

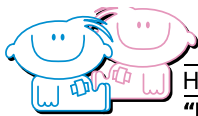
# Traceability in the Pharmacy area of the Children's Hospital "Prof. Dr. Juan P. Garrahan"

## ABSTRACT

*The pharmacy area of the Children's Hospital "J.P. Garrahan", has complied with the traceability implementation at the product Reception stage reached by the National Traceability System (NTS). In regard to the Dispensation to patients, we are working in the first stage of distribution to patients from the pharmacy.*

*To achieve these objectives implied the modification of reception and dispensation circuits and the updating of the integral computer system that the institution uses.*

*It is a long way to achieve the institutional objective of bringing drug traceability to the patient's bedside, improving the quality of care by increasing safety and preventing management errors.*



Hospital de Pediatría S.A.M.I.C.  
"Prof. Dr. Juan P. Garrahan"

## The Hospital

The Children's Hospital "Prof. Dr. Juan P. Garrahan" is a public pediatric center of high complexity that started operating in 1987. It has 510 inpatient beds, of which 120 correspond to the Intensive Care Units. In this institution we receive annually 450,000 external consultations; we perform 10,000 surgeries and 21,000 sessions of chemotherapy treatments, among other practices of medium and high complexity.



By Patricia Costanzo MD

## The Pharmacy area

The pharmacy area offers a central service integrated to the hospital structure whose mission is to guarantee the quality, support and the maximum benefit of the pharmaco-therapeutic process, which has the patient as center of all its activity from the concept of Clinical Pharmacy and Pharmaceutical care, both understood with the commitment and the responsibility that the pharmacist develops in the treatment and care of the patient.

This area provides management, supplying and distribution services and biomedical materials simple and of high technology. It is organized in different sectors: Warehouses, Reception, Technical Pharmacy, Dispensation to inpatient and outpatient, Pharmaco-therapeutic follow up, Pharmacokinetics; and Unit of Sterile Intravenous Mixtures, which includes the preparation of single doses of cytostatics and antibiotics and the manufacturing of parenteral nutrition.

## Introduction

The hospital Pharmacy Area works with a distribution system of single doses for the in-patients; this system is essentially based in the intervention of the pharmacist in the dynamics of the drugs prescription and of the control of the therapeutic of each one of the patients, through Pharmaco-therapeutic Follow-up Chart. The system, which was initiated with a manual operation, moved to an automated system for the follow up and control of the patients' therapeutic, linked to the stock management and drug distribution, and also to the work of the Reconstitution Centrals of Cytostatics and Antibiotics. The information of the Pharmaco-therapeutic Chart also allows the daily creation of the printed medical order sheets, which contributes to the avoidance of reading errors.



This system of intensive control of the prescription by the pharmacist has proved to be the most efficient method to reduce prescription errors.

The C-Page system, acquired by our Hospital, is the one we use for the pharmaco-therapeutic follow up of the patients, which also, handles stock management and the distribution, has a control format of the movements of each of the drug units from the time they enter pharmacy warehouses to its dispensation to the patient through the assignment of internal lots. This System started operating 18 years ago.

### New Traceability Resolution

In 2010, facing the migration to another database of the computer System, the need to provide improved safety to the patient was considered, and due to the fact that the original product traceability by lot was a pending issue for the Service certification, it was decided to work in a modification of the internal lot trace method of the product that would now be established by brand, original lot and expiration date of the drugs.

Amid the development of this modification, arises the need to comply with the new traceability regulations that require drugs trace by GTIN and product Serial. Facing this fact we had to reconsider the development of the new System which required the modification of some processes.

In making the first decisions we had GS1's support in reference to what type of codes to internally use, selecting the DataMatrix bi-dimensional code. Moreover, by the type of requirements of our Area which possess an important production sector, we applied for our Global Location Number (GLN), which enables us in the future to have GTINs for the products we manufacture.

The final objective that our Hospital considers institutionally in relation to the traceability system, is the assignment of the GTIN and the drug Serial used at the time of the administration to the patient – what we would call traceability at bedside; this not only would comply with the regulation but also would provide our patients a better level of safety in drug use. It would mean to take maximum advantage of the development for an improved patient's safety.

### Reception from a previous step

According to the new regulation, from June 2012 all healthcare centers had to start reporting the NTS (National Traceability System) all GTINs and Serials received from a previous step.

We worked previously modifying the management of products' reception. The first thing we did was to tag in the system's matrix that defines each one of the generics(\*) and their presentations with internal drug codes-, those active pharmaceutical ingredients (IFAs) reached by ANMAT's resolutions. A level 3 of traceability was established for those products that required it, by GTIN and Serial, with reporting to the NTS. The coded IFAs in our system and included in the listings of the resolutions 3683/2011 and 1831/2012 were some 160(\*\*) IFAs with their respective presentations.

Different reception operations were adjusted, which include purchase orders, purchases by drug store, national programs and oncologic drugs.

The reception is the first step of the product within the pharmacy that was modified so that in the cases of products tagged of traceability Level 3, the System requires the time of the data input of:

- Provider and its GLN.
- Dispatch order Identification.
- Amount of the product entered.
- GTIN.
- Original Lot.
- Expiration date.
- Loading of the Serials corresponding to this reception, controlling that the amount of Serials entered shall be the corresponding ones according to the presentation specified by the GTIN.

The GTINs and Serials loaded are performed with

(\*) In Argentina is in force a law requiring a prescription for generic drugs rather than brand name.

(\*\*) 160 IFAs handled by the hospital a total of 314 IFAs.

scanners, since its manual loading would be impossible. Moreover, the System enables the printing of a small double-sided stick tag with the data of the internal code, description, GTIN, Serials, original Lot and product Expiration date in a Datamatrix code.

The Hospital Systems' Management received assistance from ANMAT to obtain GTINs' product listings and GLNs from suppliers and was made compatible to our System to accelerate reception steps. During the first six months while the Web server was being prepared for the transfer of data to the NTS' Web services, we prepared the reception reports from a previous step through the NTS Web page via internet, individually.

With the preparation of the Web service, our System selects from the reception daily movements for the traced drugs, all the data required by ANMAT, and are placed in an Inbox for its transfer through the Web server.

The reception problem of traceable drugs from a previous step was solved and the functions associated such as devolutions –for different reasons- to the providers. The inbox transfer is also prepared to send the dispensation information to patients within the same connection with the server.

In March 2013, ANMAT implemented a modification in the information reception format; the GTIN's and Serials of the products received from a previous step do not need to be reported, only to confirm the reception from the own data which NTS allows to select. This is an advantage since the receiving institution has previous information of what will be received from the suppliers, in the NTS' Website.

Before these facts we decided to keep the reception circuit and the schedule of the computer system. The only modification will be, as a first step, to confirm the GTINs and the Serials received with ANMATs' information online. At the time of the physical reception and using the code readers, we will confirm that the GTINs, the Serials, the dispatch order data and the suppliers are the ones that correspond to the transfer sent to the NTS. Once all the data is confirmed, we enter the products received to our System through the reception in its current format and we confirm the reception to NTS, through the Web server. The input stage of Serial products is in this way completed.

### Patient's dispensation

The System is planned in a way that according to indication of the pharmaco-therapeutic follow up sheet with



data, requested drug, dose, frequency and way of administration, our system calculates the unit numbers of each product that must be delivered to each patient.

During the first stage we worked manually. Each of the traceable drug units, at the time of the reception, is tagged with the double-sided stick label where states:

- Description data
- Expiration date
- Original lot
- GTIN and Serial as DataMatrix Code

Our distribution procedure is performed by single dose and by patient. At the time of the delivery of the product a proof of delivery is created, then on the copy of the patient's ticket- which remains at the pharmacy- we put the double-sided stick label of the product with its DataMatrix code, with the GTIN and Serial information. Therefore we know what Serial we deliver to each patient and we can manually report the dispensation to the NTS. Each patient's medication is placed in an envelope identified with the patient's personal information, its location and a detail of the drug sent inside the envelope. The nurse takes the drug from the envelope, we consider the drug and the serial that we registered in the system, is the one that the patient receives. In a second stage, Systems Management gave us an additional application that enables us to use the data of the delivery tickets by patient, is attached to the products tagged as traced, the Serials and GTINs corresponding to the dispensation. These data are stored by inpatient medical chart and by patient, remaining available in the system to be reported to NTS through the Webservice.

The reading of the ticket data and of the product, is done through barcode readings at the time of the dispensation and only generates a modification in the distribution circuit, but adds to the same a third drug control of the dispensed drugs detecting errors, since the system performs crossings such as GTINs vs. generic drug, and generic drug vs. medical prescription, and rejects the cases which do not match. The system performs a control of the serials dispensed and it blocks them so they prevent Serials from being reused. In the case of pills that since there are many in each package they share the same Serial number, are packed individually and through new a software our packaging machine enables the addition of a DataMatrix code with GTIN and Serial to the label, for these pills, the system controls the Serials in a way that when the contents of the original package are used up, the Serial is terminated.

We should consider that ANMATs' regulation allows the dispensation of a same Serial for different patients until the content of the package is used up.

Clearly, it is possible through consultation functions to know which Serial each patient received, the number of units left in a Serial and in cases of returns for lack of usage, to identify the patient who did not receive his dose and investigate the causes.

This entry process of the Serial in the last stage of the dispensation, will enable us - when the conditions are appropriate - to carry the serial assignments to the administration time, that means to the patient's bedside,

which will increase significantly his safety. An error in the last step, at the time of the administration, is a risk that exists and in many cases, the damage is irreversible.

### Pending

#### a) Transfers within warehouses

Currently the system is not developed to move the Serials among internal warehouses. We work as if all the serials entered can be used from all the sectors, from a unique general warehouse.

#### b) Reconstruction Centrals for Antibiotics and Cytostatics

When preparing a unitary dose it can be requested one or more medicine bottles to complete the total of milligrams required by the dose; in this case the dose prepared will be linked to one or more Serials that later shall be reported as used in the patient that received such dose. It is possible that for a single dose of a specific drug for a patient many Serials of such drug are reported to ANMAT without creating conflict.

At the reconstitution centrals, in cases of small doses, it is possible that they share the contents of one bottle (unique serial) in the preparation of doses destined to different patients. This means that the same Serial Number will be linked to many doses and many patients. The regulation takes into consideration these types of cases and enables us to report one serial for many patients as long as it does not exceed the content in milliliters of the bottle.





This last case is similar to the one of the pills included in one package. The serial is the same for all of the pills in the package, but in an institution with distribution by single doses, the pills are assigned to different patients. When we report to ANMAT the dispensation we find that many patients use the same serial of pills and this is correct, as long as we respect the contents of the package. For example, if we had 10 pills in the package and each patient used 1 pill we can use the serial for those 10 patients.

The challenge – for centrals as ours that prepare doses for children -, is to identify GTIN and Serial at the time of the preparation and link it to the patient that will receive the dose, while the content of the package is controlled.

We should consider that each single dose that is manufactured is identified with data that include name, medical history, patient location, drug and dose. Then, to each label of dose generated by the system, it shall be added the medical chart number of the patient and the drug's internal code; during the preparation the codified data of the label will be read online – to identify patient and prescription – and it will be linked through the reading of the GTIN data and Serial of the bottle's label. The system will verify that the GTIN and Serial correspond to products received in the institution, and that match the patient's prescription, thus increasing the control and improving the safety of the preparation.

### Conclusion

To solve these issues requires great effort by the whole institution and its professionals, nevertheless it is worth it when we can have the conviction that the patient received the right legitimate drug, with the right dose, at the right time, since this is the primary objective of our work as hospital pharmacists.

### ABOUT THE AUTHOR

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*Pharmacist, graduated from the Pharmacy and Biochemistry Faculty of the University of Buenos Aires (UBA). In 1987 joined in as assistant Pharmacist at the Children Hospital "Prof. Juan P. Garrahan". She has worked as a pharmacist in the Inpatient, Training and Pharmacy Management areas of the hospital. Since 1987 she is the Leader of the Automation Project of the Pharmacy Area. Since 2006 she works at the Children Hospital "Prof. Dr. Juan P. Garrahan", as Chief of the Pharmacy Area.*