GS1 Healthcare Provider Advisory Council (HPAC) Webinar
Traceability in Healthcare

Janice Kite – GS1 Global Office
13 February 2014
HPAC Case Study Webinars

• This is the FIRST Webinar!

  “The link between Traceability and Patient Safety”

• It will be recorded!

• Webinars will take place monthly

  • Future webinars will showcase Provider Implementation Case Studies
## HPAC Case Study Webinars

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Details here: [http://www.gs1.org/healthcare/hpac_webinars/](http://www.gs1.org/healthcare/hpac_webinars/)
About GS1 and GS1 Healthcare Provider Advisory Council (HPAC)
Who is GS1?
An international standard organisation

Not-for-profit
111 Member Organisations
Over one billion members
(from SME to global companies)
Member driven
150 countries served; 20 different domains
2,500 people helping us
Over 6 billion transactions a day
About HPAC

Formation:
- December 2010

Objectives:
- A forum for sharing and discussing the practical realities of implementation of GS1 Standards
- Identify implementation projects that support the adoption of GS1 Standards
- Identify best practices and case studies for publication
- A source of expertise

Scope:
- HPAC consists of thought leaders and early adopters of GS1 Healthcare Standards from the provider environment and GS1 Member Organisations (MOs); Restricted membership.

Find out more: http://www.gs1.org/healthcare/hpac
Community Room: http://community.gs1.org/apps/org/workgroup/gs1hpac/
HPAC – Who?

Tri-Chairs – Clinical
• Feargal Mc Groarty FIBMS, Project Manager, IMS Dept., St. James’s Hospital, Dublin, Ireland

Tri-Chairs – Non-Clinical
• Frédérique Fremont, Medico-Technical Department manager and Organisation Engineer, C.H.I Robert Ballanger, Aulnay-sous-Bois, France

Tri-Chairs – GS1 Member Organisation (MO)
• Doris Nessim, Vice President Pharmacy, Patient Safety & eHealth, GS1 Canada

GS1 Facilitator
• Janice Kite MBA, Traceability Director Healthcare, GS1 Global Office
• Educational C-Suite Slide Deck
  http://community.gs1.org/apps/org/workgroup/gs1hpac/download.php/52286/latest

• Position Statement on Barcode Issues:

• Position Statement on Interoperability of IT Systems
GS1 HEALTHCARE PROVIDER AWARDS

TWO AWARDS:

• **Provider Recognition Award**
  [http://www.gs1.org/sites/default/files/docs/healthcare/20130812_GS1_Healthcare_Recognition_Award_Application.docx](http://www.gs1.org/sites/default/files/docs/healthcare/20130812_GS1_Healthcare_Recognition_Award_Application.docx)
  - The nominee has implemented GS1 Standards for at least ONE process in their organisation with clear & demonstrable Return on Investment (ROI).
  - Active participation in GS1 Standards development work.
  - Recognised as GS1 Standards advocate (locally or regionally or internationally).

• **Provider Implementation Best Case Study Award**
  [http://www.gs1.org/sites/default/files/docs/healthcare/20130812_GS1_Healthcare_Best_Provider_Implementation_Case_Study_Application.docx](http://www.gs1.org/sites/default/files/docs/healthcare/20130812_GS1_Healthcare_Best_Provider_Implementation_Case_Study_Application.docx)
  - The nominee has implemented GS1 Standards for at least ONE process in their hospital/clinic/care home/pharmacy/department with clear and demonstrable Return on Investment (ROI)

• **Details & Application forms:** [http://www.gs1.org/healthcare/hpac](http://www.gs1.org/healthcare/hpac)

**Deadline for submission 30th June 2014**
The link between Traceability and Patient Safety
Webinar Content

- Drivers
- Regulations
- GS1 Traceability in Healthcare
  - Strategy
  - Added Value of Traceability
  - Global Traceability Standard for Healthcare (GTSH)
    - Key GTSH Concepts
    - Key GTSH Definitions
- GTSH Implementation Guideline
- Implementation Case Studies
Healthcare Traceability
Drivers
Key Drivers

Regulations emerge worldwide
Supply Chain costs increase
Electronic Health Records
Medication errors
Counterfeiting
Brand Protection
Healthcare Scenario –
Crisis and Impact

Fake drugs

Online risks

Sub-Standard Implants

Faulty Implants

http://news.bbc.co.uk/1/hi/health/7865246.stm
http://www.mhra.gov.uk/NewsCentre/CON216891

Video

Globally Approximately 400,000 women may have PIP gel implant products implanted.

2001: PIP began to use non-medical-grade, silicon oil
2009: Concerns surfaced about rupture rates; results were poor
2010: March PIP placed under safety agency recall
2011: December 23, following French women seek compensation

The story (Poly implant prothèse)

BUT: Recalls and recalls

2012: MHRA recognise a small number of patients with large metal on metal full hip replacements could develop complications.
28 February MHRA issued patient management/advice to surgeons and doctors to monitor patients every year for the lifetime of their metal on metal total hip replacements

25 Jun Press release: MHRA tells surgeons to stop using R3 metal cup liner and extends patient monitoring advice

Patient identification improved by National Joint Registry but traceability in hospitals lacking

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New McKinsey & Company report quantifies supply chain issues in Healthcare

New McKinsey report “Strength in unity: The promise of global standards in healthcare”

Highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in healthcare

Available at:
http://www.gs1.org/healthcare/mckinsey or
Huge cost savings and patient safety benefits when adopting a single global standard in healthcare

• “Implementing global standards across the entire healthcare supply chain could save 22,000-43,000 lives and avert 0.7 million to 1.4 million patient disabilities”

• “Rolling out such standards-based systems globally could prevent tens of millions of dollars’ worth of counterfeit drugs from entering the legitimate supply chain”

• [We] “estimate that healthcare cost could be reduced by $40 billion-$100 billion globally” from the implementation of global standards

• “Adopting a single set of global standards will cost significantly less than two” (between 10-25% less cost to stakeholders)

GS1 Traceability in Healthcare
GS1 in Healthcare: global system of standards

**IDENTIFY:** GS1 Standards for Identification

- GLN Global Location Number
- GTIN® Global Trade Item Number
- SSCC Serial Shipping Container Code
- EPC Serialized Global Trade Item Number

**CAPTURE:** GS1 Standards for Automatic Identification & Data Capture

- GS1 BARCODES
  - EAN/UPC
  - GS1-128
  - EPC-14
  - GS1 DataBar
  - GS1 DataMatrix
  - EPC HF Passive
  - EPC UHF Passive

**SHARE:** GS1 Standards for Automated Data Exchange

- MASTER DATA
  - GS1 Registry for Healthcare® Global Data Synchronization Network® (GSN®)
  - TRANSACTIONAL DATA
  - aCode (EDD)
  - EVENT DATA
  - EPC Information Services (EPCIS)

**TRADEABLES:**

- Track
- Trace
- Authentication
- Chain of Custody / Ownership
- Returns
- Recalls

**INTEROPERABILITY:**

- Item Master Data
- Location Data
- Item Tracking
- Order to Cash
  - (Purchase Order, Dispatch, Invoice)
- Traceability
  - (Track & Trace, Pedigree, Authentication)
- Product Recalls/Withdrawals
GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production¹ to Point of Use²

- All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** (AI, e.g. Serial No. AI(21)), if applicable, at point of production
- Supply chain identifiers are associated with the patient and remain with/on items throughout their intended useful life
- All **physical locations** are identified with the appropriate **GS1 Identification Key** (e.g. GLN) across the entire supply chain
- All **patients and care givers**, when in a care giving environment, are identified with the appropriate GS1 identification Keys
- Agreed **master data** is captured and shared (e.g. via GDSN) amongst trading partners
- Agreed **transactional data** is captured and shared (e.g. via business-to-business messaging) amongst trading partners
- Agreed **event data** is captured and shared (e.g. via EPCIS) amongst trusted traceability stakeholders, based on data sharing/security policies

SO THAT:

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed
GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production\(^1\) to Point of Use\(^2\)

SO THAT:

- Items can be **tracked** (forward / downstream) across the entire supply chain (production to use) in real time
- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time
- Item identification is available for use at patient bedside to ensure the Patient Rights\(^3\) are achievable
- Patients Electronic Health Records (EHRs) are updated with agreed traceability information, including Care Giver identification
- Counterfeit products are detected when entering the legitimate supply chain
- A **product recall** would be fast, efficient and effective

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1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed
3. Pharmaceuticals (5): Right patient, right drug, right dose, right route, right time. Medical Devices (8): right device, right location, right time, right condition, right procedure, right anatomic site, right patient, right user
Global Traceability Standard for Healthcare (GTSH)

GTSH Implementation Guide
Terminology - GTSH

• Defines a **process independently** from the choice of enabling technologies
• Defines **minimum traceability system requirements** for organizations of all sizes and level of operational maturity
• Details the **corresponding GS1 [technical] standards** used within information technology tools
• Meets the **core legislative and business needs** to cost-efficiently track forward (one step down) and trace back (one step up) at any point along the entire length of the supply chain
• Describes the creation of **accurate records** of transactions and events
• Provides for **fast data communication** about traceable items between trading partners

**The GS1 Global Traceability Standard for Healthcare is not:**
• A law or regulation
• A replacement for safety or quality programs
Traceability – a definition

“Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration”.

GS1 GTSH Issue 1.0.0, Feb-2009
Implementing a traceability system within a supply chain requires all parties involved to systematically link the physical flow of materials and products with the flow of information about them.
Common themes

• Global Traceability Standard for Healthcare (GTSH) is a PROCESS Standard
• Definition of Traceability: both track & trace (downstream/upstream; forwards/backwards)
• In parallel with the flow of product there has to be a flow of information about the product
• Throughout the entire supply chain:
  • There is Internal and External Traceability
  • Inputs (e.g. receipt) must be linked to outputs (e.g. shipments / dispensing)
  • Parties can have varying roles
  • Business Requirements = Needs
  • Business Rules = control and/or constraints
Case Studies
Setting the scene
Case Studies: Setting the Scene

• **Source:** GS1 Reference Books *(2009/10, 2010/11, 2011/12, 2012/13, 2013/14)*
• **The examples are**
  • High level summaries
  • Locations around the world
  • Different points of supply chain
• **Common themes**
  • Implementation from receipt to patient takes time *(YEARS)*
  • Multi-project work programme
  • Involves all parties across the supply chain *(inc. GS1 MOs)*
  • Focus on solving key issues
  • All efforts have lead to improved patient safety
  • One size does NOT fit all!

[Links to GS1 Reference Books for different years]

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## GS1 Standards help save €106 million in Dutch hospitals (2011)

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<th>Issue(s)</th>
<th>Solution</th>
<th>Results</th>
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| • Increased pressure to improve patient safety and save costs in hospitals  
• Suboptimal management of inventory of medical devices for OR  
• Manual processes for ordering, billing, recall | • Implementation of effective IT infrastructure to track and trace products throughout the supply chain  
• Implementation of GS1 Standards, including GTIN, GLN and Global Traceability Standard | **Medical device inventory mgmt for OR - potential savings across 100 Dutch hospitals: €106 million (conservative estimate)**  
• Estimated cost to implement system per hospital: €173k (non-recurring) and €218k (annually recurring)  
• Estimated ROI per hospital in year 1: €668k; year 3: €2.5m  
• Reducing inventory levels by approx. 20%  
• Decreasing obsolete stock by approx. 80%  
• Reducing handling expenses for stock replenishment by 25%  
• Accelerating recall procedures  
• Increasing effective use of consignment goods |

- **UMC Nijmegen** - a 953-bed university hospital  
- **UMC Utrecht** - a 1,042-bed university hospital  
- **Ziekenhuisgroep Twente** - a 1,085-bed hospital group  
- **St. Antonius hospital** - a 880-bed hospital group
GS1 Standards help save 7% in medication purchasing and packaging in North York General (2006)

**Issue(s)**

- Risk of medication errors at the point-of-care due to insufficient product identification
- Lack of unit-dose bar coding of medication

**Solution**

- Installation of an automated repackager and bar coding station
- Implementation of a point-of-care bar code verification system to ensure the five patient rights
- Implementation of GS1 Standards, incl. GTIN and GS1 BarCodes

**Results**

**Reduced medication errors at the point-of-care**

**Cost savings of 7-8% each year in terms of its medication purchasing and packaging activities**

- Estimated cost to implement system in the hospital: €248k
- Efficiently affixing bar codes to unit doses
- Efficient bedside verification
GS1 Standards help enable traceability of surgical instruments at CHI Robert Ballanger (2009)

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| • Ineffective tracability of 22,000 surgical instruments during sterilization process | • Implementation of a traceability system  
• Lasermarking of surgical instruments with GS1 DataMatrix 2D barcode  
• Implementation of GS1 Standards, including GTIN, GLN and Global Traceability Standard |

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| Effective traceability of surgical instruments during sterilization process | • Increased inventory management  
• Increased traceability down to the individual instrument level  
• Migration of instruments between boxes now traced                      |
GS1 Standards help save €5 million worth of stock at St. James’s Hospital (2010)

Issue(s)

- Infected medication remained in the supply chain after recall in 2001-leading to subsequent infection and over 80 deaths
- Lack of standardised bar codes on haemophilia medication and ineffective traceability

Solution

- Deployment of multi-location Electronic Patient Record system
- Deployment of medication delivery traceability system
- Implementation of GS1 Standards, including GTIN, GLN, GS1 DataMatrix

Results

Over €5 million worth of medication stock has been removed from the supply chain

- Product wastage reduced from €90,216 to zero in the year post service implementation
- Documentation errors reduced from 12 to zero in the year post service implementation

Mock recall identified location of all (100%) medication within 10 minutes

St James’s Hospital, Dublin (Ireland) – manages the National Centre for Hereditary Coagulation Disorders (NCHCD)
Join HPAC?

- **Find out more:**  [http://www.gs1.org/healthcare/hpac](http://www.gs1.org/healthcare/hpac)
- **Community Room:**  [http://community.gs1.org/apps/org/workgroup/gs1hpac/](http://community.gs1.org/apps/org/workgroup/gs1hpac/)
- **Publications:**
  - Educational C-Suite Slide Deck  
  - Position Statement on Barcode Issues:  
  - Position Statement on Interoperability of IT Systems  
- **Healthcare Provider Awards**…  [http://www.gs1.org/healthcare/hpac](http://www.gs1.org/healthcare/hpac)
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