GS1 standards
Primer session
31st Global GS1 Healthcare conference
Berlin, Germany

04 April 2017
Agenda of the session

1. GS1 Healthcare, the global perspective
   Chuck Biss
2. Automatic Identification Data Capture
   Chuck Biss
3. Master Data Management
   and Global Location Numbers
   Pete Alvarez
4. Electronic Data Interchange (EDI)
   Craig Alan Repec
5. Event-Based Traceability (EPCIS)
   Craig Alan Repec
GS1 Healthcare, the global perspective

Chuck Biss, Senior Director, ADIC Healthcare, GS1 Global Office
GS1, most widely used standards
GS1 ensures end-to-end visibility in the supply chain

Identify: GS1 standards for identification
- GLN Global Location Number
- GTIN Global Trade Item Number
- SSCC Serial Shipping Container Code
- GIAI Global Individual Asset Identifier
- GSIN Global Service Relation Number

Capture: GS1 standards for barcodes and EPC/RFID
- GS1 barcodes
  - EAN/UPC
  - GS1-128
  - ITF-14
  - GS1 DataBar
  - GS1 DataMatrix
  - GS1 QR Code
- GS1 EPC/RFID
  - EPC HF Gen 2
  - EPC UHF Gen 2

Share: GS1 standards for data exchange
- Master data: GLN Registry for Healthcare®, Global Data Synchronisation Network (GDSN)
- Transaction data: GS1 EDI
- Visibility event data: EPC Information Services (EPCIS)

Interoperability:
- Item master data
- Location data
- Item tracking
- Order to cash (Purchase order, despatch advice, invoice)
- Traceability (Track and trace, pedigree, authentication)
- Product recall/withdrawal

The Global Language of Business
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GS1 enables

- Patient safety
- Lower costs
Global reach, local presence

110+ Member Organisations
More than 1,000,000 member companies
150 countries served
2,000 + employees
To lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies.
Our vision 2005

The vision of GS1 Healthcare is to be the **recognised, open and neutral** source for regulatory agencies, trade organisations and other similar stakeholders seeking **input** and **direction** for **global standards** in healthcare for

- **patient safety**
- **supply chain security & efficiency**
- **traceability**
- **product data**
GS1 Healthcare: an expanding, committed community of globally engaged stakeholders...

...and there are many more companies working with GS1 at a local level
...as well as with leading healthcare providers to implement...
...and with global organisations...
Automatic Identification and Data Capture in Healthcare ...an AIDC short course

Chuck Biss, Senior Director, ADIC Healthcare, GS1 Global Office
GS1 standards

Identify

Capture

Share

GS1 standards for identifying, capturing, and sharing information—about products, business locations, and more—make it possible for companies to speak the same language, connect with each other and move their business forward.
Automatic Identification and Data Capture (AIDC) refers to the methods of **automatically identifying** objects, **collecting data** about them, and **entering that data** directly into computer systems (i.e., without human involvement).”

*Wikipedia, 2009*
GS1 standards... and AIDC

Identify: GS1 standards for identification

Capture: GS1 standards for barcodes and EPC/RFID

Share: GS1 standards for data exchange

Pete will cover next...
EVERY item has ONE set of key identification data carried in ONE data carrier able to be scanned by EVERYONE at every key process step…
Scope - All healthcare products...

Pharma / Vaccine / Nutritional
Retail

Medical devices
Non-retail
Scope – ID at all packaging levels...

NOTE:  * - Potentially a new definition that is needed...

Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.
Scope - Data & Data Carriers...

**Data** – a few examples:
- Global Trade Item Number (GTIN)
- Expiry Date
- Batch / Lot
- Serial Number

**Data Carriers** – a few examples:
- GS1-128 & GS1 DataBar
- GS1 DataMatrix
- EPC / RFID
Foundation of the GS1 System...

**GS1 Identification Keys**

Provide access to information held in computer files – Information about company/location, package, product, price, etc.

1234567891234
GS1 Identification Keys...

- Item identifier = GTIN
  Global Trade Item Number

- Logistics unit identifier = SCC
  Serial Shipping Container Code

- Location identifier = GLN
  Global Location Number

...and there are more ...

- Unique
- Non-significant
- International
- Secure
- Foundational
...but sometimes there is need to capture data beyond basic item ID...

- Item identifier
- Expiry date
- Batch/Lot number
- Serial number

Trade Item Attributes
The GS1 General Specification includes 100+ "Application Identifiers" ("Key Attributes" or "AI’s") for various use cases & various sectors

..however the Application Identifiers most commonly used at this time (in various combinations) in Healthcare are:

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>GTIN (Global Trade Item Number)</td>
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<tr>
<td>10</td>
<td>Batch / Lot</td>
</tr>
<tr>
<td>11</td>
<td>Production Date</td>
</tr>
<tr>
<td>17</td>
<td>Expiry Date</td>
</tr>
<tr>
<td>21</td>
<td>Serial Number</td>
</tr>
</tbody>
</table>

Note – Other than certain efficiency recommendations within the GS1 General Specifications, the order of AI’s is not significant and should not be mandated.
GS1 Data carriers for Healthcare...

GS1-128 & GS1 DataBar

Preferred options if:
✓ Package size allows

GS1 DataMatrix

Preferred option if:
✓ Large amounts of data in a small space
✓ Variable information at high production rates
✓ Direct part marking

EPC/RFID

Additional option
✓ Non-line of sight
✓ Large amounts of data

Imager based bar code scanners are needed in HC!!

Important note for new implementations or systems updates
GS1 System Standards

GS1 General Specifications – the ONE global standard for AIDC in Healthcare
• The core standards document of the “GS1 System”... describes how GS1 keys & data carriers should be used
  - Available online at:

GS1 Healthcare GTIN Allocation Rules – GTIN assignment in Healthcare
• A guide to GS1 ID Key assignment... the GS1 GTIN Allocation Rules presented in Healthcare related terms with Healthcare specific examples – Available online at:

Many countries have already adopted GS1 Standards... and we anticipate many more!
Throughout the conference sessions there will be AIDC related presentations... as examples (but not limited to):

**Tuesday 14:00 – 15:30 – Bedside scanning**
- Mr. Rob Moss, Director of Professional Development, EAHP
- Mr. Johannes Ros, Pharmacist, Gelre Hospital, Netherlands
- Mr. Pascal Aulagnet, Market Client Partner, Europe Middle-East & Africa, Pfizer

**Tuesday 16:00 – 17:30 – Hospital Implementation**
- Mr. Andrew Raynes, Barking, Havering and Redbridge University Hospitals NHS Trust, UK
- Mr. Terry Hoy, Regional Supply Chain Manager, South West Supply & Logistics, South West Healthcare

**Wednesday 14:00 – 15:30 – Ask the Experts: GS1 DataMatrix/HRI**
- Chuck Biss - Senior Director, AIDC Healthcare – GS1 Global Office
Contact Information

Chuck Biss
GS1 Global Office
Senior Director, AIDC Healthcare
T  +1 315 252 5941
M  +1 315 480 2034
chuck.biss@gs1.org
Master Data Quality and Global Location Numbers

Inaccurate or bad data adds risk and cost

Peter Alvarez, Senior Director, Identification and Data Strategy, Healthcare
GS1
4 April 2017
Topics

• The Value of Trusted Data
• The Global Data Synchronisation Network
• Global Location Numbers & the GLN Service
The value of trusted data

Better patient care & improved efficiency

- Seamless order to cash
- Warehouse management
- Collaboration
- Traceability
- Lower costs
- Safer and better treatments
What happened to Master Data?

- Systems have evolved in “silos” over the last 40+ years
- The link between “process” and data was broken (*remains so in many cases*)
- Numerous efforts to “unify” data and process, or views of data – one use at a time
- **So what?** Businesses operated and *so did hospitals*
- **Only when costs increase, profits fall, or a patient is negatively affected** does the real impact of bad data become known!

Original source: Gartner
Digital and mobile disruption
Data errors in healthcare

### U.S.A Department of Defense Study

<table>
<thead>
<tr>
<th>% of Total Data Error</th>
<th>Manufacturer</th>
<th>Distributor</th>
<th>GPO</th>
<th>Healthcare provider</th>
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<tbody>
<tr>
<td>Missing Middle Levels of Packaging</td>
<td>15-20%</td>
<td>1-4%</td>
<td>20-25%</td>
<td>15-25%</td>
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<tr>
<td>Hard “Packaging Quantity” Errors</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
<td>2-5%</td>
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<tr>
<td>Unit of Measure Confusion/Misuse</td>
<td>2-6%</td>
<td>1-3%</td>
<td>2-5%</td>
<td>Unknown</td>
</tr>
<tr>
<td>Missing Packaging—not Middle Level</td>
<td>3-8%</td>
<td>3-8%</td>
<td>3-7%</td>
<td>5%</td>
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<tr>
<td>Manufacturer Name Problems</td>
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<td>2-5%</td>
<td>1-4%</td>
<td>30%</td>
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<tr>
<td>Obsolete Products</td>
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<td>2-5%</td>
<td>1-8%</td>
<td>5-15%</td>
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<tr>
<td>Missing Product Brand Names</td>
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<td>5-10%</td>
<td>5-10%</td>
<td>20-25%</td>
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<tr>
<td>Incomplete Item Descriptions</td>
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<td>3-12%</td>
<td>5-15%</td>
<td>10-20%</td>
</tr>
<tr>
<td>Wrong Customer Unit Prices</td>
<td>Unknown</td>
<td>1-2%</td>
<td>NA</td>
<td>1-2%</td>
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<tr>
<td>Customer Paid More Than Lowest Contract Price</td>
<td>NA</td>
<td>Unknown</td>
<td>NA</td>
<td>3-6%</td>
</tr>
</tbody>
</table>

Australian data crunch: The cost of bad data

By conservative estimates, more than $100 million in potential savings can be achieved by addressing product data quality issues by making only minor adjustments to existing processes.

Source: https://www.gs1au.org/resources/publications/

Order-to-cash before data synchronisation

1. Product Info sent
   - Errors in transposition

2. Product Info entered
   - Errors in Translation
   - Errors in Delivery / Transmission

3. Purchase Order

4. Query Order Errors

5. Adjusted Purchase Order

6. Despatch Advice

7. Goods Delivered

8. Query Delivery Errors / Claim for credit

9. Return Incorrect Goods

10. Adjusted Delivery

11. Delayed Settlement

Incorrect
Item #s
Prices
Desc
Qty
The Global Data Synchronisation Network

• 37 certified GSN Data Pools
• 1.8+ million healthcare products
• 3,500+ suppliers
• Published to 83 countries

GDSN Information: http://www.gs1.org/gdsn
Order-to-cash after data synchronisation

1. Populates
2. Publishes

3. Purchase Order

4. Query Order Errors
5. Adjusted Purchase Order

6. Despatch Advice

7. Goods Delivered

8. Query Delivery Errors / Claim for credit
9. Return Incorrect Goods
10. Adjusted Delivery
11. Delayed Settlement

Supplier / Broker

Buyer

The Global Language of Business
The Global Locations Number (GLN) and the GLN Service
The problem with location identification

Many different names
different location numbers
for 1 hospital

SAINT JOHN'S QUEENS HOSPITAL
1100004570208

ST JOHN'S QUEENS HOSPITAL
100084547

SAINT JOHNS QUEENS HOSPITAL
JAOE

SAINT JOHN'S QUEEN HOSPITAL
50003000431

SAINT JOHN'S QUEEN’S HOSPITAL
CA2053

ST. JOHN'S QUEENS HOSPITAL
OM 12345
Why use Global Location Numbers (GLN)

• A global standard for identification of legal entities and physical locations
• A GLN is an identification Key

• Vital for GS1 eCom messaging so that all parties and locations may be uniquely identified
• A pre-requisite for Global Data Synchronisation
The GLN Service: Global exchange of GLN master data

Single point of access to GLN Master Data, globally, via the local GS1 Member Organisation

Information: [http://www.gs1.org/gln-services](http://www.gs1.org/gln-services)
Data sessions this week

**Wednesday 14:00 – 15:30 – Panel Discussion: Medical Device Identification and Data Management**
- Linda Sigg, U.S. FDA
- Terrie Reed, U.S. FDA
- Georg Keller, B. Braun/Aesculap
- Jackie Elkin, Medtronic, Inc.
- Volker Zeinar, B. Braun

**Thursday 10:15 – 10:40 - Master data management with GDSN**
- Michaela Berlich, University Hospital Schleswig-Holstein
- Dr. Hajo Reissmann, University Hospital Schleswig-Holstein
Contact Information

Peter Alvarez  
GS1  
Senior Director, Identification and Data Strategy  
+1 609 557 4547  
peter.alvarez@gs1.org
EDI in Healthcare

Craig Alan Repec
Senior Manager, Supply Chain Visibility, EPCIS & RFID
Information sharing

INFORMATION FLOW

MASTER DATA
E.G. CONTACT DETAILS, PAYMENT TERMS
GDSN

SUPPLIER
TRANSACTIONAL DATA
E.G. ORDER, INVOICE
GS1 EDI

EVENT DATA
E.G. WHERE IS MY DELIVERY?
EPCIS

CUSTOMER

PHYSICAL FLOW

RFID/Barcodes Tagged Pallets & Cases
GS1 EDI Standards

Identify

Company & Location
- Global Location Number (GLN)

Product
- Global Trade Item Number (GTIN)
- Serialised Global Trade Item Number (SGTN)

Logistics & Shipping
- Serial Shipping Container Code (SSCC)
- Global Shipment Identification Number (GSIN)
- Global Identification Number for Consignment (GSNC)

Assets
- Global Individual Asset Identifier (GIAI)
- Global Returnable Asset Identifier (GRAI)

Services & More
- Global Service Relation Number (GSRN)
- Global Document Type Identifier (GDTI)
- Global Coupon Number (GCN)

Capture

GS1 Barcodes
- EAN/UPC
- GS1-128
- GS1 DataBar

GS1 DataMatrix

GS1 QR Code

GS1 Composite Barcode

Share

GS1 Standards for Data Exchange

Master Data
- Global Data Synchronisation Network (GDSN)

Transactional Data
- eCom (EDI): EANCOM, GS1 XML

Event Data
- EPC Information Services (EPCIS)

EANCOM

GS1 XML
EDI in Healthcare

- **MANUFACTURERS**
- **WHOLESALERS**
- **HOSPITAL PHARMA**
- **HOSPITAL MD**
- **RETAIL PHARMA**

- Place order: FORMAT 1 - PO; Issue Invoice: INVOICE
- Place order: FORMAT 1
  - PO; Issue Invoice: INVOICE
- Place order: FORMAT 2
  - PO; Issue Invoice: INVOICE
- Place order: FORMAT 1 - PO; Issue Invoice: FORMAT 2 INVOICE
- Place order: FORMAT 2 - PO; Issue Invoice: INVOICE; Deliver: FORMAT 2 DISPATCH ADVICE
- Place order: FORMAT 2 – PO, INVOICE; Deliver: FORMAT 2 DISPATCH ADVICE
EDI implementation drivers

1. Helping to ensure quality of care
2. Meeting regulatory or trading partner requirements
3. Facilitating product traceability
4. Increasing efficiency, accuracy, reducing cost
5. Enabling new business processes
Design Principles for GS1 EDI

- **Master Data alignment**
  - Foundational info must be agreed & shared pre-EDI
  - Use of GS1 globally unique identifiers – GS1 Keys
  - Only coded information (machine readable)

- **Guidelines**
  - Global guideline comprises core processes and data
  - Local guidelines add local requirements (e.g., regulatory)
Global Guideline - Business contents and technical information separated

1. HEALTHCARE BUSINESS PROCESS MODEL
2. BDS - BUSINESS DOCUMENT SPECIFICATION
3. BDS SUMMARY
4. MS EANCOM – MAPPING SPECIFICATION
5. MS XML– MAPPING SPECIFICATION
MAIN BUSINESS PROCESSES IN THE GUIDELINES

Master Data
Order To Cash
Consignment Stock

DESCRIPTS BEST PRACTICE VIEW OF HC PROCESSES, INDEPENDENT OF TECHNOLOGIES AND STANDARDS

Published In Two Documents

Part I:
Executive overview

Part II:
Detailed process description of HC supply chain information exchange
How to use the global guideline when creating local guidelines

1. Agree on the process to start with
   - Applicable locally
   - Add local processes

2. Global guide update

3. Agree on the data elements as described in the BDS
   - Add additional info
   - Missing data?

4. Create mapping using the mapping specification

5. Share with GS1 Global Office

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Event-Based Traceability
EPCIS

Craig Alan Repec
Senior Manager, Supply Chain Visibility, EPCIS & RFID
EPCIS: a GS1 “Share” standard
EPCIS, a GS1 open standard . . .

- defines interfaces for **capturing & sharing** data
- defines a framework data model for event data
- helps create & **share visibility data** across enterprises
- enables services & solutions for supply chain visibility GS1 Keys identify the “what” & “where” of visibility events...
  - ...encoded as data-carrier neutral EPCs
  - ...even when used with GS1 barcodes (instead of RFID)
- Approved as ISO/IEC 19987 in July 2015
Core Business Vocabulary (CBV)

a GS1 “Share” standard

- Companion standard to EPCIS
- Defines specific data values to populate EPCIS data model
- Ensures a common understanding of data semantics
- Anchors EPCIS events to business process context
- **Critical to interoperability of EPCIS implementations**
- Includes values & definitions for Standard Vocabularies
- Provides identification syntax rules for User Vocabularies
- Approved as ISO/IEC 19988 in July 2015
Four dimensions of an EPCIS event

**WHAT** objects are the subject of event?

*Individual objects (SGTIN) or groupings (GTIN + Lot/batch)*

**WHEN** did this event take place?

*Date, time, time zone*

**WHERE** did this happen, and where are the objects thereafter?

*Read Point (GLN) & Business Location (GLN)*

**WHY** did this event take place?

- Business step (e.g., “Shipping”)
- Disposition (e.g., “in_transit”)

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EPCIS enables supply chain visibility

- **Tracking**
  Where are the pharmaceuticals I shipped?

- **Tracing**
  Where did this batch of pharmaceuticals come from?

- **Chain of Custody (CoC) / Chain of Ownership (CoO)**
  Which parties had custody of these pharmaceuticals?

- **Asset Management & Maintenance**
  Where are all of the hospital's balloon pumps?

- **Recall**
  Where were meds produced on 14 April shipped to?
EPCIS implementations 2017 and beyond

- Food / Fresh Produce Packaging and Distribution
- Fish Packaging and Distribution
- Rolling Stock Visibility in Rail
- Maintenance, Repair & Overhaul (MRO) in Rail
- Asset management
- Apparel Stock-Taking & Cycle Counting
- Pharmaceutical chain-of-custody
- Hospital procedures / Bedside treatment / OR
DSCSA – Drug Supply Chain Security Act

Packaging level: Saleable units and homogeneous cases

**Deadlines**

- **2015:** Lot based
- **2017:** Serialisation by manufacturers and repackagers
- **2023:** Full traceability back to manufacturer or repackager

**EPCIS** explicitly mentioned in a 2014 USFDA draft guidance as a means for interoperable exchange of pharma traceability data

**GS1 US Rx Guideline for DSCSA:** [www.GS1US.org/RxGuideline](http://www.GS1US.org/RxGuideline)
Event-Based Hospital Visibility
EPCIS in Hospitals

Considerations on applications of EPCIS for...
- Operating theatre events
- Bedside events
- Administration of pharmaceuticals
- Automated pre-procedure checks for:
  - Expired and recalled products
  - Verification that procedure can be performed
  - Verification of correct medical devices
Clearing up misconceptions on EPCIS

EPCIS is . . .

• an open GS1 & ISO technical standard
• an enabler for traceability solutions & services
• data-carrier-neutral, suited to GS1 DataMatrix

EPCIS is not . . .

• an out-of-the-box solution
• a standalone answer to visibility issues

Serialization & event-based traceability will fundamentally change how a supply chain works... **EPCIS will support this**
For further information on EPCIS...

Craig Alan Repec
GS1 Global Office
Senior Manager, Supply Chain Visibility, EPCIS & RFID
+32 2 788 78 16
craig.alan.repec@gs1.org
GS1 Healthcare Resources

GS1 Healthcare:  http://www.gs1.org/healthcare

Public Policy:  http://www.gs1.org/public-policy/industry-sectors/healthcare

AIDC:  http://www.gs1.org/healthcare/standards

GDSN:  http://www.gs1.org/healthcare/share-data-gdsn

EDI:  http://www.gs1.org/healthcare/share-data-edi

Traceability:  http://www.gs1.org/traceability-healthcare

Case Studies:  http://www.gs1.org/industries/healthcare/case-studies

Join:  http://www.gs1.org/healthcare/membership