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Evaluation of the unique device identification system and an approach for medical device tracking

Tuncay Bayrak[a,*], Funda Özdiler Çopur[b]

[a]Ministry of Health, Medicines and Medical Devices Agency, Sogutozu Mah, 2176. Sok., Çankaya, 06520 Ankara, Turkey
[b]Biomedical Engineer Department, Baskent University, Turkey

KEYWORDS
Unique device identification;
Tracking system;
Medical device;
Traceability of medical device

Abstract
Background: Most countries have different registration and tracking system, but unique device identification based approach was recently introduced in the USA. In 2013, FDA and EU released regulations about unique device identification system. In literature, there is not any study that compares the UDI legislations on the basis of the requirements. In addition to the legal requirements, establishing a UDI system in digital environment is very challenging.
Methods: This is a theory based study that includes information from healthcare industries and key points from UDI related legislations which are discussed. To visualize the design of the proposed system, the Dia program that contains the Unified Modeling Language (UML) components was used.
Results: Implementation of the UDI based tracking system is very difficult due to two reasons. First, the relevant legislations do not give detailed information on how UDI system will be implemented. Second, each type of medical device has difficulties due to UDI labeling. We have observed that the stakeholders in the medical devices sector in Turkey, especially the manufacturers, are not yet ready for UDI-based tracking. The current registry system is not effective to track medical devices and share data.
Conclusions: To overcome compliance problems, UDI requirements should be perfectly determined and subsequently related legislation should be established. Regarding these requirements, every country should introduce an action plan and include all sector stakeholders in that action plan. We suggest a model for medical device tracking to be able to use instead of the current registry system in Turkey.

Introduction

Medical device industry is currently one of the fastest growing sectors and the global market with the expected

*Corresponding author.
E-mail address: bayraktuncay@gmail.com (T. Bayrak).

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number $398.0bn in 2017. The risks in such a big market are very huge and it can be eliminated with tracking of medical devices. Increased risks have induced the need of a track and trace system for medical devices to control the market and to observe the lifecycle process. Track and trace systems can provide improved quality health care, patient safety, efficient technology management and lower costs [1].

Especially after the scandals of Breast Implants manufactured by the French company Poly Implant Prothèse (PIP), transparency and tracking have become the most important regulatory issues. As the governments around the world continue to increase their scrutiny requirements, the medical device industry is coming under heavy pressure from politicians and regulators who are calling for increased transparency. For this reason, USA and EU have the similar globally harmonized and consistent approaches to increase patient safety. They are proposing a harmonized legislation for unique device identification (UDI) to help optimizing patient care using global standards [2].

In the USA, the Food and Drug Administration (FDA) started working on UDI in 2007. In 2013 a final rule has been established by FDA which explains a UDI system designed to adequately identify medical devices through the supply chain and usage [3,4]. Consequently, EU officials accelerate their work on the new medical device regulatory directives in the hopes of modernizing the system. One of the main focuses of this new medical device regulatory proposal is traceability. In addition, there is a recommendation referred to use of UDI in the member states dated 9.4.2013 and numbered 2013/172/EU [5]. This Recommendation does not aim to define all the aspects of the UDI system. It should be taken as a tool to facilitate the compatibility of the traceability mechanisms established at national and/or regional level and to pave the way to the mandatory implementation of an internationally compatible UDI system of the Union. In this study, we focus on a general assessment of UDI challenges and differences between the USA and EU, and we propose a new approach to track all medical devices from first placing on market until terminal point.

Background

Regulatory framework

The United States and The European Union

One of the medical device regulations from the FDA is the Code of Federal Regulations with title numbered 21 CFR and part numbered 800–1299 in US [6]. It includes several regulative rules along the medical device lifecycle. On the other hand, the EU declared three main directives as 93/42/EEC [7], 98/79/EC [8] and 90/385/EEC [9]. EN/ISO 13485:2012 provides general requirements for traceability. According to the standard, the organization shall do the requirements for the traceability such as required records, labelling and other extent of traceability. The standard also covers the requirements of traceability for active implantable medical devices and implantable medical devices. Nevertheless, the standard does not specify the specific requirements left to the manufacturer and also it is not mandatory in the EU like a certain directive [10]. Therefore, tracking should be considered as an important point in national medical device regulations.

From the perspective of FDA, turning global traceability of medical devices into a rule has taken ten years of work by regulators, medical device industry, healthcare providers. As of the dated 24 September 2013 final rule on the UDI has been published by the FDA. UDI is an unambiguous labelling system which will provide secure distribution of medical devices and to achieve multiple public health purposes over medical devices. The word “Unique” does not mean serialization of individual products, but it allows tracking of medical devices through the supply chain [11]. UDI, an alphanumerical code, which are device identifier (DI) and product identifier (PI). This code can be linear or 2-diemensional. DI, a fixed sequence, brings up to the definition of manufacturer and model or variation of the device. The other part PI may refer to lot or batch number, serial number, a specific date of manufacture or expiration date [12]. The information provided by the UDI is also linked into a database which is called Global UDI Database (GUDID) in the USA, it provides an interactive information resource for device identification. GUDID will be open to the public for search and download, also it is allowing patients, healthcare providers and other industrial partners to access the information about labelling and identification of medical devices [12].

The part numbered 830 of 21 CFR comprises of UDI requirements regarding the criteria of ISO/IEC 15459-2 related to automatic identification and data capture techniques in information technology and ISO/IEC 646:1991 related to ISO 7-bit coded character set for information interchange. When a medical device package is relabeled, a new DI must be assigned and both of DIs must be available in the recording system [5]. For this reason, a recommendation has been released by the EU Commission for member countries to set up a UDI system. Agreeing to this publication, the important aspects of UDI should be enforced and the advance applications are given to the member countries. Additionally, EUDAMED (European Database on Medical Devices), a web based application, is in use only between competent authorities since 2010. The system supplies information about manufacturer records, withdrawal or rejected certificates, vigilance based data, etc. To achieve an efficient communication on tracking of medical devices the International Medical Device Regulators Forum (IMDRF) have released a final document which has common elements for medical device identification [11].

Although the IMDRF and the EU are aiming a globally accepted UDI system for medical devices, in order to increase patient safety and market transparency, there are already differences between the EU-UDI and USA-UDI [13]. One of the main differences is that while the USA has a single final rule about UDI, dated 2013; the EU is planning to legislate UDI in two regulations for Medical Devices and In Vitro Diagnostic Medical Devices (IVD). On the other hand, while USA has already started using GUDID, the EU declared that data will be centralized via EUDAMED, a pre-existing database still being used by Competent Authorities [13]. FDA requires 62 number of data elements, whereas the EU 33 and IMDRF 44 [14].

In a more detailed approach, according to EU Recommendation, UDI shall appear in both human readable format (HRI) and also in automatic identification and data capture

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