Implementation of National Drug Traceability System at the Hospital Italiano

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ABSTRACT

During 2012 the National Drug Traceability Regulation was enforced, which requires that healthcare institutions, together with the rest of the actors in the marketing chain to implement a system that enables traceability from beginning to end of a list of drugs. At first, the list consisted of high cost and low turnover, but shortly drugs of massive consumption were added that complicated an already difficult process. The Hospital Italiano of Buenos Aires with the objective of complying with these regulations began a series of changes in its processes and computer systems, which continue to develop and require the conclusion of other related projects before completing the traceability cycle of the patient.

The Hospital Italiano of Buenos Aires is an institution of 750 beds, it consists of two high complexity hospitals and 23 peripheral healthcare centers of outpatient care. The insurance plan of the Hospital services more than 150,000 members. It also has a health computer department which develops its own computer programs; a Pharmacy Service and a Committee of Patient's Safety. All this implies that for the implementation of the Traceability Regulation the Hospital had already taken actions and performed some investments, which without being directly related to Traceability, but related to patients' safety, contributed in some aspects to diminish the implementation impact.

Computer System

The Hospital Italiano has been working in the automation of its healthcare processes for many years. It works with an electronic medical history, electronic prescription, electronic nurse sheet and works on a project to develop the electronic registry of the administration at patient's bedside.

In a complex process such as the follow up of the drug traceability through all the steps in the institution until they reach the patient, and with the volumes handled, it is inconceivable any other way than through hospital systems. Therefore, we have modified the SAF or Pharmacy Management System to add the serial number (until now it only showed lot and expiration date), and we have tagged the generics of those traceable drugs. Transactions that involve entering drugs and the ones that contemplate the use of these drugs tagged as traceable shall be the ones that will automatically and through the Net report the movements to ANMAT.

Since drug traceability is directly related to logistics, we will evaluate each step once they entered the institution.

The steps are: reception, storage, re-packing and/or fractioning; distribution and/or dispensation and administration.

Reception

The first observation to highlight throughout the complete process is that in institutions where the drug volumes are high (the hospital moves around 500,000 ampoules units, pills, bottles, etc. per month) it is impossible to carry a traceability from the reception to the patient with the use of scanners.

Secondly, and since in the laboratories the way of transporting the data required by the regulation is not

unified, it is necessary that the institutions obtain scanners that enable the reading of barcodes, DataMatrix and radiofrequency. This becomes the procedure because the availability of requested drugs to guarantee healthcare treatments at the institutions forces us to have more than one supplier.

Thirdly, since each package is by definition unambiguous, it is required that the reception be performed unit by unit to register each serial. Even with the use of scanners this activity is extremely difficult to achieve when the reception volumes are large. For example, if the hospital receives 500 units of albumin, the reception must be performed reading package by package, which delays the complete following process and the availability of the drug for its use.

For this reason, the hospital it is only reporting to the controlling authority ANMAT, the reception of drugs in Annex I, of high cost and low turnover.

To move forward it is essential, to have the information in labels that handle groups. A single reading that contains the total information of a pack will streamline the process, but this availability does not depend of the hospital but of the previous steps of the marketing chain.

Storage

This stage is closely related to a posterior process that is the re-packaging in single doses of commercial presentations with more than one unit. The transformation of the package which contains more than one pill in multiple units considerably increases the necessary volume to store the same quantity of pills, reducing our storage capacity. This situation does not arise in all institutions and it shall depend on how they have solved data registration of the serial number of each unit, for example labeling them instead of placing them in an envelope. In any case, to register the serial of each unit forces us to add processes and to destine more human resources and more physical space within the warehouses.

Re-packing or fractioning

Patient safety has always been our priority at the hospital, and drug related errors an important subject to consider. As a consequence, 15 years ago it was decided to invest in machinery that enabled the transformation of multi-doses packages in single doses, for solid pharmaceutical forms such as pills and capsules, with large labels, easy to read, that facilitated a rational dispensation and also the reduction of drug errors due to misinterpretation of the label.

This activity until the implementation of the Regulation it was performed in bulk since the data to group was the lot (1,000 pills with the same lot could be performed in one single step); today the process is delayed since we have to constantly change the label because to each package corresponds a different serial, even if they share the same lot (10 packages of 100 pills with the same lot implies 10 different serials and 10 different labels to re-package 1,000 pills).

A disadvantage that needs to be mentioned is that to interrupt the re-packaging process every time that it is required to change the serial, implies a slowing down that increases the possibility of errors in the creation of new labels. On the other hand, and for those drugs that do not follow this process such as pre-filled syringes, aerosols, bottles, etc. it is necessary to label them to be able to carry the serial to each unit, which increases the need of human resources.

We can provide an example of this: in a work shift and with a resource destined to this activity a year ago the Pharmacy re-packed 6,000 units per day. Today, under the same conditions but taking into consideration the serial, it only re-packs 4,000 units.

This process which has the objective the right identification of single doses depends of the hospitals because the pharmaceutical industry does not provide this service and forces the institutions to have re-packing lines.

It is worth mentioning that the investment in these equipments was made a long time ago, the implementation of the traceability system did not have an economic impact in the hospital.

Distribution/Dispensation

Independently of the method chosen by each institution for the delivery of drugs, Pharmacy Services have in common that we do not deliver the product directly to the inpatients. The Hospital Italiano dispenses the drugs by patient and for 24 hours of the treatments to the nurses' stations that administer them following doctor's prescriptions.

Due to the fact that the only ones that can guarantee drug administration are those who perform it, the hospital decided the registry of the administered drugs were the source of information for ANMAT notifying the patient's consumption and with this, the end of the cycle.

The electronic registry of the administration from the

nurses and other healthcare professionals at bedside, is part of a hospital's project to guarantee the five rights: right patient, right drug, right way of administration and right time, related to patient's safety.

This project is under way and once implemented the patient's consumption will be reported to ANMAT.

Conclusions

The National Traceability System has been designed as a measure to guarantee that the drugs that will reach the patients are original and safe. The objective is clear and viable, but when the indications that regulate this resolution are analyzed, we can see that originally the regulation was not planned for its implementation in healthcare institutions, where many of the drug commercial presentations once they have entered the institution follow different steps and transformations, which makes considerably difficult to achieve a successful practice. From the Associations and working jointly with other Institutions and with ANMAT, these provisions have been changing, and even though we are not completely prepared to guarantee traceability the way it is required, we are in the process to achieve it.

In our case the implementation has implied:

1. A computer system modification
2. A process modification
3. More Human Resources
4. Investment in scanners for the Hospital Italiano
5. Training of Pharmacy personnel and professionals involved in drug administration

In order to move forward we need:

1. development of labels that identified groups.
2. development of tools such as the invoice or electronic dispatch order that enables to streamline the management of information.
3. presentation of single doses correctly identified and serialized for the pharmaceutical industry.
4. development and implementation of the hospital's registration project at bedside that enables the closure of the traceability cycle in the patient.
5. Lastly, the implementation by steps that enables to demonstrate at public institutions and at private ones that it is possible to efficiently implement the measurement.

As long as all the steps in the marketing chain and the controlling authorities understand that drug related processes at the healthcare institutions and as a consequence our needs, there will be a higher probability of achieving this process which benefits everyone.

ABOUT THE AUTHOR

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Pharmacist graduated from the Pharmacy and Biochemical Faculty of the University of Buenos Aires (UBA) in 1991.

Graduated from the specialization course in Galenic Development and Pharmaceutical Production in 1998. She has worked in the hospital sector for more than 20 years. Joined the staff as a pharmacist at the Hospital Italiano in 1994 to perform clinical activities. Responsible for the Administration in the certification process of the Pharmacy Service by ISO 9000- 2001 regulation from 2002 to 2006.

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