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Why is Drug Traceability Important in a Hospital?

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The acute condition of hospital patients and the use of higher risk medication increases the consequences that counterfeit and illegitimate pharmaceutical products can have on them. Delivering the right and genuine product to the right patient is crucial.

In our globalised economy, the risks of harming the patient can stem from counterfeited medicines. It is not easy to know the counterfeit drug rate globally, because there is significant variation across countries, but it affects both developed and developing countries. The higher rates are in developing countries, and drugs that treat serious diseases such as malaria, tuberculosis, AIDS or other infections are more often the object of counterfeiting.

The most common factors leading to the occurrence of counterfeit drugs are the lack of legislation, weak national drug regulatory authorities, erratic supply of drugs, lack of control of drugs for export and import, free trade zones, corruption and conflict of interest (World Health Organization 1999).

Counterfeit drugs have rarely been efficacious, and in most cases they have been dangerous (Amon 2008; Kelisides et al. 2007; Tomić et al. 2010). The right compounding of medicines and supervision of the supply chain is a must. We must ensure the availability of a safe and efficacious drugs supply.

Benefits of Traceability

As of 1 June 2012 new regulations on the traceability of medicines in Argentina require a specific identification to be placed on a large group of pharmaceutical products. This new regulation implements effective countermeasures against counterfeit and substandard drugs.

Traceability is the ability to track specified stages of the supply chain and trace backwards

the history, application or location of the pharmaceutical products that are under consideration.

The global standardised identification system from manufacturer to patient provides a safer healthcare supply chain. The data within the GS1 (**www.gs1.org**) barcodes now enables automatic identification of the products at any point in the supply chain.

This secure system will identify products with the GS1 Standards using data carriers like Data Matrix, RFID or barcoding systems with the “traditional” linear barcode data carriers.

The traceability process is for the pharmaceutical industry also a way to an eventual effective and fast product recall of specific batches or lots of medicines from the market. These could be achieved in a relatively short time to avoid medication errors. Traceability gives also the possibility of a quick inventory. It is a challenge to analyse all the supply chain inefficiencies.

Traceability Implementation at Hospital Alemán

It is important that the external packaging of pharmaceutical products undergoes further control and security, thinking of the global pharmaceutical supply chains. This identification of each packaging of medicines such as the Global Trade Item Number or GTIN and some dynamic and variable data like unique serial number, batch/lot number and expiry date makes each packaging unique. This identification is now our regulatory and legal requirement in Argentina.

Hospital Aleman is a university hospital located in Buenos Aires, Argentina, with more than 700 doctors providing care in all specialties. The hospital has 240 beds in individual rooms, 11 operating theatres, a coronary unit, adult and paediatric intensive care units, burn area care and a transplant centre.

The barcode of the secondary packaging is just the beginning of the procedure in our hospital. During the traceability process the hospital pharmacy needed to ensure that they could accept and store the medicines in line with GS1 Standards (www.gs1.org/healthcare/standards).

The end-to-end point-of-dispensing coding involves three specific steps in our hospital:

1. Hospital reception of traceable drugs;
2. Single dose fractioning at the inpatient pharmacy with the GTIN (static data) and the dynamic data of the drug in each unit dose;
3. Administration to the patient after nurses have scanned the barcode symbol.

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

The suppliers must provide the barcode of the secondary packaging as a proper identification of their pharmaceutical products in accordance with the national regulations.

At the hospital reception the internal digitising of the supply chain with increased efficiency begins. Each item of packaging is checked against a database and the information is sent to a division of our Health Ministry, the ANMAT, ensuring that the patient received a genuine drug. The ANMAT exercises duties in inspection, oversight and control over food, medications, and medical devices in Argentina.

They manage the National Traceability System for Pharmaceutical Products to the GS1 Standard. The scan reveals if there is any duplication of data on the packaging. In this case, the ANMAT System sends the pharmacy an immediate alert about the possibility of a fake medicine.

Before dispensing to a patient in the inpatient ward, the traceable drug is fractioned in unit doses at the pharmacy. This is a huge task. A significant amount of time and effort has been spent to ensure full compliance with GS1 Standards. The medicines are re-labelled using a printed GS1-Data Matrix linking to the original information from the pharmaceutical packs.

We re-packaged the unit doses in an aseptic laboratory. A programme of maintenance is implemented in order to control the machine, the printers and the labels. All this work is carried out under the close surveillance of a pharmacist (Cina et al. 2006; American Society of Health-System Pharmacists 2011).

How it Works in the Inpatient Ward

The main objective is to achieve the five wellknown rights:

- Right patient,
- Right drug,
- Right route,
- Right time, and
- Right dose.

Providing safe healthcare depends on highly trained individuals with responsibilities, who are acting together in the best interests of the patient.

Standardising internal processes was essential. The Traceability Manual was drafted. All multitask personnel were trained, focused towards a continued improvement.

The doctors in our hospital prescribe in the electronic medical history. The pharmacy dispenses the medication and the nurse scans the unit dose of the original packs before administration to the patient happens. This is one of the critical stages of the medical treatment. Scanning allows confirmation that the right product is supplied to the right patient with an online verification of batch and expiry date. The information is stored in the database of ANMAT and the dispensing of each unit to a patient can be recorded in our electronic system.

The patient data remains confidential (except to the hospital pharmacist) during the entire process.

Outpatients

Whenever a patient comes to our official pharmacy, the pharmacist will scan the GS1 Data Matrix at the point of dispensing, and scan the GS1 Data Matrix on the medicine's packaging. It is much easier because the patient receives the complete and original pack of his medicine and we only have to scan the original Data Matrix on the secondary medicines packaging. We link the prescribed patient’s medicine to the dispensed medicine.

Conclusion

To continue improving the traceability process in the hospital it is essential:

- To train the personnel constantly, keeping a great collaboration between all members of the multitask team.
- To focus towards continuous improvement, in order to create confidence in the patients, personnel and management that the drug administered fulfills the specified quality requirements.

There is growing concern regarding counterfeit medications. Drug quality is currently receiving renewed global attention. The appearance of counterfeit pharmaceutical products in supply chains is an international public health problem that may seriously affect the security of patients. According to the World Health Organization (WHO) definition, counterfeit drugs may be generic or innovative. They do not meet quality standards and do not declare their real composition and/or source for the purposes of fraud. They may contain genuine constituents in a fake packaging, or wrong ingredients, or inactive ingredients or an incorrect quantity of the active substance.

The execution of a traceability system increases the protection of patients from falsified, expired or recalled medicine. This system generates an environment of greater safety and allows medicine confidence for the patients, the medical professionals and the management of the Hospital Aleman. Consequently it is to be hoped that criminal activities derived from the trade of illegal medications will dramatically drop in the future.

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