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Human factors engineering for medical devices: European regulation and current issues

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Abstract

A large proportion of the patient injuries or deaths attributable to medical device (MD) misuse can be eliminated and/or mitigated by adopting an effective human factors and ergonomics (HFE) approach. The implementation of a usability engineering process is now mandatory for MD manufacturers seeking to obtain the European Union's CE Mark. Here, we describe the European Union's HFE regulation and highlight the challenges faced by (i) manufacturers implementing this regulation and (ii) regulatory bodies charged with assessing the compliance of usability files. In Europe, 95% of MD manufacturers are small- and medium-sized enterprises; compliance with the CE Mark regulations is a real challenge to their competitiveness. Levels of knowledge about HFE vary greatly from one regulatory organization to another, which can sometimes lead to very different expectations. We also present the specific use-related risk management approach required by the HFE regulation. Lastly, we focus on the limitations of the HFE regulation for MDs and on future HFE challenges in further reducing and/or eliminating MD use errors. The main challenge is the need to go beyond technology design and the premarket assessment and to look at the postproduction stage; the coupling between an MD and a sociotechnical system can lead to consequences that were not predicted during the design process. This implies the need to consider the emerging properties of technologies in use by involving all the stakeholders.

Key words: ergonomics, risk, human factors, medical device

Introduction

Over the last few decades, innovative medical devices (MDs) have become increasingly important for better patient care and public health [1]. Technological innovation is always considered to be a key factor in healthcare; it promises ever better care and, in most cases, cost-effectiveness. Surprisingly, the human factors and ergonomics (HFE) community has accorded little importance to MDs. The number of HFE publications referring explicitly to MDs has only started to grow over the last 10 or so years. The PubMed database contains fewer than 300 publications on this topic, starting in 1983 (Figure 1).

HFE studies of MDs are strongly influenced by the European Union's CE mark regulations. The objectives of the present article are to (i) describe the genesis of MD HFE regulation in Europe, (ii) describe current issues in the HFE regulation, (iii) specifically address the difficulties raised by the use-related risk management approach to MDs required in the European Union and (iv) discuss future challenges in HFE research on MDs.

The genesis of the HFE regulation in the field of MDs: from user error to use error

The MD market is highly innovative, very large and very diverse; it encompasses more than 20 000 types of product, ranging from single-use consumables (dressings, compresses, etc.), personal protective equipment (PPE), implants (breast prostheses, pacemakers,

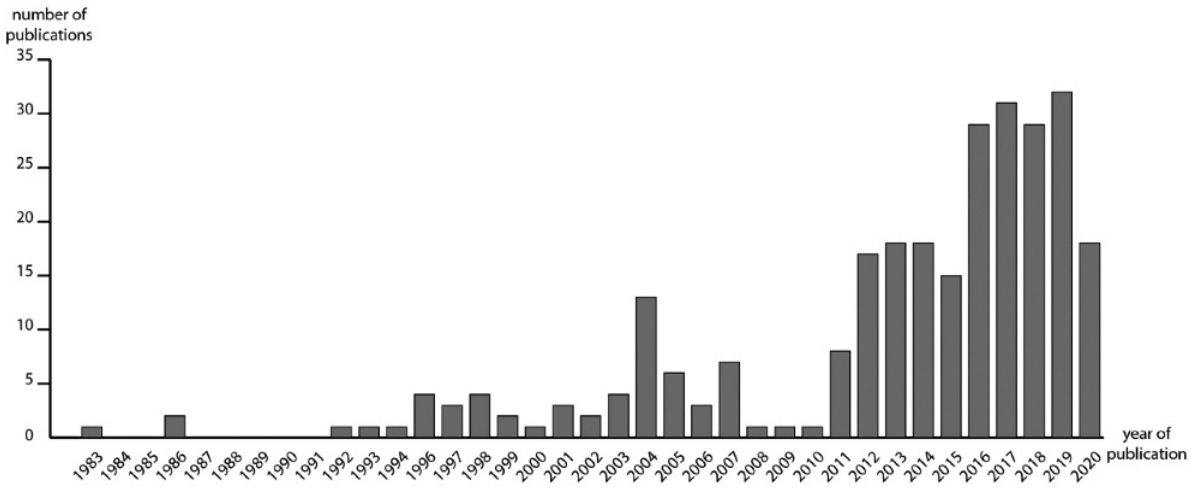

Figure 1 In June 2020, the PubMed database (titles and abstracts) was searched with the following keywords: 'Human Factor*' OR 'Ergonomic*' OR 'Usability' AND 'Medical device*'.

etc.), infusion pumps, medical beds, diagnostic devices, reagents and lab robots. The European Union's Regulation 2017/745 defines an MD as 'any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) […]' [2]. The medical indication claimed for an MD is thus critical.

However, the way an MD is used by its users has an impact on its clinical benefit and, more broadly, on the quality of care or even patient safety. The HFE and patient safety literatures abound with stories of death due to a use error, i.e. 'a user action or lack of action while using the MD that leads to a different result than that intended by the manufacturer or expected by the user' [3]. These problems are more common than most people realize and are not limited to a small number of complex MDs. A well-known illustration is the case of Denise Melanson—a Canadian who died after an infusion pump was programed by a nurse to deliver a medication over 4 hours rather than 4 days [4]. Another example involved 34 German patients who required re-operation because their knee prostheses were implanted in the absence of bone cement [5].

If an MD has a problem, the user was always the first to be blamed [6]. Indeed, if the device has performed technically as intended, then the user is typically accused of lacking training, being inattentive or incompetent or not reading the instructions. However, there is a growing recognition that 'user error' ('human error') is not independent of the broader work system within which users act and interact [7]. Under this view, errors are considered as a consequence of a failure of one or several parts of the system, rather than being entirely attributable to the individual involved. The European Union's regulatory system for MDs has acknowledged this conceptual change by replacing the term 'user error' by the term 'use error' [8]. Design-induced use errors are therefore seen as a possible cause of patient injury or death. This change in mindset raises the question of the appropriateness of design choices for the use of an MD by specific users and in specific contexts [9].

The change also highlights the importance of taking account of actual work procedures, habits and collective aspects of use, as well as the characteristics of the work environment within which humans and technologies interact. The MD will impact work practices and changes must be anticipated during the MD design phase. This system-based approach to designing tools is widely acknowledged by the HFE community as being essential. The approach requires an understanding of all the factors related to how an MD is used. However, it is known that some issues go beyond the MD per se and concern (for example) collaboration on shared processes—even when people are not using the MD—or institution's broader organizational policies.

In Europe, EN 62366 [8] is the harmonized HFE standard for MDs. It was adapted from the international standard IEC 62366 (Figure 2) and came into force in 2007—a few years after the USA adopted similar regulations [10, 11]. This European standard was then significantly revised and reorganized [3,12] so that it was more in line with the 2011 draft guidance on human factors of the FDA [13]. These HFE standards are standards for the analysis, design, verification and validation of safety-related usability through the MD development cycle.

It should be noted that the terms 'human factors engineering' and 'usability engineering' are considered to be synonyms in the above-mentioned standards and can be used interchangeably [14]; we will use the term 'HFE' hereafter.

The human factors engineering regulation for MD and the corresponding method: a use-related risk management approach

The HFE process is based on human-centered design for interactive systems [15]. This method is intended to make systems usable and useful by (i) focusing on users and their needs and (ii) applying existing HFE knowledge and techniques [16]. This approach promotes effectiveness and efficiency and improves human well-being, user satisfaction, accessibility and sustainability.

The objective of the HFE process (as required by the MD regulations) is to maximize the likelihood that new MDs will be safe and effective for the intended users, applications and context of use [12, 17]. The HFE process is therefore closely intertwined with the risk management process (Figure 3); it evaluates and mitigates usability-induced use errors that could result in risks for patients and healthcare staff. With this goal in mind, manufacturers have to minimize use-related hazards and risks and then confirm that these

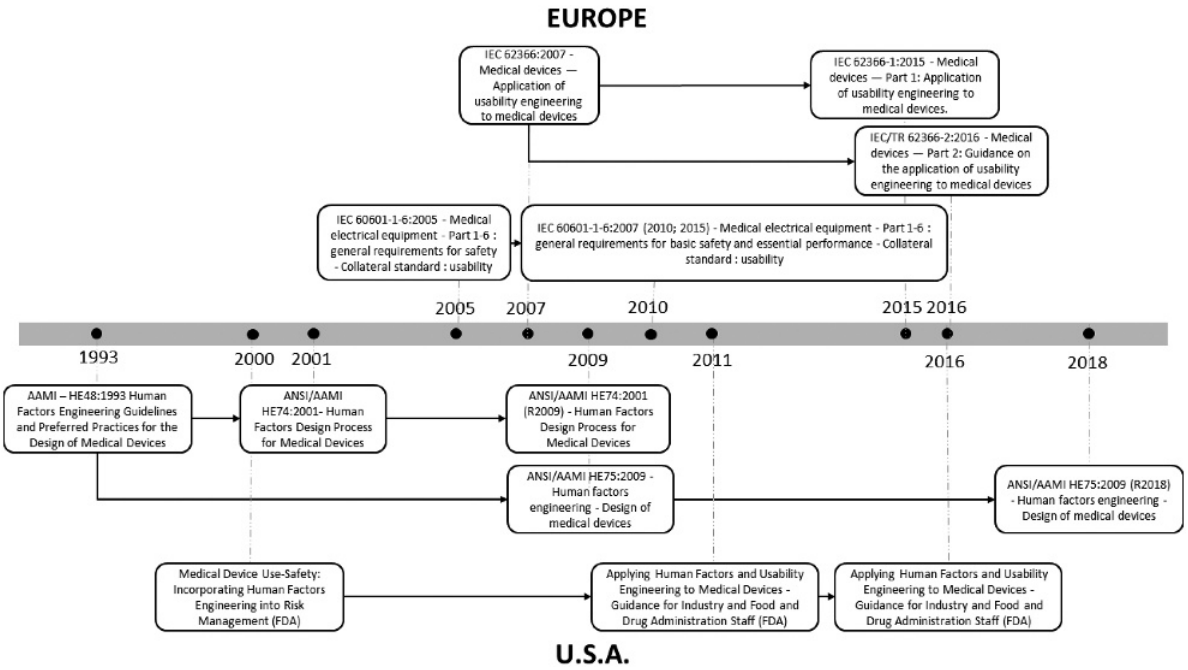

Figure 2 The main HFE standards and guidance applicable to MDs in Europe and in the USA.

efforts are successful and that users can use the device safely and effectively. The manufacturer has to perform a usability evaluation of the reasonably foreseeable hazard-related use scenarios and evaluate the residual risk. If the HFE process has been complied with, then the usability of an MD as it relates to safety is presumed to be acceptable—unless there is objective evidence to the contrary. The design control process must include an analysis of the risks associated with device use and the measures implemented to reduce those risks.

The HFE effort can be tailored with regard to the risks created by usability problems and the risks' severity. The MD function is also important; a technically simple MD might pose greater use-associated risks and call for much more HFE studies than a more complex one. When the development effort modifies an existing MD, a smaller-scale HFE effort can be then focused on the modified elements and the latter's effects on use of the MD.

The use-related risk prevention process is not easy to understand and implement. It is well known that the normative documents and guidelines that are supposed to facilitate the implementation of the process are themselves affected by usability problems [18]. Based on these documents, manufacturers are not able to imagine the HFE process that is truly expected of them: they may think that they already have implemented the HFE process by applying the risk management process. Some manufacturers do not understand what use-related risks are. From the perspective of the notified body (NB), the HFE documents do not provide relevant criteria for assessing compliance with the essential requirements. Implementation of the HFE process clearly requires more than the application of a standard or guideline. Even though the HFE documents must be usable and helpful to their users (e.g. manufacturers and NBs), they cannot alone substitute for in-depth expertise in HFE.

Manufacturers must therefore improve their skills in the field of HFE. This raises the question of the company's initial level of maturity in HFE [19] and then the level required to achieve a satisfactory cost–benefit ratio. Educating technical and managerial staff about HFE provides companies with long-term benefits [20]. Whether a company should hire a full-time HFE expert will depend on the company size, and the complexity and types of MDs being developed. In this respect, the learned societies for HFE in Europe created a professional certification system in 1992: the Centre for Registration of European Ergonomists is a nonprofit organization that certifies HFE professionals as 'European ergonomists' ('Eur.Erg.') and is endorsed by the International Ergonomics Association.

Human factors engineering regulation for MDs and current issues

Like all manufacturing industries, MD manufacturers are subject to high costs and time pressure. The MD market is global, dynamic and innovative, with short product life cycles. In Europe, the MD sector comprises around 32 000 companies, 95% of which are small- and medium-sized enterprises [21]. Maintaining an MD manufacturer's competitiveness and capacity for innovation is a real challenge when it has to comply with the regulations for CE marking. Moreover, new European Union regulation on MDs [2] is set to come into force in the spring of 2021; it will tighten requirements and require high levels of clinical evidence. Small- and medium-sized enterprises often have limited internal resources and skills—especially when it comes to HFE. Furthermore, the requirement related to MD HFE is only one of the regulations with which the MD manufacturers must comply. The impact of the new MD regulations and the economic crisis associated with the coronavirus disease 2019 pandemic might be fatal for many manufacturers but represents a unique opportunity for others.

From the regulatory bodies' perspective, the European market is significantly fragmented because many countries have their own set of rules [22]. Even though the regulations are harmonized within the European Union, their implementation is left to the discretion

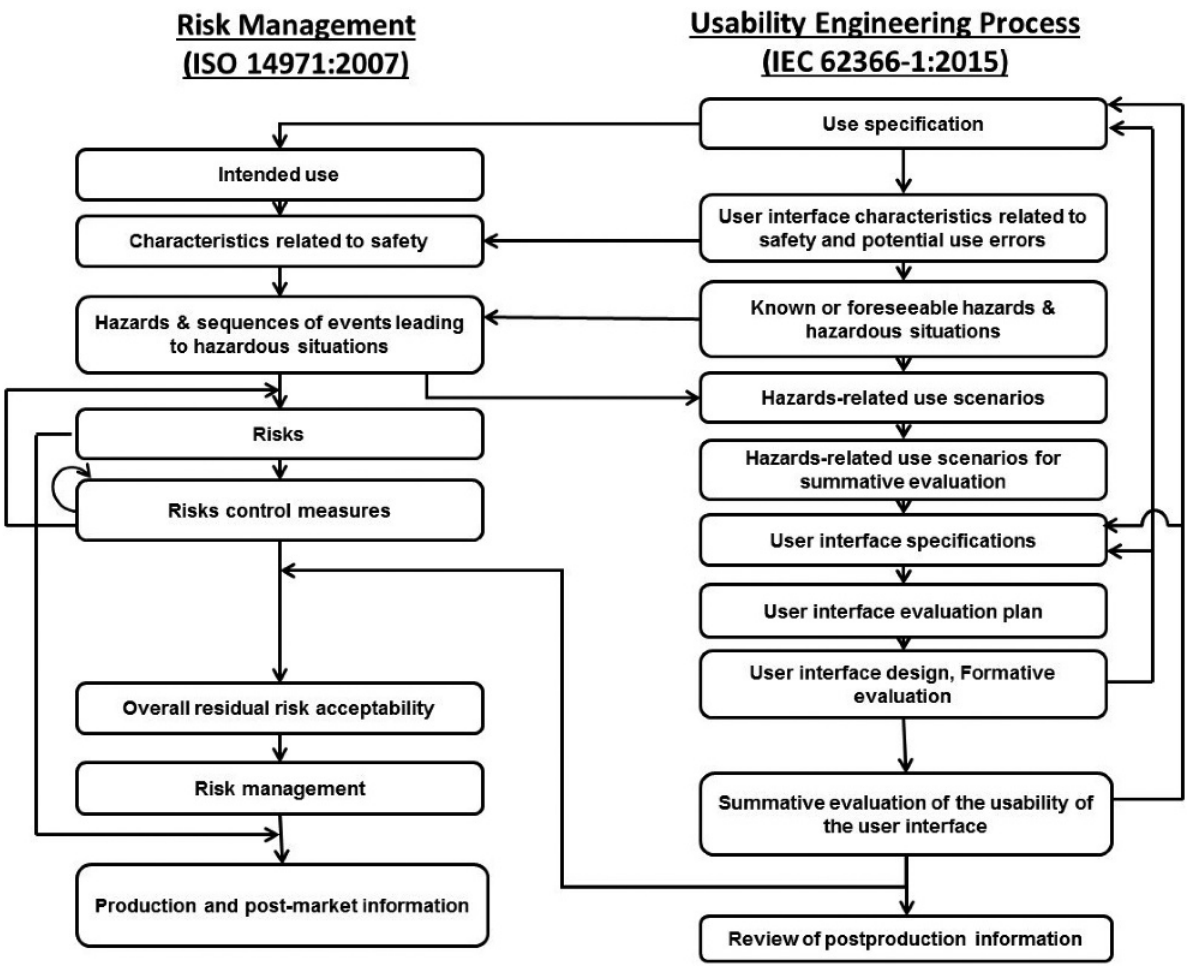

Figure 3 Steps in the HFE process and their relationships with applicable parts of the risk management process, as described in the IEC 62366–1:2015 usability standard.

of the Member States. NBs are authorized by a Member State to determine whether a marketable product complies with regulatory requirements. The level of emphasis on HFE for MDs and the corresponding skills and knowledge vary markedly from one NB to another. After several scandals [23, 24] and ahead of the imminent introduction of new MD regulation [2], the requirements with which NBs must themselves comply have been radically reinforced. A number of NBs have closed down in the last 5 years, and only 20 are currently designated in the European Union's regulation 2017/745 on MDs [25].

In this context, one can legitimately question the actual impact of these regulatory enhancements (particularly the HFE regulation for MDs) on patient safety and quality of care. There has been a clear increase in the manufacturers' knowledge of the HFE process. Most of the companies no longer question the value of this approach or the meaning of 'use errors', as was the case when the regulation came into force [26]. It is currently imperative for manufacturers to ensure an effective overall market access in order to access the market as quickly as possible. This requires to (i) be able to tailor the HFE effort to the type of MD and the associated use-related risks and (ii) integrate efficiently the HFE process with all the other necessary processes (e.g. technology maturation, preclinical evaluation and health economics assessments). This winning strategy will also be a winning strategy for patients, caregivers and healthcare professionals who will have safe innovations with proven clinical benefit. In this context, HFE cannot be considered as an isolated process; the overall strategy for a MD needs to be well thought through. The various studies must be linked so that each contribution is leveraged: for instance, clinical studies can be designed so that they also generate useful usage data, and usage studies can help to avoid methodological biases linked to MD use and thus refine clinical study protocols. If possible, clinical and usage studies should ideally be combined.

On a more general level, an optimized HFE effort must be scoped at the company level by considering all the various MDs that the company markets. If the MDs marketed by a company are relatively similar in terms of the indication, context of use and/or target users, the HFE studies must be built up through the company's entire MD portfolio in order to build and capitalize on a set of benchmarks. The key challenge is to be able to exploit the user research analyses and results and optimize the testing on several MD benchmarks. Once a company has developed, understood and formalized HFE skills and methodologies for some current products, it can leverage them for other products and for the commercialization of new products. However, the greater the diversity of the company's products, contexts of use and indications, the more difficult it will be to capitalize on the corporate HFE program.

Future challenges: going beyond the premarket evaluation

The European Union's MD regulations constitute a powerful means of promote HFE studies in this field and thus preventing certain use-related risks. However, this regulatory framework is obviously not a 'silver bullet' that will ensure that all MDs are perfectly safe to use. The HFE regulation also poses major problems especially because of its coverage of the MD life cycle. Receipt of the CE mark for MDs requires postmarketing surveillance to be part of the overall risk management process; data related to use error must be analyzed in order to identify the user interface's strengths and shortcomings. However, postmarketing surveillance does not feature in the HFE standard IEC 62366–1, which makes it difficult to consider what will happen after the market launch in terms of MD use.

In fact, it is when a device is coupled to the sociotechnical system that unintended consequences (which could not have been predicted in the design process) emerge [27]. Whereas HFE methods like proactive risk assessment can identify and mitigate design vulnerabilities, they may not evidence emergent issues. The concept of 'dynamic safety' is fundamental for appropriate postmarketing surveillance. Dynamic safety is both an emergent property of a resilient system and the result of adaptive interactions between humans and technologies in a context of use; it relies on workers' tacit knowledge and ability to constantly adjust daily practices as the context of use and job demands change [28]. Let us take the example of PPE. Even though PPE has been used routinely for decades in various epidemic settings, this equipment proved unsatisfactory during the COVID-19 pandemic when outdated designs caused use problems [29].

Going beyond the MD usability during the development phase and analyzing the MD long-term, real-life use is essential. This has major implications for device design, including the need to go beyond technology design and consider emerging properties of technology in use [30]. Product design should be an ongoing process rather than a separate, upstream activity. In the field of design theory, a growing body of research has highlighting the value of ongoing, holistic design processes that are tightly coupled to device use. Thus manufacturers, users, but also other stakeholders, must be able to collaborate on MD continuous design and thus collectively address a range of organizational, technical and functional issues (e.g. at a hospital level). This approach should deliver real benefits to the manufacturer (in terms of a product's long-term viability), institutions, healthcare professionals and patients (in terms of safety and quality of care). As in a learning health system [31], an iterative, virtuous circle of learning for all stakeholders based on a knowledge generation process embedded in daily practice produces continual improvements. The concept of continuous technology implementation [32] even makes sense for seemingly simple-to-use devices, such as PPE.

Regulatory bodies could broaden their perspectives and request the implementation of more real-world performance monitoring, rather than postmarketing surveillance alone. In order to fit the system-based approach to designing tools, widely acknowledged as being essential, a shift in perspective is essential. This requires moving from a product view to a system view to maximize the safety and efficacy of MDs. This change obviously cannot only be the responsibility of manufacturers, in particular for certain complex MDs. It poses significant challenges for regulatory bodies, used to regulating products, not systems. While a full-scale move into a system approach is currently infeasible, regulatory bodies might take further steps in this direction. They could conceivably require approval, for instance, at a hospital level. The manufacturer could provide detailed information about how the MD should be integrated into the hospital's workflow and staffing system, based on an HFE analysis of how end users act and collaborate. The hospital stakeholders (e.g. the hospital information system staff, human resources staff, heads of clinical units, and general management) should then commit to certain human resources, training and specific implementation procedures to comply with the defined requirements. In the future, regulatory bodies might require even more things, such as periodic retraining and periodic usage inspections. This may seem restrictive from the point of view of the user sites, but some of them are looking for help, guidelines to support the implementation of complex tools, and this is ultimately a winning strategy for all. For home-based MDs, taking a system-based approach is more difficult to consider from a regulatory perspective.

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