The Global Language of Business

Safer, more efficient care starts with a simple scan

Trends and developments in healthcare around the world

Tania Snioch, Director Healthcare, GS1 Global Office
September 2018

Agenda

- Global GS1 Healthcare
- Why is healthcare moving to global standards
  - Pharmaceutical traceability
  - Unique Medical Device Identification (UDI)
  - Aid organisations using GS1 standards
- A case study - Australia

Global GS1 Healthcare

Our vision

GS1 Healthcare envisions a future in which the healthcare sector achieves harmonised implementation of global standards in business and clinical processes enabling interoperability, optimal quality and efficiency of healthcare delivery to benefit patients.

patient safety

supply chain security & efficiency

traceability

GS1 is a Standards Development Organisation working with others

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

Personal Connected Health Alliance

Joint Initiative Council

World Health Organization

International Hospital Federation

International Society for Quality in Healthcare

International Council for Commonality in Blood Banking Automation

European Association of Hospital Pharmacists

European Federation of Pharmaceutical Industries and Associations

European Association of Medical device and diagnostics industry

Medicines for Europe

GS1: global system of standards

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 hospitals and government agencies to implement GS1

The GS1 Healthcare Strategy 2018-2022

Three main activities designed to:

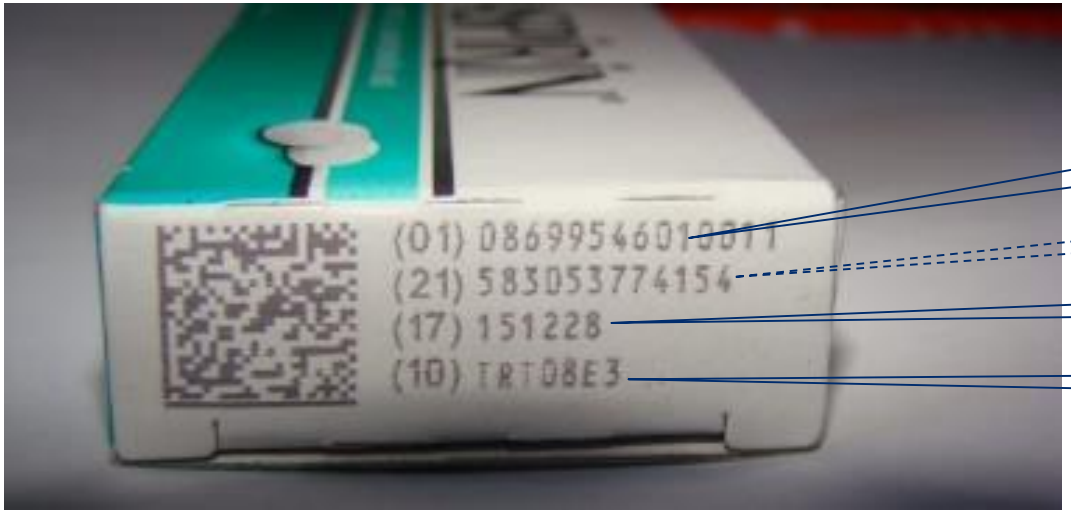
- Ensure that current activities are maintained to drive deeper implementation
- Further enhance the already increased focus on the healthcare providers (hospitals and retail pharmacies) and bring the patient increasingly into focus
- Allow monitoring, influencing and action, where appropriate, to engage with emerging technology developments

www.gs1.org/healthcare/about/strategy

Why is healthcare moving to global standards?

For Pharma – the focus is serialisation

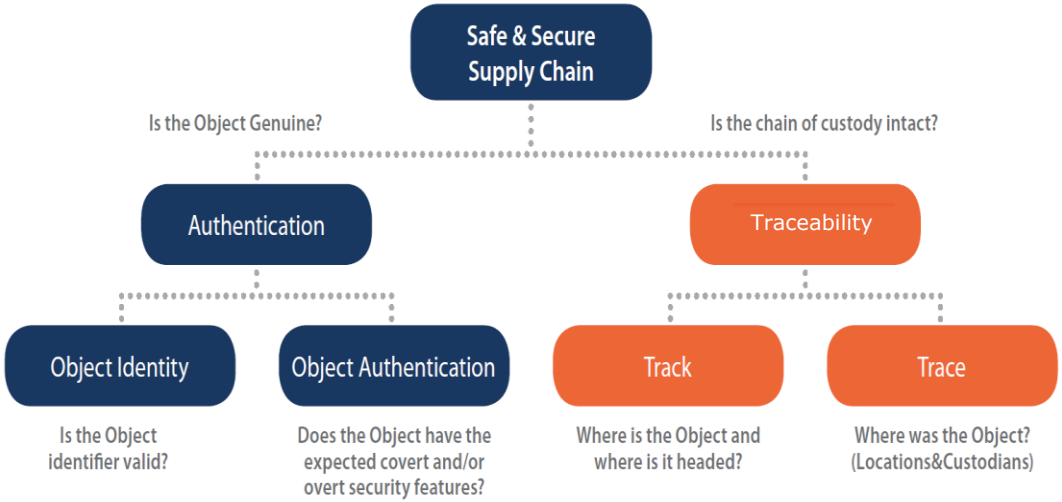
The trend - A (serialised) secondary pack…



But some countries are also focussing on teritary packaging and primary packaging

Why? To enable traceability or authentication

- Can the product identification features be verified?
- Can the product be tracked to where it is – or traced from where it has been?



The drivers…

- Regulation
- Government requests
- Hospitals / hospital groups
- Humanitarian organisations

Without globally standardised identification

- Multiple bar codes on one package – which one to scan?
- Different types of bar codes – inconsistency; incompatibility
- No bar code – need to bar code; re-package; re-label

Counterfeit products can ‘appear’

According to Interpol more than **one million people** die each year from counterfeit drugs!

“More than **120,000 people a year die** in Africa as a result of **fake anti-malarial drugs alone**, says the World Health Organization, either because the drugs were substandard or simply contained no active ingredients at all.

Even medicines that are substandard - containing an insufficient dosage of active ingredients, say - can be deadly, leading to drug resistance, a particular issue for infectious diseases like malaria and tuberculosis.”

https://www.bbc.com/news/business-37470667

Protecting patients - the EU Falsified Medicine Directive

EU Falsified Medicine Directive 2011/62/EU (FMD)

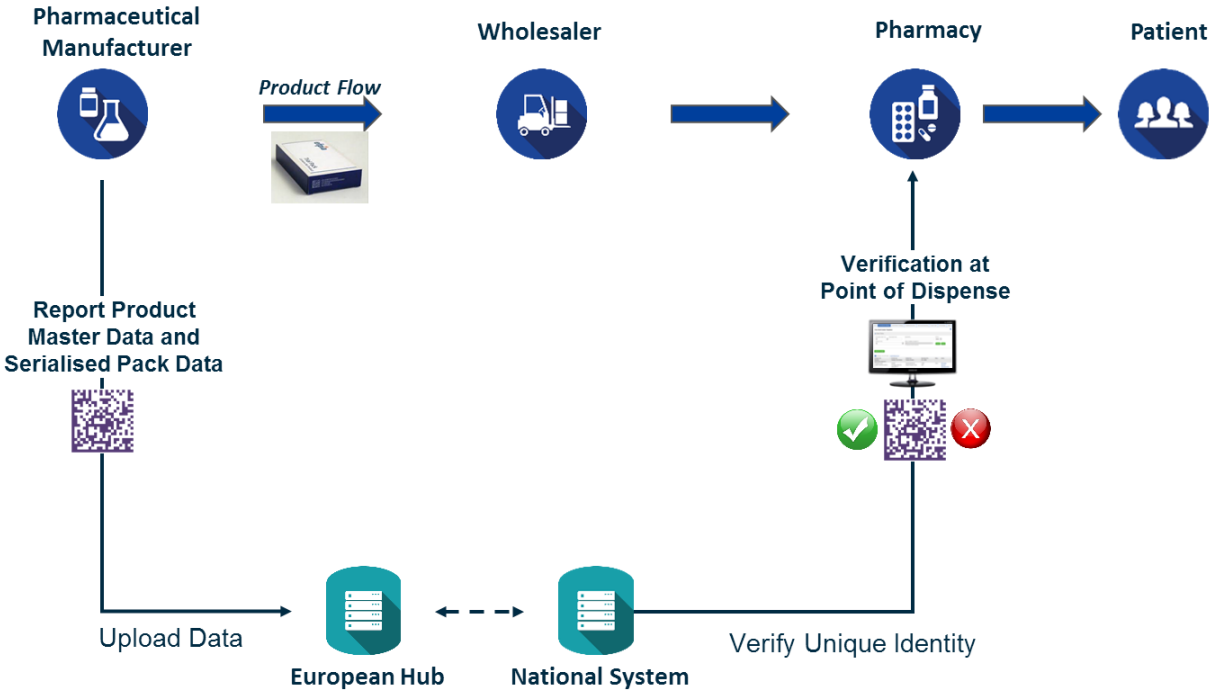
http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

EU Commission Delegated Regulation 2016/161

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

Prevent the entry into the legal supply of falsified medicinal products by requiring the placing of safety features consisting of a **unique identifier** **and an anti-tampering device** on the packaging of certain medicinal products for human use for the purposes of allowing their **identification and authentication**.

EU FMD representation - Authentication



A safe and reliable supply chain in Turkey

- The main challenge in Turkey was to ensure and guarantee the reliable supply of drugs to patients
- The solution is traceability, which is defined as full, end to end, actionable visibility of finished pharmaceuticals in healthcare globally, from point of production to point of use.
- Results of Turkey's efforts have been tremendous, and in these five areas alone, the nation is seeing savings of 1 billion US dollars annually.

http://www.gs1.org/sites/default/files/docs/healthcare/gs1_healthcare_reference_book_2015-2016.pdf

Prof. Özkan Ünal,
President of Turkish Medicines and Medical Devices Agency since December 2014.

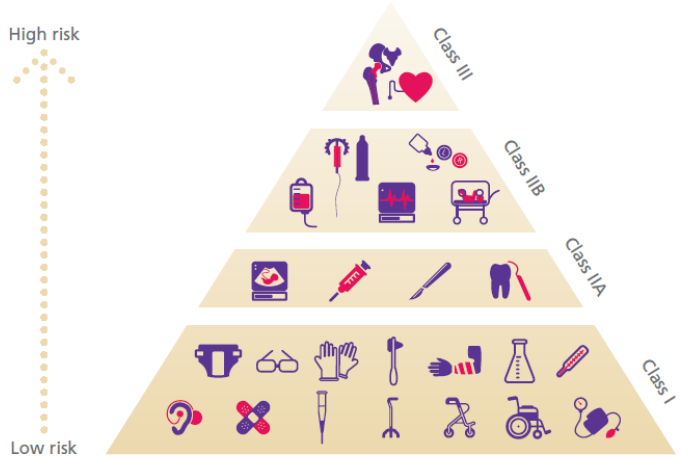
For Medical Devices – the focus is identification

Some of the reasons hip implants were recalled (Nov 2002 – July 2013)

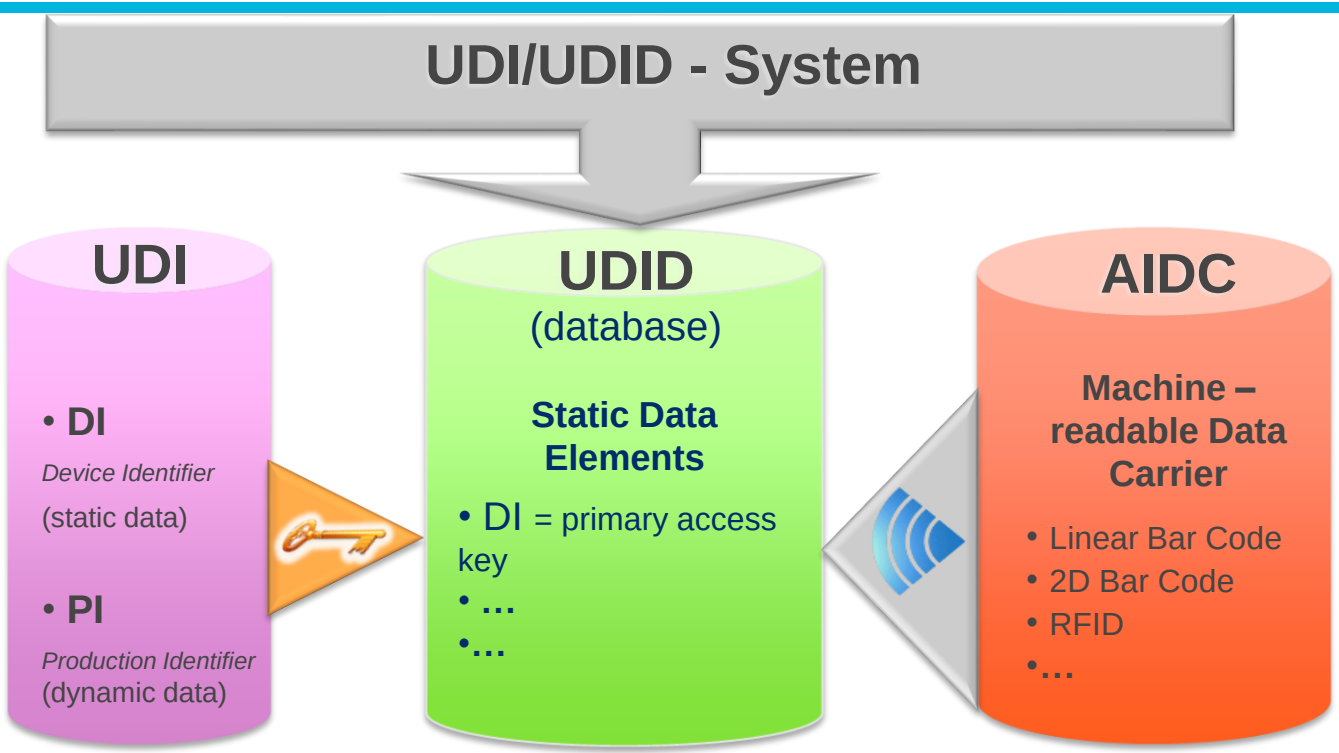
- **Fracturing:** flawed implant (head) can fracture; tools (cup inserter, femur torque handle) used during surgery could fracture
- **Design flaw:** the implant device (femoral stem) may cause "impingement" and not allow the stem and to lock; faulty femoral hip stems
- **"Ongoing post-market surveillance of all products"** due to high failure rate of metal on-metal hips, including femoral head and acetabular cup
- **Early Failure:** tools (broach handle) used during the surgery experienced early failure
- **Migration Issues:** screws used to repair femoral fractures may "migrate"
- **Design Flaws:** femoral head popped out of the liner during surgery; procedural tool to hold legs in place may break during surgery
- **Cracking:** hip stem coating may crack
- https://safepatientproject.org/wordpress/wp-content/uploads/2013/09/Hip-Recalls-Summary-Final-9-9-131.pdf

UDI purpose…

A common, **worldwide system for product identification** should eliminate differences between jurisdictions and offer significant benefits to manufacturers, users and/or patients, and regulatory authorities.



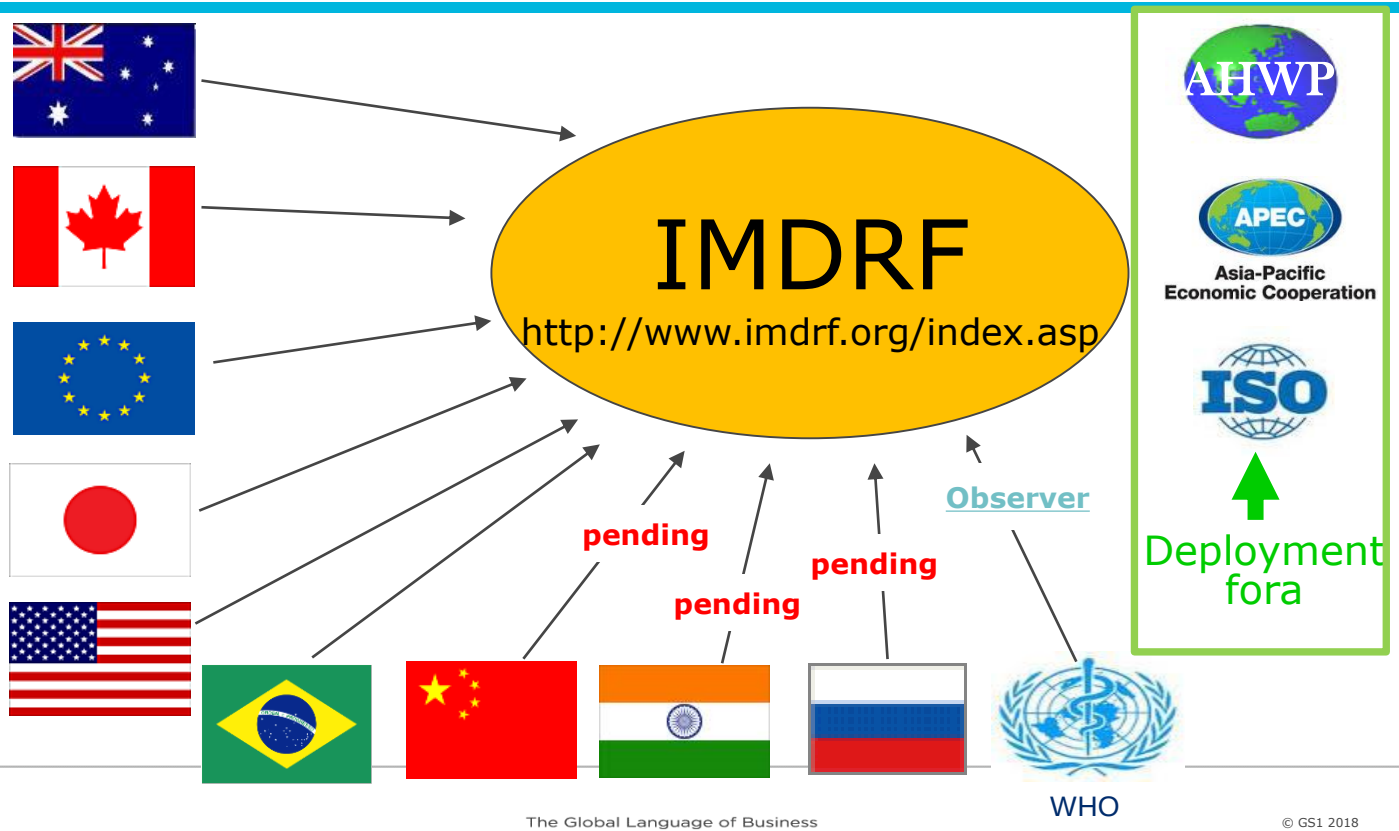
UDI system…



UDI system…

- Assign a globally unique standardised identifier (the "UDI") to medical devices
- Place that "UDI" on the label / package / item in both plain human readable text (HRI) and also in an appropriate form or type of Automatic Identification and Data Capture (AIDC) data carrier
  - Apply "direct marking" for those devices which are intended to be reused or reprocessed
- Submit the required data related to product to a globally accessible database (e.g. US FDA's Global UDI Database or "GUDID")
- Follow through… IMPLEMENT for all medical devices as & when required!

Many countries moving forward with UDI and aligning with IMDRF guidance



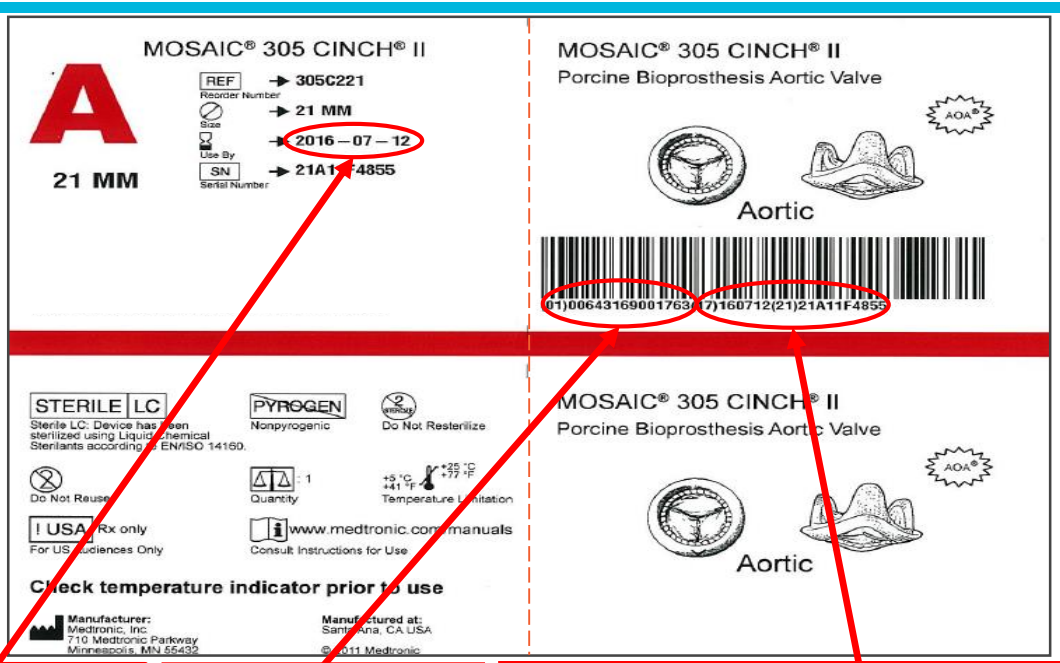
Original Slide Source: European Commission

UDI & the GS1 system…

- UDI in GS1 identification (identify) terms…

UDI Unique Device Identification	**GS1 Standards** Product Identification
DI Device Identifier (DI)	**GTIN** Global Trade Item Number
PI Production Identifier (PI) (If applicable)	**AI** Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ
Production Identifier data will vary by medical device type and manufacturer current practice.	
DI + PI = UDI	**GTIN or GTIN + AI(s) = UDI**

UDI Example - #1… Medtronic…

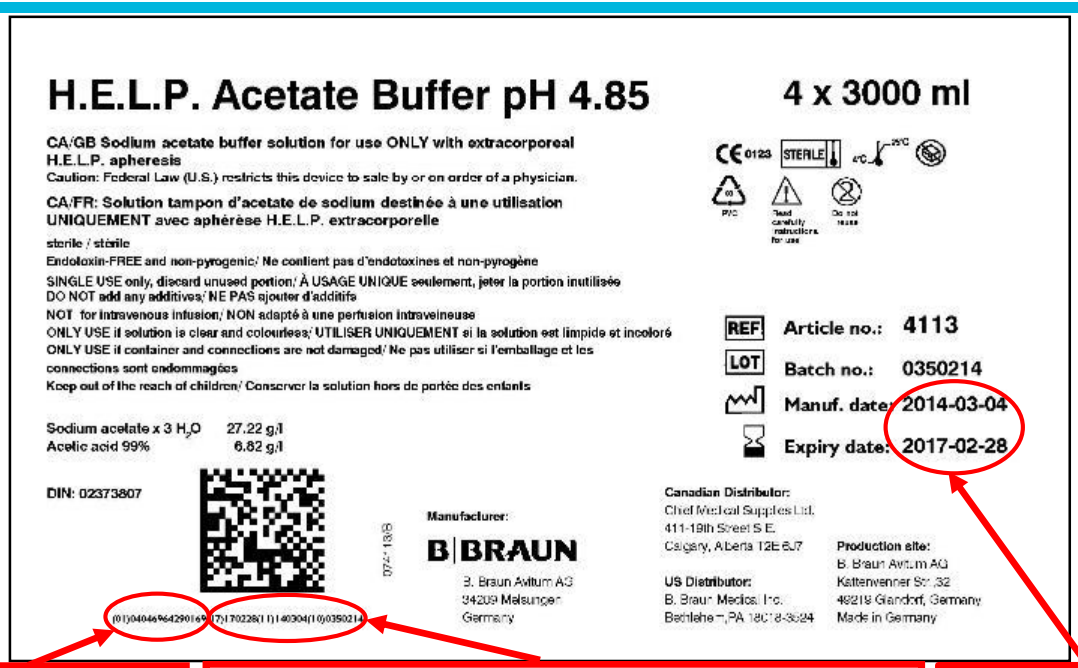


US FDA UDI required ISO 8601 date format

Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)

UDI Example - #2… B.Braun…

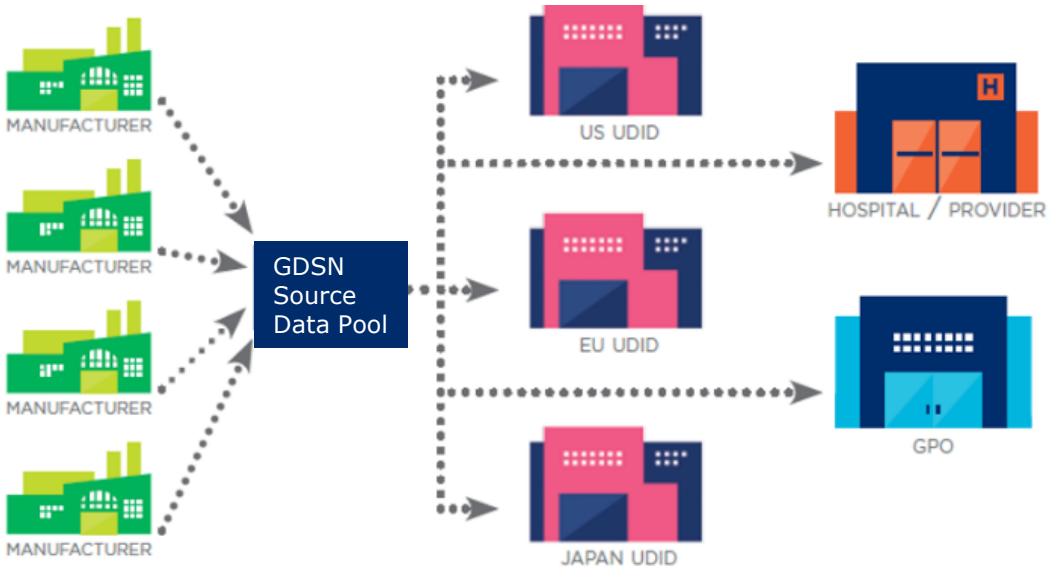


Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)

US FDA UDI required
ISO 8601 date format

Managing data and global standards: The Global Data Synchronisation Network



Manufacturers are able to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection

For aid organisations – identification and traceability

WHO VPPAG

- **Vaccine Presentation and Packaging Advisory Group (VPPAG) for improvements of vaccines packaging**
- Created bar code subgroup in 2011 as barcoding becomes prevalent for medicinal products to improve inventory visibility and patient safety in developed markets
- How to leverage for vaccines in developing markets
- Challenges – data definition, structures, symbologies; investment into marking technologies; integration into existing systems in the field

The issue: Need to secure the supply chain

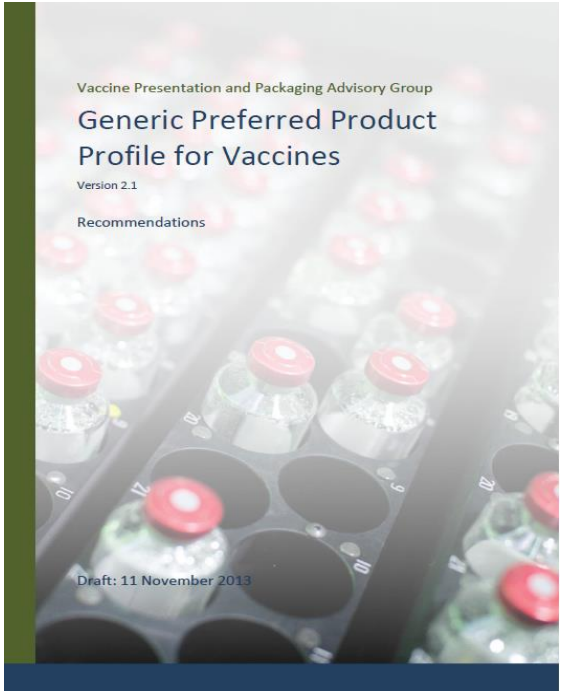
Often the supply chain is broken

- Medicines are expired or not stored correctly
- Medicines are not available when needed
- Inventory management is not optimal
- Traceability is not achievable
- Responsibility towards donors not fulfilled

WHO VPPAG recommendation

In 2015 Generic Preferred Product Profile for Vaccines (PSPQ2) recommends barcodes with **GS1 standards (GTIN, lot number and expiry date) on all packaging levels** used by manufacturers, with the exception of primary packaging

http://www.who.int/iris/bitstream/10665/148168/1/WHO_IVB_14.10_eng.pdf



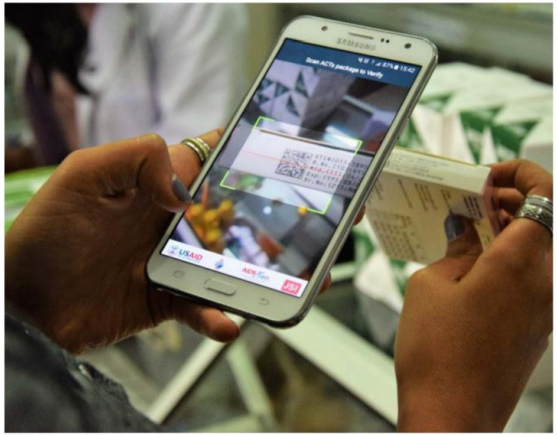
Read at…

http://blog.path.org/2015/10/mapping-journey-barcodes-data/?utm_referrer=http%3A%2F%2Fwww.google.be%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3D%26esrc%3Ds%26source%3Dweb%26cd%3D1%26ved%3D0ahUKEwiBhKi62qfNAhUFSRoKHbgPBacQFggbMAA%26url%3Dhttp%253A%252F%252Fblog.path.org%252F2015%252F10%252Fmapping-journey-barcodes-data%252F%26usg%3DAFQjCNEiFEt05_cwD8q0tv4hjOPNNR-qBQ%26sig2%3DHwmqPsMq_9YbjpjhbObXFw%26bvm%3Dbv.124272578%2Cd.d2s

Barcodes: quenching a thirst for data

In Africa

Verification of malaria medication



- **What it does?**
  - Manufacturers of ACT provide serialized GTIN used for the ACT products that are shipped to Ethiopia.
  - Using this app the public can scan the ACT package and verify that this product is a genuine manufactured ACT and imported by PFSA

Outcome

- Enabling the public to verify the authenticity of the product by developing a tool that uses global standards to verify malaria commodities
- Learn from the implementation for scale to other category of commodities

Source: Traceability and verification of anti-malarial commodities in the Ethiopian supply chain - Al Shiferaw, Deputy Country Director, JSI, Ethiopia; Teddy Berihun, Senior Health Information Systems Adviser USAID, Ethiopia, GS1 Healthcare Conference May 2018

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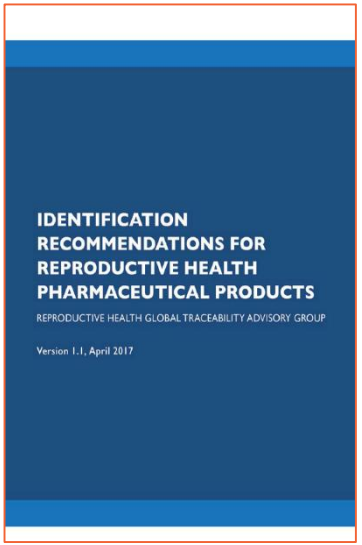
USAID requiring GS1 standards

- After publication of guidelines for Reproductive Health Products USAID is now starting to implement GS1 standards.
- Letter sent to 700 suppliers sharing **USAID requirements for product identification, labeling, and data exchange following GS1 standards**, with a phased implementation from 2018 – 2022.
- Supporting material such as technical implementation guides, FAQ's etc. have been published – details can be found at

  http://www.ghsupplychain.org/globalstandards

USAID
FROM THE AMERICAN PEOPLE

USAID – putting the standards into action



Interagency Supply Chain Group (ISG) Adoption of global GS1 standards

The ISG: **Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, GAVI, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO** published a position paper in August 2017 on the **adoption of GS1 standards** committing to the process of transitioning to include established, global data standards as part of their procurement requirements and support country uptake of these standards.

From the Interagency Supply Chain Group:

Visibility for Health Systems: Adoption of Global Data Standards (GS1)

About the ISG

The broad purpose of the Interagency Supply Chain Group (ISG) is to share information and seek greater alignment across supply-chain investments to bring more impact to individual agency supply chain strategies. The group promotes coordination both globally across programs, and locally through national leadership with the overall aim of improving the efficiency and effectiveness of in-country supply chains. The ISG is an informal partnership of 15 major actors involved in providing supply chain support to countries: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.

Boxes of medical supplies are sorted before being distributed among the mobile health brigades at the Chicuelecuele District hospital in Maputo, Mozambique, in July 2016. ©UNICEF/Rich.

Background

Medicines supply chain execution and responsiveness require synchronization of supply and demand, as well as the orchestration of three flows of commerce, that are the movement of goods, information and funds, across an increasing number of logistics and trading partners, spanning a wide (if not global geographic) region. Whilst the implementation of traceability systems has been identified by National Regulatory Authorities as a useful and efficient tool to combat falsification and illicit distribution of medical products, only some countries have issued progressive traceability regulation. Many have not, and are still assessing various implementation mechanisms, alternatives or otherwise have not approached this topic at all[1]. The international community has recognized the need to support countries in determining what these best approaches are. Since 2014, the international development community has promoted the use of global data standards (GS1) to provide a wider and harmonized framework for supply chain visibility, strengthening anti-counterfeiting measures and sharing of data between parties. The Interagency Supply Chain Group recognizes the value for advocating for both effective and sustainable solutions to enable traceability and safe passage of medicines through national supply chains and have committed to strengthening this response accordingly.

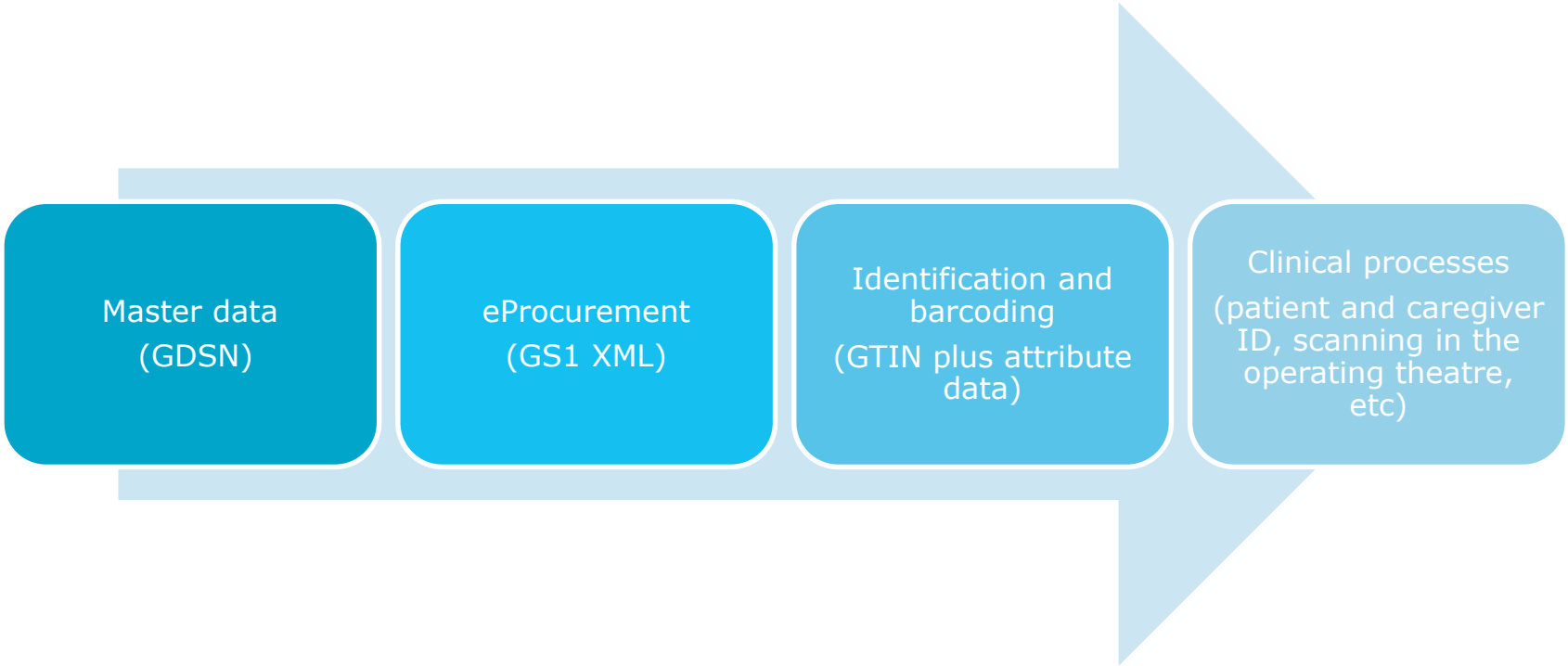
Current activities of the ISG

- Strengthen global and country advocacy for the adoption of GS1 standards and traceability systems with countries, in collaboration with other relevant stakeholders.
- Accelerate the understanding and adoption of an open and global supply chain standard, globally, through technical support, education, and collaboration with manufacturers.
- Collaborate to improve donor procurement guidelines, including the requirement for the use of GS1 standards for identification and barcoding on the different packaging levels, and coordinate with manufacturers on an implementation timeline.
- Develop a roadmap & timeline for the adoption of GS1 standards in labelling all health commodities and products.
- Provide technical assistance to several countries in defining parameters necessary to implement National Traceability Systems. These include development and finance implementation plans for barcoding of health commodities for member states. e.g. support to the Government of Ethiopia to implement a nation-wide adoption of barcoding technology.

[1] Fourth meeting of the member state mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, 13 November 2015, provisional agenda item 4C. Existing technologies and 'track and trace' models in use and to be developed by member states. Draft document submitted by Argentina.

A case study – Australia

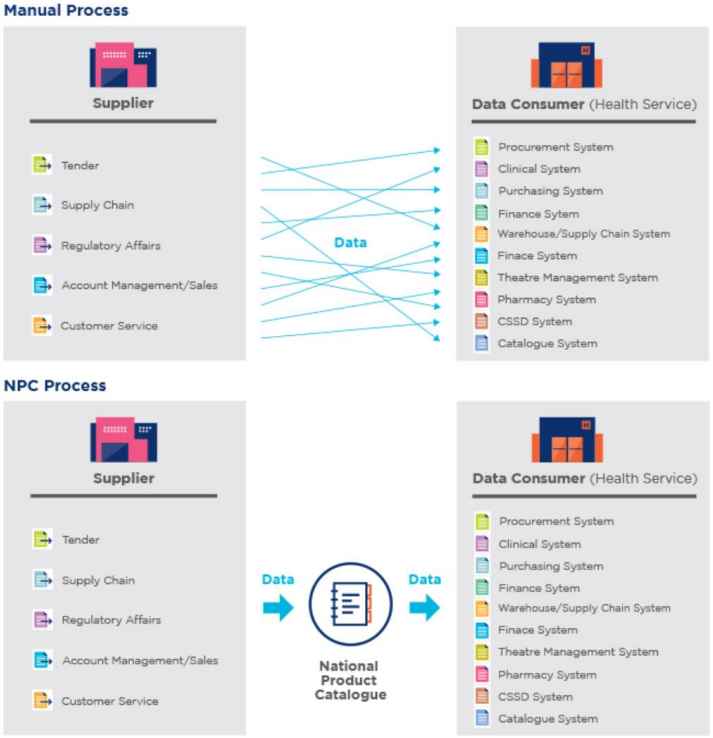
A slightly different approach



Master data – National Product Catalogue

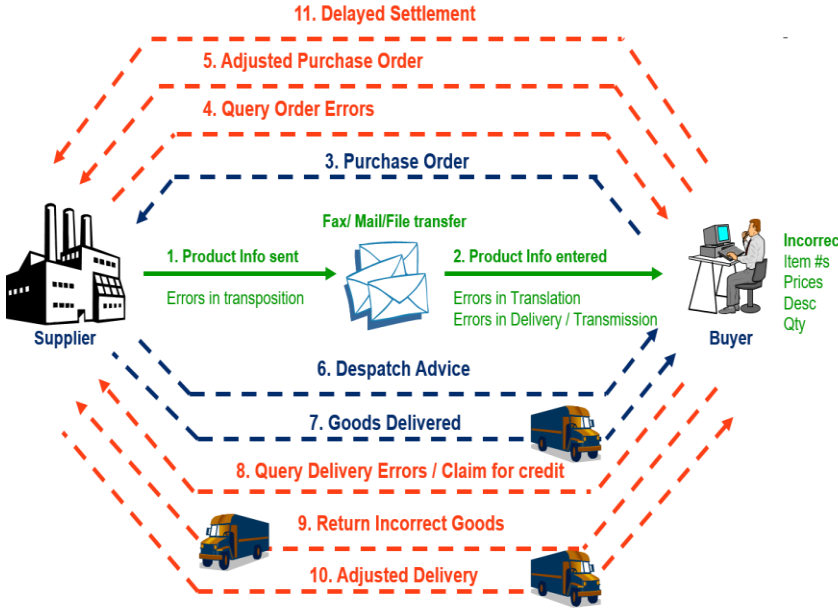
- The National Product Catalogue was implemented in healthcare to **support the industry need for standardised, supplier managed data across the whole of the healthcare** value chain to ensure accuracy and efficiency.
- Based on the principles of 'data synchronisation', the National Product Catalogue in Healthcare enables the sharing and updating of quality standard data that is required to link physical products to clinical practice as well as supporting quality processes, data capture and analytics within health.

- https://www.gs1au.org/for-your-industry/healthcare/npc-in-healthcare/

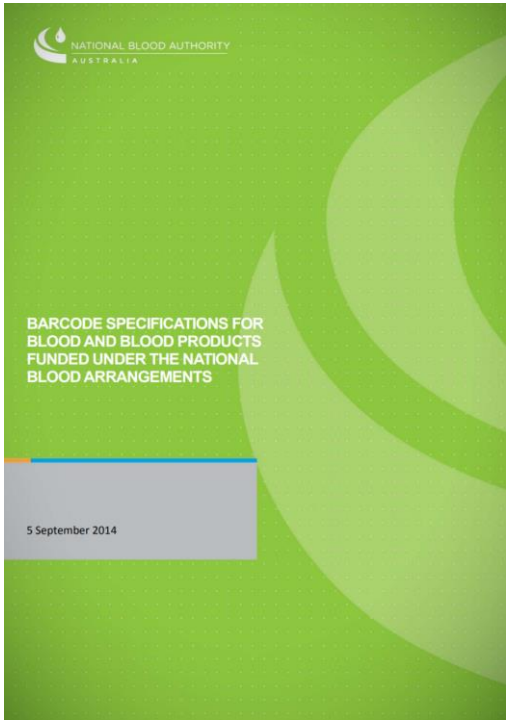


eProcurement – GS1 XML

- eProcurement provides a st**andardised messaging format** to **electronically communicate standardised and accurate product and price data between Australian health departments and private hospital providers**.
- The messages contain technical and business requirements for common procurement messages including purchase order, purchase order response, advanced shipping notice, invoicing and purchase order changes.
- **<u>The eProcurement messaging uses the product information provided by suppliers in the National Product Catalogue.</u>**



Identification and barcoding



The National Blood Authority on behalf of all Australian governments will in all current and future procurements for blood and blood products funded under the National Blood Arrangements, require suppliers and distributors to implement the following global barcode standards in relation to funded products:

- ISBT 128 DataMatrix for all fresh blood products (Red Cells, Platelets, Clinical Fresh Frozen Plasma, Cryoprecipitate, Cryo-depleted Plasma and Serum Eye Drops)
- GS1 DataMatrix for all plasma, recombinant and diagnostic products at the level of unit packaging

https://www.blood.gov.au/system/files/documents/Barcode%20specification%20for%20blood%20and%20blood%20products%20funded%20under%20the%20national%20blood%20arrangements.pdf

Therapeutic Goods Order 91 – Standard for labels of prescription and related medicines

- All medicines must be compliant by 1 September 2020.

"machine readable code means a code that:

(a) encodes the Global Trade Item Number (GTIN) for the medicine as allocated under the GS1 System; and

(b) identifies different product variants and differentiates between different strengths, pack sizes and dose forms;

(c) is formatted as one of the GS1 Bar Codes specified within the GS1 General Specification, which includes 2D / Matrix bar codes such as GS1 DataMatrix;

- Note: The machine readable code may also include additional information such as batch number and expiry date details."

- https://www.legislation.gov.au/Details/F2018C00437

Hospital implementations

The Reality

Without robust identification standards embedded within our EMRs, how can we be confident of the information being captured?

What does this mean for care that we deliver based on this information?

https://www.gs1.org/docs/healthcare/events/17-10-17/5-_utilising_standards_to_create_a_safer_patient_environment_in_our_hospitals_-_mavin.pdf

Implementing the Standards Framework

- First Step: Implement building blocks
- Proof of concept NICUCAM: scanning **Location ID (GLN)**
- Focus effort for greatest risk/benefit: **Patient ID (GSRN + SRIN)**
- Created middleware solution to generate GS1 Patient Wristbands without PAS upgrade
- Modified security system produces GS1 Staff Cards: **Staff ID (GSRN)**
- Implement new systems that leverage the building blocks
- Upgrade/replace old systems to leverage the building blocks

ACT Health implemented the GS1 identifiers with minimal integration, then built value through integrating systems

https://www.gs1.org/docs/healthcare/events/17-10-17/5-_utilising_standards_to_create_a_safer_patient_environment_in_our_hospitals_-_mavin.pdf

Solving the problem: PPID in focus

Problem: **Wrong Blood in Tube (WBIT)**

Objective:

- Ensure specimen collection and labelling occurs with the patient, after positive identification

Challenge:

- Patient notes labels contained the same local identifier as patient wristband

Solution:

- Implement eOrders with GS1 GSRN + SRIN for patient identification defined in **ISO/TS 18530:2014** to distinguish between types of patient id.

https://www.gs1.org/docs/healthcare/events/17-10-17/5-_utilising_standards_to_create_a_safer_patient_environment_in_our_hospitals_-_mavin.pdf

My last messages

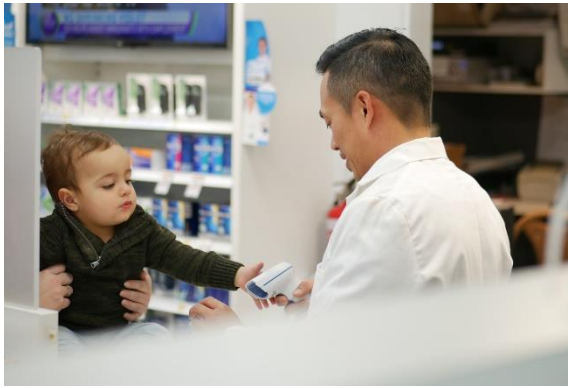
- Gain a deep understanding of developments regarding the use of global standards in Asia and around the globe
- Get inspired by your peers from pharmacies, hospitals, wholesalers, manufacturers and regulatory bodies that have implemented GS1 standards and hear about their experiences and learnings
- Learn how clinicians can improve processes when working with global GS1 standards

- **Confirmed speakers include representatives from:**
- KK Women's and Children's Hospital - Dr. Dirk de Korne - Singapore
- Stryker South Pacific - Sarah Lankshear - Australia
- Pharmaceutical and Medical Device Agency - Mr. Hiroshi Ishikawa - Japan
- Argentine Institute of Diagnosis and Treatment - Dr. Guadalupe Fernández Porto - Argentina
- Shanghai International Medical Supply Chain Alliance (SIMSCA) - Yan Liang - China
- World Health Organization (WHO) -Margaret Murphy - Ireland

- **Register at: https://healthcare-event.gs1.org/**

It shouldn’t be too much to ask

For all of us to be able to access the right (and authentic) medication, in the right dose, via the right route, at the right time, provided by an authorised caregiver…



Contact Details

Tania Snioch
GS1 Global Office, Brussels
E tania.snioch@gs1.org
W www.gs1.org/healthcare