Challenges in identification at point of care

Chaired by Charity Hovey, Project Manager, 3M, US

33rd Global GS1 Healthcare conference
Bogotá, Colombia
April 10, 2018
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National Centre for Hereditary Coagulation Disorders  
St. James Hospital  
Ireland

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France

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Manager Regulatory Affairs, Labeling Coordinator  
B. Braun/Aesculap AG  
Germany
Discuss unique challenges to identification at the point of care:

- Healthcare provider
- Drug & biologic manufacturer
- Reusable & implantable device manufacturer
Feargal Mc Groarty, National Haemophilia System Project Manager, St Jame’s Hospital, Ireland

33rd Global GS1 Healthcare conference
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Challenges in identification at the Point of Care

Feargal Mc Groarty, Project Manager,
National Centre for Hereditary Coagulation Disorders, St James’s Hospital, Ireland
Life could be so simple......!!!
What needs to be identified at the point of care?

- Patient
- Provider
- Location
- Medication/device
Non or wrong identification issues

- Incorrect surgery
- Wrong blood transfusion
- Incorrect intervention because of wrongly labelled samples
- Incorrect medication
Why is identification at the point of care important for Haemophilia?

- Haemophilia is a hereditary bleeding disorder caused by a deficiency of a clotting factor (protein)
- Characterised by excessive bleeding even after minor injury
- Incidence is between 1:5,000 and 1: 10,000 Males
- The treatment of haemophilia involves the replacement of the clotting factor (previously prepared from pooled blood) using a concentrated preparation "Clotting Factor Concentrate" (CFC)
- Treatment can be received at a number of care centres
- Patients self medicate in the home (Prophylaxis)
Haemophilia Care in Ireland

- 5,500 patients with inherited bleeding disorders
- 3 Comprehensive Care Centres
  - Dublin SJH
    - Adult
  - Dublin OLHSC
    - Paediatric
  - Cork CUH
    - Adult and Paediatric
Capture
Multi location EPR (Electronic Patient Record) deployment

National Haemophilia Center

Regional Haemophilia Centres

Care provider

Home access
Assigning a Unique identifier
Why unique identification is critical

• Information at point of care (including remote care)
• Decision support (at point of care including at home)
• Data capture to support research and service improvement
• Ability to recall
The solutions

- GS1 Barcoding
- National Electronic Patient Record
- Unique patient identification
- Home/Hospital track and trace
- Validated Cold Chain Delivery Service
Where does GS1 Fit?

- Manufacturer
- Cold Chain Supplier
- Medication
- GS1 Barcodes
- Patient
- Hospital
- Patient Home
Where is GS1 in our systems?

**Manufacturer**
- GS1 standard barcode on medication (serialised GTIN)

**Medication**
- All medication has GS1 barcode either labelled at source or overlabelled

**Cold Chain Supplier**
- Rewrote their WMS to accept GS1 identifiers including PMGSRN

**Hospital**
- EPR modified to produce GS1 PMGSRN

**Patient Home**
- Each patient home identified with a GS1 GLN

**Patient**
- Mobile Phone (cellphone) App used to scan GS1 PMGSRN and record medication compliance
Once in place, how do we use the unique identifier?
Smartphones with scanning App
Log-in

Secure Login by

• Scanning unique GS1 ID on Card
Scan Product

Barcode on Vial box is scanned to check

- Product detail (prescription)
- Expiry date
- Recall status
- Shorter dated stock
Process Complete

Process concludes, system synchronises data wirelessly to web application
### Home Scan System

**Bleed Report**  
23/06/2010 - 23/06/2010

<table>
<thead>
<tr>
<th>Date</th>
<th>Prophylaxis</th>
<th>Bleed Site Details</th>
<th>Products Name</th>
<th>Batch No.(s)</th>
<th>Units</th>
<th>Vials</th>
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<tbody>
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<td>LE01J025AY</td>
<td>1500</td>
<td>1</td>
</tr>
</tbody>
</table>

**TOTAL:**

16500  12
GS1 Patient ID for Ireland

Individual Health Identifier (IHI) Legislation:

- “the IHI Number will consist of a core 9 digits + 1 check digit, embedded within an 8 digit globally unique identifier.”

An **Overview Note** on the IHI number has been prepared by the HSE and is below.

- Overview note from HSE states:
  - **Table 2: Illustration of IHI Number format**

<table>
<thead>
<tr>
<th>Format</th>
<th>GS1 GSRN Prefix (Global identifier)</th>
<th>Core IHI Number</th>
<th>Core IHI Number check digit</th>
<th>Final GS1 check digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Format</td>
<td>9999-999</td>
<td>999-999-999</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Illustrative example</td>
<td>5393-014</td>
<td>923-456-789</td>
<td>1*</td>
<td>2*</td>
</tr>
<tr>
<td>Full example IHI Number</td>
<td>5393-014</td>
<td>923-456-789</td>
<td>1*</td>
<td>2*</td>
</tr>
</tbody>
</table>

*check digits are not valid – demonstration only
Acknowledgements

All staff in National Centre for Hereditary Coagulation Disorders, in particular…..

- **Dr. Barry White** (Clinical Director)
- **Evelyn Singleton** (National Co-ordinator for CFC)
- **Rachel Bird** (National Haemophilia system data manager)
- **Vincent Callan** (Director of Facilities Management)
Thank you for listening!
Identification at the Point of Care
Unit Dose Marking
Tatjana Pathare
About Roche

A pioneer in Healthcare

- Founded in 1896 by Fritz Hoffmann-La Roche
- 1897 onwards Roche starts to expands worldwide
- 1968 Roche enters Diagnostics Market

TODAY – ROCHE CREATES INNOVATIVE MEDICINES AND DIAGNOSTIC TEST THAT HELP MILLIONS OF PATIENTS GLOBALLY

- Largest Biotech Company
- Frontrunner in Personalised Healthcare
- Global leader in Cancer Treatments
How Did Everything Start at Roche?

2011 – Vial Label Adaptation

Before

Barcode for internal identification

After

GS1 DataMatrix with GTIN

Barcode for internal identification
First Attempts to Meet Hospitals Needs (as of 2011)

*Static GS1 DataMatrix with GTIN only*

- **AMGROS Requirement in Denmark**
  (except for blisters)

- **Voluntary implementation for all injectables in Switzerland**

- **Voluntary implementation for infusion solution vials for all EU countries**
  (centrally registered products)

*Pictures for illustrative purposes only. Do not reflect the actual layout for the specific market.*
Issues and Challenges

Multiple Constraints Making It Difficult to include a Barcode

- Very small containers
- Reflecting lidding foil of blister
- Amount of text and font
- What is more important? Text or barcode?

Font size: 5 pt

Font size: 3.25 pt
Issues and Challenges

*Multiple Constraints Making It Difficult to include a Barcode*

- Readability of barcode on syringes with safety device
- GTIN on bottle = 50 tablets, not 1 tablet!
- GTIN on multi-dose vials = full content, not single dose!
- GTIN on non single-unit blister = 21 capsules, not 1 capsule!
Phased Deployment Approach at Roche

*Addressing Complexity by Technology*

**Labels** (bottles, parenterals, syringes)

- **GTIN only**
- **GTIN + Expiry date + Batch number**

**Blisters** (single unit)

- **GTIN only (per cavity)**
- **GTIN + Expiry date + Batch number (per cavity)**

GS1 DataMatrix content

1 element (static)

3 elements (variable)
Phased Deployment Approach at Roche

Status of Implementation

1a. GTIN only (static) on labels
- Easy to implement if label format and text font size allow
- Implemented on 70% of Roche vial labels

1b. GTIN only on single unit blisters
- Does not require online printing equipment (part of artwork)
- Blister format and text font size to be checked
- Anti-reflection lidding foil material

2a. GTIN+Exp+Lot on labels
- Requires online printing equipment
- Label format and text font size to be checked
- Implemented on 10% of Roche vial labels (started in 2017)

2b. GTIN+Exp+Lot on single unit blisters
- Requires online printing equipment
- Blister format and text font size to be checked
- Anti-reflection lidding foil material
Solve Technical Issues

- Technical challenges requiring new label formats and enhanced lidding foil non-reflective material require **substantial investments** to be solved.

Implement Processes and Systems

- Line equipment alone is not sufficient to allow single unit coding. All **surrounding processes and systems** must be in place (IT, master data, label change management)

Prioritize Project Internally

- Single Unit Coding projects at manufacturers are **competing** with other regulatory-driven projects and might get de-prioritized in case they do not directly impact regulatory compliance.
Internal Challenges

During the project

- **Technical Issues**
  - Barcode **printing quality** (grading) on online equipment requires further improvement
  - **Line performance** (productivity) can be negatively impacted by the additional barcode printing step
Take Home Messages

- Promote wider **use** and **scanning** of **GS1 barcodes** on the labels
- We are open to hospitals’ **feedback** for improvements
- Use of **GS1 standards** (**DataMatrix, GTIN**) is key, with inclusion of Lot/Batch Number and Expiry Date where possible
- Potential use of **GDSN** to share product information at unit dose level
- Leverage **exchange platforms** (like this conference) to better collaborate and understand each other’s needs
Doing now what patients need next
Georg Keller, Manager Regulatory Affairs, Labelling Coordinator, B.Braun / Aesculap AG, Germany

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GS1 HEALTHCARE CONFERENCE
CHALLENGES IN IDENTIFICATION AT POINT OF CARE
Georg Keller  Manager Regulatory Affairs/Coordinator UDI/Labeling
Bogota, April 10 2018
We have competence in 18 therapy fields.

<table>
<thead>
<tr>
<th>Therapy Field</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Blood Purification</td>
<td><img src="image1.png" alt="Image" /></td>
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<tr>
<td>Apheresis</td>
<td><img src="image2.png" alt="Image" /></td>
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<tr>
<td>Cardio-Thoracic Surgery</td>
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<tr>
<td>Continence Care and Urology</td>
<td><img src="image4.png" alt="Image" /></td>
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<tr>
<td>Degenerative Spinal Disorders</td>
<td><img src="image5.png" alt="Image" /></td>
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<tr>
<td>Diabetes Care</td>
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<tr>
<td>General Open Surgery</td>
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<tr>
<td>Hemodialysis</td>
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<tr>
<td>Infection Prevention</td>
<td><img src="image9.png" alt="Image" /></td>
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<tr>
<td>Infusion Therapy</td>
<td><img src="image10.png" alt="Image" /></td>
</tr>
<tr>
<td>Interventional Vascular Diagnostics and Therapy</td>
<td><img src="image11.png" alt="Image" /></td>
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<tr>
<td>Laparoscopic Surgery</td>
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<td>Neurosurgery</td>
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<tr>
<td>Nutrition Therapy</td>
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<td>Orthopaedic Joint Replacement</td>
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<td>Ostomy Care</td>
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<tr>
<td>Pain Therapy</td>
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</tr>
<tr>
<td>Wound Management</td>
<td><img src="image18.png" alt="Image" /></td>
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</table>
Aesculap focuses on products and services for all surgical processes and interventional cardiology – from surgical instruments and implants to suture materials.
UDI Requirements Overview

1. Standardized Numbering for unambiguous Device Identification (UDI)
   - ISO-based Numbering
     - Master Data

2. UDI on the Label or on the Medical Device itself
   - human readable and machine readable Format
   - Barcode Identification
     - Barcode

3. Central UDI-Database with further information to the Medical Devices
   - Data Maintenance & Exchange
     - Processes

Aesculap AG
AIDC : Label Samples (DI + PI included)

- Avoid multiple barcode on the same level
- Barcode on product or patient stickers to serve
- Implant Registries
- Implant Card ("new" MDR requirement for Class III implants)
- Documentation (Health Records)
- Inventory Control
- Re-ordering Process
- Reimbursement

GS1-128 (concatenated)

GS1-DataMatrix

GTIN (GLOBAL TRADE ITEM NUMBER)
LOT NUMBER
EXPIRY DATE

 UDI is used for scanning
 Data exchange with own standards
Reusable Devices ...

... requiring sterilization or high-level disinfection between uses e.g. surgical instruments

- UDI must be on the device
- UDI must be readable after each sterilization or high-level disinfection
- UDI Production Identifier be defined by the manufacturer according the QM system - e.g. lot or serial no

Exceptions possible
- DM interferes with the safety or effectiveness of the device
- DM technically not feasible

Direct Part Marking (DM) or other permanent marking method!

FDA: When a device must bear a UDI as a direct marking, the UDI may be provided through either 'Plain Text' or 'AIDC' or both.
EU-MDR: 'Plain Text' and 'AIDC'.
Marking Technologies

- Possible corrosion (passivation steps)
- Annealing marking fading
- Rough surface no readable code

- Resistant against corrosion
- Independent from viewing angle
- Different Materials and surface possible to mark

- high-quality Direct Marking technology required
  - (laser, etc)

<table>
<thead>
<tr>
<th></th>
<th>Laser etching with Picosecond laser</th>
<th>Structural bonding</th>
<th>Common laser etching</th>
<th>Engraving</th>
<th>Dot peen</th>
<th>Electro-chemical marking</th>
<th>Labeling</th>
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<tbody>
<tr>
<td>Durable</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
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<td>Not detachable</td>
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<td>☺️</td>
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<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
</tr>
<tr>
<td>Surface not damaged and corrosion resistant</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
</tr>
<tr>
<td>Able to be applied to limited area</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
<td>☺️</td>
</tr>
</tbody>
</table>
DM : AIDC vs. Human Readable Information (HRI)

- Size of data matrix can be at a minimum 2mm (GS1 Gen. Specs) with the current data content.
- Current reading technologies would allow to read below 1mm.
- Human Readable Information by itself is compliant with regulation, but is it useable? Or readable?

AIDC should be preferred.
Use of Direct Marking (DM)

Scanning Data-Matrix with common technologies - e.g. smartphone or tablet

Access product data, instructions - cleaning, reprocessing, assembling
Tracking

Where to track?

- Completeness check at the assembling place
- Maintenance intervals
- Frequency of Uses
- Reduction of Instrument losts
- Management of single instrument

Assembling requires:
- good reading technologies
- documentation system
THANK YOU
FOR YOUR TIME