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NOTES

Guidance Note: Risk Management of Workers With Medical Electronic Devices and Metallic Implants in Electromagnetic Fields

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Medical electronic devices and metallic implants are found in an increasing number of workers. Industrial applications requiring intense electromagnetic fields (EMF) are growing and the potential risk of injurious interactions arising from EMF affecting devices or implants needs to be managed. Potential interactions include electromagnetic interference, displacement, and electrostimulation or heating of adjacent tissue, depending on the device or implant and the frequency of the fields. A guidance note, which uses a risk management framework, has been developed to give generic advice in (a) risk identification—implementing procedures to identify workers with implants and to characterise EMF exposure within a workplace; (b) risk assessment—integrating the characteristics of devices, the anatomical localisation of implants, occupational hygiene data, and application of basic physics principles; and (c) risk control—advising the worker and employer regarding safety and any necessary changes to work practices, while observing privacy.

magnetic fields microwave interaction pacemaker artificial joint

1. INTRODUCTION

The range of medical electronic devices—such as pacemakers, and metallic implants such as orthopaedic prostheses—being placed in people of working age is increasing as they are found to be effective treatments for many conditions. Simultaneously the use of, and exposure to, electromagnetic fields (EMF) in workplaces is increasing. This conjunction may result in adverse effects for workers. Therefore physicians, employers, and others require an approach to manage these situations. The following guidance note on managing risk associated with electronic devices and metallic implants for workers in EMF has been drafted on the basis of the authors' experience over many years [1]. It is intended to assist physicians in assessing workers who have electronic medical devices or metallic implants and are required to work in EMF (0–300 GHz) above public exposure levels but below occupational limits for the relevant jurisdiction.

EMF if sufficiently intense may interfere with electronic medical devices causing malfunction and subsequent injury or illness. Much work has been done to create an electromagnetic compatibility (EMC) framework to avoid interference problems. For example, under Standard No. IEC 60601-1-2:2001 [2], all medical equipment must be declared suitable for use in fields up to 3 V/m over the frequency range 150 kHz–80 MHz. This

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framework is intended, amongst other objectives, to protect the general public who have medical devices; hence exposure to EMF at levels up to public exposure limits is not considered in this guidance note. As part of the framework medical devices are designed to be immune to interference from common EMF but this may not apply in industrial settings.

EMF if sufficiently intense may interact with metallic implants causing injury or illness. Static magnetic fields may cause displacement of implants, fields <10 MHz may cause electrostimulation of nerve or muscle, and fields >10 MHz may cause undue heating of tissue.

This risk needs to be avoided by proper management of workers with these devices. Risk management may require the combined efforts of a physician and a scientist each contributing their knowledge about the interactions of EMF with the body and the devices or implants. Legal matters such as privacy, equal employment opportunity, and duty of care also warrant careful attention.

These guidelines are not intended to apply to medical patient diagnosis or treatment involving exposure to EMF because a very different risk assessment applies regarding likely benefit and harm to patients, as distinct from the healthcare workers who attend them.

2. RISK MANAGEMENT

The risk for workers can be managed using the conventional steps in risk management of risk identification, assessment, and control.

2.1. Risk Identification

The first step is creating awareness of the extensive range of electronic devices and metallic implants now in use, and possible diverse exposure to EMF in a workplace.

2.1.1. Electronic medical devices and implants

The range of electronic devices and implants is rapidly increasing. Many are listed in the Appendix on p. 222. Hearing aids are a special case; modern ones are designed to be immune to nearly all EMF that may be encountered in industrial worksites. Dental fillings and plates are generally not regarded as posing health risk because teeth are relatively inert to electrostimulation and to heat. Costume jewellery (watches, rings, etc.) is worn superficially so any interaction with EMF is easily detected and is likely to have little consequence for the health.

2.1.2. EMF in workplaces

As part of the general management of EMF in a workplace the range of frequencies and associated field intensities above public exposure need to be identified and controlled. Such exposure may occur from electrolytic cells, electric furnaces, arc and resistance welders, induction heaters, radiofrequency (RF) welders and sealers, industrial microwave ovens, communication masts and towers, radar and navigation systems, powerful two-way radios, etc.

The extent to which workers may be exposed above the public limits in each industry needs to be assessed in relation to work practices. EMF associated with processes and equipment should be measured and mapped as per good industrial hygiene practice. Signage should be placed advising of risk to persons with medical devices or implants entering an area of high exposure and/or equipment should be tagged with a warning label.

Workers and management in industries with EMF exposure above public limits should be educated about the possibility of interference with electronic devices or interaction with metallic implants. Companies should develop a policy for assessing such persons at recruitment and thereafter as required. A model questionnaire is provided in the Appendix on p. 222.

2.2. Risk Assessment

The second step is to assess a worker with a device or an implant regarding their medical history and actual occupational EMF exposure, and then to gauge the susceptibility of the device to interference, or the possible interactions of a metallic implant with EMF. Electronic

devices and metallic implants will be considered separately as they require different risk assessment.

2.2.1. Electronic devices [3, 4, 5, 6, 7]

2.2.1.1. The worker. A worker with an electronic device may be identified at a preplacement examination and referred to the physician or an existing employee may seek advice of one. The medical reason for the device needs to be ascertained and the possible health consequences of interference with the device need to be considered. The tasks of the job need to be considered with regard to safety risk if the device malfunctions. For example, when working at a height on a communication mast with a pacemaker or an insulin infusion pump, a malfunction could result in collapse and a fall.

EMF exposure to the worker and the device should be determined regarding frequencies and worst-case field strength. Occupational hygiene data regarding EMF measurements should be referenced. Computer programs may help model the deposition of fields into the body; however these programs are often based on a standard man standing in a free field and the reality of this model to movement and postures in the work situation may need to be considered. Ideally, the physician should visit the worksite to observe work practices in relation to fields.

2.2.1.2. Electronic devices. Data on the electronic characteristics of the device may be sought from the manufacturer and/or the medical specialist who implanted the device. Devices with electronic sensors, such as defibrillator leads, are of particular concern because fields may cause their interpreting fields as abnormal electrical activity. (Some devices may have anti-antenna leads which provide a reverse loop and are designed to cancel out voltage gradients). Manufacturers often have useful information regarding immunity of devices; however the requesting physician needs to ensure the information provided is applicable to the specific frequencies and intensities of EMF to which the worker will be exposed. Also it should be ascertained if the device is fail-safe, i.e., if interference occurs will the device revert to a safe mode of operation? For example, will a pacemaker revert to a fixed rhythm rather than cease stimulation to the heart, or will an insulin infusion pump stop rather than cause an overdose of insulin, etc.

In some situations it may be helpful to conduct an in-vitro laboratory trial of the safety of the device in fields typical of the workplace. This test removes normal body shielding and so gives a very conservative result for devices which are deep in the body. An in-vivo trial may be considered with the patient's informed consent and providing all reasonable precautions are taken. Real-time monitoring by telemetry of the device while the worker performs usual tasks at the worksite may be useful for detecting possible interference.

Data regarding the device and its immunity need to be considered with regard to the worst-case fields to which the worker could be exposed, and the consequences of malfunction (if any) of the device should then be assessed.

2.2.2. Metallic implants [8, 9, 10, 11, 12]

2.2.2.1. The worker. A worker with a metallic implant may be identified at a preplacement examination or an existing employee may seek advice of the physician because of awareness of a risk after being treated using a metallic implant, e.g., a stent. The medical reason for the metallic implant needs to be ascertained so the underlying pathology is known, e.g., trauma or vascular disease. Further details about the technical aspects of the implant, such as its metallic composition (and hence electrical properties), may need to be obtained from the treating doctor or the manufacturer. For example, aneurysm clips are sometimes made of low-ferrite material and so will not be affected by a static magnetic field. Manufacturers often have useful information regarding implants and possible interaction with EMF; however the requesting physician needs to ensure the information is applicable to the specific frequencies and intensities of EMF to which the worker will be exposed.

X-rays should be obtained to enable (a) accurate anatomical localisation of the implant,

particularly in relation to sensitive tissue such as adjacent nerves and blood vessels; and (b) accurate understanding of the implant's size and shape, particularly if points such as screws or pins are present (where energy tends to concentrate) or current loops are formed.

EMF exposure to the worker should be determined regarding frequencies and worst-case field strengths. Occupational hygiene data regarding EMF measurements should be referenced. Ideally, the physician should visit the worksite to observe work practices in relation to fields.

2.2.2.2. Metallic implants and EMF. Data about the EMF exposure needs to be assessed in relation to the implant in the patient. Different frequencies have different interactions with metallic implants and hence possible effects on adjacent tissue. Reasoning from the first principles of physics and electrical engineering about the interaction of static and time-varying fields with metals may be useful in the assessment.

Static magnetic fields cause displacement of implants (like a magnet attracts metal particles), which may be important in implants such as cerebral aneurysm clips. There are magnetic forces between magnetic materials (various types of iron or steel including some but not all stainless steel) and a static magnetic field. If the magnetic flux is known, forces on the implant may be calculated.

Extremely low frequency (ELF) and intermediate frequency (IF) (1 Hz–10 MHz) fields can couple with the implant and stimulate adjacent electrosensitive tissue such as a nerve or a muscle. Loops formed of a metallic material (e.g., leads, complex orthopaedic plates and screws) will be subject to induced voltages from time-varying magnetic fields. If the loop is closed, high currents will flow in the loop limited only by the voltage induced and electrical resistance. An open-circuit loop will exhibit induced voltage between the ends. Loops can take any shape; the voltage induced is proportional to the area enclosed. (A closed loop will set up a magnetic field equal and opposite to the field in which it exists producing a force opposing the source field).

RF (10 MHz–300 GHz) fields can couple with the implant to concentrate energy and so to heat adjacent tissue. Reasoning from the first principles such as applying the antenna theory to the implant may be used, after allowing that RF fields in the body are no longer in free space and so their wave-length changes.

Computer programs may help model the deposition of fields into the body and the likely interaction with an implant. However several limitations of computer modelling should be noted. Models make assumptions regarding normal blood perfusion of tissue for cooling and/or oxygenation and nutrition. This assumption may not apply after trauma, disease or surgery, which can alter vascular architecture. This may impair cooling after exposure to RF and/or increase tissue excitability during exposure to ELF. Also models may have difficulty in accurately assessing the concentration of energy at points such as the tips of screws. Computer modelling should be used like any other data from a laboratory test to assist medical decision-making but should not be the sole determinant.

2.3. Risk Control

On the basis of risk assessment the physician should provide advice to the worker and to the employer.

2.3.1. The worker

Advice in plain words should be given to the worker and any proposed alteration to the job discussed and documented. If employment is feasible, the worker should be told to promptly notify any symptoms suggesting interference with their device or implant at work. The worker should be told to notify if the electronic device is changed or upgraded as the risk of interference may need to be reassessed.

2.3.2. The employer

The employer should be advised on the need to restrict exposure to any specific frequencies or field strengths, or needed changes in work practices. If such advice is not feasible to

implement, normal employment procedures would apply. The medical reasons for the device or implant are private and should not be stated to the employer unless agreed to by the worker.

2.3.3. The workplace

The workplace should be monitored for changes in EMF or work practices resulting in changed exposure to workers.

3. SUMMARY

The guidance note is intended to provide a generic risk management framework for physicians and scientists to use when assessing risk for workers with electronic devices and medical implants when working in intense EMF, whilst being consistent with diverse legal requirements.

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APPENDIX
Employment pro-forma for EMF worker

Name:_____

Job:_____

Your work will involve exposure to electromagnetic fields. Electromagnetic fields may interact with medical devices and metal implants so we wish to know if you have any of them in your body. Some examples of metal implants and medical devices are listed below:

- Metal rods, plates, screws, pins or nails;
- Artificial limb or joint;
- Surgical clips or staples;
- Leads associated with devices such as pacemakers;
- Aneurysm clip or coil;
- Intravascular coil, filter or stent;
- Heart valve prosthesis (artificial valve);
- Patches for drug delivery may have an aluminium foil layer (e.g., hormone replacement therapy, angina, nicotine);
- Diaphragm/IUD (coil);
- Any foreign body, shrapnel, bullet or other metal fragments;
- Cardiac pacemakers and defibrillators (ICD);
- Insulin or other drug infusion pumps;
- Continual glucose monitoring (CGM);
- Spinal cord stimulators for back pain;
- Cochlear implants;
- Neurostimulators, e.g., for epilepsy, parkinsonism, or incontinence.

For your safety please answer the following question. If you answer "yes" you may be referred for further medical assessment. If you are not sure please say so.

Have you had medical treatment involving placing metal implants or electronic devices into your body?

Yes. (If you have an implant or device you do not have to specify which one until you see a doctor because this is confidential). ☐

No. ☐

Signed:_____

Date:_____/_____/_____