

Providing healthcare services of high quality, safe and reliable

ABSTRACT

Sanatorio Güemes is a private institution which has 450 beds and one of its quality policies includes the accreditation by ISO Regulation 9001:2008. The National Traceability System allowed to envision the possibility of its implementation as an opportunity to improve patient care safety. Five essential stages in the healthcare process were defined: reception, re-packaging, distribution, administration and returns, in which traceability data related to the drugs is captured. To achieve this type of developments interdisciplinary work is essential, and also the training of all human resources involved.



Due to counterfeiting problems and other irregularities that took place in our country and which caused an important warning in our health system, the sanitary authorities of Argentina decided to implement the National Traceability System. This solution enables the identification, validation, communication and registration of all drug movements along the marketing chain.

The Argentine pharmaceutical market characterizes for being extremely complex because numerous actors participate in it, as well as an extensive amount health insurance companies, pre-paid or private insurance, laboratories, distributors, logistic operators, drug stores, official and assistance pharmacies.

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tation by ISO Regulation 9001:2008.

One of our principles is "to provide healthcare services of extensive quality, safe and reliable".

Since the Sanatorium is aligned with a quality management system, it envisioned the possibility of the implementation of a traceability system as an opportunity to improve the quality and the safety of the patients, as a way to offer excellence in the care.

Before the requirements established by Resolution 435/2011 by the Ministry of Health, which stated that all actors belonging to the marketing, distribution, and dispensation chains must implement a traceability system until it reaches the patient, the institution was already generating its own traceability system framed within the projects of the electronic medical history and other internal developments.

In that sense it was decided to automate the stock management linked to drugs, both ours and those of third parties, which are received normally from different health insurance companies and pre-paid insurances.

Together with the automation of the stock management we began working in internal supply traceability. For this reason, a tool was developed wherein to record all the documentation and information corresponding to each one of the drugs received, taking the data from the patients from the general ledger, performing an automatic control of the expiration and other data linked to the origin and the commercial documentation of the supplies of high cost and low incidence.

This implementation and its change in our stock management was what it helped us to be better prepared for the implementation of the compulsory traceability and it was decided to start our own development through

our systems department to move forward with this new challenge. *Figure 1*

mercial code (Global Trade Item Number – GTIN) and serial each one belongs.



Figure 1: Stock Management

At the time of the development of the internal traceability of all our processes 5 essential stages were defined involved with our healthcare process:

- Reception
- Re-Packaging
- Distribution
- Administration
- Returns

In each one of these stages traceability data is captured associated to each of the drugs; this way the internal traceability becomes created. The communication to the National Administration of Drugs, Food and Medical Technology of Argentina (ANMAT) it is performed in two stages: a) reception and b) administration, what we consider the dispensation at patient's bed-side.

It is important to mention that in our legislation it was determined that the identification of each drug must be conducted in the secondary package no matter what type of data carrier is used: it can be a lineal code, DataMatrix or Radiofrequency, but in any case GS1 standards were designated; therefore, in the healthcare area where the daily doses are prepared to be delivered to different sectors for each one of the patients (like in our case), it is necessary to re-pack pills and ampoules to dispense them and identify to which product com-

Reception:

In a first stage all the documentation that accompanies the drug is verified: dispatch order, invoice, etc., and it is loaded manually to the system. It is important to mention that from the implementation of the national system of traceability, each individual package of the drug is considered a specific supply (with GTIN and SERIAL) that must be controlled against the documentation; it is no longer enough to count the total units. In a sanatorium with 450 beds the supply volumes that are handled are immense, therefore we consider important and necessary to move forward to reach an electronic standardization of

commercial documents (EDI) of the different actors that operate in our country to be able to handle electronically a massive load of data.

The second step in the reception is the reading of the identification code of the package with the scanners that in our case enable bar code and DataMatrix. Once the data is incorporated to the sanatorium system (beginning of internal traceability), the connection is established via Web Service with ANMAT's server and the confirmation of reception of each one of the units (external traceability) is transmitted. *Figure 2.*

Re-packaging:

A pill re-packaging and fractioning machine was purchased which has the characteristic of preserving the primary package intact; this way the good manufacturing practices are preserved and the quality with which they were manufactured at the place of origin, and its expiration dates. At the time of the fractioning and re-packaging, the product is identified with the data of the active ingredient, strength, pharmaceutical type, lot, original expiration date, GTIN and Serial.

Actions have been taken to achieve through the sanitary authorities that the pills should come individually identified at the point of origin (laboratory manufacturer) with all the necessary data for its traceability, but the answer was not satisfactory, therefore to be able to move forward with this challenge it is necessary to fraction,



Figure 2: Drugs reception in the system

re-pack and re-label at the hospital, which forces the creation of a production line. This is a critical step because it is not only required a substantial amount of human resources and larger costs, but also exists the risk of error in the identification of the re-packed product. *Figure 3.*

Distribution:

Our institution provides to different internal areas by the daily dose method or by stock reposition; among these areas we can find the Intensive Care Unit (UTI), on duty emergency room, emergencies, satellite pharmacy for the surgery room, coronary unit (UCO), UTI children, oncologic outpatient hospital, medical clinic, outpatient services, etc. The sanatorium decided to perform internal traceability, that is, to have internal knowledge of at what physical place can be found each of the traceable drugs that entered our institution. For this reason, we have a medium-term project of having reading devices for codes and an automated system that enables the capture of the drug data in each of the areas mentioned above. This is the necessary step before the registration of the patient’s administration.

Administration:

The institution decided that the administration of the drug to the patient shall be reported to ANMAT when the institution is ready to comply with the five rights: right patient, right drug, right dose, right way and right time. For this reason we are implementing as a pilot test the following processes in the oncologic outpatient hospital, these processes shall be repeated in the rest of the areas:

First, we organized a multi-task work with different sectors: patient admission, appointments, medical specialists involved in the area, nurses’ station, pharmaceuticals, outpatient area, with the approval of the administrative and medical directors to perform improvements in the processes aiming at patient safety.

Oncology protocols and all the infusions administered regularly at the oncologic outpatient hospital (HDO) were standardized, conducting administration protocols for each of these infusions, in which only the doctor administers the

drug dose; this stage at present is documented but it will be included soon in the electronic medical history.

On the other hand, we have an area of preparation of oncologic mixtures where we have a stock management system in which the internal traceability of all this type of drugs is registered. We have also developed a knowledge database for the preparation handling and manufacturing of these drugs; where different controls and warnings are performed before their manufacturing and we obtain what we call a virtual preparation in which all drugs that we have in stock for a specific patient are analyzed with its corresponding traceability we perform the theoretical preparation of each protocol and we



Figure 3: Repacking machine

obtain the detail of how to do it after we have performed all the verifications: expiration date, dose, interactions, stability, etc. Once we have this preparation, our system assigns a DataMatrix code that enables the reconstruction of all the drug history used.

A the time of the patient's admission in the institution, we place an identifying wristband which has, besides all the identification data, the identification of the therapeutic schedule or protocol that he will receive at the oncologic outpatient hospital. This information is in DataMatrix format.

Furthermore, each of the oncologic preparations is identified with a POF number (Oncologic Pharmaceutical Preparation), automatically originated at the time of the virtual preparation. Each POF is linked to the drug traceability data which makes up the mixture. Simultaneously, the POFs assigned to the patient are registered in the electronic medical history.

At the time of the administration to the patient we scan the code in the patient's wristband, the drug label and the personal identification of the assisting nurse. Once the system verifies the matching of the POF to the medical history to the drug to be administered and to the right patient, the infusion can be administered. At

the end of the administration we register the time and automatically we communicate the administration of the associated preparations to ANMAT. Figure 4.

Training of the pharmacy team involved in the traceability system

With the objective of normalizing the personnel task which consists of tracing the supplies which required it before the ANMAT's WS, the pharmacy department worked on a training program that includes theoretically and practically, all that the personnel needs to know in order to efficiently achieve the reception and dispensation objectives of all traceable drugs.

Conclusions:

The implementation of the traceability system is an opportunity to improve internal processes, for the safety of the patients and for all who are involved in the marketing, distribution and dispensation-administration chains.

It is important to mention the importance of the training that all health team personnel must have in these cases, especially Pharmacy Service personnel and Nurses, who play an important part for the correct implementation in each of the stages.

It is imperative the multi-task work to achieve these



Figure 4: Administration at patient's bedside

types of developments; the disposition and the involvement of the systems and pharmacy departments play an important role. Moreover, it is essential to have the support and the complete commitment of the institution's directors, without them, it would be impossible to implement the project.

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