Medicine Traceability in a Hospital Environment

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Newborn and Women’s Health

2012 data:

- 158 neonatal beds
- 313 admission beds
- 65 adults intensive and semi-intensive care beds
- 8 operating rooms
- 16 surgical delivery rooms
- 6 natural childbirth suites
- 26,168 deliveries
- 10,057 surgical procedures
What’s the difference?

Retail Pharmacy ≠ Hospital Pharmacy

Containing 30 coated tablets
Brazilian Regulation

- Ordinance 801/1998
  - Establishes GTIN + EAN 13 as a standard on secondary package
- RDC 71/2009
  - Establishes rules for drug labelling
    - Security mechanisms on packagings that enable traceability from manufacturing to dispensing...
- Law 11.903/2009
  - Creates the Drug Traceability National System
- Public Consultation 10/2013
  - Traceability rules
Best Practices

Recall mechanisms
Drug effect monitoring in the patient
Dispensing for administration as ready as possible.

National Accreditation ONA
International Accreditation JCI
International Accreditation Canadian
Hindrances in the process

• Main hindrances:
  – Products have internal codes in each step of the logistics chain (industry – distributor – hospital)
  – Manual insertion of batch and expiry date due to the lack of identification.
  – Oral solids do not have identification in the unit of use.
    • Commercialization in blister packs – EAN/GTIN – 13 secondary packaging
  – Ampoules and vials without bar codes
Logistics Flow - Hospital

**Reception**
- Manual insertion of batch and expiry date

**Storage**
- Vigilance
- Small unit identification

**Dispensing**
- By time
- By patient
- Small unit

**Checking**
- Product X Prescription

**Administration**
- Right patient
- Right time
- Right route...

**MEDICAL PRESCRIPTION**
Small unit identification

Production order

Labelling

Production Release
Manual Process
Production Checking
Weak point
• Errors of product identification:
  – System – Manual insertion of batch and expiry date
  – Physical product:
    • Wrong label issuing
    • Identification of the wrong product
• Contamination and product loss
  – Excessive handling
  – 75% reduction of the remaining expiry date.
• Technical responsibility exchange
• Additional workforce costs
Small unit identification:

• Administration errors avoidance:
  – Right patient
  – Right medicine
  – Right dose
  – Product expiry date

• Patient allergic to the product

• Duplicate administration
Standards

GS1 DataMatrix: GTIN + Batch and Expiry date
Logistics chain with GS1 DataMatrix identification in the small unit

- **Reception**
  - Batch and expiry date electronic insertion

- **Storage**
  - Vigilance
  - By time
  - By patient
  - Small unit

- **Dispensing**

- **Checking**
  - Product X Prescription
  - Right patient
  - Right time
  - Right route...

- **Administration**
PROJECT: Partnership with the Pharmaceutical Industry

HC WG GS1 Brasil
- 2005 – The first step GS1 RSS
  - Albert Einstein and Hypofarma
- 2008 – GS1 DataMatrix
- 2009 – Santa Joana / Pro Matre Paulista Hospital and Maternity and Osvaldo Cruz German Hospital
- 2011 – Moinhos de Vento Hospital

Current status: disseminated project in the country

DataMatrix - they began...

...others are joining
Results

• **Efficiency increase and costs reduction**
  – End of the need for relabelling and associated risks
  – Workforce reduction
  – Automated dispensing control

• **Visibility and traceability**

• **Assurance of the 5 rights**
  – Verifying feasibility at bedside through CB

• **Quality requirement:**
  – ISO 9000, ONA (National Accreditation Organization), Joint Commission, etc.
Thank you!

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