Place of High-risk Medical Devices in European Recommendations with a Focus on End-users

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Abstract As shown by recent incidents and scandals related to the use of high-risk medical devices an adapted regulation throughout the European Union is important. The European directives and the regulation issued by the member states include recommendations which apply to high-risk medical devices. The present study aims at collecting the recommendations regarding high-risk medical devices and specific to each country. Legislation, guidelines, scientific publications and grey literature have been searched. Different trends seem to appear in the states with the most advanced legislation: an increase of controlled trials, a better traceability, development of specialized registries, an improved vigilance system and an increased involvement of end-users. Although poorly present in the legislation, the end-users are more and more integrated to the development process of medical devices. Ergonomics and user experience can be seen as key factors of a successful medical device. Several important issues are stressed regarding the training and information of healthcare practitioners for implantation of the medical device and its initial setting if required. New avenues have also to be envisioned such as context of use analysis and user-centred design.

1 INTRODUCTION

Medical devices cover a wide range of products ranging from eyeglasses to active coronary stent, via wheelchairs. Medical devices are also characterized by a short life in the market, small patient populations and a high potential for innovation.

Due to medical advances and to recent scandals new European Union (EU) legislation was launched in 2017. This new regulation has led to the deployment of a transition period during which manufacturers may choose to refer to Directive or Regulation. Each country of the EU has transposed the directive into its national texts and has treated the fallout from recent scandals in a manner specific to its health and vigilance system. As a consequence, the guidelines and the recommendations for high-risk medical devices are uncoordinated and treated in different ways throughout the EU. For example, the recommendations for the surgical revision of Metal-On-Metal (MoM) hip replacements vary according to the different regulatory authorities: some rely on a specific protocol, other on blood metal ions. (Matharu et al.2018).

The diversity of medical devices, their increasing complexity, as well as the development of devices for personal use have increased the risk associated with misuse. There is a very wide variety of user profiles and a lot of attention is paid to end-users.

End-users are considered to be people who interact with or who manipulate the medical device. There can therefore be more than one user of a medical device. Among these, a distinction between professional users and non-professionals (Shah et al., 2009) can be made.

The degree of interaction between the patient and the device may vary. For example there is no interaction for a pacemaker, but the interaction is of capital importance in the use of some devices such as injectors, or pumps intended for administering drugs. The same goes for devices requiring changes or recharging of the battery or having a control interface.

Manufacturers are increasingly integrating patients to the development of products before they enter the market. This approach is considered to be safer for the patient and result in more effective devices (Martin et al., 2006). In addition, the awareness of handling errors made it possible to

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envisage the usability of medical devices as an integral part of their development.

A major trend is to move from isolated end-user, as in traditional clinical evaluation, to patient groups and focus groups.

The use made by "operators", by health professionals must also be carefully evaluated to reduce the risk of incidents. Finally, the global environment (care structure, etc.) must also be taken into account. The concept of user experience indeed takes on its full meaning by aggregating the factors linked to the end-user, the device and their environment.

The aim of this work was to scan the regulatory environment and the development phases of a medical device. The benefits as well as the potential challenges to integrating the users' point of view into the clinical evaluation medical devices will be discussed. Then, examples from different countries of the European Union will illustrate what can be done. Finally a discussion will focus on European disparities with regards to the place of users.

2 CONTEXT

2.1 Regulations

The legislative framework has been developed on the principle of the new approach, the principle from the 1980s which provides for the approximation of laws between states.

Until 2017, three directives were available:

- Directive 90/385 / EEC (EUR-lex, 1990) of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
- Directive 93/42 / EEC (EUR-lex, 1993) of June 14, 1993 relating to medical devices
- Directive 98/79 / EC (EUR-lex, 1998) of the European Parliament and of the Council of October 27, 1998 relating to in vitro diagnostic medical devices

Other more technical directives have been added as technologies evolved. For example, at the initiative of the French Presidency of the European Council, the general directives were revised by Directive 2007/47 / EC (EUR-lex, 2007). The clinical evaluation has been made compulsory, under the conditions specified in a new annex (in force in France in 2010).

These directives must be transposed into the national law of each country of the European Union (EU).

In 2017, two European regulations entered into force:

- Regulation (EU) 2017/745 (EUR-lex, 2017a) of the European Parliament and of the Council of 5 April 2017 on medical devices
- Regulation (EU) 2017/746 (EUR-lex, 2017b) of European Parliament and the Council of 5 April 2017 on in vitro diagnostic medical devices.

Immediately applicable, a regulation does not require transposition into national law.

Currently, in 2019 we are in a transition period, that is to say that a manufacturer may choose to mark a medical device EC Directive or under the new regulation.

Shortcomings of the current system are frequently described, some being strongly related to end-users:

- An inadequate declarative vigilance system and post marketing monitoring
- A lack of transparency and information sharing

2.2 High-risk and Medical Devices

Classification according to risk (class I, IIa, IIb or III) allows to get as close as possible to the concept of high risk. But high-risk and class III are not necessarily totally overlapping. Our point of view is that a medical device is considered as high-risk in case of:

- A sensitive anatomical location
- The implantable nature of the medical device

and / or

- The use of new technologies

and / or

- The use of new materials

2.3 Usability and End-users

2.3.1 End-users, Usability, and Suitability for Use

Users of medical devices cover a wide range of people, professionals or non-professionals. It can be the person responsible for fitting, adjusting the device, but also maintenance people, their families and caregivers in general (Shah et al., 2009).

Defining end-user is more difficult. End-users are people who interact with or manipulate the device. The term of end-users could restrict the previous list to the operators and to people who uses the device (the patient). End-users have a wide variety of profiles. Among non-professional users, a special place must be made for people with special needs, especially the elderly or disabled (Shah et al., 2009). It is noted that many of these users are likely to have disabilities hindering their use of medical devices or difficulties due to technological advances, in

particular with interfaces. Moreover, as stated in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA), “as healthcare evolves and patient care is transferred to the home or public environment, less skilled or even unskilled users, including patients and caregivers, must be able to use quite complex medical devices safely.” (MHRA, 2017).

The MHRA explains that Human Factor refers to how a person will interact with the systems surrounding them, including the technology they use. It often encompasses other terms such as ergonomics and usability.

The concept of usability has become increasingly important and combines ease of use and training. It is described as the characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction while usability engineering is the application of knowledge about human behavior, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate usability (International Electrotechnical Commission or IEC 62366:2015, International Organization for Standardization or ISO, 2015)

2.3.2 The Need to Take into Account End-users and Potential Barriers

The awareness of errors in handling medical devices has highlighted the need to place usability at the center of the development of medical devices.

The FDA recognizes the importance of usability and includes requirements in this area in GMPs (FDA, 2018a) and in other documents such as, for example, guidelines for designing interfaces for usability tests (Story, 2012).

Medical devices meeting users’ needs are described as safer (Kaye, 2000) (al., 2004). On the contrary, ignoring their needs can have disastrous consequences (Stone and McCloy, 2004).

Meeting users’ needs is known to (Martin et al., 2006):

- Improve the safety of devices
- Improve the usability of devices
- Reduce Device Recalls
- Limit the need for ad hoc changes
- Improve efficiency of users
- Improve patient outcomes and satisfaction

Knowledge based on user experience is a source of valid evidence which is used to complement the contribution of health professionals and researchers.

One could say that without this view "from within", the panorama of Research is incomplete.

In addition, taking into account the end-users’ point of view makes it possible to manage the expectations of this population, expectations which are often poorly understood, as well as the gap between these expectations and those of manufacturers and / or professionals.

Several barriers were however identified. The researchers, manufacturers may have difficulties to perceive the benefits of including end-users, especially if it is felt that they do not have the knowledge to understand or to help the Research process (Bridgelal Ram et al., 2008).

In 2007, Brideglelal at al. (Bridgelal Ram et al., 2008) made the following observation: “Although there has been academic research on user engagement, there is a lack of commensurate work on the practicalities of such engagement”. If the interest in involving end-users is no longer questioned, the way to do so remains generally insufficiently documented and there is a lack of evidence.

The difficulty of easily accessing end-users by manufacturers, in particular subcontractors, was underlined (Li et al., 2011).

2.3.3 Concrete Measures

Manufacturers resort to early consultation with professionals and non-professionals. This is even more crucial for high-risk medical devices.

The usability of devices must be evaluated by firstly taking into account the specific difficulties and limitations of end-users and in various environments (technological, social, etc.).

The user experience (UX) makes it possible to integrate the voice of end-users at all stages of medical devices development. Heuristic evaluations are carried out. Pillalamarri et al. describe it as building a highly usable, safe and efficient system that goes beyond the requirements of end-users (Pillalamarri et al., 2018). These same authors divide the user-experience evaluation into 4 distinct phases:

- The Research phase: identification of unmet needs
- The conceptualization phase: a synthesis of the identified needs is performed with a translation into specifications for the future medical device. It is at this stage that user groups are defined
- The design phase
- The test phase: prototypes are developed to simulate the product that will be marketed and then evaluated by potential users based on the identified patients groups described above

The authors explain that these phases are iterated until all the success criteria are met.

It is very important that people conducting research based on UX work with specialists in human factors or ergonomics in order to optimize medical devices for their use by the user and in the environment where they will be used. For medical devices, the human factor process is used to minimize the risks associated with use (formative assessment), and then used to confirm that these efforts have been successful and that users can use the medical device safely and effectively (summative assessment).

The FDA mentions the following benefits to applying HF / usability engineering (FDA, 2019):

- Easier-to-use devices,
- Safer connections between device components and accessories (eg, power cords, leads, tubing, cartridges),
- Easier-to-read controls and displays,
- Better user understanding of the device's status and operation,
- Better user understanding of a patient's current medical condition,
- More effective alarm signals,
- Easier device maintenance and repair,
- Reduced user reliance on user manuals,
- Reduced need for user training and retraining,
- Reduced risk of use error,
- Reduced risk of adverse events, and
- Reduced risk of product recalls.

Patients can also fill out moodboards, storyboards and participate in questionnaires on the creation of user interfaces, then test prototypes.

The instructions for use and labeling are also part of the measures that must be taken to lead to good usability of the medical device.

2.4 Our Research

2.4.1 Aims

Our goal was to identify the recommendations / guidelines issued in the countries of the European Union on high-risk medical devices. In this part of our work, we then focused our Research on the aspects affecting end-users.

2.4.2 Identification of Sources and Reading Documents

The sources consulted fell into two categories: scientific literature or gray literature. The latter type of literature refers to documents from governments, universities, companies, and organizations in the form of print and electronic media, and not controlled by commercial publication.

A list of authorities and national agencies for the 28 EU countries, then websites of interest has been drawn up, country by country. To this end training tool kits from the French Clinical Research Infrastructure Network (F-crin) site (European Clinical Research Infrastructure Network (ECRIN, 2019a)) and the F-crin campus (ECRIN, 2019b) were used, as well as documents from the World Health Organization (WHO, 2019).

The documents were then read, with a focus on end-users, human factors and usability.

Examples of recommendation targeting end-users will be presented below.

3 PLACE OF THE END-USERS IN THE EUROPEAN RECOMMENDATIONS

The end-users have an increasing role to play at various stages of the life of the medical device from its conception to its appropriate use which requires both adequate information and training. The role of end-users is also important in care-organization, traceability, registers and vigilance which are keys in the optimal use and monitoring of medical devices.

3.3.1 Patient Associations

According to the European Patient Forum (EPF), patient associations are partners providing feedback through stakeholder advisory groups, experts, public consultations or institutional meetings of the European and / or national government. Patient associations are able to help decision makers understand the experience of living with a given disease. They use this “end-user perspective” to promote the interests of patients at all stages of policy development and in a range of institutional contexts (EPF, 2017).

In France, for example, the High Authority of Health (HAS) has launched a number of patients consultations for some high-risk medical devices), like intracranial stents (HAS,

In the Netherlands, the General Inspectorate will initiate discussions with patient associations to carry out initiatives aimed at encouraging patients to report incidents and complaints to healthcare professionals and / or the healthcare facility concerned, in the case of MoM hip prostheses.

Patient associations are therefore consulted by various national or European bodies. It is very difficult to identify consultations of patient associations by manufacturers themselves maybe because confidentiality and intellectual property issues might have impacted the availability of data.

3.3.2 Co-design, Co-development, and Focus Groups

The European regulation states that: "Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: the risk of injury, in connection with their physical features, including the volume / pressure ratio, dimensional and where appropriate ergonomic features" and also that: "Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account the intended purpose, users and the environmental conditions in which the devices are intended to be used "

The regulations insist on taking ergonomic characteristics into account at the design stage.

In spite of the limitations mentioned above, manufacturers use focus groups which integrate the science of user experience at the early stages of development of their medical devices.

Focus groups are small groups that intervene before the product is placed on the market. They allow (Bridgelal Ram et al., 2008):

- The definition of unmet needs
- The translation into development concepts
- Their validation by retroactive loops

Focus groups turn out to be very interesting and informative. They consist of small groups of selected people with whom interviews are conducted in the presence of a moderator. Lehoux et al describe these focus groups as comprising 6–10 participants and lasting between 1.5–2.5 h (Lehoux et al., 2006). According to the same authors, if the focus groups share characteristics of other qualitative methods, what makes them unique are the interactions that develop between the participants, and between the participants and the moderator.

No reference to focus groups was identified in this preliminary consultation of the gray literature on recommendations related to high risk medical devices.

3.3.3 Training / Information for Health Professionals

Many of these recommendations concern specific medical devices, generally those which have been the subject of questioning or controversy.

There are few more general recommendations that is to say that are not formulated in response to a given problem

- In Belgium

According to report 158 of the Belgian Health Care Knowledge Centre (KCE), particular attention must be paid to the qualification and training of health professionals (HulstaertHulstaert et al., 2011). This human factor will often contribute to the safety and then to the efficiency of the device in routine use and therefore influences the external validity of the test.

In KCE report 249, professional end-users are implicitly pointed out (Baeyens, 2015). It is mentioned that clinical practice recommendations may stipulate that specific interventions must only be carried out in specialized centers and by trained operators and teams experienced in performing complex procedures. In general, however, the immediate impact of such a measure after obtaining a CE label is limited given the time required to develop such clinical recommendations. In addition, these recommendations are not binding.

Information is the crucial element to allow the healthcare professional to consider the use of a device and to allow the patient to make an informed choice on this subject. The patient must therefore be properly informed of the risks associated with the use of a new high-risk medical device and of all the possible alternatives. Merely mentioning that the device has the CE label is not enough.

Health professionals may also be required to report to the authorities the use of a high-risk medical device in advance.

- In Austria

General recommendations have been identified:

According to Annex 1 of the Medizin produkte betreiber verordnung (MPBV) law, the devices for which special safety precautions must be taken include the external active components of the active implants (BASG, 2019). For these devices, the operator must perform an initial inspection (or have it carried out) before the first application.

The external active component intended for the patient being delivered only after the implantation operation, the operator must also carry out verification for this component.

- In France

There are no general recommendations on these aspects, but only in reaction to situations or concerning specific medical devices.

Several arrangements have been made regarding professional end-users for the placement or the removal of a medical device. For example, the decree of July 3, 2012 limits the practice of implanting aortic valve bioprostheses by transcutaneous arterial route or by transapical route to certain healthcare establishments in application of the provisions of article L. 1151-1 of public health code (Legifrance, 2012).

The decree of December 14, 2018 limits the practice of the act of explanting devices for tubal sterilization (ESSURE) to certain health establishments in application of the provisions of article L. 1151-1 of the public health code (Legifrance, 2018).

Associations, such as Euro-Pharmat, a voluntary association, put online sheets for the proper use of certain medical devices classes, such as for example skin substitutes (Euro-Pharmat, 2014) or catheters with implantable chambers (Euro-Pharmat, n.d.).

Recommendations to professionals also come from medical societies. The National College of French Gynecologists and Obstetricians (CNGOF) provides professionals with a technical file on the removal of ESSURE final sterilization implants as well as a data collection sheet to be used before and after removing the implant (CNGOF, n.d.). The professional board of plastic surgeons has issued recommendations relating to breast implants and the risk of anaplastic large-cell lymphoma, stressing that when there is no reasonable alternative solution, the benefits brought to patients by breast implants, both in reconstructive surgery and in cosmetic surgery, are currently infinitely higher than the risk of contracting this specific lymphoma (Directoire Professionnel des Plasticiens, 2018 Professionnel des Plasticiens, 2018). The HAS provides documents on “good use of health technologies” (for example on implantable spinal neurostimulators (HAS, 2014) or for coronary angioplasty (HAS, 2012).

The French National Agency for Medicines and Health Products Safety (ANSM) offers recommendations to healthcare professionals. This is the case of the recommendations intended for surgeons for MoM prostheses (ANSM, 2014).

- In the UK

The National Institute for Health and Care Excellence (NICE) has made guidelines available for a number of clinical situations (NICE, 2019), including implants for example:

- Transcatheter aortic valve implantation for aortic stenosis (TAVI) (NICE, 2017a).
- Leadless cardiac pacemaker implantation for bradyarrhythmias (NICE, 2018).
- Artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure (NICE, 2017b)

- In the Netherlands

Many recommendations follow products for which scandals have broken out.

For example in the case of the vaginal mesh, the NVOG “Dutch Society of Obstetrics and Gynecology” in 2014 made recommendations for operators / team performing interventions with the mesh (not exhaustive) (NVOG, 2014):

- That the competent urogynecologist is the person carrying out the intervention. Anyone who has made at least 20 mesh placements is considered competent. For urogynecologists starting out with this technique, this experience must be acquired under the supervision of a competent urogynecologist. To maintain the quality of the placement, and after a satisfactory learning curve, it is recommended that the specialist performs at least 10 placements per year.
- That in the most complex cases it is advisable to refer to specialized centers

3.3.4 Training / Patient Information

The new regulations for medical devices stipulate (EUR-lex, 2017a):

"In eliminating or reducing risks related to use error, the manufacturer shall:

(a) Reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

(b) Give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

- In Austria

General recommendations have been found, in particular concerning active implantable medical devices (BASG, 2019):

The parts of the system which are given to the patient as a non-professional user must be handled by him/her in accordance with the manufacturer's instructions, a standard training of the patient being necessary.

The patient or, where applicable, his legal representative must receive information in

accordance with § 81 MPG: information on the implant, instructions for use, time when a professional must be consulted ... Furthermore, in accordance with § 81, paragraph 4 when patients are informed about the use of medical devices, it is necessary to take into account the instructions provided in the instructions for use.

As the patient is a “lay” user, this must be taken into account. It is the responsibility of the manufacturer to provide instructions for use, accompanying documents and other information necessary for safe use for the intended users.

After the implantation and the appropriate information of the patient by the person in charge of the implantation of a medical device, the patient becomes responsible for the respect of the dates of the medical visits of control, etc.

Patients and groups of users must therefore always be taken into account: infants, patients having suffered a stroke, patients suffering from mental and / or physical impairments, etc.

It is the responsibility of the manufacturer of the medical device / of the implant to establish appropriate instructions for monitoring the patient (duration, deadlines) and possible verifications. This also includes the need to establish an active reminder to patients about their appointments for follow-up exams (for example, by the treating physician or the health facility).

- In France

There are recommendations in response to events that have occurred for specific medical devices

For the ESSURE ® final sterilization device, the ANSM, the CNGOF and the Ministry of Solidarity and Health have made available a patient information sheet "You are a carrier of the ESSURE final sterilization device" (Ministère des solidarités et de la santé, 2018) and a "removal of ESSURE ® device" sheet (CNGOF, 2018).

The professional directory of plastic surgeons has posted files for breast augmentation for aesthetic purposes and for breast reconstruction (SoFCPRE, 2019), (SOFCRPE, 2019). The HAS made it possible to adapt the first sheet to provide answers on reconstruction: "Additional information to be included in the sheet intended for patients of the French Society of Plastic, Reconstructive and Aesthetic Surgery of April 2015 before the placement of a breast implant for cosmetic reasons” (HAS, 2015). The French Foot Surgery Association (AFCP) provides an “ankle prosthesis passport” for patients (AFCP, 2012), as well as an information letter (AFCP, 2012).

3.3.5 Care Organization

- In Austria

The implant (including external components if applicable) is under the responsibility of the healthcare establishment until implantation (from appropriate storage to controls recommended by the manufacturer). After implantation, the implant becomes the property of the patient and, from this moment on, the patient is considered as the "user" of this implant (BASG, 2019).

- In Belgium

The KCE report 249 (Baeyens, 2015) mentions the limitation of routine use of specific medical devices to reference centers. Belgian hospital law already provides for the possibility of using referral centers to guarantee a high level of quality of care. The obligation to reserve the use of high-risk medical devices to a limited number of healthcare facilities for a certain period could in some cases be justified.

After placing on the market, reference centers may be asked to carry out an "appropriate study" (eg RCT) - with an assessment of proportionality on a case-by-case basis.

- In the Netherlands

In the context of vaginal mesh, recommendations were made by the NVOG “Dutch Society of Obstetrics and Gynecology” in 2014 for the structure that offers this type of intervention (not exhaustive) (NVOG, 2014):

- That at least two Gynecologists with a sub-specialization in urogynecology, competent in mesh surgery are present in the institution.
- That the structure engages in a quality assurance approach which is specific to this use
- That the structure registers the implant and records any complications in a database allowing the national scale monitoring of patients based on the social security number.

Recommendations intended for collaboration with manufacturers (not exhaustive):

- The introduction of new materials should only take place within the framework of studies.
- The studies will be coordinated and approved by the Urogynecology Consortium. Observational studies require a minimum of 118 participants, with at least one year of follow-up
- Complications must also be reported by the practitioner to the company that developed and marketed the product.

3.3.6 Traceability

Steps have been taken in Belgium where all implant placements lead to their registration on the central register of traceability. The medical devices plan, a public health improvement project in Belgium, aims to improve traceability. On June 15, 2015 the French Care Supply Branch (DGOS) made general recommendations as well as recommendations to the hospital care system (DGOS, 2015).

3.3.7 Registers

The creation and the keeping of the registers is the most represented recommendation found in the EU countries, and there is currently a wave of creation especially for breast prostheses.

The setting up of registers can be seen as a measure oriented towards end-users because it requires the active participation of the operators and of the patients

The Scandinavian countries have a culture of registers; some of them focusing on high-risk medical devices. The first ever created register was collecting information on joint replacement. The establishment of such records is considered to have lowered the hip prosthesis revision rate in Sweden (Herberts and Malchau, 2000). The creation of new registers (Lyratzopoulos et al., 2008), (or the revision of existing records) should include a reflection on the filling system (mandatory? Voluntary?). This should be complemented by consideration on the patient's consent to extend its data and on the criteria to be met to get enough information, while respecting the protection of patient data.

3.3.8 Medical Devices Vigilance

Countries agree that the system suffers from significant underreporting. However, no specific recommendation for high risk medical devices was found. However, it is suggested to encourage health professionals to report incidents to manufacturers. Databases listing the incidents are available but most of the time, their access is not public or restricted.

The MAUDE (Manufacturer and User Facility Device Experience) database in the USA allows patients to make their own statements (FDA, 2019b). It is probably a very interesting opening on the role of patients as end-users

4 DISCUSSION

This work illustrates the growing awareness of the role of end-users in medical high-risk devices in Europe. Very recently, and for example in France, the HAS (HAS, 2019) and ANSM (ANSM, 2019) have initiated patient association consultations and public hearings to consider the patient's voice.

The place of the end-user is unequally represented in the recommendations of various European countries. As with other types of recommendation, most of them were issued following incidents affecting specific medical devices. For example, this is the case of the vaginal mesh for which the Netherlands have issued a number of recommendations for professionals [32]: peer-training, "minimal" number annual implantations, specialized centers ... It is the same for hip prostheses with metal-metal friction couple (Inspectie Gezondheidszorg en Jeugd, 2015) (GOV.UK, 2017), or the Essure ® device mentioned above. Most of the documents found were concentrated in France, Belgium, the UK and the Netherlands. Belgium and Austria have issued more general guidelines about the training / information of patients and health professionals. The Nordic countries have further developed the registers. This requires an active role of professional and patient involvement.

Another point worth highlighting is the work provided by academics and professionals. Although little or not mentioned in the texts and recommendations issued by the authorities, networks of professionals have organized themselves to best address the question of end-user. For example, in France, the Clinical Investigation Centre for Innovative Technology (CIC-IT) network was set up in 2008 by the Inserm and the Ministry of Health (CIC-IT, 2016). Recent and creative initiatives have emerged such as living labs. Living labs are based on user-centered methods which operate in real-life conditions. As a result, patients are involved in the co-developement of innovations from the very beginning. ENoLL, the European Network of Living Lab is the international, independent non-profit association of bench-marked living labs with more than 340 accredited living labs worldwide characterized by its diversity and multidisciplinary perspective (Europeana, 2014). The involvement of patients in an approach gathering companies, academics and research centers such as that promoted by EIT Health is of importance. It is worth to note that some initiatives are developed by patients themselves e.g. the European Patients' Academy on Therapeutic Innovation (EUPATI).

A question remains to be answered: is the harmonization at the European level desirable? For example, would it be advisable to "delegate" the administration and collection of data from arthroplasty registers to countries having the best experience (Sweden, Denmark) or would it be desirable that each EU country takes its own register?

This preliminary work has limitations. First, translations of documents and the language barrier may have led to understanding defects. Then imperfect knowledge of health systems in each country may also have influenced the way to treat the subject. A certain degree of subjectivity, for example in drawing up of the list of sites of interest, is recognized. Finally, this work should be put in perspective with other fields such as methodology or economy, to get a more comprehensive view of the subject.

Maybe the main limitation of this study is to be centered on the way guidelines, focus groups or training are tackled by the European countries and their regulatory authorities. A new field of progress regarding the role of end-users is known as context of use analysis. This type of analysis is directed toward the intended users and associated constraints either technical or due to the environment of use. User-centered design is an innovative approach that remains to be applied to medical devices in order to promote their adaptation to all the various users' profiles, practices variability, working environment, and conditions of use.

5 CONCLUSION

The consideration of ergonomics is increasingly important, and its place will further develop. It seems important to stress that many agree on the fact that a medical device should be inseparable from the operator, from the recipient (patient), and from the care structure. Patient information, training / information of professionals and usability are the essential components.

As a consequence, the role of end-users in high-risk medical devices is a major public health issue. Significant progress is to be done and the recommendations have obviously to be adapted. New trends of medical devices development need to be included such as context of use analysis and user-centered design. It therefore seems necessary to develop new guidelines and recommendations. But the diversity of technologies and devices available is such, with the constant emergence of innovations that it is legitimate to consider if global recommendations are possible or even desirable.

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