

Argentina

Sanatorio Güemes improves patient safety through traceability initiative

Sanatorio Güemes is a 522-bed private hospital in Buenos Aires, Argentina, that has established best practices regarding patient safety and quality of care. The leading hospital supports the implementation of the country's National Traceability System as a means to improve safety and security in the pharmaceutical supply chain and the care provided to patients. The hospital has implemented processes and policies to enable electronic medical records and improve inventory management, and are meeting many requirements of the National Traceability System as a result. These new processes improve four key areas that the hospital identified as crucial for capturing traceability data for pharmaceuticals: receiving, repackaging, distribution and administration. Successful implementation requires a multi-disciplinary approach, and is dependent upon internal support of and belief in standardisation, not only from hospital management, but also from each staff member responsible for the facilitation of data in the supply chain.

by Dra. Estela Izquierdo

Sanatorio Güemes

Background

Sanatorio Güemes, an ISO-accredited institution, has a mission to provide safe, reliable and quality care to the population of Buenos Aires and surrounding areas. Because the hospital is working based on a quality management system, it is implementing policies and processes to enable pharmaceutical traceability within its hospital in order to improve patient care and the security of the national drug supply chain.

Challenge

The pharmaceutical supply chain in Argentina is not immune to actions that negatively impact the safety of patients, including the introduction of counterfeit drugs, theft and diversion. In order to combat these problems and be consistent with

what is being done on a global scale, Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT) has established a National Traceability System. The system enables the identification, validation, communication and registration of all drug transactions and movements along the pharmaceutical supply chain.

The Argentine pharmaceutical market is complex, and contains numerous supply chain participants, including manufacturers, distributors, provider organisations such as clinics or hospitals, health insurance companies (including pre-paid insurance), social welfare organisations, logistic operators, retail drug stores, and welfare pharmacies. These stakeholders are at various stages in their adoption of electronic processes, and are using disparate information systems that may not be compatible with each other. In addition, in Argentina it is required to identify all drugs with the GS1 Global Trade Item Number (GTIN) and serial number, encoded either in a linear barcode, GS1 DataMatrix or RFID tag.

Solution: the traceability system

In order to improve the quality systems within the hospital while complying with the newly implemented National Traceability System mandated by ANMAT, Sanatorio Güemes decided to develop its own internal traceability system as well. The hospital set out to automate the stock management for all drugs, including those received directly from pharmaceutical manufacturers or distributors, and those that come from different health insurance companies or social welfare organisations. In addition to working on the automation of stock management, the hospital looked to improve its capability to trace drugs internally. Further it developed a tool that could electronically capture all documentation and information related to each drug it received. The system verified the expiration date and origin with the commercial documentation provided. Working on ways to improve and automate stock management helped the hospital prepare for ANMAT's compulsory National Traceability System.

During its automation and process improvements, the hospital identified four areas that are important to capturing traceability information:

- Receiving
- Repackaging
- Distribution
- Administration

The data (GTIN and serial number) associated to the secondary package of each drug is captured at each of the above steps, building the foundation of the traceability system.

To comply with the national (external) traceability regulation, communication to ANMAT then occurs at 2 key moments:

- Receiving
- Administration to patient

Receiving

Information linked to the drug (despatch order, invoice, etc.) is encoded in the system and checked against the actual product using GS1 standard identifiers (GTIN and serial number).

In addition, the barcode of the product is scanned and the data (GTIN and serial number) is recorded in both the hospital traceability system (internal) and the central database hosted by ANMAT (external traceability system).

Repackaging

The Argentine legislation requires that each drug is identified on the secondary package, but does not specify the type of data carrier to be used (1D/Linear barcode, 2D/Matrix barcode, RFID, etc.).

As the daily doses are prepared and given directly to the patient, it is necessary to re-pack the pills to dispense them. Therefore, it is important to identify to which commercial product code each drug dose belongs to. Sanatorio Güemes acquired a pill repackaging and fractioning machine, which ensures that the primary package remains intact as they cut each individual blister and repackage it in a pouch. That way, some of the data from the secondary package along with the data delivered with it (expiration date, commercial information, etc.) is transferred to the pouch. When fractioning and repackaging, the product is identified with the following information: original expiration date, lot/batch number, GTIN and serial number of the active ingredient, strength, and pharmaceutical type. The hospital has not yet been able to

STOCK DE MEDICAMENTOS CITOSTATICOS

Partida: Partida Nº 20110610-65328 Fecha de carga 13/06/2011

Paciente: Paciente PRUEBAADICION Institución SANATORIO GÜEMES H.C. 2848377- Fecha Nac 17/10/1958 Edad 52 años 7 meses Entidad HOMBRES-PLAN SALUD S GÜEM Origin Medicación OBRA SOCIAL

Descripción	Unidades	Presentación	Cantidad	U. Stock	V/L	Lote	Venc	Materia
PACLITAXEL 150 MG	2.00	Amplios/Frasco	300.00 mg	Nº Intermedio 1234	05/2011	ROCHE		

Validación
¡ERRORES! VERIFIQUE LA FECHA DE VENCIMIENTO
Aceptar

Stock management

STOCK DE MEDICAMENTOS CITOSTATICOS

OPERADOR: GLN

Partida: Partida Nº 20120922-88851 paroxal previo a salir Transabilidad Remito 123456 Carga 22/06/2012 GLN 9999991800000 Farmacia Magnin

Paciente: Paciente INSTITUCION SANATORIO GÜEMES H.C. - F.Nac 77 0 años Entidad - Venc (17) Lote (10)

Código	P. Activo	Descripción	Unidades	Presentación	Cantidad	U. Stock	V/L	Lote	V/L
UNOCROSO	OCTESTEA	OCTESTEA 0.1 MG AMP 3	0.50	Amplios/Frasco	0.50 mg	5/12/148	20		

Localiza en Remanentes

Drugs reception in the system

capture the manufacturers information required by ANMAT; instead, it is fractioning, repackaging and relabeling the drugs onsite, forcing the creation of a hospital-created product line in the system.

Distribution

As the hospital provides the daily drug doses to different internal units (intensive care unit, emergency room, clinical areas, satellite pharmacy for the surgery room, outpatient hospitals, etc.), it has purchased barcode scanners for each clinical area to automatically capture drug information. Doing so enables internal traceability; the hospital knows at all times the location and quantity of each drug.

Administration

The hospital decided that the administration of the drug to the patient would be reported to ANMAT once the system could demonstrate that it was ensuring the five rights: right patient, right drug, right dose, right route and right time.

Sanatorio Güemes started by implementing a patient safety pilot at their oncologic outpatient hospital that would be extended later to other clinical areas.

In the pilot, Sanatorio Güemes implemented the following policies and processes:

- A multi-disciplinary team was set up to look at business process and interactions with other departments within the hospital to improve patient safety.
- Oncology protocols and all the infusions administered regularly at the oncologic outpatient hospital were standardised. Only the doctor administers the drug dose for infusions, and the action is recorded in the electronic health record.
- The preparation of the oncologic mixtures is done through a stock management system enabling internal traceability. The hospital has also developed a knowledge database for the preparation, handling and manufacturing of these drugs which checks for each preparation expiration date, dose, interactions, stability, etc.
- Once the preparation is made, the internal traceability system assigns it a GS1 DataMatrix. The patient who receives the medication is also identified with a wristband marked with a GS1 DataMatrix (2D barcode), which contains the patient's identification number and medical history, as well as the therapeutic regimen or protocol that the patient will receive. Furthermore, each of the oncologic preparations is identified with an Oncologic Pharmaceutical Preparation (POF) number, automatically generated at the time of its preparation. Each POF is linked to the drug traceability data. Simultaneously, the POFs assigned to the patient are registered in his electronic medical record.



Administration at patient's bedside



Repacking machine

- During the administration process, the patient's wristband is scanned, as is the drug label and the identification label of the nurse/doctor treating the patient. Once the system verifies and matches the POF with the drug and the right patient, the infusion can be administered. At the end of the administration, the procedure is automatically recorded and communicated to ANMAT.

These procedures ensure that the drugs and dosages are correct, and are matched with the right patient at the right time, minimising errors and providing a line of sight to the movement of the pharmaceutical within the hospital.

Benefits

Implementing a traceability system helps ensure the five patient's rights: the right patient receives the right drug, at the right time, at the right dose by the right person via the right route. Sanatorio Güemes is now able to track and trace all the drugs from the moment they are being received up to the moment the patient receives the treatment and beyond. Clearly patient safety is improved, but healthcare professionals are also more protected from errors and mistakes.

Conclusion and next steps

Following the success of the pilot in the oncology department, these processes will be implemented in other departments of the hospital. To ensure consistency and utmost quality, hospital staff must be trained on traceability and improved treatment protocols, especially pharmacy and nursing professionals who come into contact with drugs as part of their daily jobs. These healthcare professionals play an important part in the delivery of safe, quality care to patients, and are on the frontline of the industry's transformation to using electronic data capture to enable valuable drug traceability. The implementation of the traceability system is an opportunity to improve internal processes, for the safety of all patients.

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About the author



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and Technical Director of the Pharmacy Service of Sanatorio Güemes. She is also Director of the residency programme of the hospital, coordinator of the Hospital Pharmacy College of Pharmacists and Vice-president of the Argentine Association of Audit and Healthcare Plan.

About Sanatorio Güemes

Sanatorio Güemes is the largest private healthcare institution in Latin America with over 40.000m².