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Importance of Training Health Care Professionals in Medical Technology

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The progress of medical technology during the past 60 years is the driving force of the radical change in the way health care is delivered nowadays. Many simple devices like syringes, needles, personal protection and many other sterilizable products in the 1950's have been replaced by single use devices that are produced in quantities of tens of billion items each year with an accelerated pace. Implantable devices, like knee and hip prostheses or dental implants, are common practice with a huge variety of products on the market. The same holds for active implantable medical devices (AIMDs) like pacemakers, defibrillators, or infusion pumps. The progress in the In Vitro Diagnostics (IVDs) is also impressive with thousands of tests available today. It is estimated that over a million products available on the world market today are classified as Medical Devices.

A clear indicator of this progress is the number of patents released every year for medical devices. Just as an example, according to MedTech Europe, more than 15,000 patents applications are deposited at the European patent office (EPO), that represents 41% of the worldwide total medical technology patent applications. The medical device sector together with Digital communication are top of the list overpassing all other sectors, like Pharmaceuticals or Computer technology in this aspect.

In response to these developments and to assure the quality and safety of the product that are reaching the market, in most countries there have been established regulatory mechanisms for medical devices approval before been placed on the market. In the EU for instance after the introduction of the Medical Devices Directives (MDDs) for AIMDs (90/385/EEC), MDs 93/42/EEC and IVDs 98/79/EC. These directives have been accompanied by several guidelines on classification, nomenclature, and vigilance, just to name some. A certification system has been established through the involvement of Notified Bodies assigned for this task by the Competent Authorities of each member stage, or other linked non-EU countries to this system. Hundreds of harmonized technical standards or European norms (EN) have been and are continuously developed and updated by CEN/CENELEC to face the needs. These directives of the 1990's have been replaced in 2017 by two regulations: One for IVDs (2017/746) and one (2017/745), for all other MDs including AIMDs. These regulations are stricter than the previous directives aiming to improve safety and better protect the patients, in a balanced way to avoid big obstacles for innovation. Therefore, control of the EU market seems well regulated, and it is similar in other parts of the world.

Additionally, the regulatory frameworks for MDs over the world contain a provision of a vigilance system, that follows them after they have entered the market with an associated adverse event reporting system and in some cases an obligatory parallel post-market surveillance system. These systems aim to increase patient safety by preventing the recurrence of adverse events, like already reported ones. This is achieved by mandating users and manufacturers of medical devices to report to the health authorities, incidents where a medical device has potentially contributed in death or injury of a patient or user, and where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.

Health technology assessment (HTA) for medical devices has also attracted the interest of regulators and a new Regulation (EU) 2021/2282, has been voted recently aiming to coordinate the way assessment is done for medicines and certain medical devices groups, by the respective national HTA agencies. This regulation is planned to be applied by January 2025. For medical devices it also is recently recognized that they need a different approach of assessment, considering their big differences with medicines, in their way of application, action and use.

It is therefore clear that both placing MDs on the market and their assessment are well regulated. However, the third pilar of medical technology safety, that is management of MDs during use, remains nonregulated. In fact, the way the medical devices are maintained, repaired, and used is left to the healthcare units they belong. Quality control, preventive maintenance, repair or withdraw, do not necessarily imply certified involved parties or users. This last issue is very critical, since correct application of medical technology, as intended by the manufacturer, is of prime importance for diagnosis, treatment, and overall safety of the patients.

According to data extracted by the Manufacturer and User Facility Device Experience (MAUDE) database, of the US Food and Drug Administration (FDA), almost 3 million adverse event reports, involving MDs, are submitted each year. A large proportion of them are due with use errors.

There are several reasons behind the large increase in the number of adverse events attributed to non-appropriate use of medical devices. The variety of devices available today, their non uniform instructions for use, the non-self-evident user interfaces of the medical equipment that are often computer driven, etc. For instance, in a medium sized modern hospital of less than one thousand beds, one could find more than 15 different types/models of infusion pumps, 17 different types/models of portable ventilators, 10 different types/models of ICU ventilators, 20 different types/models of multiple vital physiological parameters monitoring systems and 35 different types/models of bedside monitoring systems. This situation creates a burden for the medical and paramedical staff that must pass from one device to the next, with completely different user handling requirements, thus increasing the risks for an adverse event due to use error.

Therefore, it is very important to establish regular and continuous user training programs to maintain the knowledge and skills of medical and paramedical personnel, in the principles of operation and the practical use of medical devices. There are various ways to implement such programs nowadays. Apart for the traditional face to face or distance learning courses, there are numerous alternatives for synchronous or asynchronous teaching approaches that have been developed to respond on the needs imposed by the covid-19 pandemic. Additionally, new simulation means are available for virtual training and finally, the use of AI is expected to greatly increase the way courses will be prepare and presented in the future.