Patient safety around the globe

33rd Global GS1 Healthcare Conference
Bogotá, Colombia
April 10, 2018

Jean-Michel Descoutures, Hospital Pharmacist Centre Hospitalier Victor Dupouy, Argenteuil, France, IHF
Tony Scanio, Director Data Management and Business Intelligence, Christus Health, US
Feargal Mc Groarty, National Haemophilia System Project Manager, St. James’s Hospital, Dublin, Ireland
Mrs Hennie Mulder, Registered Nurse (OR nurse), Maxima Medical Centre, Eindhoven/Veldhoven, the Netherlands
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Jean-Michel Descoutures, chair,
Hospital Pharmacist Centre Hospitalier Victor Dupouy, Argenteuil, France, IHF

April 10th, 2018
Some data on quality and safety

- Medical devices: serious adverse events in US tripled from 2008 to 2011 (18 000 to 55 000): pacemaker and defibrillator pulse generators, pacemaker and defibrillator electrodes, hip implants ... (*1)

- Medication errors: 10 - 20 % of in-patient admissions in US and UK. Higher rate in developing countries. Globally 50-100 million (*2)

(*1) MAUDE Data Base
Some data on quality and safety

- Incidence rate of preventable adverse drug events:
  - 2 – 7% of hospital admissions in developed countries (*2)
  - 13% in developing nations (*3)
  → Thousands of patient deaths and millions of short and long term disabilities every year (*2)

- Associated potential healthcare costs: 18-155 billion dollars (*2)

(*3) WHO paper (Benkirane and al, 2009)
Some data on quality and safety

• 1 in 10 medications in low and middle income countries are substandard or falsified (*3)

• The international trade in false medicines is estimated to harm hundreds of thousands of people every year (*3)

• 700 000 deaths per year due to falsified antituberculosis and antimalarial drugs (*4)

(*3) WHO Report, 2017
(*4) OECD, 2013
The « six rights »

- **Right patient**
  Verification of the patient’s identity

- **Right medication**
  Does the medication label match the order?
  - look alike, sound alike medications

- **Right dose**
  Confirmed against the prescription
The « six rights » -2-

• **Right time**
  Does the administration time match the order?

• **Right route**
  Does the route match the order? Can the medication be crushed or mixed in other substances?

• **Right documentation**
  Document immediately after the medication is administered → medical record
But before that ...

Be sure the patient does not receive a counterfeit health product

- Drug Supply Chain Security Act (DSCSA): US
- Falsified Medicines Directive and the delegated act on the safety features (EU) → unique identifier (serialization) + anti tampering device on the secondary packaging
- Unique Device Identifier for medical devices in US & in Europe → improves traceability, prevents counterfeit and falsification
The use of global identifiers, a major opportunity for improving safety

Standardised identification + Automated tracking of health care products

→ From factory to bedside

Adopting a single set of global identifiers:
• will bring higher safety
• and costs significantly less than two or more

McKinsey, October 2012
The different needs to start to reduce medical products errors

- A globally standardised product identification with a barcode (or datamatrix) on secondary packaging carrying:
  - article identification
  - batch number
  - expiry date
  - serial number

- A pure added value: product identification with a barcode (datamatrix) on the primary packaging (unit dose) to enable bedside scanning → linked to a database containing the medication
The different needs to start to reduce medical products errors

- Scanners to read barcoding
- Wrist band bearing barcode linked to the patient’s EHR
- A barcode identifier of the staff
- A location number
- IT: software and systems
The barcode verification system

Barcode verification is used as part of the medication and medical device processes in hospitals
Savings

= The added value of barcode verification on patient safety → pre-tests and post-tests

- Evaluation of the reduction of errors at the different steps of the whole process
- 50% reduction in medication errors causing potential harm to patients - Dutch studies: Poon 2010, Hassink 2012
- Savings in terms of patient safety: reduction in hospital admission, in length of stay, ...
- Savings in terms of logistics: reduction in waste, inventory levels, recalls ...
Costs

- Hospitals apply barcoding to their medical products → repackaging = cost + risk of errors

- **Major problem** → solution for medications: automated barcoding by the unit dose dispensing robot (Center for specialised Pharmacy, Nijs, 2014)

- Wholesalers apply barcoding at the primary packaging level

- Manufacturers carry the process

Bar coding medicines to the single unit  
EAHP Statement, up-date 25.01.2018
Other implementation costs

- Purchase of relevant scanners
- Software and systems
- Training of staff
- Maintenance of the whole system

In the end measure the Return on Investment
Bottom-up or Top-down approaches? -1-

1. Bottom-up strategy:

- Be persuasive and clearly outline the goals
- Start small and simple with a ward, an operating theater, ... to implement the barcoding application
- Use metrics to analyse the tangible results
- Analyse the implementation challenges
- After the pilot period, extension to other wards, other parts of the hospital, ... the on-going program
2. Top-down strategy:

- The health authorities want to:
  - Prevent harm and mortality
  - Protect patient from substandard and defective products
  - Protect patient from counterfeit health products
  - Increase patient safety in a word
  - The health authorities want to reduce costs in hospitals

- Consequence: the use of global standardised identifiers becomes mandatory
Panel Patient safety around the globe

Chair: Jean-Michel Descoutures

Tony Scanio: Using Product Data to Protect Patients

Feargal McGroarty: The benefits GS1 standards bring to healthcare providers in the delivery of care, and ultimately to patients

Hennie Mulder: The experience: an OR-nurse scanning medical devices
Using Product Data to Protect Patients

33rd Global GS1 Healthcare Conference
Bogotá, Colombia

Mr Tony Scanio, Director Data Management and Business Intelligence, Christus Health, US

April 10th, 2018
USING PRODUCT DATA TO PROTECT PATIENTS

TONY SCANIO
DIRECTOR, DATA MANAGEMENT & BUSINESS INTELLIGENCE
CHRISTUS HEALTH

<table>
<thead>
<tr>
<th>Cause</th>
<th>Annual Deaths</th>
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<tbody>
<tr>
<td>Heart Disease</td>
<td>633,842</td>
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<tr>
<td>Cancer</td>
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<td>Chronic Lower Respiratory Diseases</td>
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Source: https://www.cdc.gov/nchs/data/hus/hus16.pdf#019

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Hospital medication error kills patient in Oregon

Nurse Gives Patient Paralytic Instead of Antacid

By CHRISTINA CARON  Nov. 21, 2011 abcNEWS

10-fold Dose Error Transferred with Patient, Death
Results

By Tara Beuoy, RN
CHRISTUS Health

- 600 centers
- 45,000 employees
- 15,000 physicians
- 3 Sponsoring Congregations
**Country: Chile**

2 Hospitals, Medical Centers, Family Health Centers, Central Lab

**Beds:** 550+

**Primary Business Partner:** Manufacturers

---

**Country: Colombia**

2 Hospitals, 80+ Ambulatory Centers, Home Health Care

**Beds:** 280

**Primary Business Partner:** Manufacturers and Distributors

---

**Country: Mexico**

9 Hospitals in 5 Cities, Clinics, Medical Centers, Oncology Center, Ambulance Services

**Beds:** 675+

**Primary Business Partner:** Distributors
Challenges Currently Faced

Product Approval  
Product Ordering  
Product Receipt  
Product Use  
Usage Record  
Recall Process
Challenges Currently Faced

Product data source of truth?
All information available?
Approval valid for service line, hospital, country?

$\frac{1}{2} \text{ truth} + \frac{1}{2} \text{ truth} \neq \text{ Truth}$
Challenges Currently Faced

- Processes in place to eliminate “rogue” purchasing?
- Systems in place to reduce purchasing errors?

Sample CHRISTUS International Hospital Purchasing (USD Millions)
Challenges Currently Faced

Product Approval → Product Ordering → Product Receipt → Product Use → Usage Record → Recall Process

Item ordered is item received?

Quantities in Unit of Measure correct?

Correct price charged?
The Importance of Communication in Ordering
Challenges Currently Faced

- Checks in place to prevent incorrect product usage?
- Systems established to convert Units of Measure?
- How to ensure that products are not expired?
Prevent Incorrect Product Usage

High Risk

Look-Alike, Sound-Alike
Challenges Currently Faced

- Product Approval
- Product Ordering
- Product Receipt
- Product Use
- Usage Record
- Recall Process

Correct information captured?

Information associated with correct patient?
Challenges Currently Faced

How to find patients affected?

How to contact effected patients?

How to be fast, efficient, and control costs?
Patient Safety

People

Data

Processes

Systems
CHRISTUS International Implementation Roadmap

Master Data
- MFR
- CAT NO
- Product Categories
- GTIN

Systems
- Product Information Management
- Clean Up
- Integrations

Implementation
- Policies and Procedures
- Continual Monitoring
- KPIs
Closing Story – The Great Baltimore Fire of 1904

Patient Safety around the Globe

The benefits GS1 standards bring to healthcare providers in the delivery of care, and ultimately to patients

Mr Feargal Mc Groarty, National Haemophilia System Project Manager, St. James’s Hospital, Dublin, Ireland

33rd Global GS1 Healthcare Conference, Bogotá, Colombia

April 2018
Irish Links with Colombia

• Irish soldiers fought in Colombia during the War of Independence with Spain in 1816-1822
Other facts that show close relationship between Colombia and Ireland!

• National sport Tejo combines gunpowder and beer
• More rainfall than anywhere else (The isolated Pacific coast, known as the Choco)
• Peace agreement ended 50 years of armed conflict
• Christmas lasts for a whole month
• It’s Colombia, not Columbia
• Men on the coast **really** like donkeys....... (Caribbean coast and the costeños)
Healthcare in Colombia

• The first graduated medical doctor, Alvaro de Aunón came to New Granada from Seville Spain, in 1597 and stayed for a short time. The first drug-store in Colombia was opened at the same time, in the main square of Bogotá.

• As of October 1, 2014, there were 3,620 health establishments in Colombia, including hospitals, clinics and ambulance services. Private healthcare establishments account for 57% of all establishments within the country.
Where Colombia ranks

<table>
<thead>
<tr>
<th>World Health Organization Ranking: The World's Health Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 France</td>
</tr>
<tr>
<td>2 Italy</td>
</tr>
<tr>
<td>3 San Marino</td>
</tr>
<tr>
<td>4 Andorra</td>
</tr>
<tr>
<td>5 Malta</td>
</tr>
<tr>
<td>6 Singapore</td>
</tr>
<tr>
<td>7 Spain</td>
</tr>
<tr>
<td>8 Oman</td>
</tr>
<tr>
<td>9 Austria</td>
</tr>
<tr>
<td>10 Japan</td>
</tr>
<tr>
<td>11 Norway</td>
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<tr>
<td>12 Portugal</td>
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<tr>
<td>13 Monaco</td>
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<tr>
<td>14 Greece</td>
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<tr>
<td>15 Iceland</td>
</tr>
<tr>
<td>16 Luxembourg</td>
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<td>17 Netherlands</td>
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<td>18 United Kingdom</td>
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<td>19 Ireland</td>
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<td>20 Switzerland</td>
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<td>21 Belgium</td>
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<tr>
<td>22 Colombia</td>
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<tr>
<td>23 Sweden</td>
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<tr>
<td>24 Cyprus</td>
</tr>
<tr>
<td>25 Germany</td>
</tr>
<tr>
<td>26 Saudi Arabia</td>
</tr>
<tr>
<td>27 United Arab Emirates</td>
</tr>
<tr>
<td>28 Brazil</td>
</tr>
</tbody>
</table>
This is the challenge!
How do we break these barriers?

Noel Burch 1970
Using GS1 standard at St. James’s Hospital
**Business Process Innovation/improving patient care: Implementing GS1 Standards**

<table>
<thead>
<tr>
<th>Year</th>
<th>2003/4</th>
<th>2011</th>
<th>2012</th>
<th>2014</th>
<th>2017</th>
<th>FUTURE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Haemophilia Track and Trace project commenced GS1 Datamatrix</td>
<td>First hospital to pilot the Surgical Instrument track and trace programme using GS1 Standards</td>
<td>eProcurement project (Standardised coding, data and messaging) GTIN GLN GS1 XML 3.0</td>
<td>1st Sep 2014 First Supplier to GoLive</td>
<td>Scan for Surgery Go Live</td>
<td>Full Traceability to EHR (roll out of scan for surgery)</td>
</tr>
<tr>
<td></td>
<td>SAP Installed (EPR &amp; GUI)</td>
<td></td>
<td></td>
<td>Communications and meetings with Top 50 Suppliers</td>
<td>RFID tracking of Precious samples (Live)</td>
<td>Working towards implementation of eProcurement with all Suppliers</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Next Projects:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rollout of Scan for Surgery, RFID tracking of patients, staff, assets</td>
</tr>
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</tbody>
</table>

**FUTURE**

- Business Process Innovation/improving patient care: Implementing GS1 Standards
- Full Traceability to EHR (roll out of scan for surgery)
- Working towards implementation of eProcurement with all Suppliers
- Target to be first hospital fully compliant to GS1 Standards
Traceability at St James’s Hospital enabled by GS1 Standards

Track and Trace in the Hospital
Real time visibility of what happened
Right product, right place, right person

.....Linked to the right procedure,
Real-time, accurate data from the point of care!
On-going Projects

Instrument T&T
Scan4Surgery
Automatic tracking
(RFID)

Haemophilia T&T
Others...

eProcurement

SJH Healthcare Campus

implementing GS1 standards across the hospital campus
Supported by Regulation for medical devices and pharma
Haemophilia Project

• A hereditary bleeding disorder caused by a deficiency of protein called a clotting factor

• Characterised by excessive bleeding, even after minor injury

• Very expensive medication: approximately 200 patients with severe form need this medication

• **Patients self-medicate in the home** to help prevent bleeding emergencies
Crisis: our service needed to change

- Infection of patients with Hepatitis C and HIV (late 1970’s – 1985) due to contaminated blood products
- Infected products remained in the supply chain after recall, leading to subsequent infection
- Over 100 patients suffering from haemophilia died

Corrective action after government investigation:

- Improve communication between treatment centres
- Blood products supplied to persons with haemophilia should be of the highest standard and of the safest nature that are available
Smartphones with scanning App

Barcode on Vial box is scanned to check

- Product detail (prescription)
- Expiry date
- Recall status
- Shorter dated stock
Share...integrated care
Hospital Sterile Services Unit
Overview of the number of procedures year on year in SJH HSSU

Anecdotal evidence: Moved from 5,000 Transcriptions per day in one hospital

* Between 2013 to 2017 increase in workload with less staff
Track and Trace Solution
Loan set – Example

**Not GS1 Coded**
- 30 loan sets
- 60 reprocesses
- Huge paper trail
- Manual tracking
- Very time consuming
- Manual rekeying and transcription of data

**GS1 Coded**
- 4 loan sets
- 8 reprocesses
- Huge paper saving
- Electronic tracking
- Very time efficient
- Unique identification of set (GS1 barcode)

*ST. JAMES'S HOSPITAL*

SJH HSSU during 1 week in Feb 2015
SJH and RFID – What was the hospital requirement?
Traceability based on standards so solution would be future proofed and scalable:

✓ **Vulnerable patients**
  ✓ High-risk if patient wanders

✓ **Precious samples** (eg: Biopsy taken in theatre)
  ✓ Paper based traceability
  ✓ Samples can go missing
  ✓ Impacts patient safety
  ✓ Risk for the hospital

✓ **Valuable art** (test case for tracking assets around the hospital)
  ✓ Wheelchairs, infusion pumps
The Solution:
Automatic tracking of Vulnerable Patients using RFID

Hospital tracking system
The Solution:
Automatic tracking of Precious Samples using RFID

Hospital tracking system
Evolution of Supply Chain and Procurement at St James’s Hospital

1985 – 1995
• Price Takers
• Reactive practices
• Poor Quality information
• Pre-PC era
• Move to purpose built Warehouse

1995 – 2003
• Hospital wide computerisation project
• Supplies Department computerised in 1995
• Mainly purchasing and stock control
• Coding and classification system based on NSV

2004 - 2014
• Standard business processes adopted
• Internal Supply Chain integration
• Wireless Kanban
• Supply Chain Management viewed as a strategic support.
• High outputs of reliable, accurate data.
• Started to incorporate GTIN Identifiers
• EDI Messaging

2016 – Future
GS1 Standards Enabler for:
• Standardised Coding for all supply chain partners
• Full E-Procurement (EDI)
• Full track and Trace to Patient Episode

Passive Independent Supportive Integrative

Standardisation = Interoperability
Problem

• Lack of standardised product identification (and unit of measure)

• Lack of standardised location identification

• Multiple product catalogues

• Inaccurate and inefficient procurement practices

Solution

• Use GS1 Global Trade Identification Number (GTIN) Barcode

• Use GS1 Global Location number (GLN)
  • Who we are
  • Who you are
  • Where to deliver

• Single Product Catalogue (NPC)

• Automated messaging using EDI that incorporate standard identifiers (GTIN, GLN)

• Purchase Order (Starting point)
  • Advance Shipping Notice
  • Receiving Advice Notice
  • Invoice
Scan for Surgery

Operational Efficiency
- Automation of product supply chain processes for nursing
- Make additional time available for patient-centric activities
- Managed minimum inventory levels

Patient Safety
- Product Traceability to individual patients
- Product Expiry Identification

Patient Level Cost Analytics
- Increased visibility of real-time patient and procedure level costs
- Improved data analytics for decision making
Operational Efficiency

Before

• 20 hours per week to check and reorder stock (and other stock activities)

• Over-qualified role doing non-value added activities

• ? Time for patient care

Mary O’Brien
Assistant Director of Nursing

After

• 2 hours per week on supply chain activities

• More time for patient care !!
Operational Efficiency

Patient Scan

Automated
Message to SAP

- Scanning system sends automated message to SAP based on Stock Requirements

Automated
Message to Supplier

- SAP sends automated / manual PO to Supplier

Supplier Fulfils Order

- Supplier Fulfils order
- Replacement products are delivered to Theatre

Nursing Time Taken to Order T1/2 (Hours)

<table>
<thead>
<tr>
<th></th>
<th>Theatre 1</th>
<th>Theatre 2</th>
<th>Overall Est.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual</td>
<td>10</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Automated</td>
<td>2</td>
<td>1</td>
<td>4</td>
</tr>
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</table>

ST. JAMES'S HOSPITAL

Theatre 1

Theatre 2

Overall Est.
Cost Analytics

Theatre Cost Analysis

Complexity: 4.34
Patient Activity: 122
Average LOS: 10.83
Median LOS: 8

Measures:
- Total Product Cost
- Total Pay Cost

Procedures:
- Coronary artery...
- Lobectomy of lung
- Replacement of...
- Replacement of...
- Pleurectomy
- Wedge resection...

Chart showing total costs for various procedures.
Patient Safety

DEVICE RECALL

3,516 Irish had recalled hip device fitted

THE IRISH TIMES
'I trusted that I would be fitted with a safe implant. That's not what I got'

PATIENT IDENTIFICATION PROCESS

Traditional

Scan for Surgery
SJH Whitepapers, Case studies, posters, in the news
Thank you for listening!

fmcgroarty@stjames.ie
Anyone for a game of Tejo???
The experience: an OR-nurse scanning medical devices

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Mrs Hennie Mulder, Registered Nurse (OR nurse), Maxima Medical Centre, Eindhoven/Veldhoven, the Netherlands

April 10th, 2018
Maxima Medical Centre and Ministry of Defense
No conflict with any commercial interest
Kahoot.it

Pin:
1. Use your mobile phone and go to www.kahoot.it
2. Fill out the GAME PIN on your screen
3. Answer the questions
The story of Mrs A

Mrs A, 75 old and married to Mr A. Mr A is 10 years older and he 'is not in optimal shape'. They like to spend their time cycling, hiking and enjoying their grandchildren.

Since some time quite some pain in her right knee impairs Mrs A while cycling and hiking, which diminishes her joy and freedom of movement.

Her GP sent her to the orthopedist, who diagnoses her with severe arthrosis and advises her to have a knee replacement procedure in the nearby hospital.
The surgical procedure is scheduled

The orthopedist orders the needed material

Mrs A organises someone to take care of her husband while she’ll be in hospital
Old situation
Old situation
New situation
Need for agreements!

Necessity to align and agree

Hey, who was here first, you or me?!!
In line with EU MDR

Dutch Agreements on unique coding of medical devices supported by industry, healthcare providers and the ministry of health (ADC)
National implant registry

- Barcode scanning of medical devices
- Facilitates the work of the OR nurse
- Traceability within the hospitals
- Direct uploading in implant registry
- (Global) product traceability
So ......................
Patient Safety around the globe

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Wrap up
April 10, 2018
Patient Safety around the globe: Wrap up

GS1 is an enabler for assuring the patient rights in healthcare

Regulation support GS1 standards / identifiers as a driver to be sure the patient does not receive a counterfeit health product

Bottom-up (added value) in combination with top-down (regulation) is needed for success

GS1 in the supply chain and correct product data: support quality & safety, efficiency & cost containment

A vision, a plan, a roadmap and global sharing facilitates good implementations
Patient Safety around the globe

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Bogotá, Colombia

Panel discussion

April 10, 2018
Thank you very much for your attention

Muchas gracias por su interés