Frequency of workers with active implanted or wearable medical devices potentially subjected to interference problems at the workplaces

Alberto Modenese
Dep. Biomedical Metabolic and Neural Sciences
University of Modena and reggio Emilia
Modena, Italy
alberto.modenese@ unimore.it

***Abstract*— Almost all the workplaces determine a certain level of occupational exposure to electromagnetic fields (EMF) for the workers employed. If these workers have Active Implantable Medical Devices (AIMD) or Active Wearable Medical Devices (AWMD), they are considered at particular risk and even if the exposure levels are low, i.e. comparable to those of the general public, it cannot be excluded a priori a risk of electromagnetic interference for all these types of devices. Also for these reasons, for risk assessment and health surveillance (HS) purposes these workers have to be taken into particular consideration, and their identification is fundamental for prevention purposes. Objective. To estimate the amount of workers with AIMD and AWMD and to have an overall panorama of the main types of portable medical devices possibly affected by interference problems in the workplaces. A survey was administered to 132 Occupational Physicians (OPs) in Italy through Google form. The data provided by the OPs refer to a population of >200,000 workers and indicate that the 0.8% of them can be considered as particularly sensitive to occupational EMF risk for the presence of AWMD or AIMD. The most common AWMD resulted hormones/drugs pump and hearing aids, worn by the 0.4% of the working population. Considering AIMD, the most frequent resulted cardioverter defibrillators and pacemakers, implanted in about the 0.2% of workers. In conclusion, an increased susceptibility to the occupational EMF risk has to be specifically considered for a proper risk assessment and HS of the exposed workers. Our data indicate that a number of medical devices can be affected by potential interference problems at the workplaces, and that about the 1% of all the workers (NB: this percentage can possibly increase, as the working population is progressively aging and the indications for the use of these kind of medical devices are icreasing) can be interested by this problem.**

Keywords—electromagnetic interference, active implanted medical devices, active wearable medical devices, occupational exposure, health surveillance

I. INTRODUCTION

Occupational exposure to electromagnetic fields (EMF) is nowadays almost ubiquitous [1]. Even if in the large majority of the scenarios EMF exposure levels at work are kind of low, often lower than the ICNIRP reference levels for the general public [2-3], electro-magnetic interference (EMI) in case of presence of subjects with Active Implanted Medical Devices (AIMD) or Active Wearable Medical Devices (AWMD) is possible. The 2013/35/EU Directive defines these workers at "particular risk" and for them it is indicated to take special actions for the prevention both during workplace risk assessment and occupational health surveillance (HS) [4]. In fact, the EMI risk in workers with AIMD or AWMD an may result in problems such as inappropriate stimulus or impossibility to detect the signals or desetting of the devices. These issues seem not frequent, but some cases have been reported in scientific literature, e.g. for cardiac pacemakers (PM) and for implantable cardioverter-defibrillators (ICD). According to these premises, the main objective of our work is to estimate the frequency of the workers with AIMD and AWMD at the workplaces. Moreover, we wanted to provide a panorama of the main types of devices used, potentially experiencing EMI problems.

II. METHODS

Within the Italian national project BRIC22-ID36 supported by the workers' compensation authority (i.e. *Istituto Nazionale per l'Assicurazione contro gli Infortuni e le Malattie Professionali*, INAIL), we administered a questionnaire to 132 Medical Doctors practicing as Occupational Physicians (OP) in various Italian companies. We used the Google Forms platform and we contacted the doctors in the occasion of specific training courses and directly via email. We asked them to respond based on their HS activities for exposed workers during the previous year. We wanted to know from them the estimated numbers of workers visited who had an AIMD or an AWMD.

We provided to OPs a list of nine different AIMD and AWMD, including images (Fig 1), and then a further tenth item asking to indicate any other device encountered in survailled workers.

III. RESULTS

In the Figure 1 a representation of the nine types of medical devices investigated for their frequency in workers within our questionnaire is shown (Fig. 1). They are:

AIMD

a) PM

b) ICD

c) implanted loop-recorders

d) cochlear or brainstem auditory implants

e) implanted central nervous system (CNS) neurostimulators

f) implanted peripheric nervous system (PNS) neurostimulators

AWMD

g) active wearable prostheses for arms or legs or other wearable aids for motor functions

h) wearable pumps for the infusion of drugs or hormones

i) wearable hearing aids

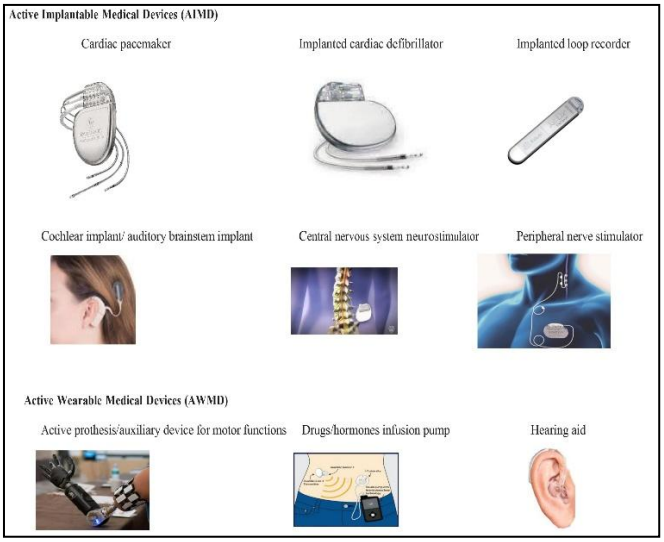

Figure 1. The nine active implanted and wearable medical devices investigated for their frequency within our questionnaire

The 132 OPs who responded to our questionnaire visited a total of 204,585 workers within companies' HS programs during the previous year, Only about the 7% of the workers visited have been judged as "occupationally exposed to EMF". These workers are potentially exposed to EMF levels higher than the reference levels considered for the general population and for them an assessment of the EMF risk at the workplace was available in the occupational health and safety documents of the companies, with specific preventive measures emplaced.

In Table 1 we present the frequency of AIMD and AWMD detected by OP during HS in workers, distributed according to the nine types of devices investigated, plus indication of additional devices identified by the OP (NB: only the glucose wearable sensors for continuous monitoring of glycemia have been identified specifically by the OP in addition to the other devices) (Table 1).

Cardiovascular AIMD, as a whole, resulted by far the most frequent AIMD, considering the 0.15% of the workers having a PM, the 0.1% carrying an ICD and the 0.04 with an implanted loop recorder (Table 1).

Implanted neurostimulators were found as not frequent in workers, involving only the 0.02% of the population under HS (Table 1).

Considering wearable devices, hearing aids resulted the most frequent, with a percentage even higher than the one found for PM: the 0.26% of the workers were found with an AIWD for their auditory function (Table 1).

Also wearable pumps for the infusion of hormones or drugs resulted frequent, again more frequent than PM: the 0.17% of the working population had one of these devices (Table 1).

On the other hand, active wearable prostheses and other auxillary devices for motor function resulted rare, having been reported only for the 0.02% of the population, with the same percentage also for glucose wearable sensors (Table 1).

Finally, OPs reported that there is another 0.01% of the working population having either an AWMD or an AIMD, but they were not able to recall the specific type of device encountered (Table 1).

TABLE I. FREQUENCIES OF ACTIVE IMPLANTED MEDICAL DEVICES AND OF ACTIVE WEARABLE MEDICAL DEVCICES AMONG WORKERS UNDERGOING HEALTH SURVEILLANCE IN ITALIAN COMPANIES AS REPORTED BY THEIR OCCCCUPATIONAL PHYSICIANS

	DEVICES	***Percentage (%) and total number (n) of workers with the device visited in the past 12 months by the Occupational Physicians***
AIMD	Pacemakers	0.15 (299)
	ICD	0.09 (188)
	Loop recorders	0.04 (87)
	Cochlear implants	0.06 (126)
	CNS neurostimulators	0.01 (24)
	PNS neurostimulators	0.01 (15)
AWMD	Active prostheses	0.02 (36)
	Drug/hormone pumps	0.17 (349)
	Hearing aids	0.25 (521)
	Sensors for continuous glucose monitoring	0.02 (32)
Other devices (not specified by the Ops, not clear whether AIMD or AWMD)		0.01 (25)

Table Legend: AIMD= Active Implantable Medical Device; AWMD= Active Wearable Medical Device; ICD= Implantable Cardioverter-Defibrillator; CNS= Central Nervous System; PNS= Peripheric Nervous System

IV. DISCUSSION

The results of our questionnaire-based investigation involved 132 OPs, referring to an overall sample of 204,585 workers subjected to HS by the OPs during the previous year, of which 13,360 (6.53%) represented the "workers professionally exposed" to EMFs according to the risk assessment documents. The analyzed results indicate, as expected, that the most common AIMDs found by the OPs in workers during their daily practice of HS are related to the support of cardiovascular function, and, according to our data, may involve up to 0.3% of the working population. In fact, 55% of OPs visited workers with PM in the previous year: one OP reported having visited 20 workers with PM, twelve others reported having visited 10-15 workers, while the remaining OPs reported lower numbers. 60% of the OPs visited workers with ICD: only two OPs found ICD in 10 workers and three in 6-7 workers, while the remaining OPs reported lower numbers. The ILR was reported by 40% of OPs, with one practitioner indicating having examined 12 workers with this device and two OPs reported having visited respectively 4 or 5, while the others 3 or less. Considering this, the major potential interference problems in the case of occupational EMF exposure for workers with AIMD could affect subjects with implants for the cardiovascular function, involving 574 workers (Table 1). This data is in line with the number of medical devices implanted in Italy in 2017, when, according to the Italian Hospital Discharge Database, have been implanted 49,716 PMs and 24,255 ICDs [5].

With regard to other types of AIMD, these resulted much less frequent when compared to those related to the cardiovascular apparatus, so that, even grouping together neurostimulators and cochlear implants, our estimates indicate that less than the 0.1% of the working population could have these types of implanted devices. In particular, our data show that during HS only the 35% of the OPs reported to have visited workers with cochlear/brainstem hearing implants, the 14.4% examined workers with central neurostimulator and the

10.6% visited workers with peripheric neurostimulators (Table 1).

The most studied AIMDs are PM and ICD, in terms of interference with EMFs [6-12]. Although in vivo data collected during occupational activities regarding AIMDs and possible interference problems are scarce, they suggest that such issues may occur but are reversible and fortunately clinically silent, and could be discovered during the periodical clinical checks of the devices [9-11]. In fact, only interference occurring at the same time as a necessary stimulation could result in severe clinical manifestations, since a modification in the sensing function of a PM may not recognize a cardiac rhythm alteration. Moreover, interference between EMFs and cardiac active devices could also result in an unnecessary stimulation [13].

For what concerns in vivo occupational studies, Souques et al. found no interference problems studying an electricity company where three workers with ICD were exposed to 50 Hz EMF [14]. Moreover, Tiikkaja et al., studied 11 volunteer workers with PM and 13 with ICD exposed to 2-200 Hz magnetic fields, electronic article surveillance (EAS) gate emitting EMFs, an induction cooktop and a metal inert gas welding machine, finding no interference problems in any of the scenarios involving PM with bipolar settings and ICDs [15]. They only found interference between three PMs with unipolar settings and 2-200 Hz magnetic fields and one of them showed interference problems with the EAS gate and the welding machine [15].

On the other hand, analyzing studies performed on trunk simulators, Mattei et al. found significant interference problems between AIMD and static magnetic fields of MRI scanners [10-12]. Korpinen et al. found interference problems in several types of PM in work scenarios with workers struck by spark discharges or immersed in magnetic fields of shunt reactors at 400 kV substations [8-9].

For what concerns interference in standard exposure conditions, some studies involving various types of AIMD show that interference problems may occur more often in case of devices with unipolar settings, while electromagnetic interference affects less the most recent devices with bipolar configurations, as depicted by Huang et al. in case of GSM mobile phones exposure [7] or by Guag et al. in case of walking-through metal detector security systems [6]. On the other hand, it should also be considered that AIMD classified as “MRI-conditional”, which can be used while undergoing a MRI scan as patients after an appropriate setting of the devices [16-17], cannot be evaluated as safe for workers exposed to EMF e.g. as MRI operators, since it is not possible to modify the settings of the devices every time the workers would need to approach closely to the MRI scanner [13].

Regardless the exposure conditions, a specific individual risk assessment needs to be performed for workers with AIMD or AWMD. For AIMD, the European Standards of the family EN 50527 provide guidances to perform such risk assessment. The particular standard EN 50527-2-1:2016 contains specific guidance for pacemakers [18], whereas the EN 50527-2-2:2018 focuses on ICD [19].

No international standards or technical documents are currently available, on the other hand, for the individual risk assessment of workers with AWMDs exposed to EMF [13]. Nevertheless, our data show that some of these devices are frequent within the working population, and should deserve considerations during HS activities with respect to possible EMF interference problems. For what concerns AWMD, the most frequent devices were hormone/drug pumps and hearing aids, for a total of 870 devices, constituting approximately 0.4% of the total workers subjected to HS by OPs in the previous year.

External hearing aids were reported by 93 OPs (70.5%): six doctors reported having visited more than 10 workers with these devices, of which two OPs reported having visited 50 (Table 1). It should be noted that interferences in these cases may be heard as buzzing noises by the subjects [20]: in principle it is questionable whether this represents a real direct adverse effect to be considered for prevention, but it should be considered that in many workplaces it is fundamental to be able to hear alarm and warning sirens for the prevention of occupational accidents, avoid any indirect consequence related to a malfunction of the wearable devices. Furthermore, this type of malfunction could lead to a loss of concentration by the worker which could have consequences on safety.

The other frequent AWMD resulted from our investigation are the pumps for the infusion of hormones and/or drugs: 94 OPs (71.2%) visited at least one worker with this device, and in ten cases the number of workers involved was greater than 5 (maximum value = 20) (Table 1). Case reports describing EMI phenomena in wearable infusion pumps at workplaces have been documented in the literature [21-22]. In this case, the effects of the interferences are potentially severe, as they can have an impact on the appropriate delivery of the therapeutic treatments [23].

Consider other types of AWMD, we did not find that active functional limb protheses and/or other AWMDs assisting motor functions are common in the Italian working population nowadays: only 17 OPs (12.9%) reported to have visited such workers, for a total of only 36 workers.

Finally, it is interesting the data related to a further type of AWMD, directly reported by the OPs as it was not included as a specific item within the administered questionnaire: doctors estimated a number of 32 workers, presumably affected by diabetes, with wearable active sensors for glucose monitoring visited in the previous year during HS. It should be underlined that this data could be underestimated in our study as we did not specifically ask for this device to the OPs.

Summarizing our estimates of the workers with AIMD and AWMD present at the workplaces, it has to be considered that these workers are definitely at increased risk of EMF-indirect effects and represent about the 1% of the working population. Nevertheless, the data referred by the OPs indicate that approximately the 6.5% of the whole working population they follow within HS programs for the companies are exposed to relevant levels of EMF. Accordingly, if we refer to this subgroup of workers and we apply to it the proportions of workers with active implanted or wearable medical devices, we may find out that up to the 13% of the total working population with relevant EMF exposure could be potentially considered as “workers at particular risk” according to the EU 2013/35 Directive [4]. Another aspect that must be considered is the increasing diffusion of AIMD and AWMD, as well as the ageing of the working population and the ubiquity of EMF emitting sources at the workplaces, and the new technologies and sources developed: it is therefore fundamental that OPs know the most common devices that can be affected by interference problems, in order to carry out appropriate HS

programs for risk prevention and promotion of workers health and wellbeing.

V. Conclusions

The results of our study show that the 0.8% of the working population can be estimated as "particularly at risk" with respect to occupational EMF exposure for the presence of active implanted or body-worn medical devices. According to our study, the most common AIMD are cardiologic devices (PMs, ICDs, ILRs), while the most common AWMD are hormones/drugs pumps and hearing aids. Very scant data are available on the frequency of neurostimulators, cochlear/brainstem implants and wearable active prostheses among workers. This condition of increased susceptibility must be carefully considered by OPs during HS activities, and it should be specified that potential interference problems could also occur for levels of exposure to EMFs comparable to those measurable for non-professionally exposed populations, in the case of particular proximity to relevant sources. Adequate health surveillance and fitness-for-work evaluation of these workers must be carefully implemented to reduce this risk, also by consulting, in specific situations, the devices' manufacturers and/or the doctors specialist in the disease(s) requiring the devices.

The data presented in this work provide a solid foundation for quantifying the actual impact of workers with AIMD and AWMD on the overall framework of HS programs. Additionally, they help better focus efforts on improving awareness and sensitivity among OPs toward this particular group of workers.

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