



The Global Language of Business

GS1 standards Primer session

31st Global GS1 Healthcare conference
Berlin, Germany

04 April 2017





Agenda of the session



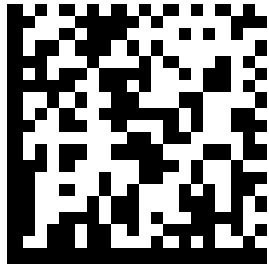
- | | |
|--|------------------|
| 1. GS1 Healthcare, the global perspective | Chuck Biss |
| 2. Automatic Identification Data Capture | Chuck Biss |
| 3. Master Data Management
and Global Location Numbers | Pete Alvarez |
| 5. Electronic Data Interchange (EDI) | Craig Alan Repec |
| 6. Event-Based Traceability (EPCIS) | Craig Alan Repec |

GS1 Healthcare, the global perspective

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



GS1, most widely used standards



(01)07612345678900(17)100503

(10)AC3453G3



(01) 0 0012345 67890 5

GS1 ensures end-to-end visibility in the supply chain



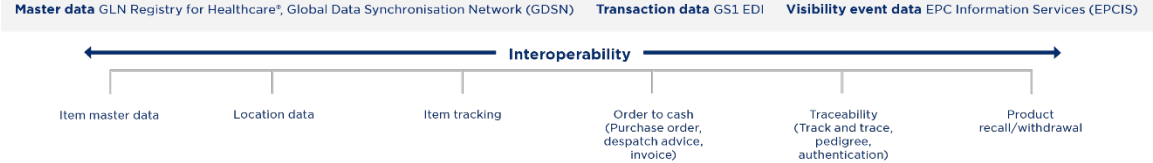
Identify: GS1 standards for identification



Capture: GS1 standards for barcodes and EPC/RFID



Share: GS1 standards for data exchange



GS1 enables



- Patient safety



- Lower costs

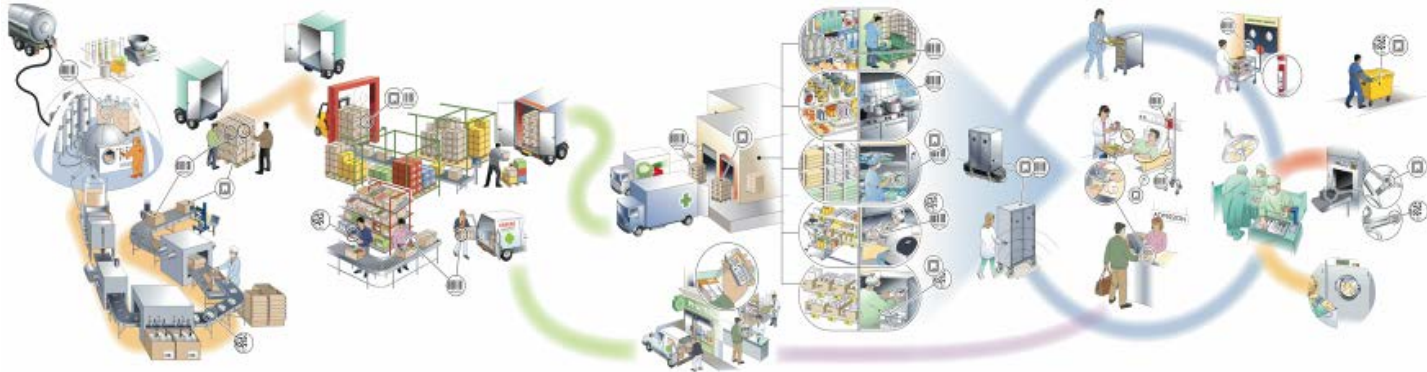


Global reach, local presence



110+ Member Organisations
More than 1,000,000 member
companies
150 countries served
2,000 + employees

GS1 Healthcare - Voluntary, Global Healthcare User Group



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...



International Organisation for Standardisation



European Committee for Standardization



Health Level 7 International



International Health Terminology SDO



Clinical Data Interchange Standards Consortium



Integrating the Healthcare Enterprise



Digital Imaging and Communications in Medicine

 **Joint Initiative Council**



World Health Organization



World Customs Organization



International Hospital Federation



International Council for Commonality in Blood Banking Automation



International Society for Quality in Healthcare



European Association of Hospital Pharmacists



European Federation of Pharmaceutical Industries and Associations

European Federation of Pharmaceutical Industries and Associations

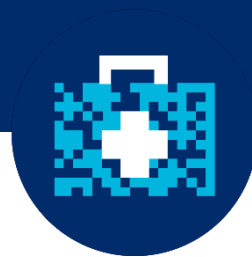


European Medical Devices Industry Association



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 & Data Capture (AIDC)

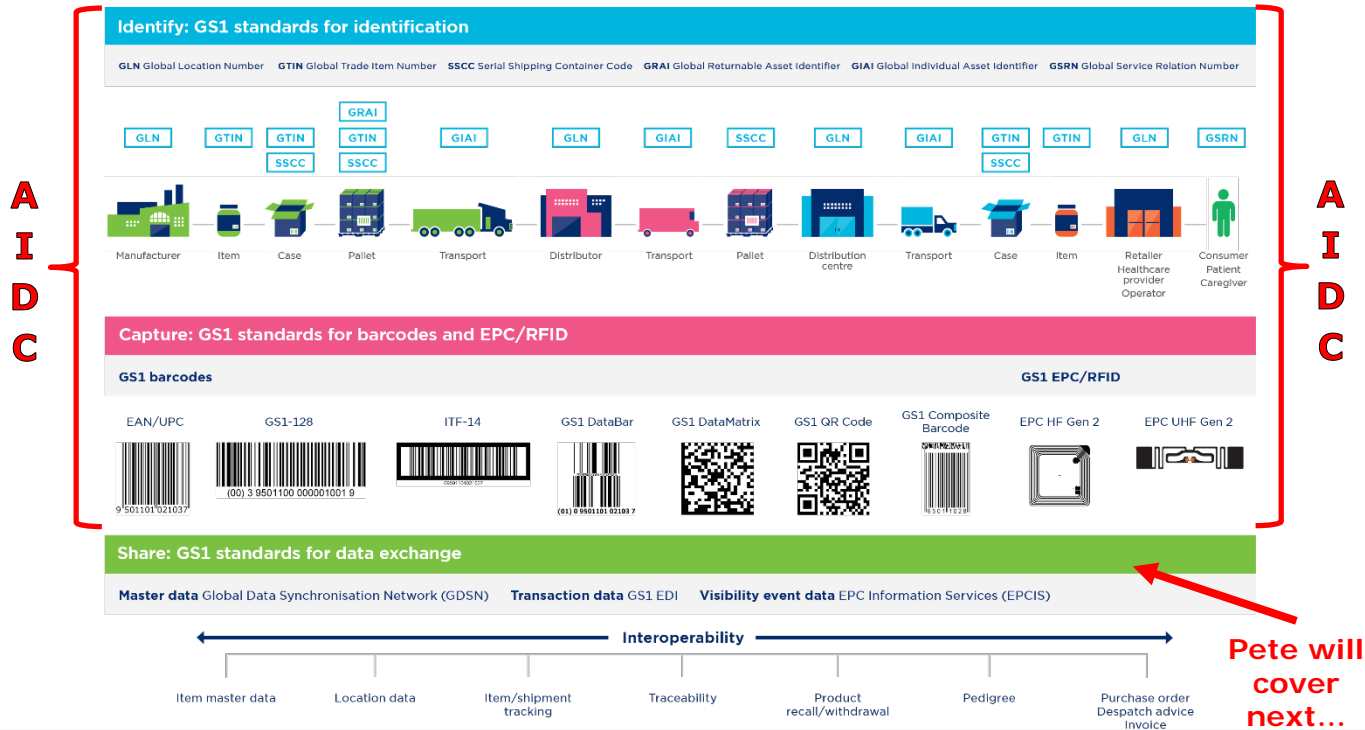


“Automatic Identification and Data Capture (AIDC) refers to the methods of **automatically identifying** objects, **collecting data** about them, and **entering that data** directly into computer systems (i.e., without human involvement).”

Wikipedia, 2009



GS1 standards... and AIDC



AIDC for Healthcare... the Vision



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



Medical devices



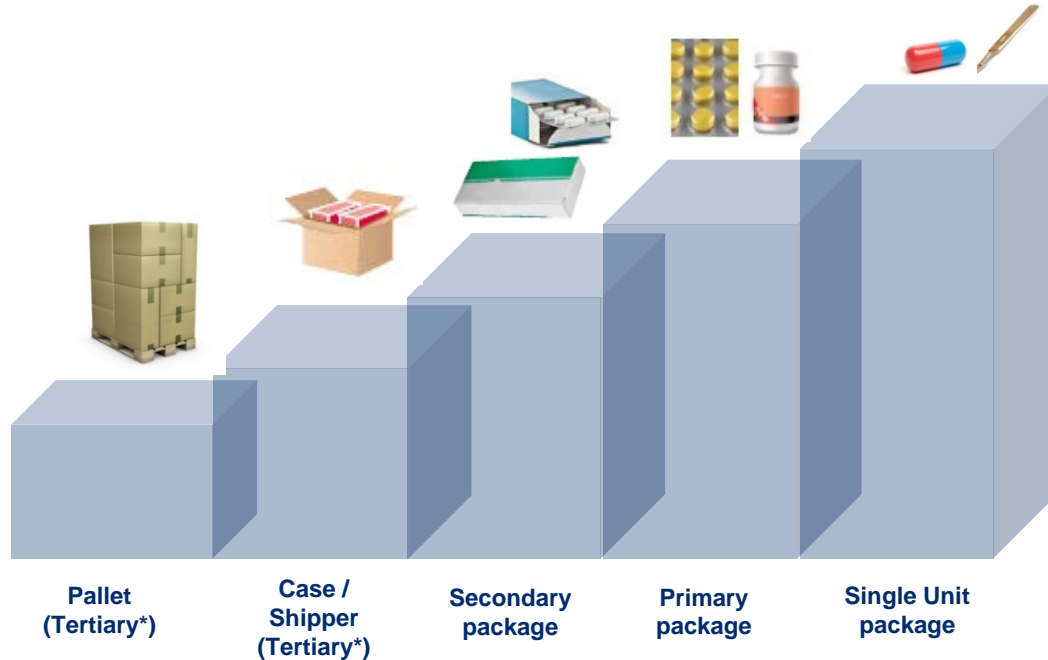
Retail



Non-retail



Scope – ID at all packaging levels...



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

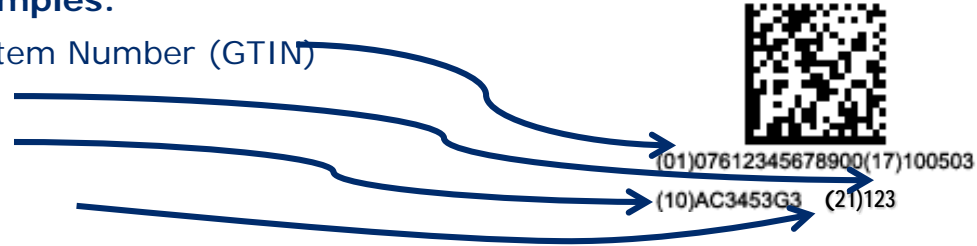
Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.

Scope - Data & Data Carriers...



Data – a few examples:

- Global Trade Item Number (GTIN)
- Expiry Date
- Batch / Lot
- Serial Number



Data Carriers – a few examples:

(01) 0 0012345 67890 5
12150012345678905

**GS1-128 &
GS1 DataBar**

(01)07612345678900(17)100503
(10)AC3453G3

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.



GS1 Identification Keys...



Item identifier = **GTIN**

Global Trade Item Number



Logistics unit
identifier = **SSCC**

Serial Shipping Container Code



Location identifier **GLN**

=

Global Location Number

- Unique
- Non-significant
- International
- Secure
- Foundational

...and there are more ...

...but sometimes there is need to capture data beyond basic item ID...



GS1 Application Identifiers...



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:

01	GTIN (Global Trade Item Number)
10	Batch / Lot
11	Production Date
17	Expiry Date
21	Serial Number

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...



(01) 0 0012345 67890 5



GS1-128 & GS1 DataBar

Preferred options if:

- ✓ Package size allows



(01)07612345678900(17)100503
(10)AC3453G3

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: http://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

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: http://www.gs1.org/docs/gsmc/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

Many countries have already adopted GS1 Standards... and we anticipate many more!

AIDC this Week...



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



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The Global Language of Business

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



- The Value of Trusted Data
- The Global Data Synchronisation Network
- Global Location Numbers & the GLN Service

The value of trusted data



Source: The Value of Trusted Data - <http://www.gs1.org/healthcare/share-data-gdsn>

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!**



1970s



1990s



2000s

Digital and mobile disruption



Data errors in healthcare



U.S.A Department of Defense Study



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

Source:

http://2016archive.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?command=core_download&entryid=933&language=en-US&PortalId=0&TabId=785

Australian data crunch: The cost of bad data



Potential cost of manual checking of unit of measure



Potential cost of manual PRC clarification by hospitals



Potential savings from improved data quality³



Potential cost associated with independently sourcing product weight and dimensions



Potential cost of urgent deliveries due to undersupply



Potential savings for 5 scenarios studied

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.



Potential lost revenue from unclaimed joint replacement prostheses

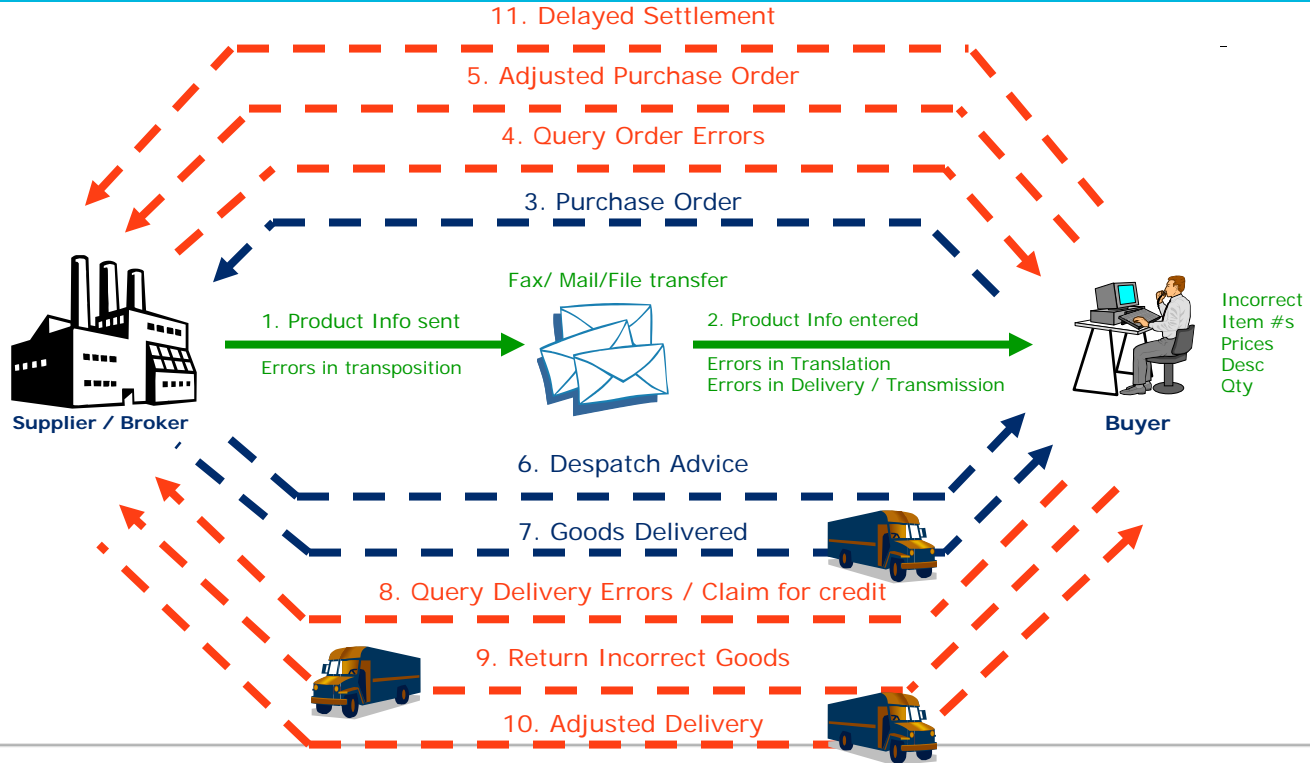


Conservative potential savings from improved data quality for all business processes met by the NPC data set

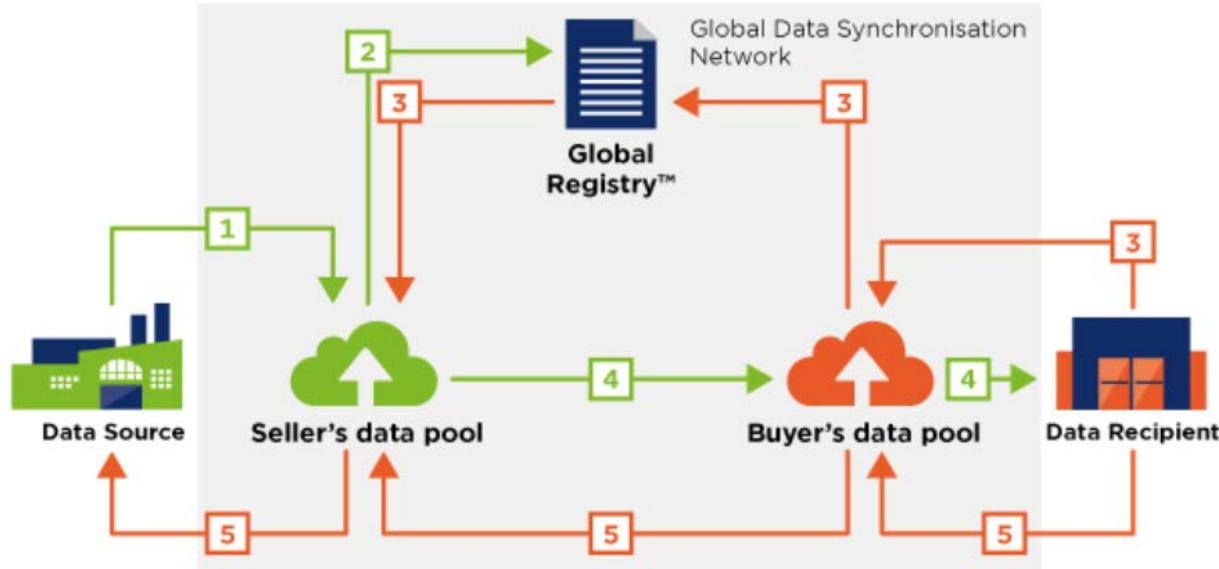
Source: <https://www.gs1au.org/resources/publications/>

Source: <http://www.gs1.org/articles/1563/australian-healthcare-industry-data-crunch-report-reveals-high-cost-bad-quality-data>

Order-to-cash before data synchronisation



The Global Data Synchronisation Network



1. Loading of company data
2. Registering of company data
3. Subscription to seller's data pool
4. Publishing of company data
5. Confirmation of receipt of company

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

Order-to-cash after data synchronisation



The Global Locations Number (GLN) and the GLN Service



The problem with location identification

SAINT JOHN'S QUEENS HOSPITAL
1100004570208

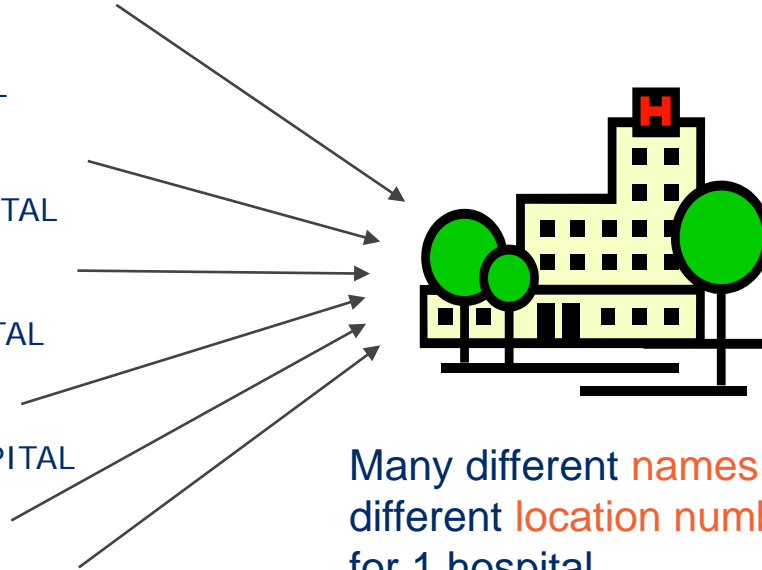
ST JOHN'S QUEENS HOSPITAL
100084547

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



Many different **names**
different **location numbers**
for 1 hospital



Why use Global Location Numbers (GLN)

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

Different locations in a hospital

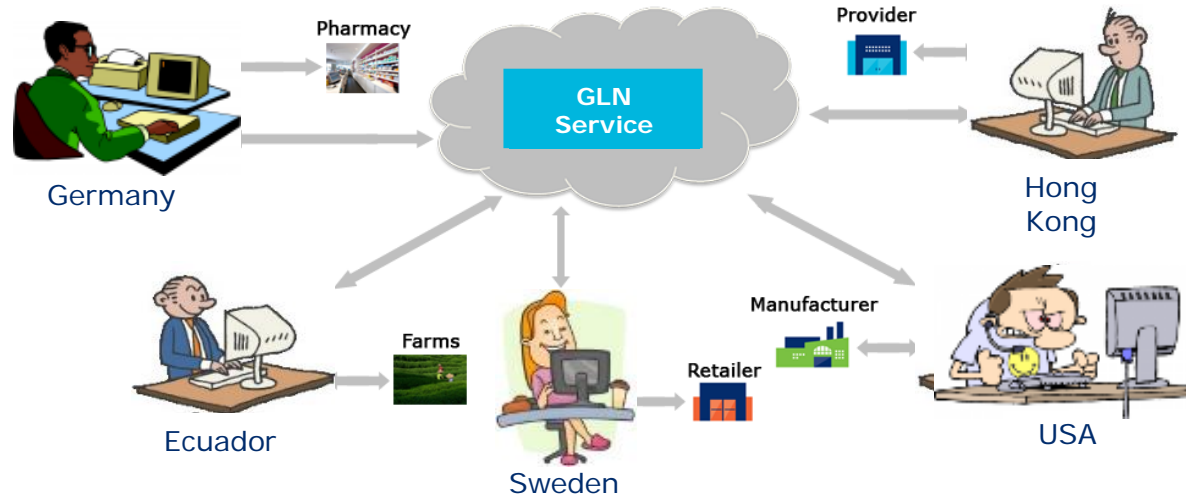


- Vital for GS1 eCom messaging so that all parties and locations may be uniquely identified
- A pre-requisite for Global Data Synchronisation

The GLN Service: Global exchange of GLN master data



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





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

Join Us!

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

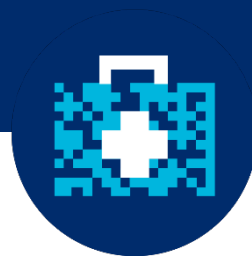
+1 609 557 4547

peter.alvarez@gs1.org

EDI in Healthcare

Craig Alan Repec

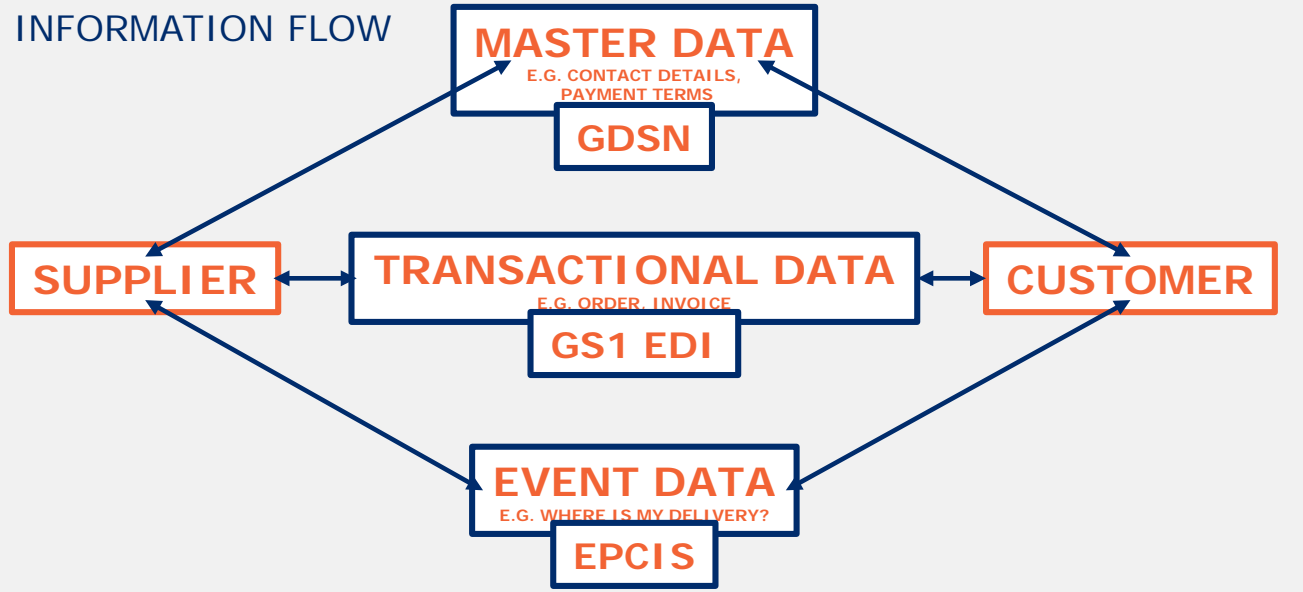
Senior Manager, Supply Chain Visibility, EPCIS & RFID



Information sharing



INFORMATION FLOW



PHYSICAL FLOW



GS1 EDI Standards



Identify

GS1 Standards for Identification

Company & Location

- Global Location Number (GLN)

Product

- Global Trade Item Number (GTIN)
- Serialised Global Trade Item Number (SGTIN)

Logistics & Shipping

- Serial Shipping Container Code (SSCC)
- Global Shipment Identification Number (GSIN)
- Global Identification Number for Consignment (GINC)

Assets

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

Services & More

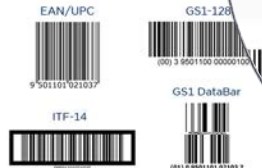
- Global Service Relation Number (GSRN)
- Global Document Type Identifier (GDTI)
- Global Coupon Number (GCN)



Capture

GS1 Standards for Barcodes & EPC/RFID

GS1 Barcodes



GS1 EPC/RFID



Share

GS1 Standards for Data Exchange

Master Data

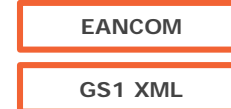
- Global Data Synchronisation Network (GDSN)

Transactional Data

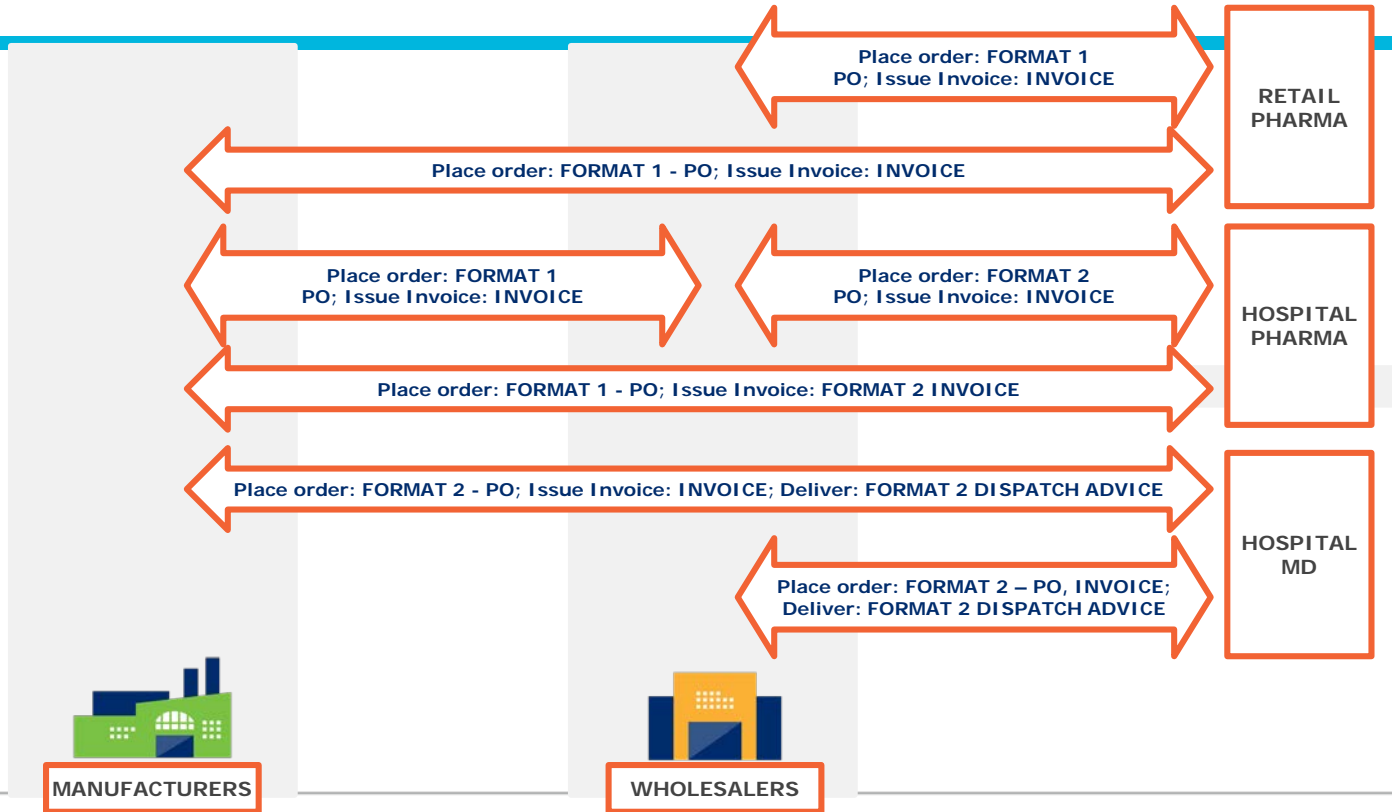
- eCom (EDI): EANCOM, GS1 XML

Event Data

- EPC Information Services (EPCIS)



EDI in Healthcare



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**

Healthcare Business Process Model



MAIN BUSINESS PROCESSES IN THE GUIDELINES



Master Data



Order To Cash



Consignment Stock

DESCRIBES 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



Event-Based Traceability EPCIS

Craig Alan Repec

Senior Manager, Supply Chain Visibility, EPCIS & RFID



EPCIS: a GS1 “Share” standard



Identify

GS1 Standards for Identification

Company & Location

- Global Location Number (GLN)

Product

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Logistics & Shipping

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Services & More

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



Capture

GS1 Standards for Barcodes & EPC/RFID

GS1 Barcodes

- EAN/UPC
- GS1-128
- ITF-14
- GS1 DataBar
- GS1 DataMatrix
- GS1 QR Code
- GS1 Composite Barcode

GS1 EPC/RFID

- Electronic Product Code (EPC) RFID
- EPC HF Gen 2
- EPC UHF Gen 2



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)



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?

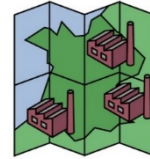
- Business step (e.g., "Shipping")
- Disposition (e.g., "in_transit")

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

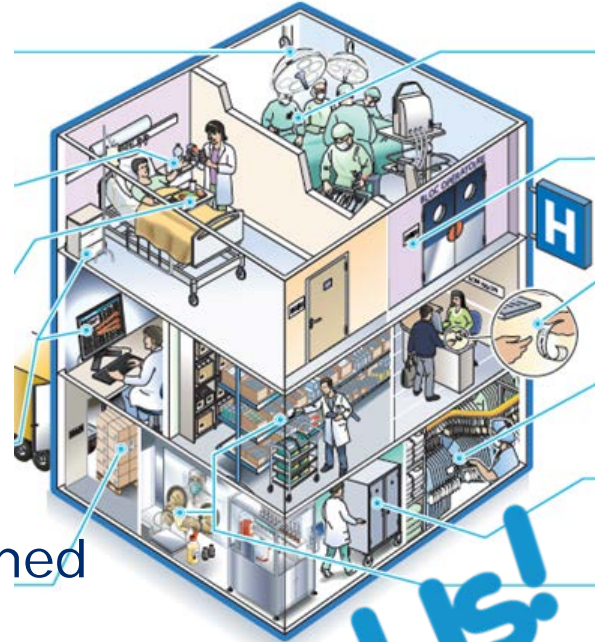
Event-Based Hospital Visibility

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



Join Us!

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...



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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>

