Traceability of Drugs: “Implementation in a hospital pharmacy in Argentina”

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San Francisco, USA 1-3 October-2013

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Hospital Alemán
Buenos Aires ...
The Hospital Alemán of Buenos Aires:

- Opened its doors on August 26, 1867 just as a cholera epidemic devastated BsAs.
- University Hospital of high complexity.
- More than 700 professional doctors.
- All specialities and care for the acute sick.
- Diagnosis and treatment with advanced technology.
What is traceability of drugs?

- It is a tool that allows us to know the history of the drug along all its steps:
  - verification of its ORIGIN.
  - register of records all along its DISTRIBUTION CHAIN.
- Patients have the right to receive legal drugs.
Acquisition of drugs directly from audited laboratories and drugstores (GLN).

Reception of traceable drugs with record of lot and expiration date, GTIN and serial number.

Dispensation and Administration of right drug in daily dose.
Drug traceability, why and how to use it in a hospital?
Traceability as an implementation of healthcare improvement:

- plays a vital part in providing patients with best quality of medicines.
- traceability is part of a safety culture, enables trust.
Building a safer Health System

“first, do no harm”

Experts estimate that more people die annually from medication errors in hospitals, than from workplace injuries, motor vehicle accidents, breast cancer, etc.

The traceable medicine helps to prevent use of expired and recalled medication.
What is patient safety?

- *Patient safety* is the absence of preventable harm during the process of healthcare.

The vision:

- Every patient receives safe healthcare, every time, everywhere.
## Drug safety: global scenario

**Note N°275 /May 2012 / OMS**

<table>
<thead>
<tr>
<th>Counterfeit drugs</th>
<th>Country/Year</th>
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<tbody>
<tr>
<td>3- Truvada and Viread (HIV/Aids)</td>
<td>U.K., 2011.</td>
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</table>
Drug safety

- Unsafe drugs prevent patients from relieving their **suffering** and improving their **quality of life**.
- **Counterfeit medicine is fake medicine.** It may be contaminated or contain the wrong or not active ingredient.
The term “Never Event” was introduced in reference to particularly shocking medical errors. These errors should never occur in a healthcare organization. The list has been expanded in 2011 to include adverse events:

For example: **Product or device events:**

- Patient death or serious injury associated with the use of contaminated drugs...
International background: FDA

- The FDA has recommended pharmaceutical laboratories to start using Radiofrequency Identification Technologies (RFID) to improve the traceability of their products.
  - (WHO N°275/ Feb. 2006).
- RFID chip next to a grain of rice
National background

- Apr-2011
  The National Ministry of Health established the creation of the SNT of drugs, in order to ensure the control of these products and limit the use of illegal drugs.

- It has been instrumented by ANMAT: National Administration of Drugs, Food and Medical Devices of Argentina
What did the first stage of the SNT include until June 15th, 2012?

- The traceability of about 200 medicines with “high cost and low incidence”, such as Cancer, HIV, Hemophilia, Rheumatoid Arthritis, Cystic Fibrosis.
... in March-2012
and deadline also 15-JUN-2012 !!

• **ANMAT** added:

...2,300 more traceable medicines
And finally the last stage of the SNT this year ...

- The Ministry of Health added 11 more Active Pharmaceutical Ingredients (API)

This is equivalent to 500 additional medicines.
How to implement traceability at the Hospital Alemán?
The traceability-system involves 4 specific steps in our hospital:

- hospital reception
- single dose fractioning
- dispensing
- administration

... its a big teamwork!!
It is possible to make changes, recognizing the positive effects...

And implementing traceability with the 4 E’s:

• Engage
• Educate all levels of staff
• Execute standardising processes
• Evaluate
Teamwork

- Providing safe healthcare depends on highly trained individuals.
- They are working together for patients to improve health and wellbeing.

Patients come first in everything we do.
The Quality Program: “standardising processes”

• the Traceability Manual is drafted
• all multitask personnel is trained
• it is focused towards a continued improvement.
• Applicable systems: ISO 9001, accreditation Joint Commission, etc.
Reception and administration of traceable medicines in hospital directly linked to ANMAT Website
The history of the drug goes from its reception to the moment it is used by patients: **traceability inside the hospital.**

The system based on GS1-Standards.
GTIN: Global Trade Item Number

- Each individual package has a unique, unrepeated random code:
  (01)GTIN and (21)serial number
- It is placed by the laboratory/drugstore.
- It will allow the patients to verify the authenticity of the product.
This unique identification is placed on the secondary packaging with one of the three Data-Carriers:

- Linear bar code
- DataMatrix
- RFID
GTIN/serial number is read at the reception with:

A) batch/lot number
B) expiry date

associated with GLN Code

GLN is the identification number of the institutional provider
Once the drug is **received**, ANMAT is informed and an ID is obtained:

- The traceability of the drug is verified at ANMAT’s Website using the transaction ID:
  - from GLN of origin
  - to GLN of destiny (**Hospital Alemán** as informant agent)
<table>
<thead>
<tr>
<th>GTIN</th>
<th>LOTE</th>
<th>NRO SERIAL</th>
<th>NOMBRE</th>
<th>DETALLE</th>
<th>GLN</th>
<th>RAZON SOCIAL</th>
<th>GLN</th>
<th>RAZON SOCIAL</th>
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<td>51896887</td>
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Reception of traceable drugs in the HA:

Inicial status (JAN-15-2012) and current (up to JUN-15-2013)
TOTAL TRACEABLE PRODUCTS INFORMED TO ANMAT

June 2012

PRODUCTOS TRAZABLES RECEPCIONADOS EN EL HOSPITAL ALEMAN

TOTAL DE PRODUCTOS TRAZABLES INFORMADOS AL ANMAT
TOTAL DE PRODUCTOS TRAZABLES NO INFORMADOS AL ANMAT (Sin código de Trazabilidad)
TOTAL TRACEABLE PRODUCTS INFORMED TO ANMAT

June 2013
Single dose fractioning at the **Pharmacy in the Inpatient Ward**
Unit dose re-packaging is done through an aseptic process where the original blister packs are cut and each unit dose individually overwrapped.
This single unit packages for pills, tablets or capsules:

- Identify their contents accurately.
- Protect their contents from environmental effects.
- Allow quick, easy and safe use.
For this single-unit packages: drugs were re-labeled with GS1-code:

- we can only print these labels for the number of units indicated in the original package.

- 60 tablets = 60 labels with the same DataMatrix code

We hope that in the future we will have regulation for the primary packaging based on the GS1 DataMatrix identification.
We also labeled each vial or ampoule... with a DataMatrix-code printer.

- It was hard work to adapt the size of the label so that it could be read by the scanner in the case of the smallest ampoules.
Quality of the re-packaging-process: 
technology-related vulnerabilities compromise patient safety

• A programme of preventive maintenance is implemented in order to control the machine, the printers and the labels.

• The work of the technician is under the close surveillance of a pharmacist.
Administration to inpatient from the Nurses’ Station
The main objective is to achieve the five well-known rights:

- Right patient,
- Right drug,
- Right route,
- Right time
- and Right dose
The role of the Nurses in the Traceability Process

- is fundamental in the HA- programme.
- Prior to administering the medication to a patient, nurses read the barcode of the medicine dispensed by the pharmacy.
- Then they confirm usage of the drug in the electronic system.
Electronic prescription orders at 3 p.m.
Dispensation to outpatient from Outpatient HA-Pharmacy:
Scan reveals possibility of counterfeit, expired and recalled medication
Bill that the outpatient receives with GTIN/serial after buying his medicine
The patient can validate the legitimacy of the medicine at ANMATs webpage before consuming it.
Conclusion

- The system is focused on guaranting genuine products, preventing counterfeit, fraud and smuggling.
- It gives greater transparency, safety and quality to the healthcare supply chain.
To continue improving the traceability process in the hospital it is essential...

- to train the personnel constantly, keeping a great compromise between all members of the multitask team.

- The continuous improvement create confidence, in patients and Management that the drug fulfills the quality requirements.
The New Global Health
...reflects the realities of globalization, especially the increased movement of persons and goods...

“People are beginning to understand there is nothing in the world so remote that it can’t impact you as a person.”

Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 19, No. 8, August 2013
In Hospital Alemán:

- decisions about the traceability process are first taken with patient safety in mind,

but...

- it is a daily challenge!!
As an industry expert described recently when implementing serialisation:

“Serialisation is like having children... people tell you what to expect, but you don’t know until you have your own...”

*Introduction for the Pharma-IQ’s Serialisation and traceability Conference – Geneve (6-7th Nov 2013)*
Thank you for your attention!

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