Panel I – Impact and issues around implementation of barcodes

ONE barcode, one product with two different GTIN, multiple barcodes, barcode quality, etc.

Tuesday, 26 March 2019
Noordwijk, Netherlands
Connect to the Wi-Fi

Network: GS1
Password: Healthcare2019
You have a question?

1. Go to slido.com
2. Enter #GS1HCNoordwijk
3. Select the panel session you are in
4. Go to “Questions”
5. Enter your FULL NAME
   *if the questions you’ve raised are not selected, the GS1 team will follow up with you you!
6. Post your questions
On your smartphone browser, type slido

Enter event number: #GS1HCNoordwijk

Select the panel session you are in
Insert your contact

Questions

Ask the speaker

Type your question

There are no questions asked yet.

Ask the first one!

My profile

Basic info

Your name

Your company

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Privacy Preferences
Panelists

Greg Magrane, eCommerce Project Manager, St. James’s Hospital, Dublin, Ireland

Charity Hovey, Regulatory Affairs Manager, 3M, US

Tatjana Pathare, Global Supply Chain Management Team, F. Hoffmann La Roche Ltd, Switzerland
St James’s Hospital

- 60 Acre Campus, 52 separate buildings
- €440m annual spend
- 1,050 beds
- 25,000 IP Discharges
- 48,000 Day Cases
- 280,000 OPD
- Largest Academic Teaching Hospital in Ireland
- Focus on innovative projects
- Robotic Dispensers installed in Pharmacy 2017
- Electronic Patient Record (Go Live Oct 2018)
Evolution Of a Medical Campus, “Shared Vision”

Mercers Institute for Successful Ageing
National Children's Hospital
Evolution of Supply Chain & 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 – 2020
GS1 Standards Enabler for:
- Standardised Coding for all supply chain partners
- Full E-Procurement (EDI)
- Full track and Trace to Patient Episode

Standardisation = Interoperability
On-Going GS1 Projects

- Instrument T&T
- Scan4Surgery
- Haemophilia T&T
- eProcurement
- Automatic tracking (RFID)
- Others...

SJH Healthcare Campus

...implementing GS1 standards across the hospital campus

Supported by Regulation for medical devices and pharma
SCAN FOR SURGERY
Project Overview

Operational Efficiency
• Automation of supply chain processes for nursing
• Make additional time available to spend with patients
• Managed minimum inventory levels

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

Patient Level Cost Analytics
• Increased visibility of patient costs
• Improved data analytics for decision making
SJH plans to send All Purchase Orders to Supplies via E-Procurement
Drivers for Standardisation

**Obstacle**
- 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 Identifier **GTIN**
- 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
GTIN Implementation Maturity

- **Level 1** – GTIN assigned to one packaging level
- **Level 2** – GTINs assigned to all packaging levels
- **Level 3** – GTINs used in pilot projects
- **Level 4** – GTINs are used in transactions (order/invoice)
- **Level 5** – GTINs used in transactions to actively trade with critical mass of partners
The Correct Association of the UOM is Crucial

All levels of packaging from the individual unit to the case should be regardless of whether it is sold commercially.
The Reality of Healthcare

• If a Hospital was a supermarket your product would not appear on the shelves if it did not have the following

  • A GTIN
  • Traceability data
  • Pricing file as at the day of sale

First barcode to be scanned in Retail in 1974
Il Buono, Il Brutto, Il Cattivo
The Good

Case/Carton GTIN: (01) 04054596148703

Box/Outer GTIN: (01) 04054596115422

Each/Inner GTIN: (01) 04054596059214

4 boxes in a case, 50 eachs in a box

Box/Outer GTIN: (01) 04054596115422

Each/Inner GTIN: (01) 04054596059214
The Good

- Description is in 26 Languages
- GTIN is in 1 language (the universal language printed only once and can be scanned in every country…. and every Hospital)
The Not So Good

No barcode at any level

Barcode on outer, none on inner
The Very Confusing

- 5 Instances of same product
- 4 different GTINs
If retail can do it at the humblest level why can’t we?
Key Learnings and Experiences

- Healthcare way behind retail
- Cross-Learning from experiences
- Development work – the first few steps are the hardest and take the most time
- GS1 partnership
- Co-Operation with other hospitals and healthcare organisations especially in UK (NHS and Trusts Demonstrator Sites Scan4Safety)
- Patience - it takes time to get connected to the right people in the Supplier organisations and to create awareness
- FDA/EU UDI regulation
Our request to you

• Make the commitment
• Assess Procure-to-Pay capabilities
• Commit resources
• Engage with the SJH project team
• Join GS1 if not already a member
• Publish product data (at all levels !)
Panel I: Implementation of barcodes

Charity Hovey
March 2019
3M at a glance:

- Sales in ~200 countries
- $32.8 billion in sales
- Five business groups
- 93,000 3M employees globally

- $1.8 billion invested in R&D
- 109,000+ patents
- >100 straight years of dividends
- One of 30 companies on the Dow Jones Industrial Index

*2018 figures
3M vision

3M Technology Advancing Every Company
3M Products Enhancing Every Home
3M Innovation Improving Every Life

3M Health Care strategic intent

“Care pathway innovation for improved and cost effective health outcomes”
All external facing data needs to match for customer & regulatory requirements.

- Label (all levels)
- IFU or Insert
- License, registration & DoC
- Website
- EDI transactions
- Sales orders/invoices
- Customs declarations
- Bill of Lading
- Customer syndication
- Regulatory data syndication
Business impact of mis-matched data

- Delay at Customs
- Customer Perception of Falsification
- Delay in Getting Paid
- Forced workaround at distributors & customers
Unique device identification (UDI)

UDI enables all of this data at customers’ fingertips

Scan barcode at:
- Receiving to add inventory
- Surgical supply to allocate materials
- Bedside to access product safety data – UDI databases
- Bedside to enter data into electronic health record
- Central supply to access sterilization method – Digital bridge
- Central supply to return to inventory

Customers who pull UDI from GUDID, ÜTS, Eudamed, etc.
- Catalog
- Description
- Brand owner
- Single use only
- Latex
- Supplied sterile
- Customer sterilization method
- Clinically relevant sizes

Customers with 3M GDSN
- Warnings
- Chemicals of concern
- Country of origin
- Length, width, depth, weight
- Minimum order quantity
- Lead time
- Truck load quantity
- Waste classification
- Post-consumer recycled content
Data sharing & data continuity
Syndication is the current business standard
Global Data Synchronization Network (GDSN) is the tool of choice

Maintain

3M

Single point to update

Store

Secure clouds do not use, aggregate or sell data

Share

Trusted source of data

Customers and governments require data to be shared electronically and maintained current at all times
## 3M Data attributes requested

### Supply Chain/eCommerce
- Stock keeping unit (3M SKU)
- Catalog
- Description
- GTIN/UPC
- Quantity
- Weight
- Length/width/depth
- Out of package dimensions
- Minimum order quantity
- Lead time
- Storage/handling temperature
- Brand owner
- Model/version
- Saleable unit, orderable unit, shippable unit
- UNSPSC
- Marketing features & benefits
- URL
- Product image or image link
- Equivalent product – GTIN/UPC

### UDI Fields
- UDI issuing agency
- Product hierarchy
- Manufacturer per label
- HCBG address (GLN)
- Rx vs. over the counter
- Clinically relevant sizes
- Sterility status
- Sterilization method
- Single use only
- MRI compatibility
- Latex warning on label
- Global medical device nomenclature (GMDN)
- Product classification by country
- License/registration number
- Production controls – lot/serialization, date of manufacture, expiration date
- Human cells or tissues
- Drug reimbursement code
- European representative

### Extended Attributes
- Materials of concern
  - Animal derived material
  - DEHP/phthalates
  - Latex containing
  - Carcinogen, mutagen, reproductive toxicant, endocrine disruptor
  - Bisphenol A & derivatives
  - Halogenated flame retardants
  - Nanomaterials
  - Ionizing radiation
  - PVC
- Sustainability
  - Post-consumer recycled content
  - Packaging recyclable
- Expanded regulatory attributes
  - Reprocessed, single use only
  - Limited number of reuse
  - Basic UDI-DI (family designation)
  - Critical warnings/contraindications
  - Country of origin
  - Shelf life
  - Calibration or maintenance required
  - Contains software
  - Contains batteries
Why would a manufacturer ever have multiple GTINs for the same product?

Large multi-national companies make the same products at multiple locations
- May have same catalog code, but different company identifiers for different target markets
- Government or military contracts may require a certain country of origin
- Some products may be needed for emergency response and global supply pool is critical
- De-centralized companies have different legal entities for different locations

The data syndicated needs to match the product received
- A GTIN hierarchy can only have 1 legal manufacturer
- A GTIN hierarchy can only have 1 country of origin
- Not all business partners understand or have a place to store the “equivalent product” data provided
National Code considerations

NTIN requirements: May cause significant localization activities and delay critical medical treatments. Also, safety responsibility would transfer from legal manufacturer to local importer depending on the level of marking needed.

Example - change to re-usable instruments:

- Importer will need to obtain QMS certification as a manufacturer
- Importer will have to unpack sterile goods
- Add equipment at local re-packaging sites to laser etch, re-print or attach labels and tags
- Re-package
- Re-sterilize
- Over-label all other packaging
- Data syndication would be highly customized and may not be submitted by OEM due to changes in manufacturing responsibility

In 3M experience - over-labelled packaging can be perceived as counterfeit or less desirable by the customer.
How do you manage all this data and these rules?
What is Data Governance?

Textbook Definition:

“Formalizing behavior around the definition, production, and usage of data to manage risk and improve quality and usability of data.”
Data Quality

• Quality Data is trusted and reliable.

1) Data Quality Rule Creation: **Declarative statements** the resolve to **True/False, Pass/Fail**

   *All dogs must be classified as Canines.*

2) Data Quality can be **measured** and **repeated**.

3) Accessible to consumers in the form of a **scorecard** that is **accessible** and easy to understand.
What it takes to build better data
3M UDI experience 2014-2018

• **Resources**
  - **Initiate:** 1 project manager, 1 syndication associate, 3 person data collection & cleanse team, 129 participants from other functions (Master Data, R&D, Regulatory, Quality, Marketing, Packaging & Labeling, Microbiology, etc.)
  - **Maintain:** 3 syndication associates, 1 health care governance team, 1 corporate governance team, and the entire company to maintain quality

• **Time**
  - 6 months of project & data architecture planning, 2+ years of system development & enhancement
  - 38 months of data collection & cleanse for 104 initial fields of approximately 17,000 SKUs
  - Currently managing over 2 million attribute fields across several systems, to multiple governments/customers/websites/registries/distributors

• **Change management + new attributes**
  - Each new attribute takes between 3-6 months to: Set governance, collect & cleanse initial values, identify data partners, and syndicate
  - Communication plan in place for eCommerce, regulatory and customer syndication, because many local 3M sites use the data beyond UDI now
  - Every product & data change has to go through regulatory review for impact to syndicated data.
Impact and Issues around Implementation of Barcodes
Noordwijk/Amsterdam March 26, 2019
Tatjana Pathare
About F. Hoffmann-La Roche

A pioneer in healthcare
We have been committed to improving lives since the company was founded in 1896 in Basel, Switzerland. Today, Roche creates innovative medicines and diagnostic tests that help millions of patients globally.
About F. Hoffmann-La Roche

• Company headquarters are located in Basel, Switzerland

• In 1934, it became the first company to mass-produce synthetic Vitamin C, under the brand name Redoxon

• In 1957 it introduced the class of tranquilizers known as benzodiazepines – brand names Valium and Rohypnol

• To present date we manufacture several cancer drugs

• Today Roche ranks among the world’s leading healthcare companies and has two strong core businesses: Diagnostics and Pharmaceuticals

• Frontrunner in personalised healthcare -With our combined strength in pharmaceuticals and diagnostics, we are better equipped than any other company to further drive personalised healthcare
Which barcode should I scan to get the relevant information on a single item?
Use the Digital Link!

GSI Healthcare has come up with a solution by providing a Digital Link standard to connect the existing GS1 DataMatrix barcode for more information WITHOUT adding a URL/URI in the barcode.
Digital Link standard - How does it work?

- Resolver

MANUFACTURER GIVES INPUT ON URL/s and CORRESPONDING GTIN/s

END USER SCANS 2D DATA MATRIX CODE USING AN APP FOR EXAMPLE AND GETS DIRECTLY TO THE INFORMATION
The prototype GS1 resolver (id.gs1.org)

| Item Description: | ESBRIET FILM COATED TABLETS 267 MG 21 |

Resolver Reference: [https://id.gs1.org/](https://id.gs1.org/)  
Global Trade Item Number: 07613326003872

**Resolver Destination Attributes for language**

<table>
<thead>
<tr>
<th>Attribute Name</th>
<th>Alternative Attribute Name</th>
<th>Response Destination URL</th>
</tr>
</thead>
</table>
WE need to address this now

As Regulators are already moving

**EU** – EC (European commission), EMA (European Medicines Agency) and HMA (Heads of Medicines Agencies) joint press release in January 2016: a 6-month public consultation on draft ‘Key Principles for the Electronic Product Information of EU medicines’

**Singapore** - Singapore HAS (Health Science Authority) is working with SAPI (Singapore Association of Pharmaceutical Industries) on a draft guidance on e-labelling

**Taiwan** – Taiwan FDA 2019 prioritizing objectives, one of them being e-labeling

Patients and Healthcare providers asking for trusted electronic information

*We should strive for a standard solution*
What are we planning to do with the Digital Link standard?

In the planning stage:
• Pilot in Belgium to link to a data base with eLeaflets for some medicines sold in Belgium and Luxembourg

• Pilot in Norway to link to a data base with eLeaflets for some medicines sold in Norway

.........And we can do more

• Add more features – info about recalls, adverse event reporting

• More proof of concept in other countries
TAKE HOME MESSAGE

USE ONE BARCODE AND USE THE DIGITAL LINK STANDARD
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3. Enable “Notifications” so that we can send you updates and announcements over the next few days.
4. Enter your email address (the same one used for conference registration)
5. Enter the password “GS1events” to log in.
Be sure to complete each feedback form!

For every feedback form completed in the conference app, GS1 will donate €5 to the chosen conference charity.
Need any help? Contact us!

Look for the turquoise scarves and ties - we are happy to help you!
Poster Reception tonight

Join us at 17:30 – 18:30 in Bentley Bar
Explore the world-wide healthcare success stories.
COFFEE BREAK
Additional supporting slides follow
Doing now what patients need next
Disadvantages of having too many codes on the pack

• Takes up valuable space package and label space - smaller font size of text on folding box /label/blister foil cavity to fit in the different codes

• Multiple barcode symbols can lead to potentially confusion for the user

OUR AIM – use only **ONE** barcode
Use the existing barcode so that the end users can use this code to get digital information

- **Linking** to verification as protection against counterfeiting
- **Linking** to information about the product (videos, audios, illustrations, texts…)
- **Linking** to electronic health records etc.
- And more
Example: Roche data for BE (a URL that directs the user to the product information)

<table>
<thead>
<tr>
<th>Packaging Level</th>
<th>GTIN</th>
<th>User Language</th>
<th>URL of Target Data Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>07640128018216</td>
<td>NL</td>
<td><a href="https://www.e-compendium.be/nl/bijsluiters/patient/1220/1530">https://www.e-compendium.be/nl/bijsluiters/patient/1220/1530</a></td>
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</tr>
</tbody>
</table>
What do you require?

• An app to scan the 2D Data Matrix code (some countries have their own apps / some solution providers)

• GS1 Digital Link standard

• Database containing the information (e.g. e-compendium.be; felleskatalogen.no)
Doing now what patients need next
Contact Details

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