The General Directorate

Maisons-Alfort, 1 April 2016

OPINION
of the French Agency for Food, Environmental and Occupational Health & Safety

on the electromagnetic compatibility of medical devices exposed to sources of radiofrequency radiation

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES's public health mission involves ensuring environmental, occupational and food safety as well as assessing the potential health risks they may entail.
It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with the necessary information concerning these risks as well as the requisite expertise and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are made public.
This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 1 April 2016 shall prevail.

On 12 July 2011, ANSES received a request from the Directorate General for Health (DGS) and the Directorate General for Risk Prevention (DGPR) to carry out an expert appraisal to assess the "Electromagnetic compatibility of medical devices exposed to sources of radiofrequency radiation".

1. BACKGROUND AND PURPOSE OF THE REQUEST

The use of mobile telephones in hospitals was addressed in a circular, DH/EM 1 no. 40 of 9 October 1995, concerning electromagnetic interference of certain medical devices (MDs) generated by mobile telephones. This circular warned about the risks of interference with medical devices from electromagnetic fields emitted by mobile telephones. It invited healthcare establishments to take steps to inform their staff and patients of this potential hazard, and insisted on the need to switch off mobile telephones in healthcare services.

In 2003, a study by the Committee for the Evaluation and Dissemination of Technological Innovations (CEDIT) indicated that the interference caused by the use of mobile telephones would not affect medical devices if they were more than 1.5 m away and was not hazardous for people with active implanted medical devices, provided that certain precautions were taken. These conclusions have in some cases led to the relaxing of bans within certain health establishments.

In March 2010, the French Ombudsman alerted the Minister of Health and Sports to the cost of telephone calls for hospitalised patients in some establishments that had delegated this provision to external service providers, as well as the use of mobile telephones within establishments, suggesting that the rules for use be relaxed.

At the same time, the use of mobile telephones within hospitals has become very common. Widely used by healthcare professionals, including for certain professional applications (calculating scores, monitoring-transfer alarms, emergency calls, etc.), they are also used by patients and their families, in the various rooms and sectors of the hospital. The recommendations made on the basis of the Circular of 1995 are thus applied less and less.

In view of the sources of electromagnetic fields, such as mobile telephones, Wi-Fi (Wireless Fidelity) and any other relevant source identified by ANSES as contributing to the exposure of medical devices used within hospital establishments and of patients with implantable medical devices, this request mainly asked ANSES:

- to produce an opinion on the potential risks of electromagnetic interference of these medical devices;
- to propose minimum safety distances to be respected according to the different sensitivities of medical devices, in the event that a risk of electromagnetic interference has been identified.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French Standard NF X 50-110 “Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)”.

The expert appraisal falls within the sphere of competence of the Expert Committee (CES) on Assessment of the risks related to physical agents, new technologies and development areas. ANSES entrusted the expert appraisal to several expert rapporteurs belonging to this CES. The methodological and scientific aspects of the work were regularly submitted to the CES. It was adopted by the CES at its meeting on 14 December 2015.

ANSES analyses the links of interest declared by the experts prior to their appointment and throughout the work, in order to avoid potential conflicts of interest with regard to the matters dealt with as part of the expert appraisal.

The experts’ declarations of interests are made public via the ANSES website (www.anses.fr).

To investigate this request, the rapporteurs identified the regulatory and normative texts as well as the scientific publications of interest. They chose to limit the literature search to the period 2003 - 2014, for two reasons:

- the 2003 CEDIT report covers the earlier bibliography;
- the stock of biomedical devices has been almost entirely replaced since the beginning of the 2000s. Therefore, because the technologies have evolved, the study of the electromagnetic compatibility of implanted devices prior to 2003 was of little interest for the expert appraisal.

The report published by the French Health Products Safety Agency (AFSSAPS) in 2005 also served as a bibliographic basis for the expert appraisal work carried out by ANSES. Reports of cases of adverse effects were also sought in the literature and taken into account.

At the same time, hearings were conducted with manufacturers of medical devices and the healthcare professionals who use or implant them, to collect any unpublished data or information and gather feedback from healthcare professionals.

The expert appraisal focused on electrical and electronic medical devices used in care services, as well as on active implantable medical devices (AIMDs) used outside these services. The sources of electromagnetic fields considered were the mobile communication systems of caregivers, patients and patients' families: mobile telephones, Wi-Fi and Bluetooth devices, DECT (Digital

Enhanced Cordless Telephones) and walkie-talkies, especially TETRA type (Terrestrial Trunked Radio). RFID (Radiofrequency Identification) technologies, which are very common today in hospitals, were also taken into account in the expert appraisal. Exposure of AIMD wearers to the fields emitted by the use of induction hobs and by security gates (at airports or in shops) was also considered.

Loudspeakers, including those of headphones and audio headsets, which in principle fall outside the scope of the request because they emit static magnetic fields (magnets), did however undergo a supplementary analysis, due to reports of incidents specific to these devices.

The expert appraisal of the risks of possible disruption of MDs or AIMDs due to electromagnetic interference with MRI equipment is outside the scope of this expert appraisal, because it falls within the competence of the French National Agency for Medicines and Health Products Safety (ANSM).

3. ANALYSIS AND CONCLUSIONS OF THE CES

The Expert Committee on Assessment of the risks related to physical agents, new technologies and development areas adopted the work of the expert group and its conclusions and recommendations at its meeting of 14 December 2015 and informed the ANSES General Directorate accordingly.

Electromagnetic compatibility

In the context of biomedical technologies, electromagnetic compatibility (EMC) is defined as the ability of a device (MD) to operate satisfactorily, i.e. to fulfil the expected functions, in a given electromagnetic environment. The malfunctioning of a medical device, whether it concerns, for example, life-support systems in an intensive care unit or implanted medical devices, consecutive to electromagnetic interference, could clearly have serious consequences for patient health. The expert appraisal report thus distinguishes between two specific environments:

- healthcare establishments, in which many medical devices are found, as well as several types of sources of electromagnetic fields;
- the environment outside the hospital, the living environment of patients wearing active implanted medical devices.

Regulations and standardisation for EMC of medical devices

The placing on the market of medical electrical equipment in the European Union is conditional on prior CE marking. CE marking is under the responsibility of the manufacturer, which must submit the MDs to a procedure for assessing conformity with the essential requirements described in the applicable European directives. These directives rely largely on testing standards, in particular for testing the electromagnetic compatibility of the MDs. The 60601-1-2 Standard (on electromagnetic compatibility of medical electrical equipment) puts forward three principles:

- guarantee a level of emission and "immunity": the standard imposes a level of immunity for MDs, currently 3 V/m for devices not presenting a significant risk, and 10 V/m for so-called vital assistance MDs, such as anaesthesia and resuscitation equipment. This is the level of field for which it can be demonstrated that the product is "immunised", which does not mean that above this level the product will necessarily malfunction. The evolution of the standard provides that if a wireless radiofrequency communication device is likely to be used in close proximity to a medical electrical device, the latter must be subjected to a test of immunity to the specific electromagnetic field, with a level of 30 V/m;

- issue recommendations on use: the second principle involves imposing instructions for use for this equipment to ensure it is used properly in a representative environment. The recommendations must be simple and readable, included in the instruction manuals, and even visible on the equipment. In the documents accompanying the device, therefore, it is requested that a minimum separation distance be specified between the medical electrical devices and radio transmitters such as mobile telephones, base stations or any other type of radio transmitter. The recommended separation distances between mobile telephones and MDs are 3.3 m, both for life-support devices (tested at 10 V/m) and other types (tested at 3 V/m). When the immunity of MDs exposed to telecommunications devices has been verified at 30 V/m, the recommended separation distances are lower: 33 cm for example for a 2G mobile telephone, 18 cm for UMTS (3G);
- risk analysis by the manufacturer: if the manufacturer believes that the use of its MD does not respect the basic guarantees defined, it is responsible for verifying the immunity of its product at higher levels. The risk analysis will seek to minimise the impact on the patient in the event of failure of the equipment.

Medical devices and equipment in healthcare establishments

In hospital care services, non-implantable medical devices are used for diagnosis, prevention, monitoring and the treatment of disease or injury. Their technologies and uses vary greatly: syringe-pumps, respirators, monitoring systems, ultrasound equipment, electrocardiographs, electroencephalographs, electric wheelchairs, etc.

The distribution of these devices within hospitals is also very variable, from low-density areas with only a temporary presence of devices of low criticality to health (patient rooms for example) to areas of very high density with the permanent presence of high-criticality devices, such as intensive care and resuscitation services, or operating theatres.

In the hospital environment, there is a great diversity of sources of electromagnetic radiofrequency fields: mobile telephones, DECT telephones, laptops and tablets, Bluetooth devices, RFID systems, walkie-talkies, TETRA systems and various other communicating devices.

Effects of radiofrequencies emitted by mobile telephones on hospital medical devices

Several generations of mobile telephones currently coexist, which implies exposure in different frequency bands to signals that are sometimes very different (in terms of modulation or intensity). The data in the literature, as well as the measurements carried out, in particular by the National Testing Laboratory (LNE), show that the mobile telephone is potentially the highest source of exposure to radiofrequency radiation, in terms of intensity, among all the radio sources to which the population is routinely exposed. Even if mobile telephones do not permanently emit at their maximum power, this power is greater than the emission power of most of the other wireless communication devices used: DECT telephones, Wi-Fi, Bluetooth, remote controls, etc.

It should also be noted that recently available data on exposure associated with mobile telephones placed near the body, provided by the French Radio Frequency Authority (ANFR, Agence nationale des fréquences) showed very high specific absorption rate (SAR) levels. The compliance tests for telephones laid down by the regulations (Decree No. 2002-775) are carried out in worst-case emission situations (maximum power), but under the conditions laid down by the manufacturers, which advocate keeping the telephone at a distance ranging between 5 and 25 mm when it is placed near the body (apart from the head). When measurements are carried out in contact, i.e. in reasonably foreseeable circumstances of use, the SAR of the vast majority of telephones exceeds the value of 2 W/kg, and often even 4 W/kg, reaching in some cases more than 7 W/kg. When the SAR is so high, the internal electric field levels are high, increasing the probability of interference with implanted medical devices.

The results of numerous challenge studies carried out between hospital medical devices and wireless communication systems, most often in worst-case exposure conditions, are relatively homogeneous. All the studies analysed in the expert appraisal report describe interference with various tested medical devices exposed to mobile telephones, with variable levels of severity. The higher the power of the radiofrequency source, the greater the distance at which the interference is observed, sometimes up to 5 m from the emission source. Most of the authors noted a greater sensitivity of medical devices to the lower mobile telephone frequencies (around 900 MHz) and to second-generation telephones, which are the most powerful devices. The medical devices sensitive to interference that could lead to a failure include syringe-pumps and, more broadly, MDs used in intensive care units. As for monitoring and recording systems, their recording can be modified when a call is received or made in the vicinity of the equipment (50 cm) and at the same time as the examination. This modification could lead to medical errors.

Effects of TETRA and walkie-talkie type communication systems on medical devices

Despite the few studies concerning these devices, particular attention should be paid to the TETRA means of communication. These professional communication systems, whose typical maximum emission power is 1 W (possible range from 0.18 to 30 W), can lead to incidents qualified in the literature as critical, for distances of less than 3 m. The same is true for walkie-talkies at distances of less than 1 m.

Effects of WLAN (Wi-Fi) wireless networks on medical devices

The increasing deployment of wireless local area networks (Wi-Fi) in hospitals responds to objectives related to safety but also to the convenience of patients and caregivers. These networks, which use low-power terminal equipment (generally below 0.1 W), are used for the remote monitoring of certain medical equipment, for instance.

One article out of the four analysed showed one case of interference with a foetal heart rate monitor, among 612 tests performed, at a transmitter/system distance of less than 60 cm. Another study on critical-function MDs highlighted risks of interference for three of the 45 devices tested, when a Wi-Fi transmitter is placed less than 5 cm away. In two cases, the interference was likely to be critical for the patient. Lastly, one publication reported interference of signals from an ECG device worn by a patient in cardiac rehabilitation.

Effects of radio-identification systems on medical devices

The technology of identification by radiofrequencies, known as RFID, helps respond to the need for traceability, either for the identification of equipment or patients, or the tracking of health products from the pharmacy to the patient's bed.

This technology relies on a radiofrequency tag consisting of a chip attached to an antenna, all encapsulated within its housing. The information contained in the electronic chip is read remotely by an interrogator that can in turn transmit other data. The tags can be "active", when they include their own transmitter, or "passive", in which case they use the energy provided by the transmitter's radio signal to send information. The frequencies used by these systems vary greatly, from 125 kHz up to several GHz, according to the desired performance and the constraints of the propagation medium.

It is clear from the analysed publications that RFID can affect the operation of MDs, at distances of less than around 1 m for the systems tested. These results are in agreement with the observations made on systems using frequencies and powers similar to those used by RFID.

EMC of active implantable medical devices

Cardiac implants, cardiac stimulators or pacemakers (PMs) and implantable cardioverter defibrillators (ICDs) are the most widely used active medical implants. Historically, the potential

risks resulting from interference between these cardiac implants and electromagnetic environments have been studied the most. Other types of implants were less studied until the early 2000s, either because their criticality did not pose any risk to life (cochlear implants), or because they were only developed more recently (implanted drug pumps, neurostimulators).

The specific feature of AIMDs is that they are exposed to more diverse and less controllable electromagnetic environments than those found in hospitals.

The sources of electromagnetic interference responsible for AIMD malfunctions can come from electronic security systems (anti-theft gates in shops and airport security gates), medical devices using electromagnetic radiation (electric scalpel, radiotherapy and MRI units), but also domestic or personal sources of electromagnetic fields (induction hobs, mobile telephones, etc.).

The levels of criticality of AIMDs with regard to electromagnetic compatibility can be summed up as follows:

- high criticality: cardiac implants, neurostimulators, drug pumps;
- moderate criticality: certain drug pumps, valves;
- low criticality: cochlear implants.

AIMDs are located in specific areas of the body, for example, heart (cardiac probes), chest (pacemaker and defibrillator units) and head (neurostimulators). Potential interference with electromagnetic sources can thus be related to the use of transmitter devices (mobile telephone against the head or in a breast pocket).

Most pacemakers in service in France today are bipolar. This technical configuration, as well as the integration of filters for rejecting non-cardiac signals, has improved their immunity to electromagnetic fields compared to unipolar models.

Half of the publications analysed concerning high-criticality AIMDs highlighted malfunctions that were mostly temporary and/or reversible, related to sources of electromagnetic fields.

However, few publications have studied interference between AIMDs and telecommunications devices (mobile telephones, Wi-Fi, etc.). The analysed study identifying the largest number of cases (679 patients with pacemakers) found reversible malfunctions in 5.5% of cases, when the mobile telephone was placed less than 10 cm from the AIMD, in a worst-case exposure situation. An additional study conducted *in vivo* on AIMDs, by the same team and involving 43 patients, did not show any malfunctions. Three other studies, on smaller groups of patients or under *in vitro* and simulation conditions, relating to UMTS and Wi-Fi technology, did not show any interference.

While no interference from induction cookers has been documented in the literature, the same is not true for anti-theft detectors or certain RFID-type devices, for which cases of erratic neurostimulator stimulation have been reported.

Concerning other electromagnetic field-emitting sources, especially in the medical environment, various studies have focused on specific cases such as diathermy knives, articulography systems, electromagnetic navigation bronchoscopy, etc. For example, the use of an electrotherapy stimulation technique has been indicated as liable to interfere with cardiac implants, but without any risk to life. On the other hand, two studies *in vitro* and *in vivo*, carried out by the same team, reported that one implantable cardioverter defibrillator (ICD) (out of six tested) generated inappropriate systematic shocks, related to exposure to 434 MHz frequency fields emitted by an endoscopy video capsule a few centimetres away.

A few cases of interference with cochlear implants, reversible and without consequences, have been attributed to an induction hob, an airport security gate, a diathermy knife, an electric epilator and an anti-theft gate.

Lastly, outside the scope of this expert appraisal, portable music or video players have been reported as being able to cause interference in a situation in which a cardiac implant is being reprogrammed (interference with telemetry), for example, but also because of the magnets contained in the headphones, if they are hanging in the implantation zone.

Specific cases outside the scope of the request

Through the scientific publications that were analysed or the hearings that took place, the expert appraisal work on potential interference with medical devices by electromagnetic radiofrequency fields revealed sources of interference that were not part of the initial scope of the expert appraisal. This information, to the extent that it highlights the potential risks of malfunction of MDs, is nevertheless presented below. In the area of static magnetic fields, the magnets in MRIs and headphones were thus identified as sources of MD malfunction. In particular, applications using low frequencies, sometimes close to cardiac frequencies, may be responsible for interference: induction charging systems, induction cooking hobs, portable music players. Lastly, diathermy therapy systems are liable to interfere with MDs, and with neurostimulators in particular.

MRI

Active implants such as pacemakers, cardiac defibrillators or implanted neurostimulators, or any other electronic implant, may be disrupted or damaged by an intense magnetic field. Implants or implanted electrodes could also undergo excessive heating by interaction with radiofrequency waves. A doctor's opinion is therefore essential before any examination of an AIMD wearer.

Diathermy

The use of diathermy devices is contraindicated in particular in patients with implanted metal probes. They are at risk of serious injury if exposed to microwave or shortwave therapy (burns to tissues near the electrodes can cause permanent damage with a lethal risk, or temporary damage, for example inappropriate stimulation). This is true even if the implanted device is switched off and/or the probes are disconnected. Therefore, diathermy by electromagnetic waves or electrical currents is totally contraindicated in all patients with implanted neurostimulators (generators, probes or electrodes).

Speakers, headphones and their magnets

The magnetic fields produced by the magnets in speakers, for example audio headsets, can cause failures or disrupt certain implanted MDs. The effects are due to the static field of the magnets. Users should therefore be informed of the need to keep headphones away from their implants.

Recommendations of the collective expert appraisal

The request made to ANSES for an opinion on the electromagnetic compatibility of MDs with sources of radiofrequency radiation focused particularly on:

- the potential risks of electromagnetic interference of MDs from radiofrequencies;
- the "minimum safety distances to be respected according to the different types of MDs, in the event that a risk of electromagnetic interference has been identified".

For this second point, the expert appraisal work showed that it is not possible to quantify precisely one or more distances to be respected:

- in the hospital environment, due to the multiplicity of possible sources of exposure. Identifying the sources and the existence of distinct areas where medical devices are used nonetheless makes it possible to propose a response in practical situations;

- in non-hospital settings, due to the lack of available data in the literature, the diversity of potential sources of exposure and the fact that it is impossible to control them.

Note that risks in the workplace are not included in the scope of the request.

The identification of each situation, along with vigilance and education/training of health professionals and users should also help optimise and reduce the specific risks of interference, on a case-by-case basis.

General recommendations

Distances between MDs/AIMDs and radiofrequency transmitters

Given the extreme diversity of both the sources of electromagnetic fields (characteristics relating to frequency, power, signals, etc.) and the electronic medical devices, in addition to the situations of exposure of MDs, it is not possible to define a single rule, applicable to all situations, concerning a minimum distance to be respected between the medical devices and the electromagnetic sources.

It seems more relevant to prioritise recommendations tailored to the types of electromagnetic environments of the MDs or AIMDs. For this, it is important to consider the following three points:

- it is necessary to identify specific situations of potential interaction with sources of electromagnetic radiation (hospital environment, home hospitalisation, patient wearing an implant, etc.);
- in-depth analyses should be conducted of potential situations of interaction between the MDs and communication devices or new technologies with a vital interest for practitioners;
- the degree of criticality of an MD is an essential factor in the decision, in particular in light of restrictions on access to mobile and non-mobile sources (operating theatre, intensive care units).

Information for patients and training for health professionals

Most of the recommendations or advice extracted from the publications and the hearings conducted by the rapporteurs advocate better information for patients and training of health professionals, both concerning the implants and knowledge of the electromagnetic sources. Patients with active medical implants do not always find the answers to their questions or concerns relating to electromagnetic environments in their daily lives. This can be seen, for example, from the questions/discussions on medical site forums or associations of wearers. In addition, the manufacturers' instruction manuals are unable to respond to all the possible situations and doctors do not always have the information at hand corresponding to all the different scenarios.

The CES therefore suggests studying the feasibility of establishing a single point of contact (a "one-stop shop"), accessible to all, able to deal with and respond to questions from patients, patient associations and health professionals. This one-stop shop could also compile all the characteristics of the reported incidents, just like the poison control centres, to make them available to the authorities, researchers and other stakeholders.

Training for biomedical engineers in EMC in hospital environments should be developed or strengthened. It is generally these individuals who liaise with the companies that install devices emitting electromagnetic fields in the hospital environment.

Just like practitioners in hospitals, other professionals who use electrostimulators, such as physiotherapists, for example, should also benefit from such training.

Medical device vigilance

The data on medical device vigilance listed by the ANSM have limitations: in particular they cannot currently be used to systematically collect information that would enable testing of possible associations between the failure of an MD and its electromagnetic environment. The CES therefore recommends:

- raising the awareness of health professionals in order to improve the collection of incident reports by the ANSM;
- optimising the system of information reporting and data collection to take into account the hypothesis of electromagnetic interference as the origin of the failure described, in particular by using suitable indicators;
- developing remote data transmission applications available to medical practitioners, regardless of their type of practice, in order to facilitate the entry and reporting of cases of suspected adverse effects, and especially, where appropriate, ensuring that the doctor can describe the environmental factor suspected of being responsible, without this reporting being too burdensome. Currently, a doctor reporting this kind of information has to complete and return the declaration form to the ANSM, in addition to his/her main activity. This should be integrated into a general debate on how to facilitate reporting (medical device vigilance and pharmacovigilance) by doctors;
- improving the training of health professionals in medical device vigilance.

In addition, the CES recommends conducting a large-scale study, among patients and prescribers, to obtain more specific answers about the electromagnetic compatibility of medical devices.

Specific recommendations for medical devices in hospital care services

There are many MDs in the hospital environment, of different types and different generations, with the most recent often providing better immunisation against electromagnetic fields. For this reason, the behaviour to be adopted to avoid the probability of occurrence of adverse effects associated with electromagnetic interference should necessarily be tailored to the different environments.

Areas for limited use of wireless communication systems (mobile telephones and other personal communicating systems)

A ban on the use of mobile telephones and other personal communicating devices in healthcare establishments, as advocated in the 1990s, now seems unjustified. On the other hand, it is important to consider the establishment of areas where uses are authorised, limited and prohibited, which are better adapted in light of the diversity of situations in which wireless communication systems are used. Each hospital should be responsible for the precise definition of such areas, with the support of their head of risk management.

The CES thus recommends that care establishments implement measures to minimise the risks of interference with medical devices:

- for patients, visitors and medical staff using mobile telephones for personal reasons: mobile telephones should be switched off in places with critical medical electrical devices or those used for life support (intensive care units, operating theatres, neonatology, emergency services, etc.), as well as near the beds of patients connected to medical electrical devices;
- for medical staff using their mobile telephones for professional reasons: calls should not be made near medical electrical equipment.

Since the use of DECT telephones generates lower exposure than mobile telephones, the risk of interference is *a priori* lower with DECT telephones. The CES therefore recommends that medical staff prioritise the use of this means of communication.

Concerning paediatric services, remote-control toys can be authorised in public areas of hospitals but not in critical-function services such as intensive care units, operating theatres or accident and emergency departments.

In all cases, mobile telephones should not be placed directly on medical devices and should be kept as far away from them as possible during calls, to the extent possible given the dimensions of a hospital room.

Hospital MDs and TETRA systems

Despite the few studies on the subject, it seems that professional communication systems (TETRA) can cause incidents qualified as critical at distances of less than 3 m.

As far as possible, it is recommended that the emergency services avoid making calls with their individual TETRA radios in the vicinity of critical-function medical devices.

Hospital MDs and WLAN/Wi-Fi systems

The CES recommends that, prior to the installation of Wi-Fi-type networks in a healthcare establishment, a thorough study be carried out of electromagnetic compatibility with the medical devices present, on a case-by-case basis.

Hospital MDs and RFID

Faced with the development of RFID technology, in particular for identifying MDs and other equipment, and the few experimental data available on the subject, research should be specifically undertaken on this issue. Indeed, the identification of MDs by RFID involves the use of RFID readers in direct proximity to the tag and therefore to the medical device identified.

Pending the results of such studies, and if it proves really essential to improve care, the use of RFID systems in hospital establishments should only be authorised during the phases of non-operation of medical devices or while ensuring as far as possible that a distance greater than 1 m is maintained between the interrogator and the medical device.

Interference between different MDs

Certain radiofrequency sources are specific to the medical environment (diathermy knife, articulography systems, electromagnetic navigation bronchoscopy, etc.):

- it is recommended that a "risk-benefit" analysis be conducted by the practitioner before use;
- these devices can also be used in non-hospital medicine (physiotherapy, dentistry or cardiology practices) or in certain cases by the individual at home: in such cases, warnings should be issued.

Other radiofrequency transmitters

The exposure of AIMDs to certain electromagnetic transmitters that are outside the scope of the request nevertheless raises questions (remote-control toys, walkie-talkies). It is therefore recommended that their effects be studied in the framework of specific measurements and work.

In addition, the CES recommends including the issue of interference between MDs and sources of EM fields in the guide to management of risks associated with care in healthcare establishments.

Recommendations specific to active implantable medical devices

The specific feature of AIMDs is that they are exposed to more diverse and less controllable electromagnetic environments than in the case of MDs used in the hospital environment. Thus, even if feedback and technological developments can help gradually improve their levels of electromagnetic immunity, precautions should be taken in their use.

Distances between AIMDs and radiofrequency transmitters

The recommendations presented in the information booklets or instruction manuals of the implantable medical devices given to patients must be followed, particularly concerning the distances to be respected if mobile telephones are used (do not put the telephone in the chest pocket on the side of the implant, make calls with the telephone held to the opposite ear, etc.) or when passing though security gates (anti-theft, airports).

In order to minimise interference with AIMDs, it is recommended to keep a minimum distance of 15 cm between these implants and any magnet, especially those fitted to loudspeakers, and headphones of telephones or music devices. In practice, this means that wearers of cardiac implants should not allow the headphones to hang over their chests.

In addition, interference between digital music players and the telemetry communication of some implants has been observed. Even if they do not affect the actual operation of the implant, it is recommended that a distance of 15 cm be maintained between the bodies of these devices and the implants.

Lastly, it is suggested that the manufacturers of toys using radiofrequencies be required to provide clear instructions as to the levels of immunity by frequency band and the distances to be respected in their product instructions, with specific warnings for AIMD wearers.

Information for patients and training for health professionals

Information for patients, particularly that intended for wearers of AIMDs such as cardiac implants and neurostimulators, must enable them to identify the electromagnetic sources in their environment, so as to adapt their behaviour: maintain a certain distance from the source, avoid lingering near an anti-theft detector, disable the neurostimulator in the event of a clearly identified electromagnetic field area (detector), avoid letting headphones hang near an AIMD unit, etc.

To this end, the CES recommends:

- improving information for patients wearing AIMDs on the precautions to take with regard to their electromagnetic environment;
- introduce a mandatory format for the instruction manual, to ensure that these recommendations can easily be understood by patients wearing AIMDs.

It is also essential that AIMD wearers inform any practitioner they are required to consult of the type of implant they are wearing, so that the practitioner can take this constraint into account when performing any medical procedure using electromagnetic fields.

Training of health professionals should in particular teach hospital practitioners how to analyse the risk/benefit ratio for patients before practising certain therapeutic or diagnostic procedures involving the close proximity of an MD/AIMD and a transmitter of radiofrequency radiation. For example, special precautions must be observed when using MRI on patients wearing AIMDs.

Professional users of TETRA systems must also be made aware of the risks of interference in the framework of an intervention on a person wearing an AIMD.

Lastly, just like hospital practitioners, other professionals who use electrostimulators, such as physiotherapists, should receive training to help them understand how to analyse the benefits/risks

for patients associated with the practice of certain therapeutic or diagnostic procedures involving the close proximity of an AIMD and a transmitter of radiofrequency radiation.

Particular case of diathermy therapy

Patients wearing implanted metal probes are at risk of serious injury when exposed to microwave or shortwave therapy. Therefore, diathermy treatments using electromagnetic waves or electrical currents (muscle stimulators) are contraindicated in all patients with implanted neurostimulators (generators, probes or electrodes).

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety endorses the conclusions and recommendations of the CES on Assessment of the risks related to physical agents, new technologies and development areas described in Section 3. It supplements them with the elements below.

Concerning medical devices used in the hospital environment, the Agency stresses, as an example, the existence of practical risk management measures recommended, in particular, by the Canadian Agency for Drug and Technologies in Health which, in 2011, proposed establishing areas without restrictions on use, areas of limited use respecting a minimum distance of 1 m between the MD and wireless communication systems, and areas where use is strictly prohibited, such as intensive care units. Similarly, in Great Britain, in 1997 and 1999[1], the Medicines & Healthcare Products Regulatory Agency (MHRA) published recommendations for the use of mobile telephones and emergency communication terminals in the hospital. These recommendations have been implemented and adapted locally in hospitals, with guidelines that are regularly reviewed, mainly in order to take technological developments into account.

Concerning active implantable medical devices, the rapid technological evolution of mobile telephones in particular, and the near electromagnetic environment more generally, indicates the possibility of uncontrolled exposure situations at high levels, as testified by the measurements made, in particular, in 2015, by the French Radio Frequency Authority on mobile telephones, whose specific absorption rate (SAR), when the telephone is in contact with the body, has been measured at up to 7 W/kg. In these conditions, the internal electrical fields can exceed the "immunity" levels of certain implantable medical devices. The Agency therefore recommends that wearers of critical active implantable medical devices ensure that they keep away from the greatest sources of exposure (mobile telephones). Stakeholders in the healthcare chain (manufacturers of medical devices, health professionals) should be trained in order that they relay these messages to patients and their families, in particular the precautions for use recommended by the manufacturers.

The Deputy Director General

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[1] Device Bulletin MDA DB 9702 "*Electromagnetic Compatibility of Medical Devices with Mobile Communications*" (MHRA, March 1997) and Device Bulletin DB 1999(02) "*Emergency Service Radios and Mobile Data Terminals: Compatibility Problems with Medical Devices*" (MHRA, May 1999).

KEYWORDS

Electromagnetic compatibility

Electromagnetic interference

Medical device

Medical devices (MDs)

Implantable medical device

Active implantable medical devices (AIMDs)

Healthcare establishment

Electromagnetic interference

General population

Radiofrequencies

RFID

Wi-Fi

TETRA

DECT

Care service

Means of communication

Mobile telephone