Medical Devices Vigilance and Patient Safety The MEDEVIPAS project

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***Abstract* — Biomedical Technology has contributed decisively to the impressive progress of modern healthcare over the past fifty years. Although recent technological advancements have led to much more reliable and safer Medical Devices (MDs), potential risks of failure and the associated adverse incidents cannot be neglected. In fact adverse incidents, due to MDs, have recently increased in absolute terms, because of the exponential increase in the number of devices used today. Patient safety is a fundamental cornerstone of care and a critical component of all healthcare systems. To create a safer environment in terms of technology, it is necessary to provide rapid and accurate information for adverse events, in order to avoid their repetition at another time, in another place. The traditional approach of MD Vigilance based only on official user reports of adverse incidents has been proven inadequate today. A modern approach to the problem, subject of this work, is based on the introduction of additional means, such as data mining, extraction, standardization and codification of the information, from different direct and indirect sources worldwide, and its systematic classification and archiving in dedicated databases. The aim is to timely extract the information on potentially hazardous MDs and make it available where appropriate. It is expected that this work through the design, development and implementation of modern ICT tools for MDs vigilance, creates a prototype system, which provides critical, on time and customised information to health care institutions, in addition to the existing traditional systems and consequently considerably improves patient safety.**

***Index Terms* — Adverse Incidents, Data Mining, Medical Devices, Patient Safety, Vigilance.**

I. INTRODUCTION

Patient safety is a fundamental cornerstone of patient care and a critical component of health care quality. However, recent research suggests that the rate of medical errors with serious consequences for patients is extremely high, reaching 10% of admissions [1,2,3]. Some of these errors are due to adverse events related to medical devices failures. Progress in health services in recent decades has been accomplished, largely through the progress and developments in technology. Medical technology has become more reliable, efficient and secure than before. Currently, all medical devices are produced and "placed on the market" according to international standards and have the necessary certification in compliance with the Medical Devices Directives and guidelines for the EU, and/or FDA approval for the US. However, even the best designed products, which are manufactured according to international quality standards and bear CE marking, could potentially fail in clinical practice and cause serious problems or death to patients and staff [1,2,3]. To avoid such adverse incidents, or more correctly to avoid their reoccurrence at a different time or place, the European Directives on MDs include provision for the establishment and operation of MD vigilance systems in the European Union [4,5,6]. These systems must be created under the responsibility of each member state and should collect reports of adverse incidents involving medical devices, perform investigation when appropriate, and disclose the information to the other member states and the EU Commission in order that necessary precautions are taken [7,8]. It is basically a system for collecting and exchanging sensitive information similar to that of drug-surveillance [9,10,11].

Consequently, one of the most important tasks of the Competent Authorities (CAs) in the field of medical devices is the implementation of procedures for vigilance. Early warning of adverse effects should be performed by users reporting to the national authorities (User Reporting System) or to manufacturers (Post Market Surveillance) [12,13,14]. For this reason, the authorities must implement the necessary means to ensure that adverse incidents involving medical devices are indeed reported, investigated and, where necessary, appropriate measures are taken to prevent reoccurrence. This requirement is also described in the Guidelines on Medical Devices Vigilance System [4]. Greece has not taken any action in this direction, so it appears as perhaps the only EU country in which adverse incidents involving medical devices do not occur at all!

On the international level, the implementation of a

uniform system remains difficult, since a number of critical issues relating to nomenclature, coding, classification and use of information on medical devices have not been solved yet. With tens of thousands of manufacturers who put one million of different products on the international market and hundreds of thousands of local health devices producers, especially for custom made products, in local markets around the world, the problems arising are significant, making it difficult to achieve a common approach. An important effort to overcome these problems was initiated in the late nineties through the European Concerted Action EUROMEDIES (European Medical Devices Information Exchange System), coordinated by the Institute of Biomedical Technology (INBIT). That work laid the foundations for the creation in 2004 of a European Database for Medical Devices, EUDAMED (European Database on Medical Devices), which also incorporates an adverse events reporting system. At the same time a major effort began and continues up to now, in order to achieve uniform nomenclature, coding and classification of medical devices, initially at the EU level and then internationally, through the creation of a single system for all these products, namely the GMDN (Global Medical Devices Nomenclature). It has been proposed as an alternative to the UMDNS (Universal Medical Devices Nomenclature System) of ECRI (Emergency Care Research Institute) and supported by the international cooperation initiative Global Harmonization Task Force [15,16].

Despite these international actions and initiatives, changes that emerged in information exchange, mainly through the Internet, have created a new environment. Recent studies [6,8] show that the search and extraction of interesting information can and should be done in parallel, from sources outside the official systems of vigilance. This project work is headed in this direction. The establishment of a Medical Devices Vigilance System is a key element for the creation of a safer environment in healthcare and a condition for the prevention of adverse events in hospitals.

II. METHODOLOGY

The purpose of the Vigilance system is to improve the protection of health and safety of patients, users, and others by reducing the likelihood of the same type of adverse incidents being repeated in different places at different times. This is achieved by the evaluation of reported incidents and the dissemination of information when necessary, in order to prevent repetitions of the same type of incidents or to alleviate their consequences. This work includes issues related to the analysis of adverse events, codification and classification of medical equipment, data collection, data standardization and data mining. The classification of adverse events is accomplished by two different means. The first one is according to the medical equipment category and the second one according to the related cause of damage or malfunction. The medical products under investigation may be as simple as disposable gloves, or as complex as computer tomographic imaging systems. Recent studies have shown that a large number of problems are associated with devices used in medical imaging, anaesthesia and in vitro diagnostics. Concerning the causes of harm, most of them are related to the operation, production, quality and maintenance of medical equipment. Moreover, a significant number of the incidents is lately related to the operation of the software embedded or used in medical devices. A global example of the software failure was the year 2000 case, involving many medical devices, but it was treated successfully and ultimately caused no serious problems.

The data that are stored in the databases are collected from different sources with heterogeneous data sets, which can be in structured, semi-structured or unstructured form. This results in difficulty concerning the identification and collection of data, thus making it necessary to turn to data mining, data standardization, and integration. Data mining techniques have already been successfully applied in various healthcare applications, such as evidence-based medicine and epidemiology, aiming to provide reliable data-driven models, which represent more complex knowledge than typical statistics and density distributions, in order to facilitate decision support. It is estimated that 90% of the electronically available information is available in unstructured form and the amount of unstructured textual documents that are accessible through the web, intranets, fora, etc. is enormously increased every year. Therefore, identifying and extracting knowledge in unstructured documents is of paramount importance.

Efficient data mining approaches include association rule mining, neural networks, Bayesian networks, Markov models, support-vector machines, decision trees, classification and clustering methods. Inclusion of semantics into data-driven modelling is also an active research area. The range of medical applications of data mining is constantly expanding: brain injuries, stroke, geriatrics, trauma care, cardiovascular disease care, bone marrow transplantation, etc [17,18]. Several applications integrate various data mining approaches in order to obtain the most efficient and optimal results [19,20]. Integrated analysis of structured data with data available in semi-structured and unstructured form has been recently explored.

Although data exploration and mining have become an important means in a wide range of healthcare applications, the potential of data mining to enhance patient safety and improve healthcare quality in terms of medical devices vigilance, which is a crucial patient safety issue, has not yet been explored. In the context of this work, selected data mining techniques are properly adapted and combined in order to allow identification and extraction of knowledge from heterogeneous datasets and from different sources. The achievement is

the development of a novel pattern recognition system able to identify patterns that reveal adverse events and potential medical equipment malfunction. Moreover, a unified framework for the codification of adverse events and of the available information is developed; this framework could be exploited in other applications as well, besides medical device vigilance.

The prototype Vigilance system is composed of three modules with different functionalities:

• The first module consists of a database on adverse incidents and the collection, extraction and storage of the relevant information. The database of adverse incidents is populated with vigilance related information mainly provided by international sources: national authorities, international organizations, manufacturers and suppliers of medical equipment. Additional data are extracted from other sources on the web through the development of specific tools as described in the following section. Data from the different sources follow standardization process before being imported into the database. Information on adverse events directly reported by the hospitals on a voluntary basis is also been taken into account and retrieved where necessary.

• The second module is developed through the creation of a second database of medical devices, containing information from hospitals' Medical Equipment inventories and warehouse. Studies are conducted for customized information related to existing medical devices that are used in hospitals. The resulting medical equipment inventory should be maintained and continuously updated. This implies the use of Medical Equipment Management Systems (MEMS) or at least a simple e-inventory of medical devices with the necessary information to uniquely identify each item.

• The third module is a versatile Comparison and Detection Engine that identifies and reveals potentially hazardous medical devices. This means comparison of the data between the two databases of adverse events and medical devices, and detection of potentially dangerous medical devices. In the majority of cases, the information in the two databases differs significantly in terms of syntax. Therefore, to avoid the poor performance of the Comparison and Detection Engine leading to poor vigilance results, the algorithm for correlation and detection is based on flexible comparison of the manufacturer-model data between the two databases. It suggests possible matching relations which undergoes approval by the user. The procedure is based on self-training methods throughout its running, featuring continuous improvement of the vigilance results-reports, as well as improvement in the processing speed. The detection of eventually problematic medical devices is performed, either on demand by the user for one or more medical devices, or through an automatic procedure running for the total device inventory database.

The information related to the medical devices is collected from various sources, which in most of the cases provide the data with significant differences. This implies difficulties in importing the data, and imposes the need to use data mining, data standardization and integration of information before its storage. Algorithms for data mining are developed and used for the analysis, collection of the data from different sources, composing and summarizing it into useful information. The analysis is conducted from many different dimensions or angles to allow full correlation of the data. Analysis of large amounts of data from heterogeneous sources is a key factor in the implementation of the proposed MD vigilance system, aiming to provide reliable models that can be used to highlight the link between certain parameters, like device characteristics and clinical evidence, and the identification of adverse events and possible device malfunction. Such models, which are automatically trained using the available data, represent more complex knowledge than typical statistics and density distributions, and could include various machine learning and pattern-recognition paradigms. In the context of data mining, the exploration of MD vigilance-related data involves the entire spectrum of relevant data from distributed and heterogeneous sources, e.g. manufacturers' sites and hospitals' adverse events reporting systems, and requires a comprehensive approach to data analysis.

Given that data extracted from the web is in unstructured form, text mining is performed in order to extract features that can be used to support analysis of the available data in order to recognize potential risks and adverse events. These features are identified, and appropriate techniques for their extraction are designed and developed. A combination of rule-based and machine-learning approaches for extraction of the relevant information from different sources has taken place. The extracted features are assessed using statistical methods for feature selection in order to identify the most suitable ones that can be used to support MD adverse incidents system. Given the heterogeneity of the data space, a hybrid approach to both data and text mining approaches is designed and implemented. Techniques are adapted based on association rule mining, one of the most important and well researched techniques of data mining, which extracts interesting correlations, frequent patterns, associations or casual structures among sets of items in data repositories. The potential of neural networks for modelling and profiling processes and outcomes of MD monitoring and performance evaluations are also explored. In addition, the possibility of using semantically-integrated data coming from relevant fora is examined, in an attempt to take into account personal experiences of people using the medical devices under question, which may have not been officially reported; the inclusion of semantics in this context could potentially lead to the development of additional novel

data mining techniques for effective knowledge discovery.

Satisfying user requirements while providing fast access to up-to-date and accredited resources of information are prerequisites for the successful implementation of the medical device vigilance system. Nevertheless, modelling of the system design prior to the system's functionality is formally described and correct, the end-user needs are met, scalability and extensibility are supported, the system's design is visualized, checked for errors and edited before its implementation. This work suggests that the design requirements of the vigilance system are described formally using the Unified Modelling Language (UML), the current state-of-the-art language for system design. UML provides a

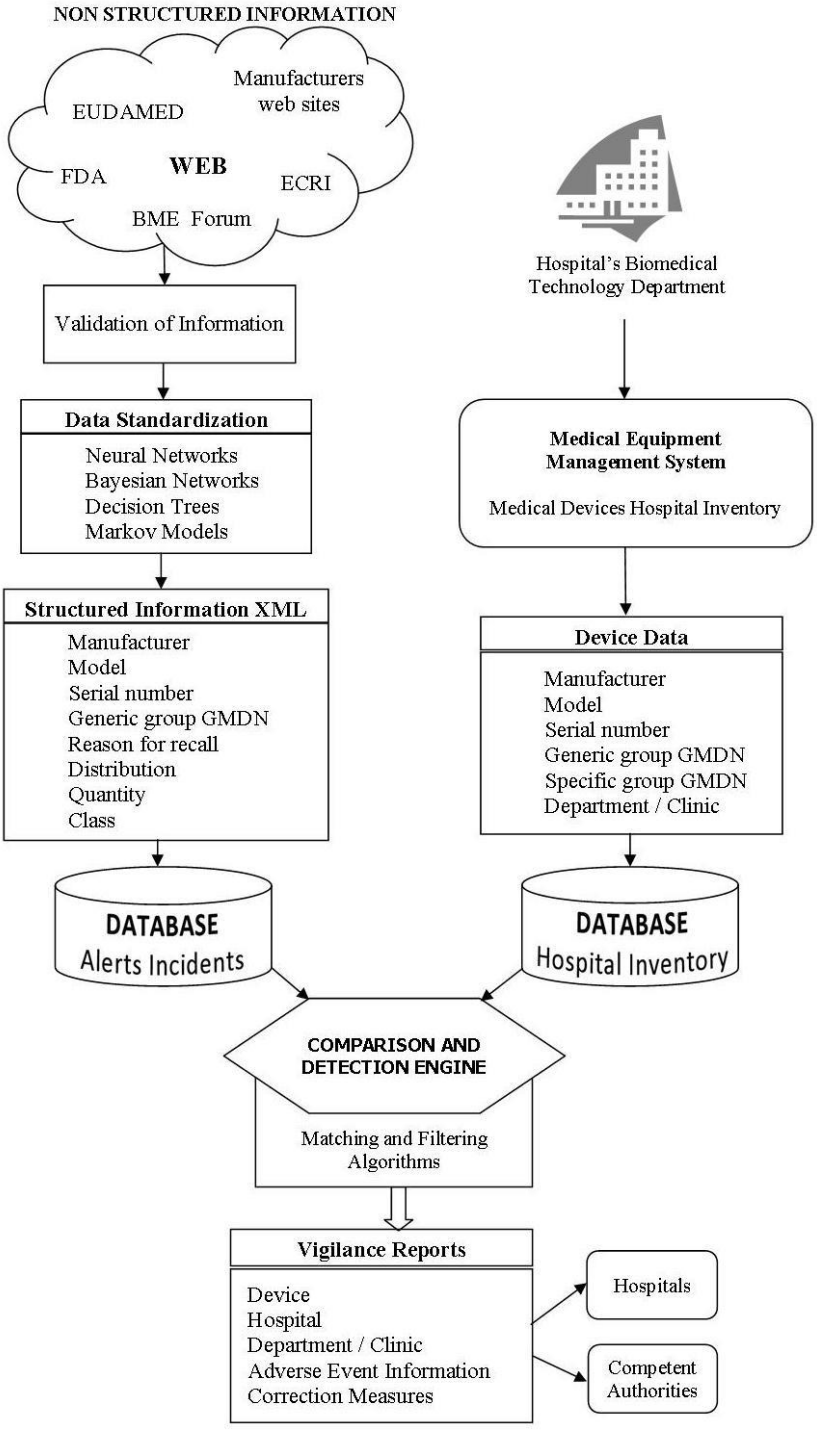

Figure 1. Overview of the system operation and information flow

implementation is an essential part for the application development. System modelling is considered to be successful when the following requirements are met: the family of diagrammatic notations by which a software system can be described at a high level of abstraction that enforces system modularization, by splitting the

system's functionality into a collection of connected components.

The design and development of the proposed vigilance and user reporting system are customized, in order to satisfy the specific requirements within the healthcare sector in Greece. An overview of the system operation and information flow is schematically shown on Figure 1. The Alerts Incidents database is populated with vigilance data provided mainly by international sources, e.g. National Authorities, International Organizations, manufacturers and suppliers of medical equipment, but additionally with information extracted through the internet using data mining techniques. Data from the different sources is going through a standardization procedure, before their import into the Alerts-Incidents database. At the same time, Alerts-Incidents database is also populated with data about adverse incidents reported by the healthcare facilities. On the other hand, in order to provide the healthcare units with customised information concerning devices locally used, and avoid the wide spread of not useful information, hospital medical device inventories should be maintained and continuously updated. This database is created and maintained by regular data import from existing hospital devices inventories, when available, or such inventories are built from the beginning, where necessary. Medical devices of the hospital inventories are periodically cross-checked versus the vigilance information from the Alerts-Incidents database, by using the Comparison and Detection Engine through a flexible comparison procedure. As a result, customised vigilance reports are generated, which are further on assessed, verified, and distributed to the hospitals concerned in order to take the necessary preventive actions.

III. RESULTS

For the purposes of the Medical Device Vigilance System, analysis and codification of adverse incidents have been first investigated and accomplished. Adverse events are classified according to the type of medical devices, according to its primary function and according to the cause of failure. Also, a key parameter in the analysis is whether the medical equipment uses software necessary for its operation and whether the failure occurs because of the software.

Classification of the adverse events according to the basic functionality of the Medical Devices has been performed in compliance with the Generic Categories of the Global Medical Devices Nomenclature (GMDN). Specifically these categories are:

01 Active implantable devices
02 Anaesthetic and respiratory devices
03 Dental devices
04 Electro mechanical medical devices
05 Hospital hardware
06 In vitro diagnostic devices
07 Non-active implantable devices
08 Ophthalmic and optical devices
09 Reusable devices
10 Single use devices
11 Assistive products for persons with disability
12 Diagnostic and therapeutic radiation devices
13 Complementary therapy devices
14 Biological-derived devices
15 Healthcare facility products and adaptations
16 Laboratory equipment.

Further on, classification of the adverse incidents has been performed according to the failure symptoms of the medical devices. Recent studies have shown that most of the problems that occur with medical devices are associated with the operation, performance, appearance and upgrade of the device software [8,13]. As a result, the adverse events have been classified into 11 categories:

1. Behavior - the system performs a physical action due to some output of a function, e.g. gantry movement.
2. Response - the system performs not expected function, e.g. sudden emission of radiation.
3. Data - corrupted or lost.
4. Display - these symptoms are related to incorrect visual display of texts, numbers or images by various means, such as monitors and printers.
5. Function - there are errors in calculations and certain functions of the code.
6. General - for the cases with no sufficient information, impossible to be assigned to other categories.
7. Input - these symptoms are related to input improper feeding of functions or modules, e.g. data entered by user or read from a storage device.
8. Output - these symptoms are related to erroneous outcome of functions or modules.
9. Service - the system performs a malfunction involving more than one subsystem.
10. System - an overall system problem.
11. User instruction - refers to mistaken manuals or other documentation for the user.

A significant number of adverse incidents with medical devices is due to software failures. An analysis of reports of medical device failures over the past several years indicated that a significant number of them are associated with software. This figure is reaching approximately 50% when adverse incidents concern active medical devices. Dealing with software safety is considerably more complex than hardware, as it cannot be fully tested in the same way as hardware, and it is easy to modify or update, potentially introducing unforeseen errors.

IV. CONCLUSION

Regarding the MD vigilance, as stated by the Medical Device Directives, the Competent Authorities are required to establish and maintain a comprehensive MD vigilance system for reporting adverse events with the involvement of all healthcare facilities in the country, as

well as the MD manufacturers or their authorized representatives. However, the most difficult target to achieve is a trustful connection between the users, the service providers and the manufacturers of medical equipment in order to facilitate the exchange of information in this crucial area. The implementation of this prototype vigilance system will play a catalytic role towards achieving this goal. Since we are currently experiencing a new era of communication, it is expected that the telematics tools, which are developed and used by the vigilance system, provide the means for an effective and mutually acceptable approach to information sharing.

In Greece, the users of medical equipment are, so far, reluctant to report adverse events to the Competent Authority. They prefer informal communication with manufacturers, which explains the very low number of vigilance reports from Greece. This situation should change in the future through a strong information campaign. Training of professionals in the healthcare sector will focus on the importance of the MD vigilance system. The establishment of effective and efficient means of communication between all involved parties to exchange information about alert and adverse events will facilitate the success of this process, although it will take time to reach the level of European Union countries with a tradition in this field.

ACKNOWLEDGMENTS

This research has been co-financed by the European Union (European Social Fund – ESF) and Greek national funds through the Operational Program "Education and Lifelong Learning" of the National Strategic Reference Framework (NSRF) - Research Funding Program: Thalis. Investing in knowledge society through the European Social Fund.

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