Argentina

Implementing Drug Traceability at Hospital Alemán in Argentina

ABSTRACT

In order to reduce the serious risks presented by the proliferation of counterfeit medicines, Hospital Alemán (HA) implemented a traceability system complying with the new legislation introduced by the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT) in late 2011.
The primary objective of the programme is to counteract the distribution and supply of illegitimate drugs to guarantee patient safety. It is based on the unambiguous identification of products through IT systems and through the use of the global and harmonised language of GS1 Standards. All drug movements are recorded in real-time in a central database managed by ANMAT using Global Location Numbers (GLNs) to identify the various agents involved in the supply chain.

by **Heidi Wimmers**

Introduction

Counterfeit drugs present a major growing concern for public health. Although there is not a universally accepted definition for "counterfeit medicines", the World Health Organisation defines the term counterfeit drugs as "medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source" [1]

The most common factors increasing the occurrence of counterfeit drugs are considered to be:

- Lack of legislation prohibiting counterfeiting of drugs
- Weak penal sanctions
- Weak or absent national drug regulatory authorities
- Weak enforcement of drug laws
- Shortage and/or erratic supply of drugs
- Lack of control of drugs for export
- Trade involving several intermediaries and free trade zones
- Corruption and conflict of interest [2]

Although it is difficult to know the exact counterfeit drug rate, estimates range from 2-4% to 5-10% globally, with significant variations across countries. Many experts estimate the rates at 1% or less in developed countries and anywhere from 10 to 30% in developing countries. [3]

What is drug traceability?

We are living in a world of global markets where there are few - if any - borders between sectors, countries and continents. The Healthcare supply chain is becoming much more complex with its increase in the variety of suppliers, products and buyers, and rise of large-scale productions in emerging economies like Brazil, Russia, India, and China, making it increasingly difficult to trace a product from the point-of-production to the point-of-use, or from pill to patient.

Although traceability has become a necessity, global supply chains need more complex business processes and information systems to achieve it. They need standards for identifying, capturing and sharing information, and this is where GS1 Standards can help.

In GS1 terms, Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration.

1 *WHO, Fact sheet N°275, May 2012: www.who.int/mediacentre/factsheets/fs275/en/*
2 *Guidelines for the development of measures to combat counterfeit medicines, WHO/EDM/QSM/99.1 consulted 30-MAY-2013: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf*
3 *McKinsey & Company "Strength in unity : The promise of global standards in healthcare, October 2012 "*

Traceability means patient safety

The progress of technology has allowed us to implement systems that were unthinkable years ago.

When the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT) implemented the provisions of their National Medicines Traceability System, Hospital Alemán put in place an internal system not only to comply with the rule, but also to ensure full traceability of single unit doses of products when fractioning, reconstituting or repackaging the products, thus making the five patients' rights (right patient, right medication, right dose, right time and right route) a reality.

When evaluating the entire cycle of drugs' use, the Hospital focused on patient safety and set the goal to obtain the certification from the Joint Commission Accreditation on Healthcare Organisations (JCAHO).

How was traceability implemented at Hospital Alemán?

In the hospital, the traceability system involves three specific steps:

1. Hospital reception of traceable drugs
2. Single dose fractioning at the pharmacy with the commercial code and serial number of the drug in each unit dose
3. Administration to the patient

The traceability process begins when the hospital receives the drugs and starts capturing the data. GS1 Standards used include:

- Global Trade Item Number (GTIN)
- Global Location Number of the supplier
- Serial Number
- Expiration Date associated with the receiving GLN

All the suppliers were previously audited as part of a quality assurance programme, which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorisation/product license (Good Manufacturing Practices - GMP).

The suppliers must also provide properly identified packages in accordance to the national traceability regulation. It is imperative that full identification using one of the three GS1 compliant Data Carriers are placed on secondary packaging:

- Linear bar code
- DataMatrix
- RFID

Figure 1: Examples of Data Carriers used

Once the drug is received, ANMAT is informed and an ID is obtained. The traceability of the drug is confirmed on ANMAT`s website using the transaction ID, from the GLN of origin to the GLN of destination (Hospital Alemán as informant agent).

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The traceable drug is fractioned in unit doses at the pharmacy in the inpatient ward. These medicines are re-labelled in all types of presentations and dosage forms using a printed GS1 DataMatrix linking to all the original information from the marked secondary packaging.

The unit dose re-packaging is done through an aseptic process where the original blister packs are cut and each unit doses individually overwrapped. A programme of preventive maintenance is implemented in order to control the machine, the printers and the labels. The work of the technician is under the close surveillance of a pharmacist[4].

4 *Cina J, et al. Medication errors in pharmacy-based bar-code-repackaging center. Am J Health-Syst Pharm 2006; 63(2):165-168*

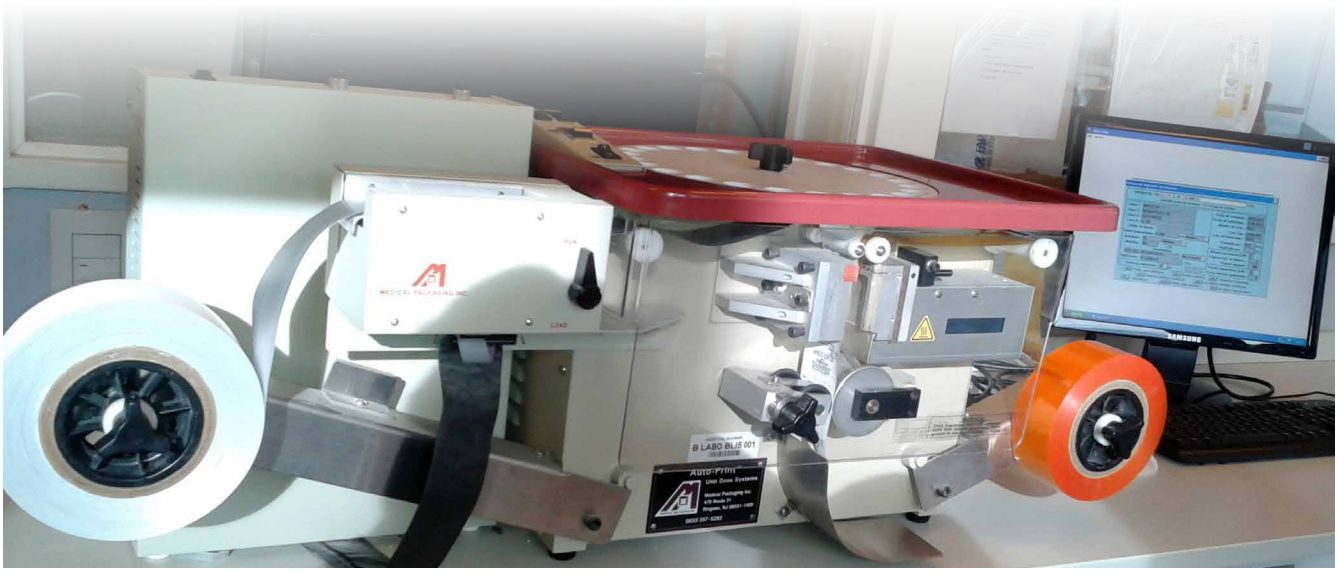

Figure 2: Machine for unit dose repackaging in the HA-Pharmacy

The role of the nurse in the traceability process

Nurses are an essential link in the supply chain. Not only do the standards help increase patient safety, but they also allow to save time. A survey conducted by the Nursing Times in the UK showed that "more than a third of nurses waste up to two hours a shift searching for missing medical items"[5].

The work of nurses is fundamental in the Hospital Alemán programme. Prior to administering the medication to a patient, which is one of the critical stages of treatment, nurses read the bar code of the medicine dispensed by the pharmacy, confirming usage of the drug in the electronic system.

Findings

Quality and safety are more important than ever. The medicine traceability process is very important for the safety of our patients, especially in the treatment of older patients who are polymedicated.

To continue improving the traceability process in the hospital, Hospital Alemán developed a comprehensive quality management system in compliance with the ISO 9001 norm[6]. One of the key findings of the implementation of a full traceability system is that it is essential to constantly train the staff, while involving internal members aligned in cross-functional teams.

Hospital Alemán targets continuous improvement and allows medicine-confidence for the patients, the medical professionals and the management, ensuring that the drugs administered fulfil the specified quality requirements.

5 *http://news.bbc.co.uk/2/hi/health/7881807.stm*

6 *Norm UNE-EN-ISO 9001/2008 http://www.quality-works.com/download/the-perfect-manual.pdf*

About the author

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About Hospital Alemán

Hospital Alemán is a university hospital located in Buenos Aires, Argentina, with more than 700 professional doctors providing care in all specialties. The Hospital has 240 beds in individual rooms, 11 Operating Theaters, a Coronary Unit, adult and pediatric Intensive Care Units, Burn Area Care and Transplant Area.