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Systematization of information for identifying similar cardiovascular implantable devices

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Abstract **Introduction**: The lack of a terminology to compare medical devices together with the arbitrary and opaque nature of product registration systems are major obstacles to a more informed decision process regarding the use and acquisition of new medical devices. This paper describes the systematization of information to help in the identification of similar cardiovascular implantable devices. **Methods**: The systematization was developed in four stages: definition of the technical attributes of each device group; classification of a sample of devices; implementation of the proposed systematization in Protégé; and evaluation of the application. The systematization dealt with a set of common attributes – indication of use, anatomic location, manufacturer, device model and lifetime; and a set of attributes specific for each type of device. **Results**: The systematization was performed by means of a hierarchy of classes with the respective properties in Protégé, which support three basic functions: data entry, query, and maintenance. 38 queries were designed to allow the identification of similar devices according to their technical characteristics. The users' evaluation showed that the application fulfilled the requirements to monitor the price of these devices on the market. **Conclusions**: Protégé was a useful tool for the systematization of cardiovascular implantable devices that can be used for the post-market vigilance of medical device safety. To better fulfill this aim, other attributes may be incorporated to better characterize the safety aspects of these devices.

Keywords: Medical devices, Price monitoring, Post-market vigilance, Management, Protégé.

Introduction

The Global Harmonization Task Force (GHTF, 2005 cited in World…, 2010) states that a medical device is "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that does not achieve its primary intended action in or on the human body solely by pharmacological, immunological or metabolic means, and that it is intended for human beings for: the diagnosis, prevention, monitoring, treatment or alleviation of disease; the diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; the investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling conception; disinfecting medical devices; and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body".

In addition to this complex definition, the acquisition of medical devices is mentioned by the World Health Organization as a complicated process, amongst other factors, due to the lack of suitable information to allow comparison amongst similar devices (World…, 2010). There is still no standard pattern to classify the medical devices that would allow such comparisons.

A review of the existing terminologies for medical devices (Otto et al., 2010), such as the Global Medical Device Nomenclature – GMDN (Global…, 2005) – and the Universal Medical Device Nomenclature System – UMDNS (Emergency…, 2009) – pointed out that they do not feature the technical details to fulfill this requirement.

The absence of a standard terminology has represented a great challenge not only for the management of medical devices by health care providers, but it has also been a barrier for an effective and transparent authorization and surveillance system (Kingsley, 1995).

The safety problems with breast implants have increased the discussions about the need for improvement in the regulation of medical devices, especially in the European Union (Cohen and Billingsley, 2011; Association…, 2012). Among the drawbacks of the European regulatory system are the unknown quantity of devices in the market, the heterogeneity of the regulations amongst countries and the lack of transparency. The European system is based on post-marketing surveillance, in which the manufacturers are required to establish a vigilance system to monitor their products once they are on the market. However,

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how they should do it is not yet mandated, and the manufacturers wait for the users´ feedback. In addition, this system is monitored by the notified bodies that are contracted by the manufacturers. In summary, the company report on adverse events related to medical devices is slow and cannot be tracked. Kramer et al. (2012), in comparing the American and the European systems, conclude that both systems need reform and research to achieve policy changes.

In this scenario, decision makers, managers and health professionals have limited access to reliable information to support the processes of incorporation and acquisition of these technologies. In fact, manufacturers take advantage of this situation to justify a higher price for a supposed new device compared with the existing similar ones (Pauly and Burns, 2008).

In an attempt to reduce the asymmetry of information about medical devices in Brazil, the National Health Surveillance Agency – whose Portuguese acronym is Anvisa – has established a system to monitor economic information of a group of medical devices with high economic impact on the health system through Resolution RDC 185/2006 (Brasil, 2006). Amongst these devices are the ones used in cardiovascular procedures such as stents, implantable pacemakers and implantable cardioverter defibrillators – ICDs.

Cardiovascular procedures accounted for approximately 24% of the estimated U$8.35 billion spent (Quotation of U.S. Dollar: U$1.00 = R$1,67 in Dec. 2010) (Brasil, 2014) on surgical procedures by the Unified Health System in Brazil in 2010. Amongst the cardiovascular procedures, implantation of pacemakers and ICDs costs around U$334 million and the deployment of stents costs around U$568 million. Together, these devices represented 44% of the expenditure on cardiovascular procedures (Departamento…, 2011).

The diversity of devices available for cardiovascular procedures combined with the mentioned scenario favour a great variation in practiced prices, which highlights the urgent need for a systematic way to identify and compare similar devices in order to monitor the existence of price distortions in the market. This paper describes the systematization of information to help in the identification of similarities amongst cardiovascular implantable devices such as stents, pacemakers and cardioverter defibrillators.

Methods

The proposed systematization was developed in a four-stage process that is described as follows:

Definition of the technical attributes of each device group

The literature concerning the three cardiovascular implantable devices was reviewed (Andrade et al., 2000; Brasil, 2009a; Deconinck et al., 2008; Emergency…, 2005a, b; França and Pereira, 2008; Instituto…, 2009; Hoffman, 2009; Kalil et al., 2006; Martinelli, 2008; Nelken and Schneider, 2004) as well as the users´ guide and labeling information of the medical devices, available at Anvisa's website (Brasil, 2003) in order to define the main technical characteristics to be considered in an initial proposal of systematization.

This proposal was validated by two experts: a cardiovascular surgeon (with wide experience in stent implantation and member of the Brazilian Society of Angiology and Vascular Surgery) and a biomedical engineer (with wide experience in the acquisition of pacemakers and ICDs and technical support to the medical team of the Heart Institute of Hospital das Clínicas of the Medical Faculty of University of São Paulo).

Classification of a sample of devices

A set of forms with data from the Economic Information Reports, requested by the RDC 185/2006 (Brasil, 2006), concerning stents, implantable pacemakers and ICDs, was used to test the practicalities of the proposed systematization (access to the Economic Information Reports was granted by direct contact to ANVISA in the scope of a research project financed by the Memorandum of Agreement *OPAS-COPPETEC BR/LOA/0900180.001*).

The forms were organized in a data file, cleaned and checked for consistency related to: redundancy of items, need of separating items presented as a device family or aggregating others, device registration number in Anvisa and technical specifications. This phase of the work was carried out under the scope of the project mentioned above.

Although the data were reported by the companies who own the right to commercialise the products, there were many inconsistencies in the informed data. The forms request data on: Device Classification, a generic description of the device according to RDC 185/2006; Device Registration and Process Number in Anvisa; and Economic Information (consisting of the device price practiced by the company in Brazil and 10 other countries; value of the expenses with advertising; and similarity with other already commercialised devices). The final data set consisted of 84 stents, 32 implantable pacemakers and 30 ICDs. In this step, the users' guides of the devices were consulted when the data were missed or inconsistent in the form.

The classification was done by two biomedical engineers, with backgrounds in physics and electronics, and was validated by the two experts as well as discussed with Anvisa teams responsible for product registration and monitoring of device price.

Implementation of the proposed systematization in Protégé

An application was implemented in Protégé to facilitate the access of users to the proposed systematization and its maintenance. Protégé is an open source software, developed in Java™ by the Stanford Center for Biomedical Informatics Research at the Stanford University School of Medicine, for the edition and maintenance of ontologies and terminologies (Rubin et al., 2007). It is compatible with several computer operational systems and freely distributed (Protégé, 2011).

The department of Anvisa, who committed this work, has no staff to develop and maintain an information system. Therefore the Protégé environment was chosen for the following reasons: the existing wide community of users; its recognition as the primary tool for the development of ontologies in biomedical sciences (Rubin et al., 2007); and no requirement of advanced skills in software implementation.

The Methodology 101 (Noy and McGuinness, 2001) was adopted since it is compatible with the Protégé software. This methodology has seven steps that include the following: determine the domain and the scope of the system; define which classes will be used and their hierarchy; define the properties that describe these classes and their values; and the data input.

The terms "Device", "Cardiovascular Devices", "Pacemakers and ICDs" and "Stents" were chosen to represent a hierarchy of classes of devices on the systematization and the characteristics of each of these classes were represented in Protégé as properties. One characteristic of this hierarchy is that the lower classes inherit the properties assigned to their ancestors. The terms "Pacemakers and ICDs" represents implantable pacemakers and implantable cardioverter defibrillators.

The properties assigned to the "Device" class were used to describe the generic attributes of the devices, namely: commercial name; Anvisa registration number; manufacturer; name; device model; Brazilian manufacturer price; indication of use; anatomical location and life cycle.

Properties assigned to the "Stents" and "Pacemakers and ICD" classes represented their specific technical attributes. The following properties were specified for "Stents": expansion type, shape, stent material, draft material, drug active principle and coating. The properties for "Pacemakers and ICD" were: connection type, ICD programming code (Bernstein et al., 1993) and pacemaker programming code (Bernstein et al., 2002). These codes are widely used by manufacturers and health professionals in the field. They were developed by the North American Society of Pacing and the British Pacing and Electrophysiology Group, which are currently named Heart Rhythm Society and Heart Rhythm UK, respectively (Heart…, 2012a, b).

The Protégé software also enables the definition of the properties' values. The possible values used for the properties of the "stents" class are presented in Table 1 and the ones used for the "pacemakers and ICDs" properties are presented in Table 2. These values were standardized through their identification in international terminologies using the Bioportal Reference plugin, which is a part of the plugin package available with the 3.4.4 version of Protégé. Examples of consulted terminologies are the Systematized Nomenclature of Medicine Clinical Terms – SNOMED CT (International…, 2009) and the National Cancer Institute Thesaurus (National…, 2011).

The commercial name, Anvisa registration number, manufacturer name, model, Brazilian manufacturer price, life cycle, pacemaker programming code and ICD programming code are free text properties.

Table 1. Properties of the group "Stents" and their values.

Stents properties	Values
Indication of use	Dilatation, Occlusion
Anatomic localization	Aortic structure, Aortoiliac, Carotid artery, Coronary artery structure, Iliac artery, Peripheral arteries, Renal artery
Expansion type	Self-expanding stent, Balloon expandable*
Draft material	N/A, Biocompatible materials, Synthetic material
Stent material	Stainless steel material, Chromium alloys, Nitinol, Platinum, Tantalum,
Coating	N/A, Bioactive*, Ceramics, Pharmaceutical preparations, Metal, Polymers
Drug active principle	N/A, Anti-inflammatory agent, Antineoplastic agent, Fibrinolytic agents, Immunosuppressive agents
Shape	Bifurcated, Conic and Straight

* Values that were not found in Biomedical Ontologies Library.

Table 2. Properties of the group "Pacemaker and ICD" and their values.

Pacemaker and ICD Properties	Values
Indication of use	Bradycardia, Heart failure, Tachyarrhythmia
Anatomical localization	Abdominal structure, Thoracic structure, Both*
Connections	IS-1, IS-4, DF-1, 3,2mm, 5/6mm, VS-1, LV-1

* Values that were not found in Biomedical Ontologies Library.

A set of predefined queries was created to help the search for similar devices. A users´ guide was also elaborated to explain the basic characteristics of the system, the steps for the input of data about the devices, the use of the query database and how to create a new query that is not in the query database.

Application evaluation

A questionnaire with 14 questions was created to evaluate the application content and interface, based on a previous instrument proposed by Tsakonas and Papatheodorou (2006) that included the following topics: general impressions of the system; relevance; applicability of the content to perform work activities; frequency of use; ease of installation; users´ guide usefulness and ease of understanding; identification of icons; access to tabs and queries and ease of new queries creation. The item "general impressions of the system" incorporated, according to Chin et al. (1988), the following criteria: pleasantness, completeness, cooperativity, simplicity, speed and security. For the evaluation items, an ordinal scale from 1 to 5 was used in which the value 1 represented the most favourable judgment and the value 5 the least favourable one.

The potential users of the system are the staff of Anvisa responsible for the management and analysis of the Economic Information Reports. By the time of this study, only three persons were carrying out these activities and they were invited to evaluate the system. The evaluators have experience in the use of computer tools such as the internet, e-mail, text editors, and are less experienced with electronic spreadsheets and databases.

This survey was approved by the Ethics Committee in Research from the Anna Nery Nursing School of the Federal University of Rio de Janeiro under protocol number 116/2010 and the free and informed consent of the subjects was obtained.

Results

Application description

The diagram of classes presented in Figure 1 reflects the proposed systematization described in section 3 of Methods. The hierarchy represents an "is a" relationship (depicted by an arrow), so that, for instance, the "Stent" is a type of the "Devices" class and inherits all its properties. Besides the data entry, the application has two other functions: query and maintenance.

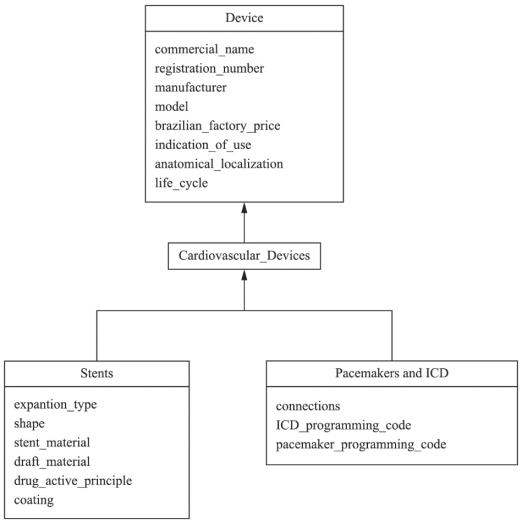

Figure 1. Hierarchy of the groups of devices and their properties.

The query function has 38 predefined queries that allow the identification of similar devices according to their technical characteristics. These queries are usually created by restricting values of class properties, combined by the Boolean operators. The output of these queries can be exported to several file formats. A pseudo code of a predefined query is shown below as an example:

SELECT all Stent where

indication_of_use = "occlusion" AND

expansion_type = "self-expandable" AND

anatomic_localization = "peripheral arteries" AND

stent_material = "Nitinol" AND

shape = "straight"

There are no rules in the application that specify the similarity among devices. It is the user who, according to his/her own needs, will determine it and design a query that reflects his/her concept of similarity.

It is possible to create different reports, such as a report with economic information of a group of selected devices that permits the observation

of price variations amongst similar devices for a specific clinical application. A few examples of the variation of prices reported by the companies for groups of similar devices are presented in Table 3. For instance, the case of implantable cardioverter defibrillators shows that the variation on the price informed by the company was reduced when the search was specified to consider the existence of the resynchronisation function.

On the other hand, it also allows the observation of price distortions that persist even when all the characteristics are similar such as in the case of stents for arterial occlusion that present a price variation from U$536.53 to U$11,377.25 (Quotation of U.S. Dollar: U$1.00 = R$1.67 in Dec. 2010) (Brasil, 2014).

The maintenance function may consist of the addition of new classes, new properties for the current classes or even changes in the values of current properties. More information on the application may be obtained in Otto (2011).

Application evaluation

All three evaluators answered 100% of the questions and their opinions are presented in Table 4. As for the general impressions of the system, the evaluators´ opinions varied from quite favourable (value = 2) to quite unfavourable (value = 4). In general, the evaluators considered the system complete, cooperative and secure, but they felt it a little complicated and the data entry process was slow.

The system content was evaluated as relevant and its usage satisfies the evaluators´ working needs. The evaluation also showed that the system improves the information access for two evaluators and the frequency of access to such information is high.

The process of installing the system was considered of medium complexity. In the evaluators' opinions, the users´ guide was considered to be easy to understand and it facilitated the usage of the system and the queries access.

Table 3. Variation of the Brazilian manufacturer price of medical devices grouped according to their technical attributes.

Medical devices	Minimum price* (U$)	Maximum price* (U$)	Groups of similar medical devices		Minimum price* (U$)	Maximum price* (U$)
Implantable pacemakers	2,589.22	16,302.40	Pacemaker without resynchroniser		2,589.22	6,494.01
			Pacemaker with resynchroniser		6,167.66	16,302.40
Implantable cardioverter defibrillators	23,959.28	50,898.20	ICD without resynchroniser		23,959.28	39,962.28
			ICD with resynchroniser		29,940.12	50,898.20
Stent for occlusion	536.53	11,377.25	Coronary Stent	Without drug	536.53	5688.62
				With drug	5,688.62	11,377.25
			Non-coronary Stent		598.80	6,586.83

*Prices obtained from the Economic Information Report received from Anvisa. Quotation of U.S. Dollar: U$1.00 = R$1.67 in Dec. 2010. (Brasil, 2014).

Table 4. Evaluators' answers for each of the questionnaire items.

General impressions of the system1	A1	A2	A3
Pleasantness (pleasant – irritant)	2	3	4
Completeness (complete – incomplete)	3	2	2
Cooperativeness (cooperative – non-cooperative)	3	2	3
Simplicity (simple – complicated)	4	4	3
Speed (fast – slow)	4	3	3
Security (secure – insecure)	2	2	2
Items evaluated[1]	A1	A2	A3
Relevance of the content (Very – nothing)	1	2	2
Use of the content on their work (Very – nothing)	2	1	2
Improvement of information access (Very – nothing)	1	4	2
Frequency of access (Very high – very low)	2	2	3
Ease of installation (Very high – very low)	3	2	3
Guide importance (Very – nothing)	1	1	1
Guide understanding (Very high – very low)	1	1	3
Ease of identification of icons (Very high – very low)	3	4	3
Ease of tabs access (Very high – very low)	3	4	3
Ease of queries access (Very high – very low)	2	2	2
Ease of creating new queries (Very high – very low)	3	3	3

[1] Scale from 1 to 5, considering number 1 the most favourable and the description of the scale anchors between brackets.

The greatest difficulties reported by the evaluators were the identification of the system icons, tab access and the creation of new queries.

Discussion

For a long time different medical device stakeholders have demanded a classification system of medical devices that allows the identification of similar medical devices. The use of such a tool may improve the decision process of acquisition and post-market vigilance (Kingsley, 1995; World…, 2011). The proposed system fulfilled this requirement for stents, implantable pacemakers and ICD. It offers a friendly environment in which to organize these devices and search for similar ones in considering a predefined set of technical attributes that allows comparisons amongst device classes regarding functionality, price and manufacturers.

To the best of our knowledge few countries carry out the monitoring of economic information for medical devices, each with its own peculiarities, which makes it difficult to have a system that caters to all scenarios. The system presented in this study made it possible to Anvisa to compare prices of similar products for the first time. On the other hand the users reported some difficulties with the system interface, which could have been prevented with a training stage before the system evaluation and the translation of the Protégé software into Portuguese.

The application was not considered to be fast during the data entry process. However, this is not due to the application itself, but it is related to the lack of expertise of users in the subject which required frequent consultation to other material before entering data. On the other hand the response to the queries was fast due to the fact that the application is not expected to be used in concurrent mode and the number of expected device entries was not large. Therefore the question of database performance is not an issue in this case.

Considering the importance of maintaining the interoperability of systems, some international terminologies were adopted to describe the properties, such as the Systematized Nomenclature of Medicine Clinical Terms – SNOMED CT (International…, 2009) and National Cancer Institute Thesaurus (National…, 2011).

From the developer's point of view, Protégé is an easy tool and the existing documentation provides the necessary support for the developers, without programming skills, to learn how to use it. Araújo (2003) also emphasizes that the environment does not require special computer resources and it can be installed in a common personal computer. In addition, it facilitates the development of interfaces with other systems and environments as well as the system maintenance.

Besides being relevant for the monitoring of economic information, the system is also valuable in the process of device acquisition. The possibility of following up the price variation amongst similar devices is powerful information in the negotiation process between health care providers and suppliers of these devices. In Brazil, anecdotal reports (Calil, 2004 cited in Almeida and Freire, 2009) have showed huge differences in prices not only amongst regions but also amongst providers in the same municipalities.

Furthermore, if the system is updated over the years, it can be a useful source of information to understand the process of marketing such products, considering the introduction of innovations by each manufacturer, changes in functionality and price, as well as products withdrawn for safety reasons or manufacturer motivation.

The system may be a tool for the post-market vigilance of medical device safety. To better fulfill this aim, other attributes may be incorporated to better characterize the safety aspects of these devices. For example, in the case of stents, the geometry of the device has great importance in tracking its failure. Currently, this attribute is neither available in the Economic Information Reports nor in the users´ guide of the device.

Considering the relevance of the systematization, Anvisa has released the description of the proposed device systematization with some queries output, showing the price variation amongst devices on its website (Brasil, 2009b). This initiative caught the interest of other agencies, government bodies and medical associations enough to establish a joint project to enlarge the systematization for other classes of devices such as orthopaedic prostheses, dialysis machines among others. Thus health professionals, managers, decision makers and regulatory authorities may come to rely on a system that enables a more efficient acquisition process and post-market vigilance of medical devices.

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