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Review

Registries of implantable medical devices in Europe

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ABSTRACT

Background: In early 2012, a number of serious events in the implant area raised public awareness and started a discussion on safety issues and monitoring medical devices in academics and politics. Apparently, there is a lack in the surveillance of medical devices. Therefore, the objective of this work is to detect and classify implant registries in Europe.
Methods and findings: A systematic search of literature was carried out to identify the different types of registries. Furthermore, to characterize the implant registries by different criteria a medical device classification system was established. One hundred and one European registries were found. Most registries exist in the field of cardiac implants and arthroplasty (38 and 29) and their distribution showed variation within Europe. For a lot of implant categories, none or very few registries could be identified. Some countries run more registries than others. There are a lot of differences in aim and structure among the registries.
Conclusion: There is only a limited number of reviews on registries and a centralized monitoring system in Europe is missing. Our results reveal a lack of transparency concerning number, aim, structure and quality of registries. This is crucial, as registries work as early warning systems for identifying and notifying patients at risk.

1. Introduction

1.1. Rationale

During the last few years the medical device industry has greatly improved. Significant progress has been achieved in many areas of the medical device industry, in particular in the fields of miniaturization, computerization and molecularization [1].

However, with the increasing quantity and diversity of medical products the number of related incidents has started to grow, too. By looking at the vigilance and notification reports of the national competent authorities (NCARs) of the European Union it is noticeable that there has been a steady rise from 2007 to 2011/12 in all kinds of medical devices (Fig. 1) [2].

Thus, the following incidents are no individual cases, but just the tip of the iceberg.

A recent example of the growing number of errors especially in the field of implant production is the scandal of the defective breast implants of the French company Poly Implant Prothèse. The company was blamed of selling breast implants filled with low quality silicone to millions of women.

In Europe, any product that has obtained a CE-mark in a European Union (EU) member state can be sold. In case of PIP implants, the company attached a CE-mark to

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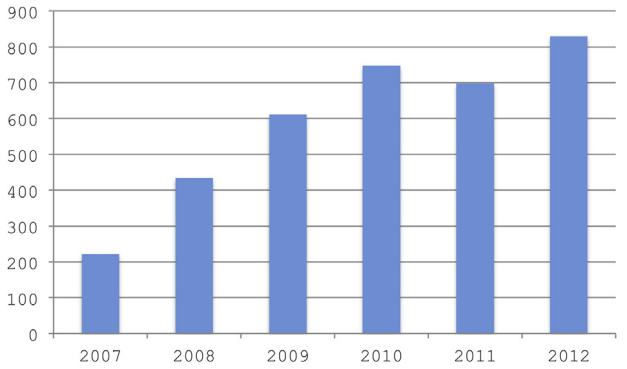

Fig. 1. Number of NCARs exchanged at European level between 2007 and 2012.

their devices suggesting that they meet all the relevant EU regulations [3]. The German notified body TÜV Rheinland was in charge of the conformity assessment of these breast implants that includes checks of safety and the compliance with regulations. The French regulatory authority discovered that the firm was using industrial silicone for their prostheses which was not detected by the responsible notified body [3].

The second incident in the field of medical devices discussed in the press concerns arthroplasty, more precisely "metal on metal" (MoM) hip implants. People from all over the world may have been exposed to dangerously high levels of toxic metals from defective hip implants [4]. The drawback of these prostheses made of two metal layers, cobalt and chromium, is in the release of metal ions by friction of the metal joints. Patients with these implants have to be re-operated more often. According to the British Medical Journal (BMJ) the prostheses came into the market although it is still unclear what impact the metal ions have on the body [5].

1.2. Objectives

In the case of breast implants, there were many difficulties to find out which women have been wearing these implants. Although breast implant registries exist within Europe, not every country has one, these are not mandatory and thus most of the women are not registered. The incident concerning metal-on-metal hip prostheses has shown that in the field of medical devices and in particular in the field of implants, there are plenty of possibilities for patient harm. Therefore, the objective of this study is to reveal the current status of medical device registries for implants in Europe and to classify their structure and characteristics.

2. Methods

2.1. Key questions

This text shows which registries exist for the different types of implants in Europe and in each particular country.

Therefore, the following questions are crucial:

- Which registries exist in Europe?
- In which area do most registries exist?
- For which implant category do most registries exist?
- How can they be classified and categorized?

2.2. Medical device registry classification

The implant registries are classified using different criteria discussed at an intern panel meeting of members of the leading edge cluster Medical Valley European Metropolitan Region Nuremberg. A checklist was developed to characterize the identified registries. The following criteria were chosen.

2.2.1. Basic information

The name of the registry, its topic and its geographical coverage are mentioned. This category also involves the scope of the registry. Registries can exist on local, regional, national, international or EU basis and can obtain data from one hospital or from more centers (Multi-Center). Mentioning a country without any supplements means that this registry has more than one center and works on a national basis. If the registry's scope is different, the variations are clearly stated.

2.2.2. Time

Furthermore, the starting time of the registry and, if available, its duration are presented.

2.2.3. Funding

To value the registry in a correct way it is important to know if it is supported by private or public means or if it is financed independently from industry or by industrial means.

2.2.4. Who uses the information?

There are different stakeholders who can use the results, for example, the industry, health insurances, health care providers, health care authorities or society.

2.2.5. Type of information provided

Registries report different kinds of information that are available for the stakeholders mentioned above. Registries can be used for adverse event reporting, active surveillance of medical products, to discover complications and risks. Information about the quality and stability of implants can