

Shanghai Food and Drug Administration

Implementation of a post-market traceability program for implantable medical devices adopting unique device identification

ABSTRACT

This article discusses the distribution and traceability model of Implantable Medical Devices (IMD) for post-market surveillance purposes, and the IT and automatic identification technology that has been used in the supply chain to complete post-market tracking in Shanghai. To build up this system successfully, it was necessary to establish a Unique Device Identification (UDI) for IMD's, based on GS1 Standards, to define the minimum information in the tracking process, and to establish a central data pool to support automatic reading in the hospital management system. Meanwhile it is necessary to have a Shanghai FDA monitor platform to collect the traceability information from the end user. This article also contains a real case study that took place in Shanghai.



Article by **Liang Yan**

Introduction

Implantable Medical Devices (IMD) pose the highest potential risk among medical devices, so they are subject to the most stringent management in the medical device regulatory system of each country, regardless of pre-market approval or post-market surveillance. Due to the high risk and high profit, such products can cause other disorderly management problems in their sales, purchase, pricing and service links, and even lead to injuries or doctor-patient disputes, so they raise serious concerns by the general public and the regulatory authorities. Shanghai began adopting Unique Device Identification (UDI) using GS1 Standards in 2007, and it was the first in China to set up a tracking system that links IMDs directly to patients.

Computerisation is an effective pathway to address post-market tracking

Shanghai began to take legal supervisory measures on IMDs as of 2002, and a follow-up study after three years showed

that the actual effect of these legal measures fell short of expectations. The following three major aspects have caused traceability problems:

- Firstly, basic IMD use information recorded during the process was inaccurate.
- Secondly, manufacturers could hardly collect the actual use data from the hospital, so they could not fulfil their legal post-market responsibilities.
- Thirdly, the information of IMD use was not transparent, which could not safeguard patients' safety, rights and interests.

The most practical and effective means to address the post-market traceability of these high risk medical devices is to make use of current computer/IT technology and allow different legal entities to easily share IMD use data under the existing legal framework. The key to setting up such computerised tracking system is to establish a standards-based UDI, to determine the traceability management mode, and to set up a feasible tracking system.

Standards for IMD identification

To establish a UDI system for IMD's, it was necessary to understand the basic requirements of its use, then determine the UDI coding rules, and finally determine the scope of traceability information.

Basic use requirements:

- 1) UDI should be applied to any possible place of use;
- 2) UDI should be able to remain independent from the above place of use;
- 3) UDI should meet the compatibility requirements of current automatic reading technology environments and should be adaptable to current legal environments;
- 4) UDI should be based on a design structure with clear validation records and good stability and reliability;
- 5) UDI should have good technological expandability and be able to accommodate various data media;
- 6) UDI should meet the requirement for simple operations, without multiple conversions during its use;
- 7) The symbols making up the UDI should be easy to use;
- 8) UDI should be able to adapt to potential changes that may occur in the production and management environments;
- 9) UDI should be affordable for organisations to implement and the benefits should outweigh the burdens;
- 10) UDI should comply with the operating rules of other regulations prevailing in the international market, such as the World Trade Organisation (WTO) rules.

Shanghai UDI rules for IMD's

- 1) Using linear barcodes. The technical environment for overall implementation of 2D barcodes and RFID is not yet mature, and in order to meet the current urgent need of tracking high risk medical device adverse events, we started from linear barcodes, and will then gradually develop into 2D barcodes and RFID;
- 2) Using the GS1 or HIBC coding standards. To allow every supplier to quickly implement the UDI system in the start-up phase, suppliers were allowed to choose either GS1 or HIBC barcodes. This rule may be changed later in the nationwide implementation of the UDI tracking system to simplify the technical system. (For reference: medical products that do not need to be traced can directly adopt the GS1 EAN13 barcode as used in the Chinese supermarkets);
- 3) Using primary and secondary barcodes; the primary barcodes are used to identify products and contain information on the country of origin, manufacturer,

product name, specification and packing level. The secondary barcodes are used to indicate key information of the product, including product's lot/batch number, and key dates, i.e. expiration date or manufacturing date;

Key traceability information in the IMD traceability system

The information provided in the IMD traceability system needs to enable the effective handling of adverse events after their occurrence, such as product recall and patient identification.

Accurately recording the UDI and patient ID is the most important link

To track the adverse event related to IMDs, regulators need the following basic information:

- 1) Basic information on product's use;
- 2) Information on the specific product involved in the adverse event;
- 3) Range of products that may have the same quality problem;
- 4) Patients involved in the product in question;
- 5) Location of the product(s) in question that have not yet been used.

Simply speaking, when we deal with an adverse event, we should use the UDI information of the product involved in the adverse event and identify the patients involved; then exercise control over the product held in inventory and bring the potential injuries under effective control in the earliest possible time.

To enable tracing to the patients, it is critical to record the UDI and patient identification (PID) at the time of use, and keep all the information in the quality system of the supplier and the hospital. Shanghai stipulates that upon completion of any IMDs surgical operation, the automatic identification of a UDI and recording of all relevant data of the patient shall be completed and linked outside the operation room of the hospital.

Minimum traceability information

To trace an IMD to a patient, the UDI needs to be associated with the following supporting information: product name, model, specification, lot number or serial number, registration certificate number, expiration date of the registration certificate, manufacturer's name, name of the after-sales service company of the imported product, and

name of the final distributor. Patient ID information should include the hospital's name, the patient's inpatient number, the patient's name, sex, name of the surgical operation, place of operation, date of operation, surgeon performing the operation, the quantity of devices used and so on.

The basic information relevant to a product is generated by linking the UDI directly to the database; the information of the lot number/serial number and expiration date of the product is generated after the second barcode is scanned; the medical information of a patient needs to be extracted from the hospital information system through the patient ID.

Information on product pricing can be included for additional purposes. But for a system that needs to run for a long period of time and to gather information on a continuous basis, the principle of “the least information, the cost-effective” shall be followed in setting basic management information requirements.

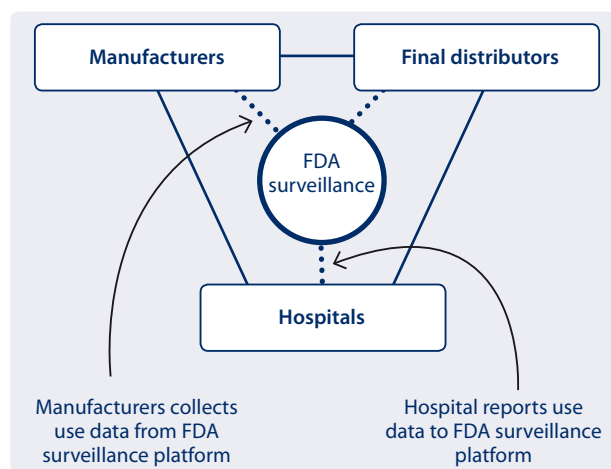
Implementation of the IMD traceability system in Shanghai

Shanghai started to implement the IMD traceability system in November 2006 according to the above architecture and management principles. The tracking system covers more than 100 hospitals using IMDs in Shanghai, and the IMDs included high-risk devices such as orthopaedic internal fixation devices, orthopaedic implants, synthetic crystals, breast implants, pacemakers, heart valves, stents and catheters. By June 2008, and through manual and automatic online reporting, the data reporting platform of the tracking system has gathered more than 175,000 entries of use data. Data analysis showed that the tracking system plays a crucial role in addressing the post-market surveillance of those high-risk medical devices, preventing the occurrence of injury events, and managing such events.

Triangular sales and supervisory model for IMDs

Shanghai developed a triangular sales and supervisory model in the exploitation of IMDs. Theoretically speaking, it is the most simplified traceability management model (See Fig. 1).

Figure 1: IMDs sales channel and device use data reporting channel



The outside of the triangle as shown in Fig. 1 is the basic sales channel of IMDs where manufacturers sell their products to hospitals directly or through a distributing chain and final distributors.

Inside the above triangle is a data reporting platform administered by the Shanghai FDA/health authorities. Hospitals report data relevant to the use of IMDs to this platform, and through which, manufacturers / distributors can retrieve information about the use of their products. This addresses the problem encountered by regulatory authorities that manufacturers can hardly obtain data relevant to the use of their IMDs from hospitals.

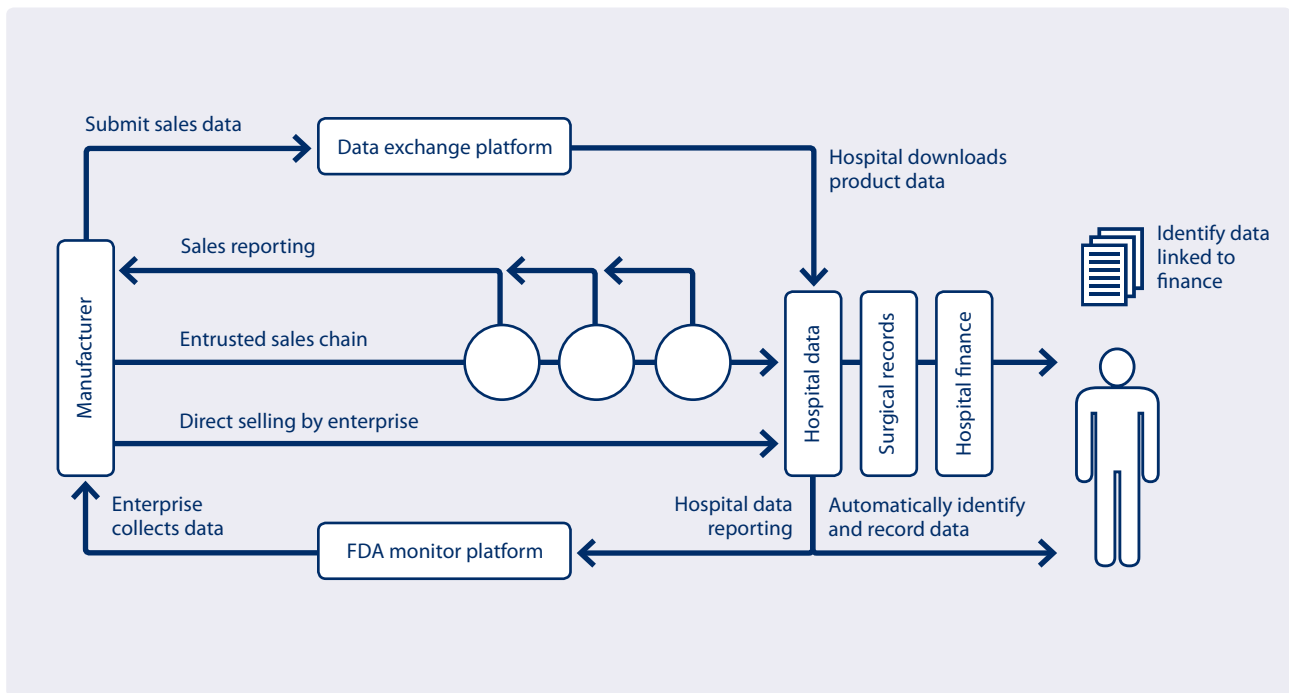
If an IMD manufacturer doubts the data available on the reporting platform and refuses to recognize such data, the post-operation safety of patients using such IMD can hardly be assured, so the government will discover it and supervision should step in as soon as possible.

Implementation scheme

The middle part in the schematic diagram of the tracking system in Fig. 2 is consistent with the triangular sales model described in Fig. 1. Enterprises sell their products to hospitals directly or through a sales chain.

Upon completion of a surgical operation, the hospital records the UDI using automatic identification technologies. The product information will be reported together with the patient information, collected from the Hospital Information System (HIS) to the Shanghai FDA health data reporting platform. At the same time, the information is linked to the

Figure 1: Schematic diagram of IMD tracking system



hospital's financial management system to manage financial records. The manufacturer can obtain hospital use data via the reporting platform.

To support hospitals in automatically reading the UDI, a product data exchange platform is set up in the tracking system. Manufacturers can submit their product data to the hospital's database, and can control distributors and hospitals directly and define the scope of the products sold to and used in the hospitals.

Legal responsibilities of each responsible party

In post-market management, the depth of government surveillance in the tracking system should be different as risks related to products and treatments are different. Each party in the tracking system shall undertake the following responsibilities:

- 1) IMD manufacturers (or the domestic legal after-sales service institutions of imported products designated by manufacturers) shall be fully responsible for the quality of their products after market release, for the management and implementation of UDI marking, tracking, recall of their products and handling of patient injuries in adverse events, and for gathering and keeping the use data through the health data reporting platform.

- 2) Entrusted by IMD manufacturers, the IMD distributors shall be responsible for providing the traceability information on the IMDs, and take their own initiatives to assist manufacturers in handling those potential adverse events. IMD distributors shall not make UDI's without prior authorization of manufacturers. UDI making must be authorized by and the entire process must be under the control of the manufacturer's quality system.
- 3) Hospitals shall establish automatic identification management, registration and reporting system for UDI's of IMD's, and keep the use records of such patients.
- 4) Patients shall obtain relevant information of the IMDs. Hospitals and manufacturers shall take their own initiatives to provide such information.
- 5) In order to safeguard the interests of the public, the government shall assume the supervisory and regulatory responsibilities in the tracking system.

In the tracking system, manufactures are required to meet the UDI requirements in labelling their product, and medical institutions to implement automatic UDI and recording system. These are the core links to ensure successful product traceability.

Discussion and suggestions on promoting a worldwide uniform tracking system

In order to enable effective worldwide tracking of key medical devices, we suggest that the domestic market tracking efforts of each country should keep pace with those in the rest of the world. The following work should be promoted and completed under the Global Harmonisation Task Force's (GHTF) medical device regulatory framework:

- 1) To coordinate the development of a globally uniform UDI system and its coding standard, allowing automatic identification equipment to be compatible with each other to the maximum extent;
- 2) To establish a global basic tracking model. The tracking model proposed by Shanghai can be utilised and discussed;
- 3) To coordinate the establishment of a unified scope of important and basic traceability information specific to medical devices; and
- 4) To facilitate the solution of a global nomenclature for medical devices as soon as possible; the globally unified nomenclature system should be used together with the UDI system in the global tracking system so as to improve the global medical devices reporting efficiency.

The establishment of the above medical device tracking system, according to our estimation, will thoroughly change the post-market surveillance of each country for medical devices, improve the pre-warning and reporting levels of medical devices, improve the efficiency of the adverse



medical device reporting and handling system, change the sales model of consumable medical devices, greatly improve the transparency of information on those high-risk medical devices, improve the safety of medical devices used by patients, and play an active role in speeding up hospital's informatisation construction and improving the efficiency of hospital's consumables management. We are willing to work with the rest of the world to establish a new global mechanism beneficial to patient safety management as early as possible.

AUTHOR

Liang Yan is the head of Regulatory Affairs Division, and the International Cooperation Division and the former Head of the Medical Device Registration Division of the Shanghai Food and Drug Administration. Mr. Yan has more than 30 years working experience in the medical-related administration of the Shanghai Municipal Government. Before the beginning of the Chinese Reformation, he was engaged in innovation and development of medical devices technology in Shanghai Medical Industry Co (SMIC). After the Chinese Reformation he

served as head of the Science and Technology Department of the Shanghai Pharmaceutical Administration Bureau, for Shanghai's pharmaceutical and medical devices industry research and development of new technology and products. In 1989, he organized a group for drafting China's first medical devices regulations. Afterwards, he continued to work with the drafting and implementation of China Medical Devices Regulation in Classification Rules, Medical Devices Registration, Medical Devices Recall area.