GS1 Healthcare Provider Advisory Council (HPAC) Webinar

Surgical Instruments Traceability and scanning

GS1 Global Office
10th April 2014
HPAC Case Study Webinars

This is the THIRD Webinar

- Patient security and supply chain optimization:
  - Surgical Instruments Traceability and scanning
- It will be recorded!
- Webinars will take place monthly
HPAC Case Study Webinars

Planning following webinars

The following topics and dates will be as follow:

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Previous Webinars:

- 13th February 2014: The link between Traceability and Patient Safety
  - View recording (please note it takes a couple of minutes to load before viewing)
  - Download presentation

- 13th March 2014: Implementation in a hospital pharmacy in Argentina
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Details here: [http://www.gs1.org/healthcare/hpac_webinars](http://www.gs1.org/healthcare/hpac_webinars)
C.H.I Robert Ballanger
Frédérique Frémont

Patient security and supply chain optimization

Surgical Instruments Traceability and scanning
Hi! Robert Ballanger Hospital

- Intercity hospital serving a population of 400,000 persons
  - 650 beds
    - 450 beds in acute care (medical, chirurgical and maternity)
    - 50 beds physical Medecine and rehabilitation
    - 170 psychiatry beds
- Outpatient clinic and pharmacy inside Villepinte detention center
- CDG airport hospital
Overview of instrument and implant traceability

Goal: Full traceability as it is mandatory and French Pharmacists are personally liable for Drugs and Sterile Medical Devices

Challenges: Managing the projects which are fundamentally linked together with too few resources (pharmacists, IT, ..)
Global Project: Medical Devices Traceability and scanning

• **Initial Business Issue**: Surgical Instruments
  – Due to Creutzfeldt-Jakob risk, the last 5 patients on which the instruments have been used must be known
  – Applies to hospital owned or loaned instruments

• **Secondary Business Issue**: Surgical Instruments
  – Contracting for taking in the sterilization of another hospital (same level of activity, different surgical procedures)

• **Business Issue**: Implants and high value Medical Devices
  – Implants: traceability is mandatory
  – Itemized billing to the patient (not included in the hospital bundled payment)

• **Who?** The head of the pharmacy has been the leading sponsor but it took 2 years to convince the top management to go to a full GS1 hospital
Focus: Surgical Instruments Traceability and scanning

<table>
<thead>
<tr>
<th>Item</th>
<th>CHIRB</th>
<th>Subcontracted Hospital</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Containers</td>
<td>16 188</td>
<td>15 399</td>
<td>31 587</td>
</tr>
<tr>
<td>Individual instruments OT</td>
<td>18 186</td>
<td>9 175</td>
<td>27 361</td>
</tr>
<tr>
<td>Individual instruments wards</td>
<td>24 069</td>
<td>17 389</td>
<td>41 458</td>
</tr>
<tr>
<td>Sets</td>
<td>16 937</td>
<td>4 477</td>
<td>21 414</td>
</tr>
<tr>
<td>Single use</td>
<td>6 016</td>
<td></td>
<td>6 016</td>
</tr>
<tr>
<td>Total produits</td>
<td>81 396</td>
<td>46 440</td>
<td>127 836</td>
</tr>
</tbody>
</table>

- Containers: 32%
- Individual Instruments wards: 25%
- Individual Instruments OT: 21%
- Sets: 17%
- Single use: 5%

Subcontracted Hospital

Total products: 127,836
Process and instrument traceability

Pharmacy

Traceability
Implantable Medical Device

Reception
Implantable Medical Device

Distribution

Operating Theater

intervention

Sterilization Unit

Pre-cleaning

Cleaning

Packaging

Sterilization

Distribution
Surgical Instruments Traceability and scanning: Preliminaries

• **Marking**: Data Matrix
  • Two carriers could be used in the operating theatre and sterilization units: RFID tags and DataMatrix 2D bar codes
  • Choice of the most pragmatic system of identifying the surgical instruments with a DataMatrix 2D bar codes.
    – Ease of laser marking existing or branded new Instruments
    – Cost of this kind of marking. a single lasermark costs between 2 and 3 Euros, whilst an RFID tag costs approximately 7 Euros
    – Existence of software that enables this kind of traceability

• **Standard**: GS1
  • Will to buy new instruments already marked by the supplier
  • Existing French supplier marking its instruments with GS1 DataMatrix
  • Knowledge of GS1 in the hospital and help by our MO
Implementation of DATAMATRIX and follow-up

1st step (2009 – mid 2012): 1 engraving subcontractor in France

- Our choice
  - Laser engraving for Operating Theater instruments
  - Infodot for wards instruments

- Challenge: Logistics
  - 360 instruments could be tagged per week
    - Depending on supplier (500 a week for our French supplier)
    - Depending on the numbers of instruments that can be sent per week

**Laser**
- Industrial tagging
- Easy reading
- Industrial treatment of instrument
- Time to tag Devices

**Infodot**
- Easy and fast tagging
- Cost
  - Deteriorate faster than the others
Implementation of DATAMATRIX and follow-up cont.

- Codification:
  - 1 GTIN for all instruments engraved under our responsibility + serial number (automatic incrementation)
  - Links with the article number in the IT system (T-Doc)
  - Each packaging unit has its own supplier code and is labeled with a unique number for each sterilization process

- Traceability at the instrument level is done in the packaging area: instrument to container
- Traceability is done to the packaging unit (container, tray,...) in the other area of the sterilization unit and in the operating theater
Implementation of DATAMATRIX and follow-up cont.

- Traceability:
  - Instrument to container
  - Container to process
  - Container to patient

Link: Patient – Container – Instrument - Process
Surgical Instruments Traceability and scanning: How it works

of the instruments up to the patient.
2nd step (mid 2012 – mid 2013): new subcontractor

- On spot engraving by the subcontractor employees
  - Micro-dot (new technology) or laser engraving depending on the alloy
  - All instruments are engraved
  - Outside Hospital instruments engraved with their own GS1 numbers

Data matrix size:
- Depending on the instrument
- Smallest size: 1.2 x 1.2 mm
Implementation of DATAMATRIX and follow-up cont.

- **2nd step (mid 2012 – mid 2013)**: new subcontractor
  - **Benefit**: Logistics
    - Instruments tagged alongside the sterilization process
Implementation of DATAMATRIX and follow-up cont.

- **3rd step (end 2013 - ...) : 100 % instruments on stock engraved**
  - **Marking needed for :**
    - Worn-off data matrix (eg. instruments used daily)
    - New instruments (if not engraved by the supplier)
  - **How :**
    - Acquisition of the dot engraving machine
    - Training of 3 sterilization operators
    - If needed, laser engraving on site by the subcontractor
  - **Purchasing : GS1 marking including in bid to tender terms**
    - OK for Operating Room Quality instruments
    - Reduced number of suppliers for others
  - **Remaining challenge : ancillaries on loan**
    - No engraving done by the suppliers
    - Need of a common request by the Health Providers
    - UDI legislation will help
Surgical Instruments Traceability and scanning

- **Business benefits**
  - **Cost reduction**: ROI around 24 weeks
    - Decrease in non-conformance and decrease of cost per box per surgical procedure
    - Decrease in the number of Operating Theater nurses needed: 2 as team leaders and referents

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Number of instruments</th>
<th>Price for engraving</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>10 063</td>
<td>35 221 €</td>
</tr>
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</table>

**Without engraving**

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Number of containers per week</th>
<th>Average sterilization cost per container</th>
<th>Cost per week</th>
<th>Non conformity - Resterilization of 8% of containers</th>
<th>Total cost</th>
</tr>
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<tr>
<td><strong>Total containers / week</strong></td>
<td>558</td>
<td></td>
<td>18 275 €</td>
<td>1 462 €</td>
<td>19 737 €</td>
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**With engraving**

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<th>Type of surgery</th>
<th>Number of containers per week</th>
<th>Average sterilization cost per container</th>
<th>Cost per week</th>
<th>Non conformity - Resterilization of 1% of containers)</th>
<th>Total cost</th>
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<td><strong>Total containers / week</strong></td>
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**Difference per week**
- Maintenance / year (new engraving)
  - 1 279 €
  - 66 508 €
  - 3 522 €

**Difference in salary per year**
- 13 315 €

**Total ROI (weeks)**
- 24 weeks
- 76 301 €
Surgical Instruments Traceability and scanning

• **Acceptance and Change Management**
  • Great sponsorship by the Sterilization Department Pharmacist
    – No prior knowledge of GS1 but had the will to learn and understand
    – Became a strong project leader and helped convince the top management
    – Recognized as a team leader by his operators

• Newly refurbished sterilization unit
  – Operators participated in the new design and new organization
  – Young team, used to scanning (their ID, containers)
  – Were kept informed and participated since the beginning of the project
  – Proud of being among the first to implement such a project

Immediate acceptance and even enthusiasm
Surgical Instruments Traceability and scanning

- **What were the key implementation challenges experienced?**
  - At first, only one engraving supplier (second entered the market in 2012)
  - Scanners are one of the biggest challenge in instrument engraving (reading of very small data matrix, 2mm x 2mm or 1.3mm x 2.8mm)
    - With a good scanner, processing time is not significantly different (can be lower)
  - Interoperability with IT process traceability
    - 4 IT systems:
      - Pharma® in the Pharmacy Department: Management of Drugs and Medical Devices and Electronic Prescription
      - T-Doc® in the Sterilization Department: Process Management and Traceability
      - Bloqual/Sedistock in the Operating Theater: OT Management and Traceability
      - McKesson: Patient Medical Record
    - Data Base integration: 1,849 references for Reusable Medical Devices had to be entered by hand in the Operating Theater IT system

- **What next?**
  - Tracing the implants and manage the operating theater stock with the WMS we have now implemented in a new Medical Devices warehouse
  - Link with automated dispensing cabinets in the operating rooms through GS1 Datamatrix or bar code reading
Next step: Traceability of Medical Devices with GS1 Standards

Pharmacy
- Reception
  - Implantable Medical Device
- Distribution

Sterilization unit
- Distribution of a sterile medical device

Operating room
- GS1
- IT Prescription
  - Implemented
- Surgery intervention
- Patient traceability
  - Patient record
    - Implementation in progress

Process
- GS1
Thank You!
Contact Details

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<td>12 June 2014</td>
<td>Michael Innes &amp; Kirk Metzger</td>
<td>Achieving supply chain efficiencies, delivery</td>
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