directive 2004/40/EC originated from the EU Directorate-General for Employment, Social Affairs and Equal Opportunities and aims to protect people working near electromagnetic fields (EMF). It was adopted by the European Union in 2004 and has to be incorporated into the domestic legislation of Member States by April 2008, with a review in 2009. Because it emanated from DG Employment rather than the DG for Research or Public Health, it slipped under the radar of the medical and scientific community, which did not appreciate the adverse implications for MRI early enough to lobby for changes before the directive's adoption.

Gabriel Krestin, professor and chairman of the Department of Radiology at the Erasmus University Medical Centre, Rotterdam, The Netherlands, says, "The main focus of the legislation was aimed at protecting workers who may be exposed to electromagnetic fields during their work from things like electricity generation and mobile phones. It was definitely not intended to affect MRI. However, one of the unintended consequences is that the directive affects radiographers, physicians, nurses and other health workers who might be exposed to electromagnetic fields from MRI. It is unbelievable that the use of MRI could be jeopardised by such a legislation."

Krestin is one of the leaders of the opposition to the directive. Not only is he having to deal with the implications of the directive at his own institution, but he is also past president of the European Society for Magnetic Resonance

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in Medicine and Biology (ESMRMB), founder and past president of the Association of University Radiologists Europe (AURE), chair of the Research Committee of EAR (European Association of Radiology) and voices the opposition of these organisations to the directive.

Flimsy evidence

The directive has set exposure limits to EMF at levels that mean anyone moving and working near MRI equipment will inevitably breach the limits. In a letter to the UK Secretary of State for Health, Patricia Hewitt, Mansfield and 11 other eminent scientists and physicians working in the field said, "The limits proposed are huge extrapolations from largely hypothetical possible conditions and are an over-cautious interpretation of very limited experimental data."

Krestin agrees. "The limits are over-cautious extrapolations. We have more than 25 years experience of using MRI with patients, and as far as anyone is aware there is no evidence of harmful effects caused by MRI in the frequency range that we use. At higher levels there can be transient effects, such as dizziness or visual disturbances, but these are not long-lasting effects."

Despite the flimsiness of the scientific evidence on which the exposure limits have been based, and the fact that more than 500 million patients have been exposed to MRI with magnetic fields set at amplitudes 100 times higher than the directive's limits, with no evidence of harm either to workers or patients, the European Commission still appears to be pressing ahead with implementation.

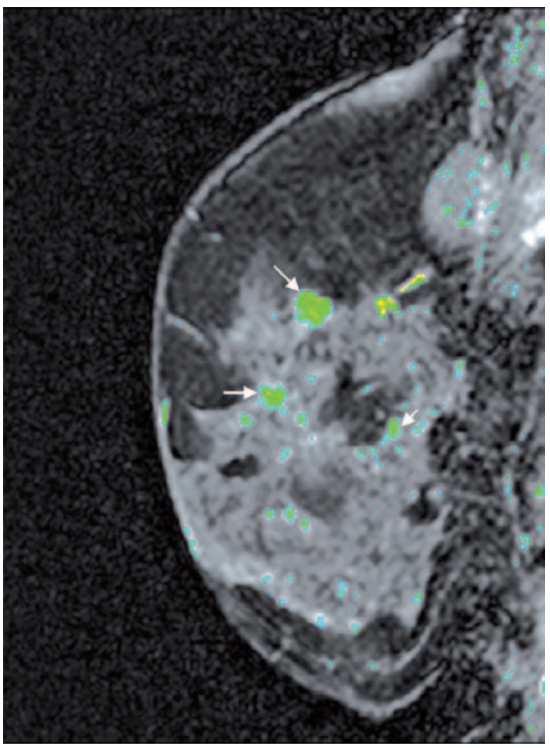
Krestin believes the impact would be disastrous. "The values described in the directive would be exceeded in every use of MRI." He points out that radiologists and health workers are not always present in the MRI room when the image is being made, but in at least 10% of cases they are. "There are instances, where professionals have to be close to the patient, for instance for interventional procedures, where MRI is being used to guide instruments during an operation, and for helping vulnerable patients and patients under anaesthesia. In my practice, the radiologists stay close to children to calm them during the examination and it works, but this would be obviously impossible under the new directive." It would also become impossible for health workers, such as nurses and radiologists, to position the patients in the scanner, as any movement close to the magnet involves moving through the magnetic field, creating the effect of a varying field, which would probably exceed the exposure limits. This would also affect maintenance and cleaning staff.

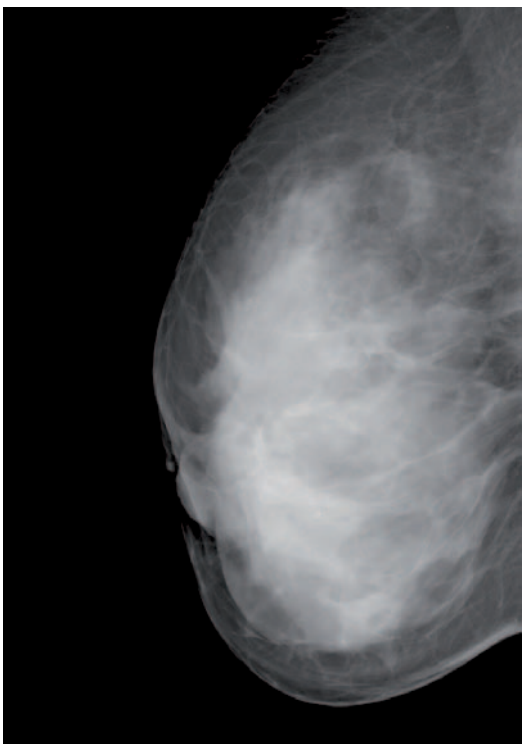
No longer feasible

"It would not be feasible to perform MRI anymore," says Krestin. "We would have to use other forms of scanning, such as X-rays, that are known to be harmful." Research would also be severely curtailed, he argues, as it is often conducted using much stronger magnetic fields than those used in clinical practice.

Janet Husband, who is president of the UK's Royal College of Radiologists and professor of radiology at the Royal Marsden Hospital and Institute of Cancer Research, has spent her whole career working at the leading edge of cancer radiology. She says the constraints the directive would have on MRI would have "a devastating effect" on the treatment of cancer patients.

"MRI has a key role in assessing patients with cancer. It has a role in cancer detection, diagnosis, staging the extent of the disease and an increasing role in follow-up. We use it to assess response to treatment, and also there is research going on that will allow targeting of specific drugs with the help of the MR contrast agents, so that we can see whether the drug has been directed to the right place." During MRI, cancer patients are injected with a dye (or contrast agent) that enables the





Early detection. MRI can be far more effective than X-rays at picking up small tumours, particularly in dense tissue. The EU directive will make it impossible for staff to undertake these types of scans, as they require injection of intravenous contrast material

Picture courtesy of N deSouza, MRI Unit, Institute of Cancer Research, London, UK

imaging to detect cancer and to distinguish between cancerous tissue and normal tissue.

"If we cannot inject patients because staff cannot be in the same room because of the electromagnetic fields, then the diagnosis, assessment and treatment of patients will be at risk."

She said MRI is particularly useful in cancers of the brain, spine, bone, prostate, liver, pelvic areas, cervix and uterus. "It's also very good for childhood cancers because it doesn't use X-rays, which could adversely affect the children's future health."

Another example is its use in breast cancer in young women, where randomised controlled trials have shown that MRI is four times more sensitive than mammography in detecting early, small tumours. A study published in the NEJM at the end of March has shown that MRI also has a key role to play in detecting cancers in the other breast of women diagnosed with breast cancer, regardless of cancer type, patient age or breast density. The imaging technique picked up 91% of all contralateral breast cancers that had been missed by both mammography and clinical breast exam, making it possible to give very early treatment where necessary, and to avoid mastectomies of healthy breasts.

Krestin agrees that postponement would be a better option than having individual countries decide in a piecemeal fashion whether to implement the directive as it stands or have an opt-out (derogation) for MRI. He warns that some smaller countries, such as Latvia and Slovakia, are already implementing the directive and this may lay them open to employees either suing hospitals on the grounds of over-exposure to EMF, or refusing to perform MRI, which would harm patient care. In addition, patients may start to move between EU countries in order to find places that still perform MRI.

Frank Boeye, founder and chair of the Belgian Brain Tumour Association, is very concerned about the impact of the directive on the care of people with brain tumours. "The treatment of brain tumours is entirely dependent on MRI," he said. "Diagnosis, interventional treatment, and follow-up all depend entirely on MRI and there are no alternatives."

In 1997, at the age of 44, he was diagnosed with a glioblastoma; the 3 cm tumour was detected by MRI after a CT scan missed it. "It was

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situated in the zone that controls locomotion in the brain. It was very difficult to extract it without causing paralysis and the accuracy of the surgery had to be in millimetres. My operation was controlled by MRI, and if it had not been then I would have died or been severely damaged, so I owe my life to the technology." Ten years on, he is fully recovered.

"MRI has been going for 25 years and is a better alternative to CT scans, which can actually cause cancer. You have a slightly raised temperature during the MRI, but it is only 0.1 ºC higher, and then you leave the machine and after a short time your temperature is normal again. When surgeons had to operate using CT scans they always had to guess where to begin and end the operation and most people were severely damaged or died."

For the sake of cancer patients and brain tumour patients in particular, he wants the implementation of the directive postponed. "I would like to see more investigation done to see if there really is any danger from MRI. I'm not against safety for workers, but in 25 years there has not been one problem, so why do this now? Investigate it – that's the logical solution."

Repeated assurances

The Labour MEP for the North-East Region in the UK, Stephen Hughes, is a member of the European Parliament committee on Employment and Social Affairs and is one of a number of MEPs who have been campaigning to change the directive. "I am quite annoyed about this because we were raising questions about whether it would affect MRI when the directive was going through Parliament. We had repeated assurances from Commission officials that it would not."

Hughes believes there is not enough time before April 2008 to get an amendment to the directive passed, and delaying action until the experts' report is published in the autumn would be leaving it "criminally late ".

He has been heartened, however, by a meeting with Vladimir Špidla, the Commissioner for Employment, Social Affairs and Equal Opportunities, in March, at which the Commissioner signalled that he understands the seriousness of the situation.

"He is ready and willing to move," says Hughes. "Commissioner Špidla has conceded that if the study that has been commissioned by the UK's Health and Safety Executive and is led by Professor Stuart Crozier, from Brisbane, Australia, shows there's a problem, he will take it as sufficient evidence to take action to postpone implementation of the directive. He won't wait for the [EC] study that will report in the autumn."

Preliminary findings from the Crozier study show that the directive will affect adversely almost all MRI procedures in the EU. The final report was expected in April.

Špidla gave Hughes assurances that, subject to the final findings of the UK report, he will issue a letter to Member States saying there's a problem and that implementation of the directive will be postponed pending further evidence from the study in the autumn. He will also begin the legal moves to amend the directive, which will involve convening the EU scientific committee to consider amendments that will ensure that MRI procedures are not affected. "This is a big step forward," said Hughes.

ALLIANCE FOR MRI

An Alliance for MRI was launched in March at the annual congress of the European Society of Radiology in Vienna to request a derogation for MRI. The alliance comprises the medical and scientific community, patient groups and MEPs. For more information about the alliance or the directive and its impact on MRI, contact Monika Hierath, European Society of Radiology, tel: ESR office: +43 153340640 ext. 20, or e-mail: mhierath@ecr.org