Development and implementation of a system for medical devices monitoring in Morocco

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Abstract. Given the importance of medical devices in improving health, a system of monitoring their use is necessary to ensure an acceptable benefit/risk ratio. The present study focuses on the post-marketing monitoring system, of which the aimis to develop, a national strategy for the establishment of a multidimensional vigilance system to monitor medical devices in Morocco.
Methods : The study is based on a systemic review selected by the PRISMA method for the period between [2011-2021] and on the Scopus, Pubmed, Science direct and Web of science databases.
Results: A preliminary analysis of the data identified some challenges such as under-reporting and lack of standardization of adverse reaction coding, standard nomenclature problem for international trade, lack of clarity of requirements for manufacturers, and insufficient regulation and significant incentives for the use of unique device identifiers. Recommendations for a more effective national system are put for ward which address the regulation and computerization of the system for the development of medical devices monitoring mechanisms.

Keywords: Materiovigilance, medical devices, post-market surveillance, UDI, regulation.

Introduction

The medical devices (MD) market is increasing thanks to the expansion of care offer in Morocco. For this purpose, and face to the increasing demand for the use of such devices, it is necessary to get ready for and conform to international requirements ,particularly in the area of materiovigilance (MV),which aims at monitoring incidents resulting from the use of MDs after they have been brought to the marketing order to improve patients' safety and ultimately improve the quality and efficiency of their use[1].Morocco, however, faces certain challenges relating to the establishment of a structured information system ,including a centralized database such as medicines ,a coherent and standardized MD coding system allowing the assessment and monitoring of the safety of these devices, with MV guides. Face to under reporting of adverse reactions [2], the present study seeks to develop a model of a national strategy for collecting, analyzing and acting on a multidimensional vigilance system to monitor adverse reactions (AR).

1 State of affairs

1.1 Regulation

1.1.1 United States

The marketing of MDs in the USA is regulated by the Food and Drug Administration (FDA). In fact, the marketing of MDs requires prior approval of FDA. The latter evaluates whether the MD meets the health requirements and then approves its quality and reliability for use.[3]In terms of vigilance, the FDA has post-marketing mechanisms which help identify emerging adverse reactions. These mechanisms include Medical Device Reporting programs that notify of any device-related ARs, a public Manufacturer and User Facility Device Experience (MAUDE) database that contains reports from manufacturers, importers or voluntary notifiers, be they health care professionals, patients or users [4].As for DMs safety monitoring, the FDA imposes regulation that institutionalizes a unique device identification (UDI) system published since 2013[5]. It is an MDs standardized identification system used to quickly identify a device in order to reduce medical errors and resolve device-reported problems[6].Indeed, since the creation of the UDI the number of articles and references recorded in the database has reached 1800000 [7].

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1.1.2 The European Union

Before 2017, medical devices regulation in the European Union (EU) was subjected to three directives, of which the objective was to set objectives for the member states which, in turn ,integrated them into and adapted them to their national laws[6].These directives are as follows : Directive 93/42/CE which is related to medical devices (excluding active implantable medical devices)applicable since June 14,1998,Directive 90/385/CE which is related to active implantable devices and Directive 98/79/CE Relating to in vitro diagnostic devices. The application of these directives has resulted in the'CE marking'on the notified private profit seeking organizations which not only certify and approve of the marketing of such devices with in the EU and also describe manufacturing standards, labeling and expected performance and safety profiles based on the compliance with the European Commission's directives [6].In 2017,the European Parliament and Council's MDs regulation (EU,2017/745) was established to consolidate these directives' contributions, support the role of the notified bodies and to place them under Europe an control, set new requirements on clinical evaluation before marketing, particularly streng then transparency and traceability thanks to a European MDs database (Eudamed) and ultimately ensure post-marketing surveillance by means of the UDI gradual and mandatory implementation for all MDs [8].

1.1.3 National context

MDs regulation has been implemented in Morocco only recently. It was first initiated by a first circularin1997 relating to the creation of an MD registration advisory commission, and then followed by a decision relating to the specific traceability rules applied to certain medical devices which did not emerge until 2012 and which included guidelines for MDs monitoring as well as the general procedures for their traceability. In 2013, Dahir no.1-13-90 promulgating law no.84-12 relating to medical devices constituted a stronger basis for a MDs regulatory framework, particularly up on the adoption in 2014 of Decree no.2-14-607 for the application of the said law. In parallel, other decrees were published in 2015 to regulate the conditions for MDs marketing in the Moroccan market .MDs registration with the Ministry of Health at the level of the Medicine and Pharmacy Directorate(DMP) is carried out in accordance with the ISO13485 reference standard ,thus ensuring that MDs comply with patient 's safety requirements[9].Similarly, an instruction sheet, including the information necessary to identify the manufacturer must be attached to the MD file. Law 82-12 also contains the MD traceability rules according to the degree of danger together with the institutionalization of a MV system that ensures the safe use of MD in post-marketing, and this is monitored by the National Consultative Commission of Pharmaco-Toxico-Reacto-Materiovigilance and Therapeutic Trials created since 1997[10].

Patient health safety is a major issue in health policy. However, the Biomedical Equipment Professionals' Association has raised the issue of lack of traceability, particularly with regard to devices illegally introduced into Morocco via smuggling zones [11].In addition, the MDs post-market safety monitoring is carried out through the anti-poison and pharmacovigilance center management in a passive way by means of safety datasheets put at the health professionals, public or patient associations' disposal at a low declaration rate [12]. Also, it is important to note that insufficient MV publications or insufficient international collaboration in terms of AEs notification in databases, following the example of drugs is another issue there to.

1.2 post-marketing surveillance strategies

Prior to MDs marketing, a series of pre-market trials must be conducted to ensure the MDs safety and reliability, account taken of the fact that after extensive use, significant safety issues may arise due to inappropriate sample size or limited follow-up time in the clinical trial[13].Likewise, additional pre-marketing clinical studies in humans do not have a significant impact on the identification of most MDs safety issues[7]. For this reason, MD safety monitoring is an obligation requiring standardized data collection and adequate methodologies for the identification of security threats and risk communication [14].

1.2.1 Passive monitoring

Passive monitoring involves continuous monitoring of ARs caused by MD use, of which external parties such as manufacturers, importers, healthcare professionals or even users / patients report data to an institutional MD monitoring body whichin turn assesses these incidents and risks of incidents in order to make the the necessary decisions and precautions [15].In some countries, clear and demanding guidelines for reporting incidents have been implemented, while in others, this is done on a voluntary basis [16].

1.2.2 Active monitoring

There exist two types of active surveillance :one is based on post clinical studies carried out either by a regulatory body to ensure compliance with essential health and safety requirements, or by MD manufacturers as part of providing continuous clinical evidence throughout their life cycle[17].These studies mainly concern high-risk MD, such as implants [18].

The other type includes active MD registers capable of generating data on the safety and performance of devices [19]. Registries are"prospective observational studies of subjects, with some common characteristics, that collect ongoing and supporting data over time on well-defined outcomes of interest for analysis and reporting» [20]. Registry data can provide long-term results in a larger population and reflect actual device performance in patients [19,21].

All these types of monitoring can be computerized by injecting the collected data into databases, a fact wich helps provide standardized reporting and fully completed forms for initiating and tracking security alerts and reminders[22].The databases can be accessible to the public via a search or private web portal under the authority of a regulatory body.

The computerization of MD vigilance system also concerns UDI coding, which allows an addition to the existing labeling requirements, and concerns MDs traceability in order to strengthen their safety, reduce medical errors linked to MDs misuse and combat counterfeiting[4].In fact, UDI is an alphanumeric code, which makes it possible not only to identify the device (ID) by affixed sequence, bearing the manufacturer and model's definition, or device variation, but also to identify the product (PI) by referring to the production batch, batch number, serial number, manufacturing date or expiry date [23]. The UDI is presented on the device label as a bar code or radio frequency identification label [24]. The information provided by the UDI may be linked to a database for the purpose of complementarity and can thus ensure MD traceability [25].

2 Materials and methods

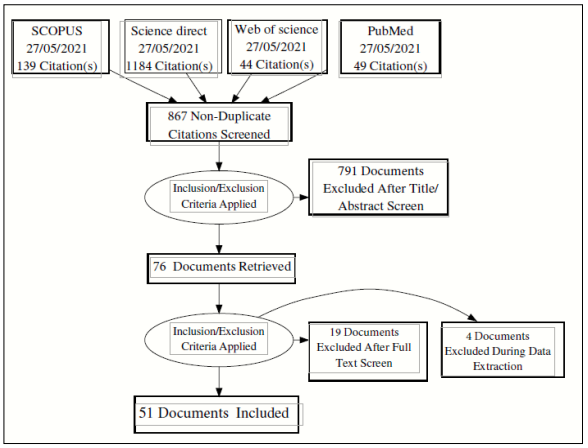
The present study is based on a systemic review for the period between [2011-2021] using a combination of keywords related to the subject (medical devices, Vigilance, Unique identifier) and four databases, namely "Web of science", "Scopus, "Pubmed" and "Science direct". The selection of the journal is developed by the PRISMA method. The steps and criteria for inclusion and exclusion are illustrated as follows in Table 1.

Table 1: Inclusion and exclusion criteria

Step	Inclusion Criteria	Exclusion Method
1	Research area (Public Health and Health Care, Medicine, Biomedical and Pharmaceutical Sciences	Automatically excludes domains not included by the database filtering tools used.
2	Unduplicated documents	Automatic exclusion of one of the documents duplicated by a bibliographic management tool
3	Documents that contain keywords: DM and (adverse reaction or Post-market surveillance or VM or security or UID or traceability)	Manual by eliminating documents not including search keywords.
4	Documents containing information relevant to this study and documents from which data may be extracted (content available)	Manual exclusion of documents that do not contain information relevant to this study and documents that cannot be retrieved.

3 Results

The results of the query resulted in the selection of 51 documents among 1416 documents, varying from articles to chapters. The number for each step is presented according to the PRISMA method (Figure 1) The frequency of words in these 51 documents is also presented (Figure 2) .The objective of this collection is to assess the implementation of MD safety monitoring strategies at the international level while exploiting the constraints associated with these different strategies.



3.1 Data classification

The Preliminary analys is of documents (51articles) revealed the following results:

-Ranking by date: 12% between [2011-2013] ;36% between [2014-2016] ;36% between [2017-2019] and16% between [2020-2021].

-Ranking by research method : 10% of surveys ;82%Descriptive ;4% comparative and 4% a project.

-Ranking by domain: 10% Health policy ; 18% Biomedical Engineering ;6% Pharmaceutical sciences and 66% Medicine/healthcare.

Description of the domain in relation to the method :

-Health policy : A survey and 4 descriptive documents

-Biomedical engineering : 8 descriptive and a project

-Pharmaceutical sciences : 3 descriptive documents

-Medicine/healthcare: 4 surveys; 27 descriptive documents ; 2 documents comparison and a project.

3 .2 Evaluation of post-marketing surveillance systems

3.2.1Degree of use

-The terms "report/signal "were mentioned in 60% of the documents collected. The link of these terms to "manufacturer/importer/manager of MD" was in 8 documentsversus7documentsfor"users/healthcare professionals/patient".
-For the register(s),67% of the documents noted this term of which 88% of these documents were linked to MD"implantable/implant(s)".
-43% of the documents contain 'UDI'. This term is related to "FDA" in 21 documents compared to 16 to "EU".
-82% of the documents raised "database (s)"of which 16 mentioned the "EUDAMED" database against 8 for "MAUDE".

3.2.2Usage domain

Registries appear to be more frequently used in the fields of arthroplasty/traumatology/orthopedics than in other medical fields. Also, there appears to be a considerable link between the UDI or registries and patients'electronic health record (EHR) as a solution to enhance the degree of MD traceability.
Inanother component, the most targeted MD classis class III, which is considered to present the highestlevel of risk.

3.3 Constraints of post-market surveillance systems

3.3.1 Reporting Monitoring

-Under reporting of AEs,which results in an underestimation of calculated prevalence.This is due to lack of awareness for its importance, fear, punishment, uncertainty and lack of time [2, 26].
-Voluntary reporting with incomplete reports and delayed interpretation due to lack of clinical examiners and problem of determining the frequency of use of a given device [13].
- Lack of standardization of coding of MD-related AEs, and lack of mapping between some of the coding dictionaries for the generation of timely safety signals [27].
- Double counting from duplicate declarations [26, 28].

3.3.2 The register

-Stakeholder adhesion and obtaining of prior consent for data extraction [21,29].
-Voluntary participation and incomplete or biased data [20].

3.3.3. The Unique Device Identifier

-A robust infrastructure in labeling [23].

-Problem of standard nomenclature for international trade due to lack of technical MD details [6,30].

-Lack of clarity of requirements for manufacturers to implement UID, lack of knowledge and understanding of its value among providers, funding problem,barriers to inter-connectivity between health information systems and lack of a standardized EED system[24,25].

-Insufficient regulation or significant incentive requiring the UDI use [31]. .
-Slow implementation of the national health technology assessment system [7].
- Regular updates from readers [32].
- Unique global label on the product[16].

4.4 Recommendations for the development of an MDs national post-marketing surveillance system

4.4.1 Regulations and procedures

Any institutional change is held through the implementation of regulatory foundations that set procedures and practices' boundaries and protect users, producers and distributors' rights. Indeed, the establishment of a monitoring system guaranteeing patients and users' safety and improving the quality and reliability of MDs use must begin with the creation of an MDs regulatory authority and are vision of the law by broadening its scope to keep pace with changes in international requirements. The change concerns first MD definition, its classification and traceability procedure to not only overcome the problems of compliance requirements, but also facilitate registration administrative procedures and traceability. The system involves stakeholders, each of which takes its own responsibility.
MD manufacturers must ensure traceability of all customer complaints they receive and establish documentation of procedures to analyze and evaluate these complaints which make it possible to notify vigilance procedures if need be [33]. Health professionals, for their part, should be aware of the importance of reporting an AR, particularly with the emergence of new situations, and this by institutionally encouraging formal education on patient safety and MD regulation [34]. Also, interested parties , who are entrusted with MD use, be they patients or consumers in this system, should assigned a role and involved in the conservation of the quality of their health.
The actual performance of a device, moreover, can be reflected by the data of the register[19] ;the extension of its use for different specialties, especially those using implants in orthopedics and cardiovascular surgery should be developed nationwide the through the implementation of reporting requirements for health care providers, a fact which will make it possible for medical organizations to monitor the care provided and comply with the direct evidence-based lines[17].The final aspect involves the establishment of a cell in each hospital for MDs-related ARs and the supervision of patient safety to ensure a close link between user and regulatory authorities. All this can be activated with the institutional accreditation of hospitals, which will be a guarantee for the consolidation and strengthening of the measures undertaken within the MV framework [28].

3.4.2 System Computerization

The use of information technology in health care processes is a reality and even a necessity for practice quality improvement. Personalized medical data on a digital platform therefore requires a multidisciplinary

approach [21].The computerization of the surveillance system can be carried out in two different but complementary ways: the first workstream consists of digitizing the adopted passive reporting process and developing collection and analysis mechanisms that depend on the accumulation of voluntarily selected AR reports and the stakeholders' commitment to implementing malfunction reports. Another more robust and efficient workstream allows automatic collection and authentic analysis of data emanating from electronic sources such as EHRs, a fact which will lead to rapid identification of safety issues and timely corrective action [7]. Similarly, patient generated data can be fed in to registries to improve performance [21].

Efforts to standardize the HER are being developed and some studies have highlighted the importance of aligning these systems with the care and business processes as well as the information flow. [21,35].It is also recommended that the implant tracking system be computerized through the elaboration of maps containing essential MD information, such as MD identification, characteristics, UID, should the occasion arise, potential adverse effects, warnings and precautions with the recording of the electronic version of the implant card in the health institution concerned [36].In another context, deploying traditional tools for storing and exploiting data can present classification, control and system sustainability problems. To do this, the elaboration of a computerized information system with applications and database allowing the consultation, updating and rational management of data is required. In this sense, the World Medical Association recommends that information on these applications be made available to the public, in order to enable users to understand and be aware of potential risks [19]. Besides, the disclosure of information in the database must be controlled by the regulator and identify which information should be confidential or released.

3.5 Conceptual model for MDs post-market surveillance

The current national MV system is based on a declaration of MD-related ARs by a data sheet that can be downloaded from the management website.An alternative online declaration is proposed to improve the frequency of reporting and involve all stakeholders in this system. The application will be in the form of a search web interface that facilitates the filling of the data provided by an interactive information resource for MDs identification, centers, and incident type with coding.

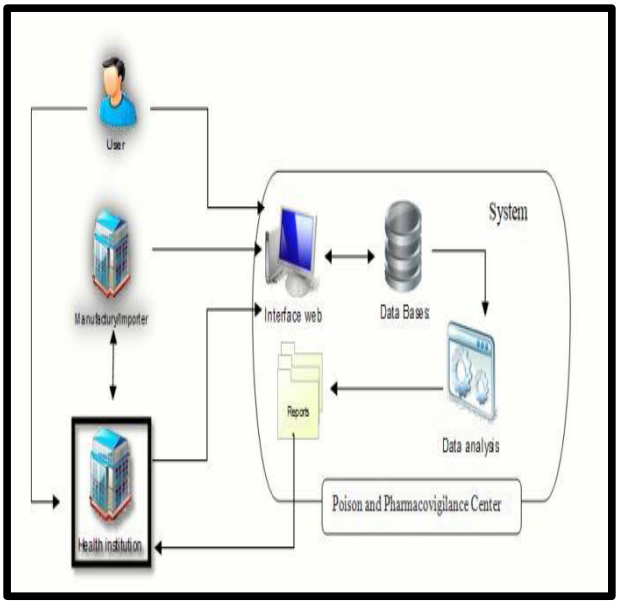


Figure3 : Architecture diagram for reporting and processing ARs

4 Discussion

Given the central role of medical devices in medicine and health, potential MDs-related ARs must be monitored and identified through a post-marketing surveillance system. The purpose of the vigilance system is to ensure the protection of patients by reducing the probability of reproducing the same type of adverse event [37].

Some reminders and alerts have demonstrated the role of this system in recent years for risk management and patient/user safety,notably with the scandals of silicone breastimplants(Poly Implants Prothese),metal-on-metal artificial hip implants,or implantable cardioverter-defibrillator leads[18].

Therefore,the strengthening of post-market surveillance is important since there is nosuch thing as zero risk of failure or AR,and incremental changes are brought to MDs through out their life cycle[2].However, the implementation of a post-market surveillance system may be impeded by certain challenges, given the unknown quantity of devices on the market, the heterogeneity of regulations in different countries and lack of transparency[30,38].

The difficulty of standardizing the import process, the diversity of sources and the problem of the significance of the assessment results after the distribution of a considerable number of MDs shoud also be taken into account. [37, 13,39]. These barriers are further exacerbated by the lack of a duty of care imposed on manufacturers to ensure efficient traceability, and on healthcare providers and patients for timely and complete reporting. In view of these challenges, new approaches in this field have recently emerged that aim to include artificial intelligence in datamining, extraction, information standardization and codification, from a worldwide implementation of sources and its archiving indatabases[2]. Other means are being investigated which consist in the production of self-

monitoring data available that can be automatically downloaded in the internal monitoring registers from the device itself as is the case with the Extraction and Longitudinal Trend Analysis system (DELTA) for cardiovascular devices [40].
The use of UDI as a tool for MDs monitoring should improve the post-market documentation process through subsequent identification and rational management of reminders [41].
At the international level, the implementation of a single system remains difficult [37].However, global harmonization is necessary not only to reduce regulatory differences between countries, but also to overcome the diversity of perspectives on the sites where MDs are used [2].The Global Harmonization Task Force (GHTF) has just supported the convergence of standards and regulatory practices related to medical devices' safety, performance and quality [42]. The inadequacy of national policies and regulations on medical devices in most developing countries has forced the World Health Organization to work with GHTF on health technology assessment,the adoption of a single medical device nomenclature and the establishment of post-market surveillance and a vigilance network [42]

Conclusion

Throughout its life cycle, a medical device requires monitoring, be it in the pre-marketing phase to obtain marketing approval or in the post-marketing phase,and more particularly during its operational phase, to guarantee its safety and reliability. The MD regulations, monitoring and quality management systems must be constantly updated at the same pace as the MD production on the world market.The involvement of all stakeholders (manufacturers, importers, regulators, healthcare providers, patients, users)is the most certain guarantee of mastering this market.

Declaration of interests

The authors declared that there is no conflict of interest.

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