GS1 Canada

The Global Language of Business

Pharmaceutical Preparation & Product Identification

HPAC Webex

Doris Nessim

September 24, 2015

Outline

Purpose:

- To enable healthcare providers globally to understand the strategy and implementation considerations for medication barcode identification so as to enable safe medication practices;

- To describe the GS1 Canada "Pharmaceutical Preparation & Product Identification Workshop and Guidelines, and associated data model, and process workflows, validated by the Pharmacy Sector , aimed at providing guidance with using a standards-based approach for enabling accurate identification and verification at each stage of the medication use process, enabling traceability, and ultimately, patient safety;

- To provide examples of global implementations that support a 'best practice' approach and helpful links and resources.

Pharmaceutical Preparation & Product Identification
Workshop Outline

- Pharmaceutical Preparation & Product Identification - Workshop Goals
- External Drivers
- GS1 Global Standards
- Key Implementation Considerations
- Principles
- Data Model
- Community Validation of Process Workflows at each stage of the Medication Use Process

Best Practice Guidelines: Pharmaceutical Preparation and Product Identification

Workshop Agenda

- **Canadian Experience: Automated Identification of Vaccines Initiative (AIVP)**
- **GS1 Community Management Model:** Key Standards Principles
- **Primer: Standard Identification Using Automated Identification & Data Capture (AIDC)**
- **Validation of Process Workflows**
- Manufacturer to Distributor
- Distributor to Pharmacy
- Pharmacy inventory and item master file
- Pharmacy re-packaging to the single unit
- Pharmaceutical compounding
- Dispensing
- Distribution
- Pharmaceutical Administration and Documentation in the electronic medical record
- **Validation of the Data Model**
- **Key Implementation Considerations & Next Steps**

Workshop Goals

- To assist the pharmacy sector with using a standards-based approach for enabling accurate identification of pharmaceutical products;

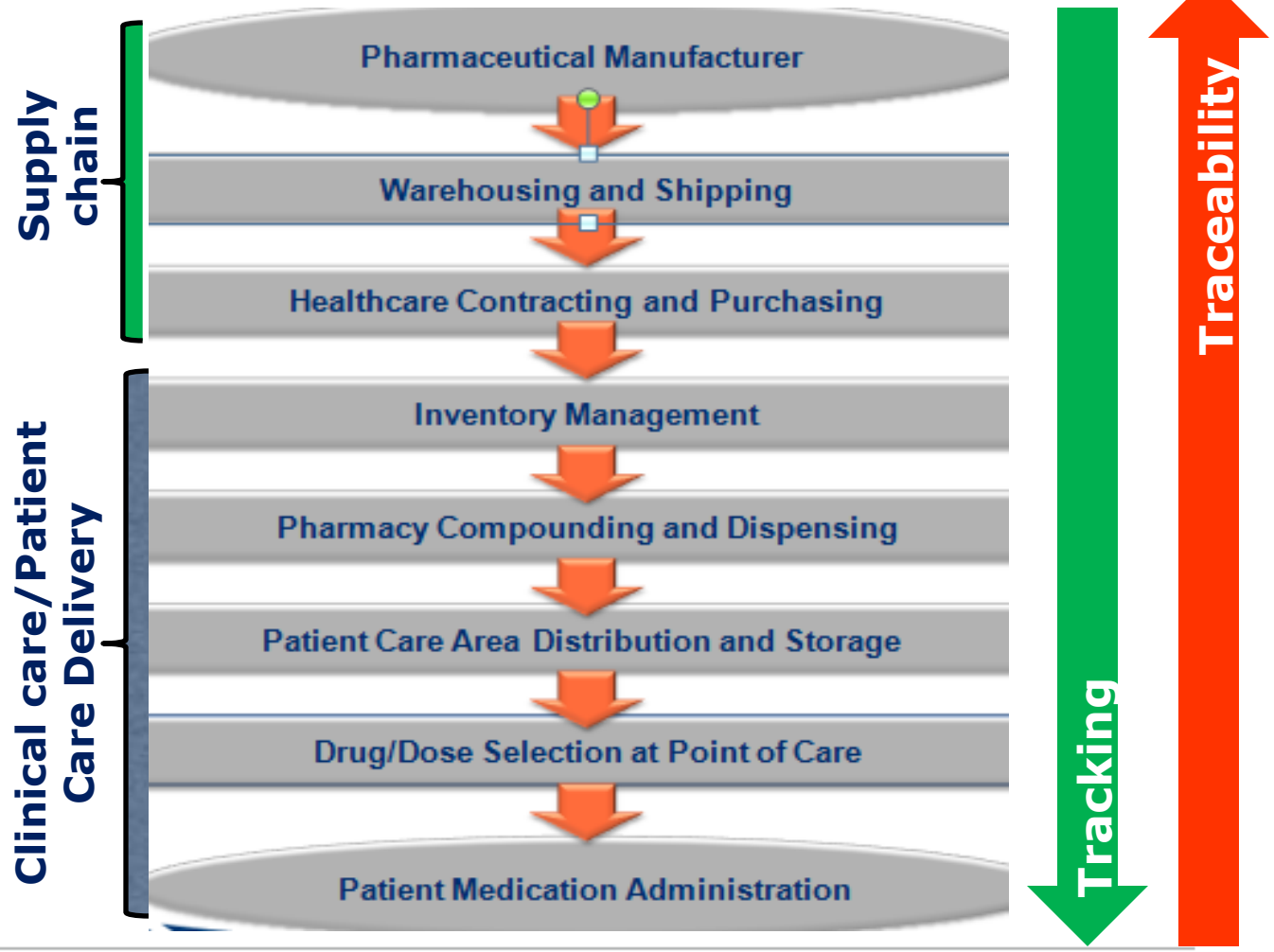
- To learn about GS1 standards, and validate business workflows aligning GS1 standard identifiers for enabling accurate identification and verification of pharmaceutical products and integration of standardized pharmaceutical attributes with the workflow processes.

- To enhance awareness of each other's roles, network, and to establish a 'working group' that may remain connected

The Medication Use Process

Patient Safety Focus from Manufacturer to the Patient

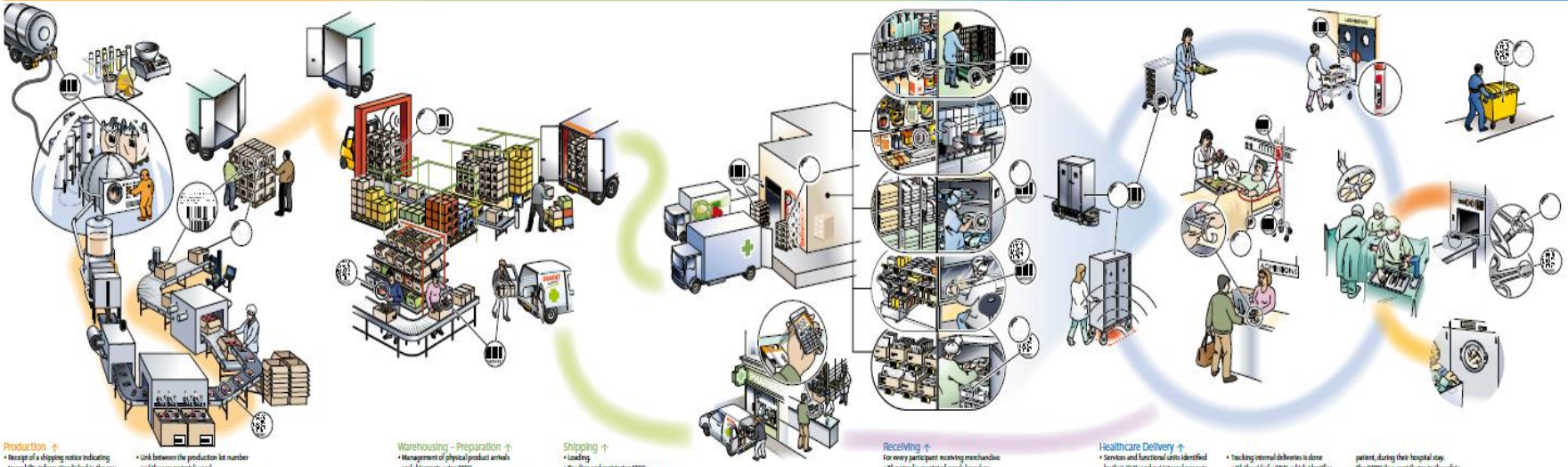
- To ensure accurate, pharmaceutical product information from point of manufacturer to the patient.



Description of the Major Supply Chain Processes

Each of these processes might be performed by different organisations or by a single entity

Industry →→→ Logistics provider →→→ Healthcare facility →→→



Production ↑

- Receipt of a shipping notice indicating traceability information linked to the raw material and packaging being used.
- Quantity control of merchandise using SSCC.
- Validation of receipt and delivery slip signature.
- Registration of lot/batch numbers and dates.
- Acceptance of primary materials.
- Recording of lot numbers used.
- GTIN assignment and marking for base units and creation of their lot numbers.
- Link between the production lot number and the raw materials used.
- GTIN and SSCC assignment for logistic units.
- Recording the links between SSCC and the content of logistic units: GTIN + lot/batch number + expiration date.

Warehousing – Preparation ↑

- Management of physical product arrivals and shipments using SSCC.
- Management of the separation and release of lots.
- Assignment of locations.
- Registering the movement of merchandise.
- Physical inventory.
- Order picking.
- Creation of logistic units, assignment and remarking of SSCC.
- Tracking inventory movements, linking SSCC, product, lot/batch number, and delivery destination.

Shipping ↑

- Loading.
- Reading and registering SSCC.
- Sending shipping notices to recipients with delivery itemization.
- Sending shipping orders to the carriers.
- After delivery, the carrier sends a transport status report.
- Integrating information in order to efficiently coordinate orders, deliveries, and invoices.

Receiving ↑

For every participant receiving merchandise:

- Planning for receipt of goods based on shipping notices.
- Unloading and SSCC reading.
- Control of receiving through efficient coordination with shipping notices.
- Coordinating orders and deliveries, sending acknowledgements of receipt.
- Entering product data into inventory records.
- Transmitting information to efficiently manage orders and invoices.

Healthcare Delivery ↑

- Services and functional units identified by their GLN send out internal requests using the product's GTIN.
- Preparation processes, assignment and registration of SSCC, delivery and receiving, all based on the same information as all other logistics processes.
- Sterilization, bleaching and restoring, are all production processes using the full range of GS1 identifiers; GTIN, SSCC, GRAI.
- Tracking internal deliveries is done with the aid of a GRAI, which identifies the material and also allows for tracking, washing, disinfecting, maintenance, etc.
- Delivery traceability is enabled by the link between the GRAI and the delivery contents as indicated by its SSCC.
- Patients, and the services provided to them, are identified using a GSRN, read and registered in a database at each stage and movement of the patient, during their hospital stay. The GSRN thus contributes to the safety and traceability of the patient.
- Products are identified by their GTIN + lot/batch number and are recorded in the patient's medical chart/records so as to ensure the complete safety and traceability of all events that take place during the patient's stay. This information facilitates itemized billing.

Drivers Supporting the Case for Medication Bar Coding

HIMMS EMRAM Model

United States EMRAM | Canada EMRAM | NEW! United States Ambulatory EMRAM

United States EMR Adoption Model SM			
Stage	Cumulative Capabilities	2013 Q4	2014 Q1
Stage 7	Complete EMR; CCD transactions to share data; Data warehousing; Data continuity with ED, ambulatory, OP	2.9%	3.1%
Stage 6	Physician documentation (structured templates), full CDSS (variance & compliance), full R-PACS	12.5%	13.3%
Stage 5	Closed loop medication administration	22.0%	24.2%
Stage 4	CPOE, Clinical Decision Support (clinical protocols)	15.5%	15.7%
Stage 3	Nursing/clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology	30.3%	27.7%
Stage 2	CDR, Controlled Medical Vocabulary, CDS, may have Document Imaging; HIE capable	7.6%	7.2%
Stage 1	Ancillaries – Lab, Rad, Pharmacy – All Installed	3.3%	3.2%
Stage 0	All Three Ancillaries Not Installed	5.8%	5.6%
Data from HIMSS Analytics® Database ©2012		N = 5458	N = 5449

HIMSS EMRAM Model

United States EMRAM | Canada EMRAM | NEW! United States Ambulatory EMRAM

Canada EMR Adoption Model SM

Stage	Cumulative Capabilities	2013 Q4	2014 Q1
Stage 7	Complete EMR; CCD transactions to share data; Data warehousing; Data continuity with ED, ambulatory, OP	0.0%	0.0%
Stage 6	Physician documentation (structured templates), full CDSS (variance & compliance), full R-PACS	0.6%	0.6%
Stage 5	Closed loop medication administration	0.0%	0.5%
Stage 4	CPOE, Clinical Decision Support (clinical protocols)	3.8%	3.6%
Stage 3	Nursing/clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology	32.2%	32.5%
Stage 2	CDR, Controlled Medical Vocabulary, CDS, may have Document Imaging; HIE capable	29.1%	28.9%
Stage 1	Ancillaries – Lab, Rad, Pharmacy – All Installed	14.5%	14.5%
Stage 0	All Three Ancillaries Not Installed	19.8%	19.4%
Data from HIMSS Analytics® Database ©2012		N = 640	N = 640

Drivers for Medication Bar Coding

- Global challenges with
  - counterfeiting,
  - ineffective product recalls,
  - medication shortages,
  - medication errors,
  - lack of inventory controls
- Evidence of Effectiveness of Bar Codes for Medication Safety
- Quality Best Practice Standards
  - Accreditation
  - Professional Association 'best practice' statements and target goals and objectives (e.g. Canadian Society of Hospital Pharmacists, CSHP)

CSHP 2015 Target Objectives

CSHP 2015 target goals and objectives:

- "**Increase the extent to which hospitals and related healthcare settings apply technology effectively to improve the safety of medication use",** with specific target objectives that:
  - 75% of hospitals will use machine-readable coding to verify medications **before dispensing**
  - 75% of hospitals will use machine-readable coding to verify all medications **before administration** to a patient

Systems Approach

- Need to recognize the system failures that could contribute to errors and processes needed for enabling patient safety
- Human error: we are all fallible and capable of mistakes
- Understand how to prevent and manage system failures
  - Safe design – require acknowledgement of each step
  - Standardization to enable predictability
    - provide automatic identification so that a drug would not be confused with another drug because of similar names, and also validate accuracy
  - Staff workflow and team work to simplify the number of steps
  - Provide alerts

Adverse Events in Canada

Baker Norton Canadian Adverse Event Study (2004)

- Annual number of Adverse Events is 185,000; **70,000 are potentially preventable**.
- Of these, **24% were related to medication or fluid errors**
- The Mean Increased **Length of Stay** related to an AE was:
  - For small hospitals: 7.7 days
  - For Large hospitals: 3.6 days
  - For Teaching hospitals: 6.2 days

… there is a need for enhancing patient safety related to medication use in hospitals

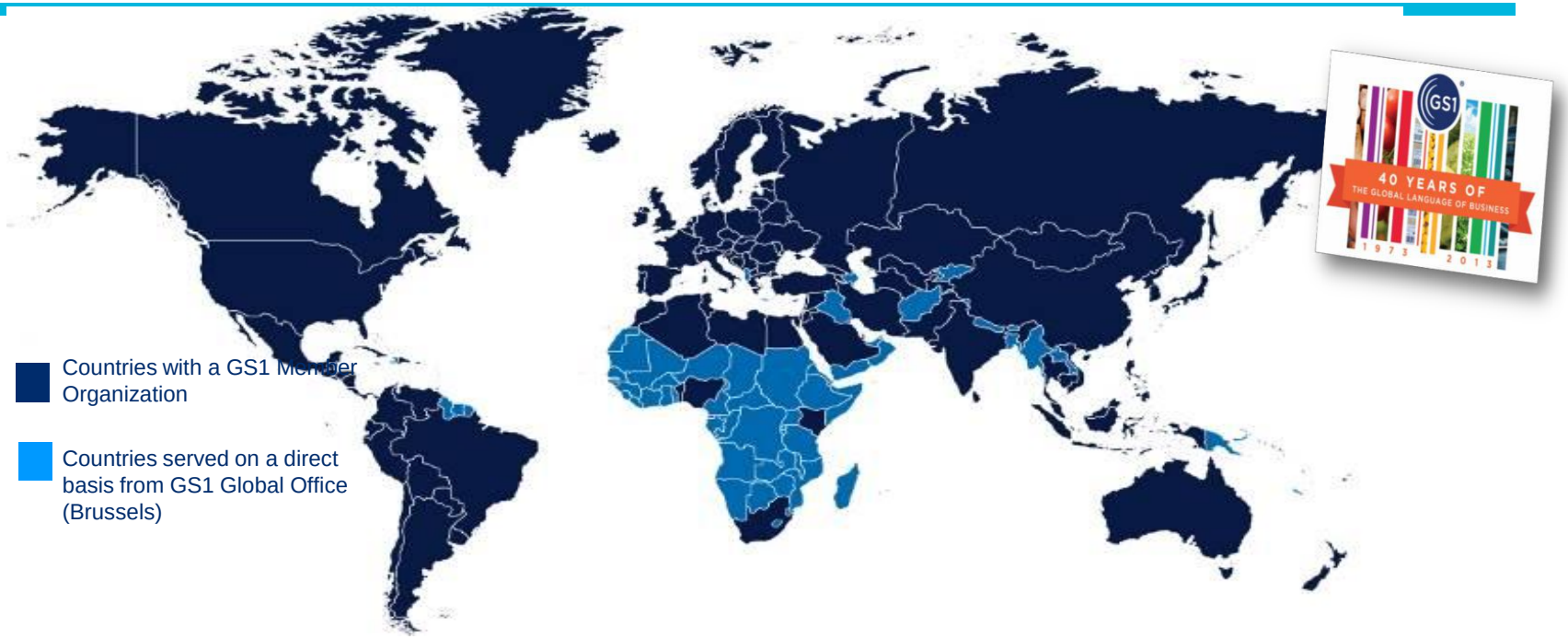
The Canadian Adverse Events Study

Drs. Ross Baker and Peter Norton, Lead investigators, CMAJ, May/04

only 2% of errors that originate at the patient's bedside are captured, making the **administration phase** of medication delivery the most hazardous phase

nurses have *no* safety net

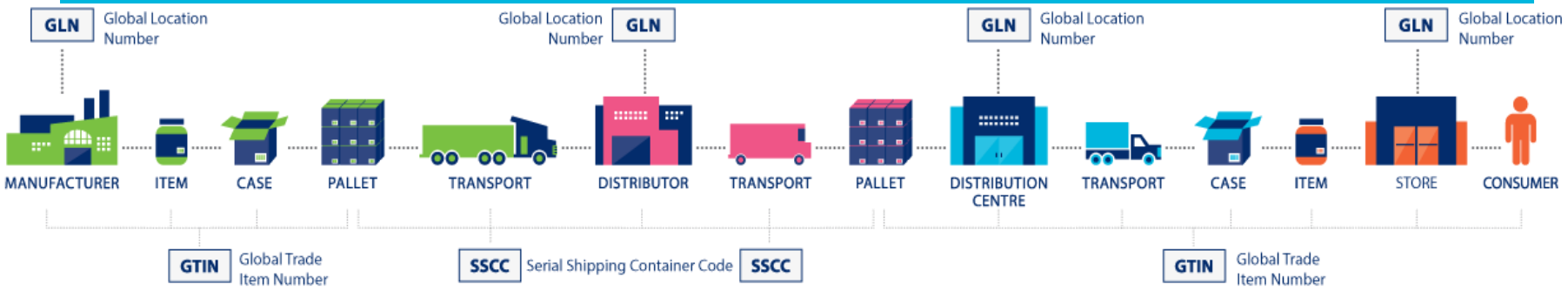
Global standards & data: A Common Language



- **Not-for-profit, neutral, user – driven organization promoting standards-based electronic business and supply chain practices**
- **111 GS1 Member Organizations in 150 Countries**
- **1,700+ GS1 employees staff worldwide**
- **2 million user companies produce over 6 billion transactions daily**

A global system of standards to ensure visibility

IDENTIFY



CAPTURE

GS1 System Data Carriers
Barcodes & EPC/RFID Tags

SHARE

ELECTRONIC COMMERCE INFORMATION FLOW

Electronic Data Exchange ••• Extensible Markup Language ••• Global Data Synchronization Network ••• EPC Information Services

ITEM DATA

NATURAL RESOURCES
- raw materials source & information
- 3rd party certification of products
- packaging sustainability attributes

PARTY DATA

ENERGY & CLIMATE
- energy costs
- greenhouse gas emissions
- empty miles reductions

MATERIAL EFFICIENCY
- solid waste reduction
- water usage reduction

NATURAL RESOURCES
- supplier management for sustainability purchasing guidelines

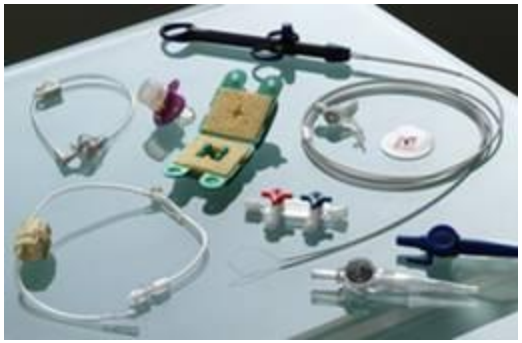
PEOPLE AND COMMUNITY
- location identification & nutrition
- community development

USE

GS1 Canada

The Global Language of Business

GS1 Standards Address Global Healthcare Challenges



- **Medication errors** result in additional treatments, disabilities and even loss of life
- **Counterfeiting** is an increasing global threat
- **Traceability** from manufacturer to patient is unworkable
- **Product recalls** can be difficult to manage, in particular for healthcare providers
- A lot of manual interventions in the healthcare **supply chain** decrease its **efficiency and accuracy**

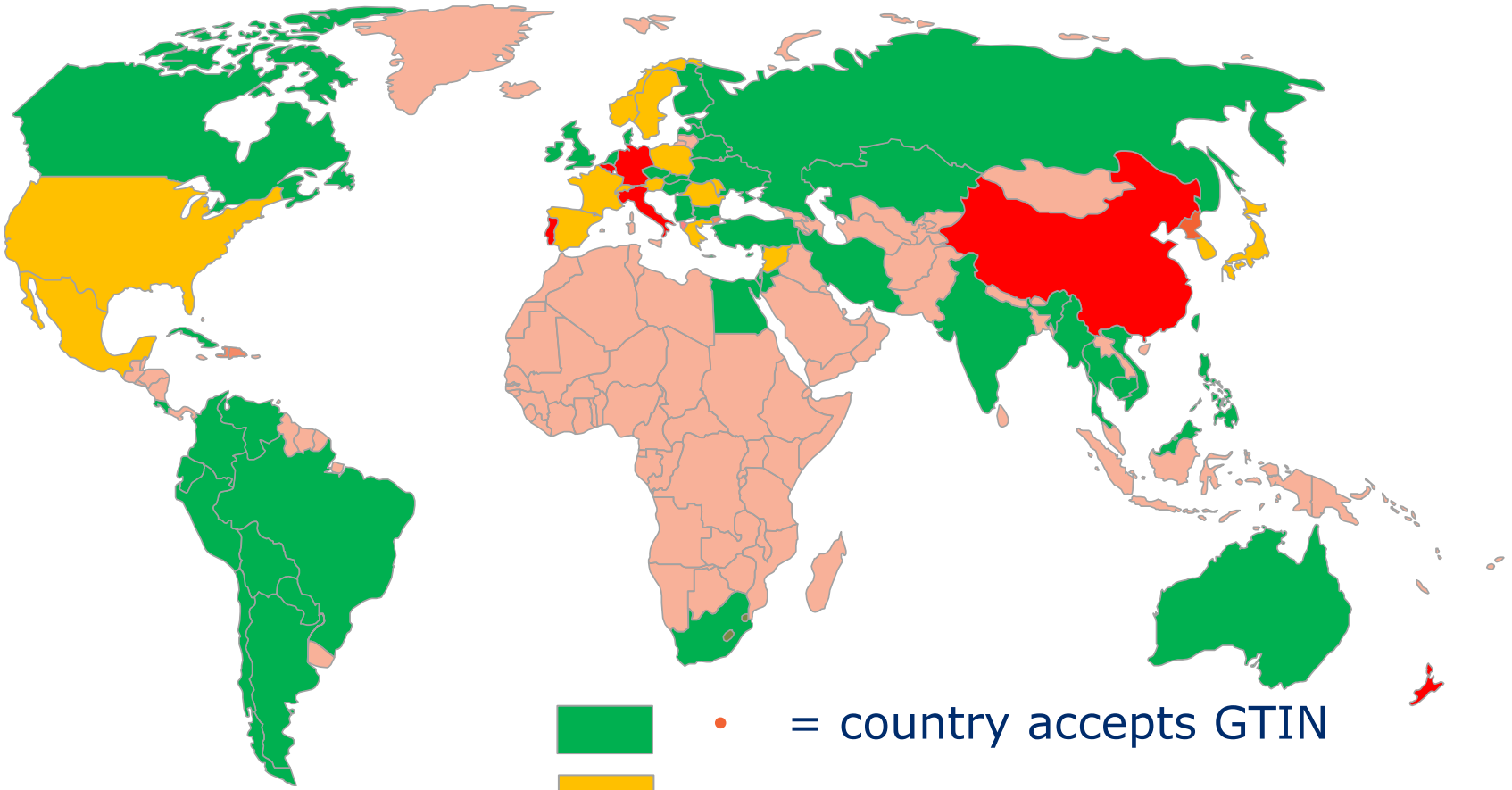
GS1 Keys Identify all Objects

Object Identification Keys

GTIN	• **G**lobal **T**rade **I**tem **N**umber: Identifies individual Products or Services
SSCC	• **S**erial **S**hipping **C**ontainer **C**ode: Identifies logistical units such as cases, cartons, totes.
GLN	• **G**lobal **L**ocation **C**ode: Identifies organizations and their individual locations
GIAI	• **G**lobal **I**ndividual **A**sset **I**dentifier: Identifies s an asset that is part of the fixed inventory of a company.
GRAI	• **G**lobal **R**eturnable **A**sset **I**dentifier: Identifies returnable assets and transport equipment.
GSRN	• **G**lobal **S**ervice **R**elation **N**umber: Identifies the business relationship between a service provider and recipient of their service(s).
GDTI	• **G**lobal **D**ocument **T**ype **I**dentifier. Identifies individual documents
GSIN	• **G**lobal **Shipment I**dentifier. Identifies individual shipments

"Global standards could be a critical enabler to improving the safety and quality of patient care in a cost effective way"
- McKinsey Report

Global Identification of Pharmaceuticals



- = country accepts GTIN
- = country requires NTIN
- = country requires national ID #
- = no input available

World-wide Regulatory Activities Involving GS1 Adoption

Council of Europe
www.coe.int

ansm
Agence nationale de sécurité du médicament et des produits de santé

DH Department of Health

swissmedic

edqm
European Directorate for the Quality of Medicines & HealthCare

Public Health Agency of Canada

厚生労働省
Ministry of Health, Labour and Welfare

FDA

SHFDA

República de Colombia
Ministerio de la Protección Social
INVIMA
Instituto Nacional de Vigilancia de Medicamentos y Alimentos

醫院管理局
HOSPITAL AUTHORITY

MINISTRY FOR HEALTH, WELFARE AND FAMILY AFFAIRS

ANMAT
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

ANVISA

Cenabast

Government of India

nehta

MANATŪ HAUORA
MINISTRY OF HEALTH

And many more…

Global Adoption Examples

UK	National Healthcare Service (NHS) e-procurement strategy and requirements; Medical Alerts using GS1 Standards
USA	FDA; Healthcare Transformation Group – Kaiser Permanent, Mao Clinic, InterMountain Health, Geisinger Health System
Australia	National E-Health Transition Authority (NEHTA)
India	Issues amendments to the Drug and Cosmetic Act
Canada	Public Health Agency of Canada, Automated Identification of Vaccines Initiative & Patient Safety Advocacy

Public Health Agency of Canada

DH Department of Health

Government of India

nehta

FDA

Effectiveness of Barcodes on Medication Safety

Effect of Bar code Technology on the Safety of Medication Administration

Poon EG, et al. New England Journal of Medicine 2010; 362:1698-707

Summary:

Using a bar coded eMAR Brigham Young, Boston

- **41.4 %** reduction in dose administration and order transcriptions, excluding potential timing errors.
- **27.3%** reduction in dose timing errors.

Conclusion:

- Use of bar code eMARs reduced the rate of errors and adverse drug events in order transcription and medication administration.
- Bar code eMAR is an important intervention to improve medication safety.

Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in Pharmacy
Poon EG, et al (2006)

Summary:
Effect of bar code medication technology on reducing dispensing errors and adverse drug events (735 bed tertiary care academic medical centre)

Conclusions:
Reduction in all potential ADEs by 74% and a 63% reduction in ADEs that could cause potential patient harm

Medication Errors in a pharmacy based bar code repackaging center
Cina JL, Gandhi TK, Churchill W, et al 2006

Summary:
Studied errors generated in the repackaging center and identified and implemented system improvements to reduce future errors using medication bar coding using a two dimensional data matrix bar code.

Conclusions:
Their findings indicated that "a multistep quality control process in an in-house bar code repackaging center effectively identified the types and rates of drug distribution errors."

Label tracking and traceability key part of compromise bill to regulate compounding pharmacies

by ENTERPRISE LABELING *on* Nov 21, 2013 • 1:33 pm

No Comments

Although lawmakers are already being criticized both for going too far and not going far enough, the U.S. Congress has taken a step toward increasing regulation of so-called compounding pharmacies, which produce medications but are not subject to the same regulations and scrutiny as manufacturers. This move comes approximately one year after a lethal meningitis outbreak sickened hundreds of Americans in multiple states.

On Monday, the Senate approved a bill that was passed by the House in September. The legislation clarifies the U.S. Food and Drug Administration's authority to inspect and, when necessary, forcibly shut down compounding facilities that handle large volumes of pharmaceuticals. However, it does not require these pharmacies to register with the FDA—a step that many in the media and the political sphere called for in the aftermath of the meningitis outbreak.

Manufacturers will have to update their labeling processes to comply with new federal tracking and traceability requirements.

Regulatory Changes Globally: U.S.


Federal Register

Thursday,
February 26, 2004

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 201, 606, et al.
Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule

Institute of Medicine Report: To Err is Human: Building a Safer Health System

-44,000 to 98,000 people die /year due to **preventable** medical errors (1999)

-**Recommended** medication bar coding as a "simple way to ensure that the identity and dose of the drug are as prescribed… and that all of the steps in the dispensing and administration processes are checked for timeliness and accuracy."

-**Challenge:** lack of standardized bar codes by manufacturers constrained adoption of medication bar coding by healthcare organizations

Focus on reducing medication errors by enabling hospitals to implement point of care, bar code enabled, medication administration systems

Mandated: April 2006

A "National Drug Package Code" (NDC Code)

BACKGROUND: U.S. Experience

- Barcoded NDC - required by the FDA since April 2004 with compliance required by April 2006
- Through support of a government mandate on drug packaging in the U.S., approximately 60% of hospitals have implemented medication bar coding (2012) (dispensing and administration)

Regulatory Changes Globally: E.U.

European Association of Hospital Pharmacists, EAHP:
Advocated for regulations for unit of use packaging with GS1 barcodes;
EU Regulations: 2015

Leuven Hospital: 2300 beds - Thomas De Rijdt, Assistant Director, Pharmacy

The introduction of bedside scanning before administration of medication, linked to hospital wide CPOE with prescriber helps us to prevent medication errors and near misses and therefore optimizes the patient's therapy and guarantees the highest possible patient safety. It took a lot of effort to achieve this but it was worth it!"

www.gs1.org/docs/healthcare/case_studies/Case_study_Switzerland_cytostatics.pdf - Windows Internet Explorer

http://www.gs1.org/docs/healthcare/case_studies/Case_study_Switzerland_cytostatics.pdf

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w.gs1.org/docs/healthcare/case_s...

Page Safety

Cytostatic treatment and bedside scanning: Improving patient healthcare at Geneva University Hospitals

ABSTRACT

Treatment of patients suffering from cancer requires the use of special medication, customised for the individual patient. At Hôpitaux Universitaires de Genève [Geneva University Hospitals] (HUG) in Switzerland, the high number of patients, who need such a specialised treatment, results in the preparation of over 14,000 cytostatic drugs

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100%

Hospital Alemán
Deutsches Hospital

Traceability of Drugs:
"Implementation in a hospital pharmacy in Argentina"

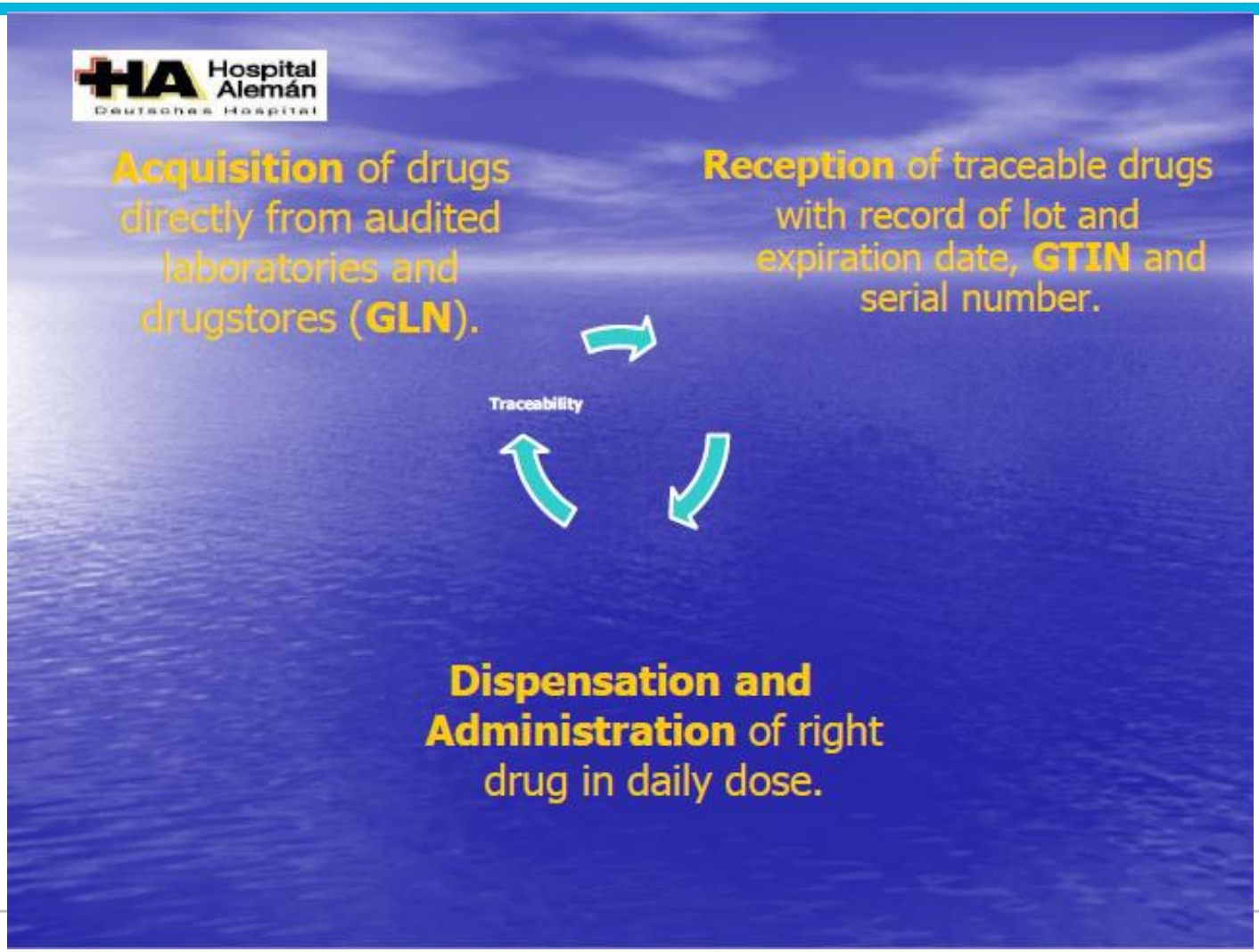
Global GS1 Healthcare Conference
San Francisco, USA 1-3 October-2013

Dra. Heidi Wimmers
Hospital Alemán

Hospital Alemán
Deutsches Hospital

What is traceability of drugs?

- It is a tool that allows us to know the history of the drug along all its steps:
  - verification of its ORIGIN.
  - register of records all along its DISTRIBUTION CHAIN.
- Patients have the right to receive legal drugs.



Hospital Alemán
Deutsches Hospital

The traceability-system involves 4 specific steps in our hospital :

- hospital reception
- single dose fractioning
- dispensing
- administration

... its a big teamwork !!

Hospital Alemán
Deutsches Hospital

GTIN: Global Trade Item Number

- Each individual package has a unique, unrepeated random code :

  (01)GTIN and (21)serial number

- It is placed by the laboratory/drugstore.
- It will allow the patients to verify the authenticity of the product.

human readable barcode

Patient Safety

Electronic patient records will soon end doctor's scrawl on paper

TAMARA BALUJA

From Wednesday's Globe and Mail

Published Wednesday, Apr. 13, 2011 12:01AM EDT

A Review of the Oncology Under-Dosing Incident – Recommendations:

Recommendation #7:

- The Ontario College of Pharmacists (OCP) (and by extension, the National Association of Pharmacy Regulatory Authorities [NAPRA]), shall stipulate specialized electronic material records and label requirements for non-sterile and sterile product preparation within a licensed pharmacy.
  - All pharmacy labeling shall **quickly progress to comprehensive bar-coded identification in keeping with global GS1 standards integration**…..
  - For non-sterile and sterile products, this bar-coding shall be connected to an electronic patient record. In this way **traceability can be assured**.
  - A timeline shall be set for such bar-coding requirement

Enabling vaccine traceability in Canada using GS1 Standards

The Public Health Agency of Canada's Automated Identification of Vaccine Project

ABSTRACT

The Public Health Agency of Canada's (PHAC) Automated Identification of Vaccine Projects (AIVP) initiative was established in 2002 to improve the safe use of vaccines, as well as immunisation record keeping, by incorporating standardised bar codes onto vaccine product labeling. To examine this issue, PHAC established the AIVP Advisory Task Group, a collaborative effort between all stakeholder groups in the area of immunisation, co-chaired by PHAC and the vaccine industry, including key representation from GS1 Canada. In 2010, the AIVP Advisory Task Group reached consensus on the use of GS1 Standards for the identification of vaccine products approved for use in Canada.

By **Dr. Monika Naus,** British Columbia Centre for Disease Control

And **Dr. Robert Van Exan,** Sanofi Pasteur Limited.

Introduction

Over 20 million doses of vaccines are administered in Canada every year, with each patient's health record manually updated by Healthcare providers to track the details of the vaccination. However, such transcription of the details of the vaccine given may not be accurate or complete. Studies examining immunisation records in the provinces of British Columbia and Manitoba estimated that between 5 and 15 percent of patient immunisation records are missing core data elements. Up to 24 percent of records lack data or contain errors that can cause

At the Point-of-Care

The idea of bar coding vaccines in Canada is not a recent development. The potential benefits of vaccine bar coding for both inventory management and efficient population of immunisation registries have been evident for over a decade, stimulated by the increasing number of vaccines in use in Canada.[1] The collaboration with GS1 Canada supports PHAC's immunisation traceability initiative, the Automated Identification of Vaccine Projects (AIVP). Established in 2002, the initiative's goal is to improve the safe use of vaccines as well as immunisation

Automated Identification of Vaccines
Public Health Agency of Canada

- Between 5 and 15 percent of immunization records are missing important information and up to 24 percent contain errors, causing delays in the follow-up of adverse events following an immunization.
  - The outcome is an increased cost to the health system and may result in adverse health outcomes for Canadians.

- In light of these findings, the National Advisory Committee on Immunization (NACI) passed a resolution in 1999, recommending that bar codes be placed on all vaccine products to improve record keeping and the safe use of vaccines.

Automated Identification of Vaccines – Public Health Agency of Canada

The **Automated Identification of Vaccine Projects Advisory Task Group (AIVP ATG)** was established to provide leadership, direction, advice and support for the development and voluntary implementation of globally standardized bar codes on vaccine products in Canada.

Collaborative effort between all stakeholder groups in the area of immunization and is **co-chaired by the Public Health Agency of Canada (PHAC)** and the vaccine industry with representation from:

- vaccine manufacturers,
- jurisdictions,
- health authorities,
- health professional associations,
- regulators,
- international standard setting agencies,
- electronic health record, and;
- clinical management software developers.

Canadian Barcode Recommendations for Vaccine Products

Recommendations

1. **Two dimensional (2D) bar codes on the primary package which include the Global Trade Identification Number (GTIN) and the lot number.**

   - Including the expiry date in the bar code is optional as it can be determined through the lot number.
   - Lot number and expiry date will continue to appear in human readable form on the primary packaging as per Canadian labelling requirements.

(01)07612345678900(17)100503

(10)AC3453G3

2D Data Matrix

Canadian Barcode Recommendations for Vaccine for Vaccines Products

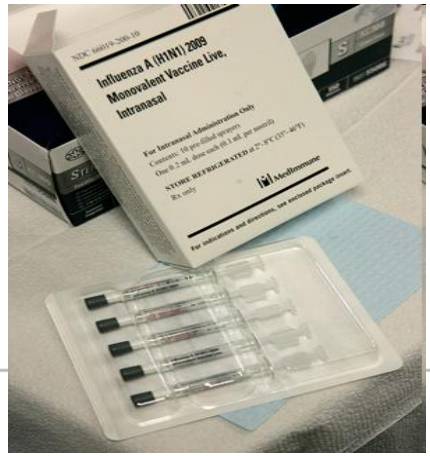
Recommendations

2. **Two dimensional (2D) or linear (also known as 1D) bar codes on the secondary package that include GTIN and the lot number.**
   - Including the expiry date in the bar code is optional as it can be determined through the lot number.
   - Lot number and expiry date will continue to appear in human readable form on the secondary packaging as per Canadian labelling requirements.

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

Linear

2D Data Matrix



The Canadian Pharmaceutical Bar Code Project

(21) ABCDEFG123456789

(01) 00314141 99999 5

(21) ABCDEFG123456789

(01) 00314141 99999 5

(01) 00314141 99999 5 (21) ABCDEFG123456789

(01) 00314141999995
(10) 987654321GFEDCBA

Patient Safety Advocate Groups Link Standards to Safety

ISMP CANADA

cpsi icsp
Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients

ISMP Canada and Canadian Patient Safety Institute Team Up with GS1 Canada to Advance Patient Safety in Canada

Two of Canada's patient safety organizations – Institute for Safe Medication Practices Canada (ISMP Canada) and Canadian Patient Safety Institute (CPSI) are collaborating with GS1 Canada, a global supply chain standards organization, to advance automated identification (e.g., bar coding) of pharmaceutical products in Canada. **To this end, the three organizations are working collaboratively to advance the Canadian Pharmaceutical Bar Coding Project.**

The Joint Technical (Task Force) Statement

Section 1: Pharmaceuticals to be Encoded

Section 2: Common National Standard

Section 3: Content of the Bar Codes

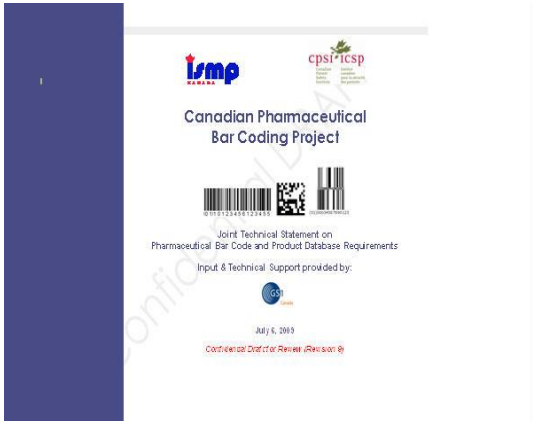
Section 4: Pharmaceutical Packaging Levels and Placement of Bar Codes

Section 5: Common Canadian Pharmaceutical Product Registry (CCPPR)

Section 6: Bar Code Symbology

Section 7: Expectations of Professional Practice Organizations and End-Users

Section 8: Timeline Adoption of Standard by each Health Sector (Pharmaceuticals Dec 2012)



GPO's Support

HealthPRO
Choice. Support. Results.

MEDBUY
Building partnerships in healthcare

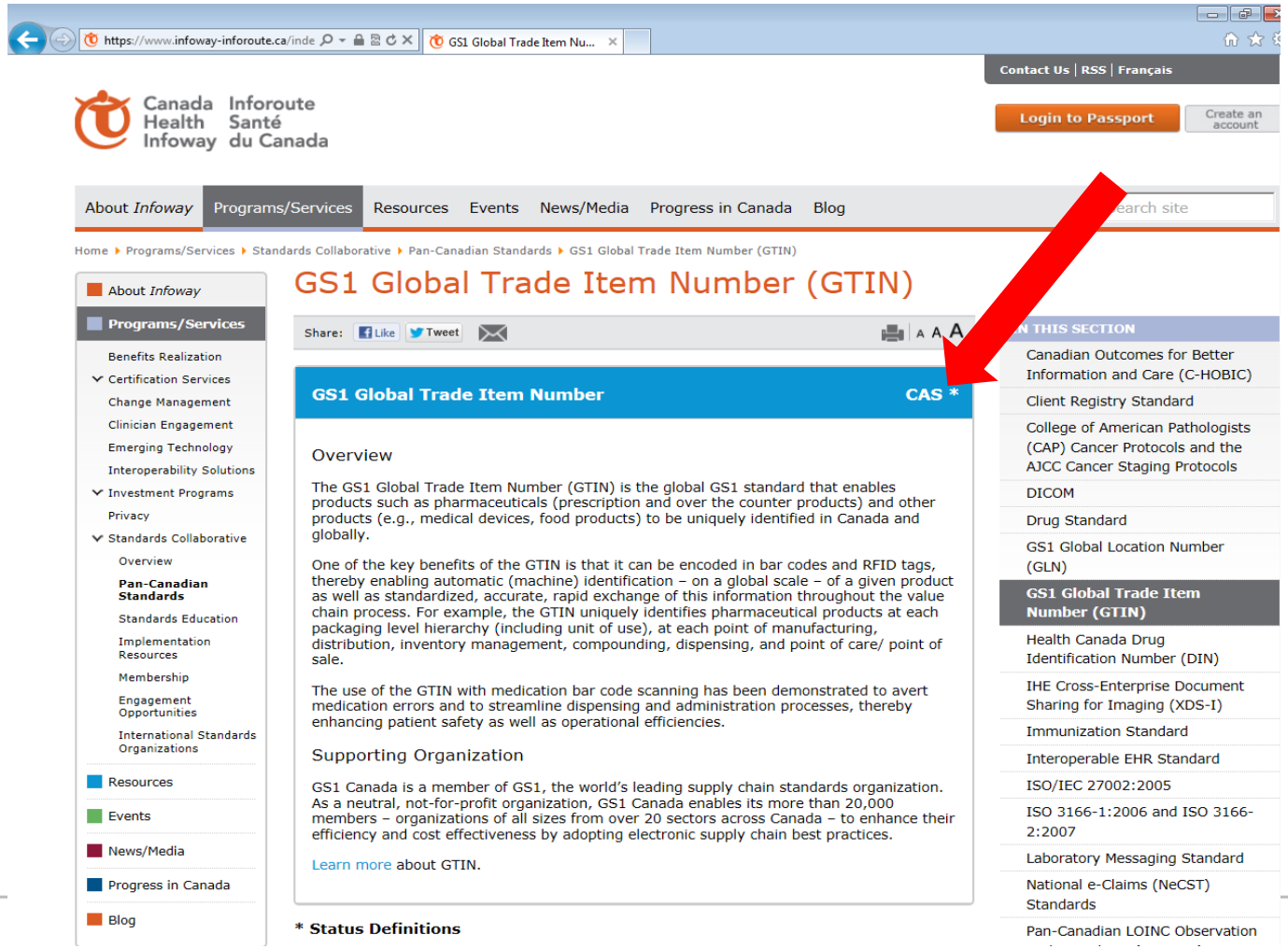
HealthPRO and Medbuy Endorse Global Supply Chain Standards to Enhance Patient Safety, Reduce Costs

Toronto, ON – December 10, 2008 – In a move that will have a major impact on driving efficiencies and reducing costs in the healthcare supply chain, HealthPRO and Medbuy, **two of Canada's most prominent group purchasing organizations, affirmed their commitment to driving the adoption of GS1 global standards with their members.** Global standards improve efficiency and visibility in supply chains, and will enable HealthPRO and Medbuy to advance their respective mandates for maximizing value and providing value-added services to their members.

GTIN and GLN as Canadian Approved Standards by Canada Health Infoway

- The GS1 Standards, the GTIN and GLN, were recognized as Canadian Approved Standards by Canada Health Infoway, enabling interoperability with the electronic health record for accurate drug, and location identification throughout each stage of the medication use process.

GTIN as
CHI Candadian Approved Standard



Design Considerations

- Pharmacy Services NOT 24 x 7
- Considerations for medication bar coding at each medication use touch point for each medication dosage form:
  - centralized and decentralized medication inventory
  - repackaging
  - compounding sterile and non sterile
  - dispensing
  - distribution to patient care area
  - patient care storage areas
  - medication administration
  - 40-50% “unit dose”– 100% re-packaged internally
- Bar code medication station
- Automated medication re-packaging system capital
- Automated medication cabinets
- Resources
- Change Management (workflow considerations)

Barcode Strategy: Design Considerations

Canadian Hospitals that seek to take advantage of the opportunities to prevent medication errors are required to:

1. **Determine the priority**
2. **Strategy**
3. **Resources**
4. **Infrastructure**
   - **Bar code identifier**
   - **Bar code symbology**
5. **Capital**

So as to implement medication bar coding internally.

Implementation Considerations

- **Leadership Support & leverage**

- **Develop the implementation team**
  - Inter-professional
  - Growth and learning
  - Change management

Implementation Considerations

System Design

- Bar Code Identifier
  - Bar code standard identifier
- Bar code symbology
  - Bar code scanners (camera ready)
- Label requirements
  - Print quality
- Bar code scanners and labels
- Information System interoperability
  - Integration of the standard
  - Master file

Implementation Considerations

System Design

- Clearly documented procedures
- Training manuals with FAQs
- Workflow considerations
  - Pharmacy
  - Nursing
- Infrastructure considerations
- Metrics
- Celebrate successes !

Key Principles

Key Principles Introduced:

- Traceability
- Globally unique identification
- Serialization
- Labelling

Standards Identification Using Automated Identification & Data Capture (AIDC)

GS1 System of Standards

- Locations
- Products
- Assets
- Patients
- Documents

- Barcodes
- RFID tags

- Electronic data exchange
- Data synchronization
- Item master file integrity

- Bedside scanning to EMR
- Product recalls
- Medication dispensing
- Order & contract management
- Global product identification
- Nutritional data & menu planning
- Consignment inventory
- Mobile/Virtual Health

What is a GTIN?

- A **Global Trade Item Number (GTIN)** is a numerical identification code that is used to identify a product as it moves through the global supply chain to the hospital or ultimate end user.
- GTINs are used to identify products and packaging configurations

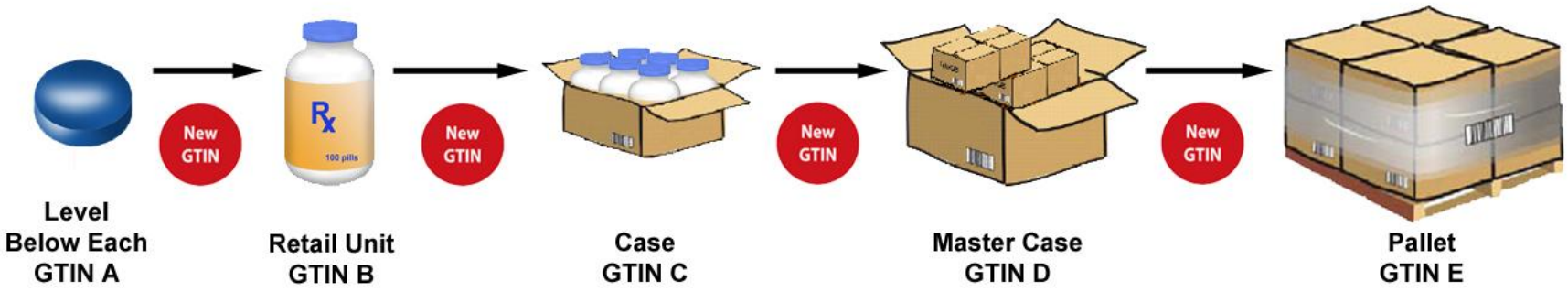
How Big is a GTIN?

Simple answer: 14 digits

Regardless of what symbology is used to transport it, the field length for containing a GTIN should be 14 digit capable.

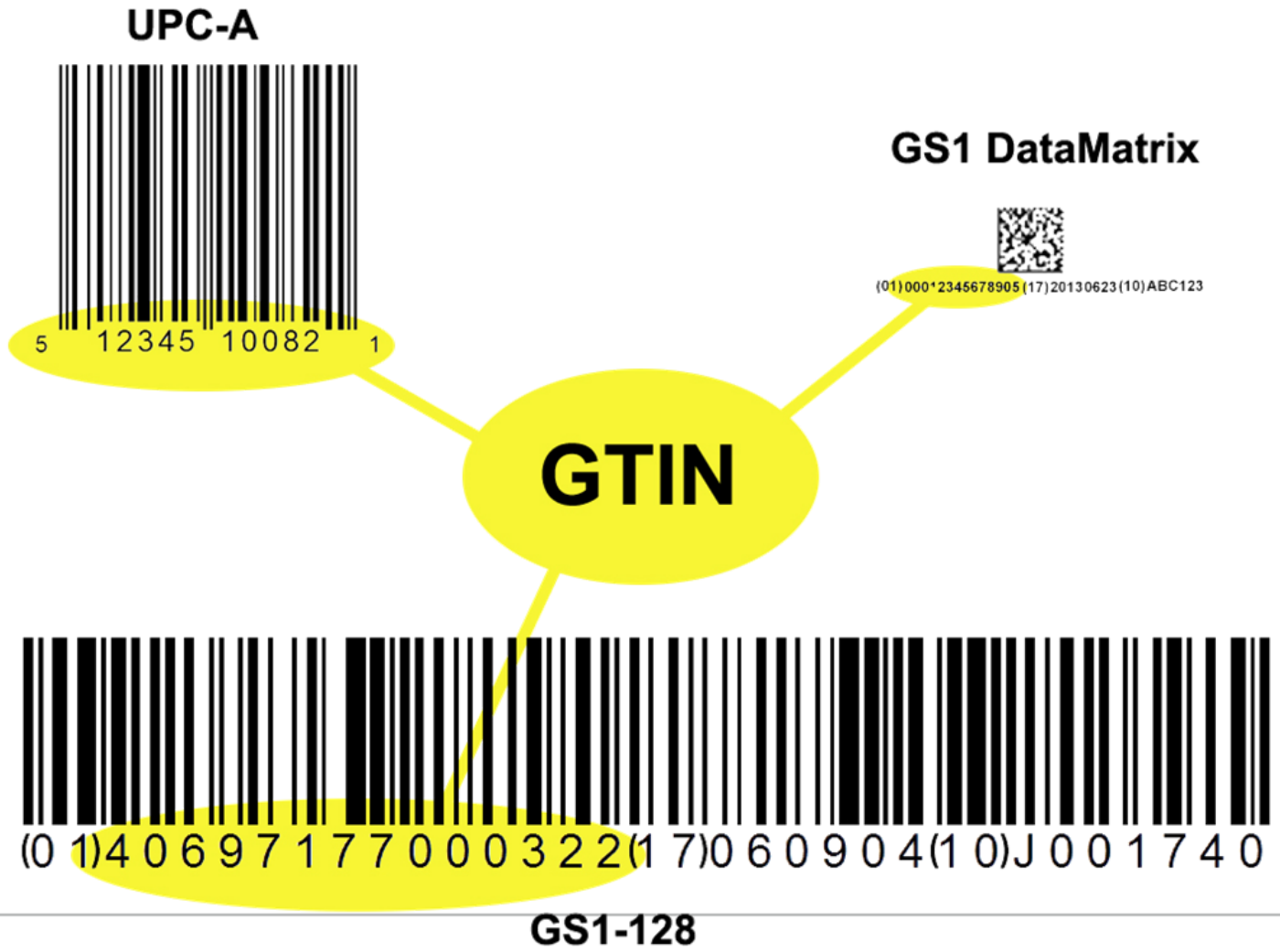
Is UPC the same as GTIN?

U.P.C. is a legacy term defined by the Grocery industry to identify the each.

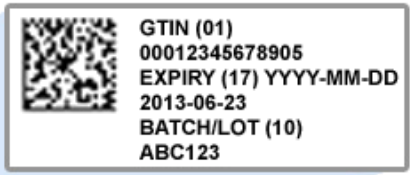


GTIN is the proper term at any packaging level

Where is the GTIN?



Different Capabilities



GS1 DataMatrix (non-retail code)
Contains GTIN12 (same as UPC-A), Expiry date and Batch/Lot
Approx size: 7mm x7mm
(size varies dependant on quantity of information included)

UPC-A (Retail code)
Contains GTIN12
No additional information can be added in this symbology.
Approx size: (Width x height)
29.83mm x 20.73 mm Minimum

Global Object Identification Keys Provide the Foundation

Standard construction

- Unique global company prefix enables global uniqueness when creating the GTIN
- Individual reference identifiers enable uniqueness within an organization
- GTIN construction is defined in the GS1 General Specifications

Example:

GTIN Number 0 0 0 6 1 4 1 4 1 0 0 0 1 2

- GS1 Company Prefix
- Item Reference
- Check Digit

Global Trade Item Number

* Check Digit Calculator at mygs1ca.org under Tools

GTIN & Data

Master Data (static) **

- **GTIN Identifier key**
  **All product levels
- Brand Name
- Quantity
- DIN

i.e. Tylenol Extra Strength 24 capsule bottle

** National Product Registry

Transactional (dynamic)

- **Lot**
- **Serial number**
- Expiration date
- Production date

Lot: ABC123
EXP: 2014/09

Global Trade Item Number

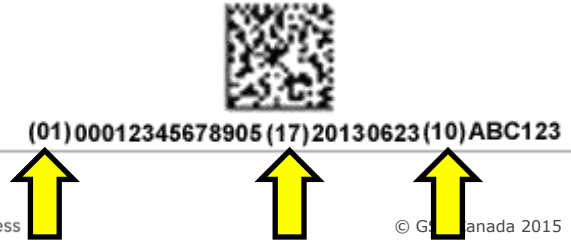
In addition to the master data (primary identifier i.e. **GTIN**), transactional information (secondary identifier) can also be represented in the GS1 System of standards. This information is referred to as **Application Identifiers (AIs)** in the GS1 System.

Secondary information can include:

- Lot Number
- Expiration Date
- Serial Number

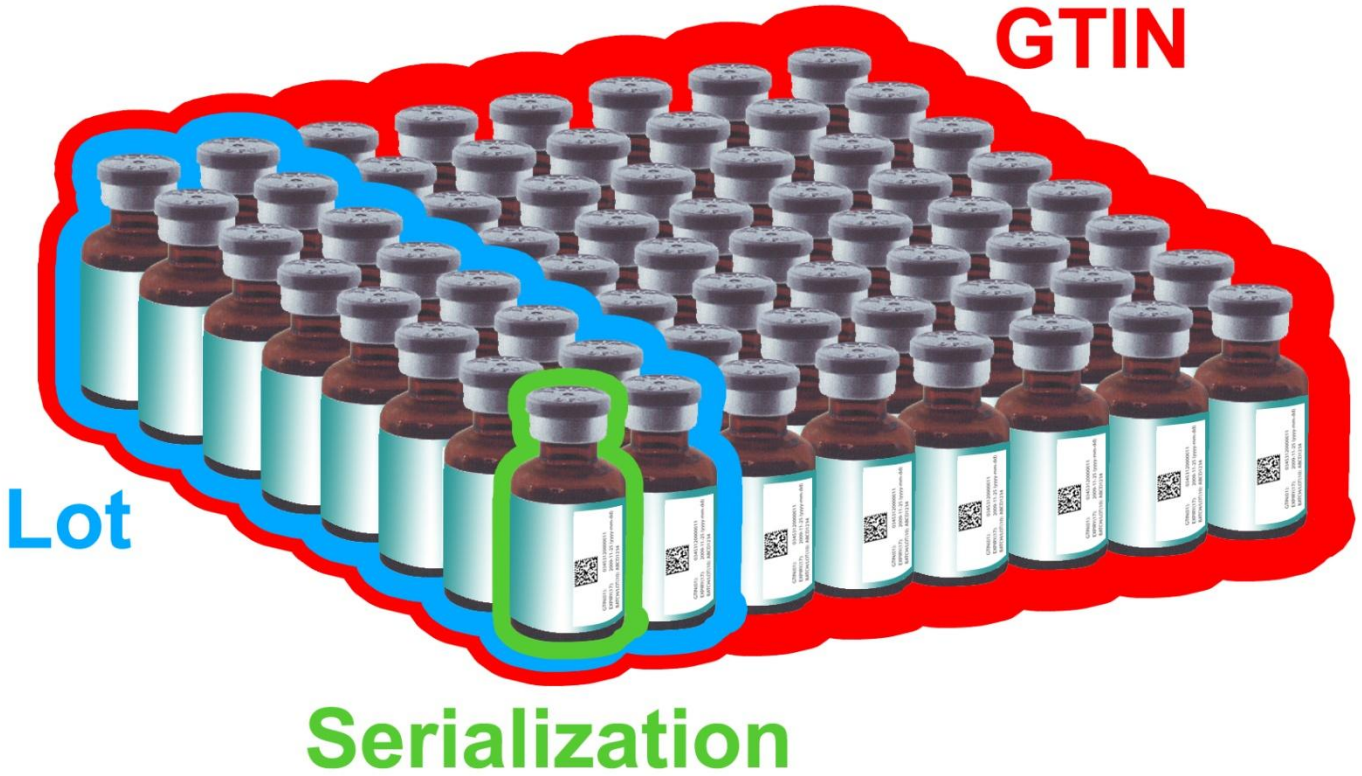
What is an AI?

- AI: Application Identifier
- A machine readable data tool used to parse strings of information into defined useful portions for capture and recording into a data base.



Serialization

Method by which a single distinct item is identified



Traceability

Track The ability to follow the path of a traceable item through the supply chain as it moves between parties.

Trace The ability to identify the origin, attributes, or history of a particular traceable item located within the supply chain by reference to records held.

"Tracing back" and "tracking forward"

Global Standards for the Identification of Products & Services:

The foundational concepts & Principles

GS1 identification standards are global

- Integrity of GTIN assignment
  - When do I assign (allocate) a new GTIN?
  - When can I re-assign (re-use) a GTIN?
  - Impact of changes in ownership

GTIN Assignment

**repackaged/compounded

Global Standards for Managing Integrity of GTIN Assignment

GTIN Allocation rules

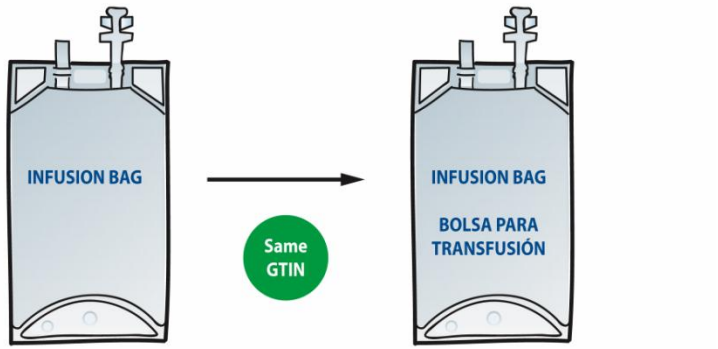
- Enable consistent application of critical data relationships
- Can be automated and managed as part of Community applications

www.gs1.org

Global Standards for Managing Integrity of GTIN Assignment

GTIN Allocation rules

- Example: when do I create a new GTIN?
  - Product name, brand, description
  - Formulation
  - Strength
  - Dosage
  - Net Quantity
  - Packaging configuration
  - Form, fit or function
  - Grouping



GS1 Standards for Barcode Creation and Placement

DataMatrix
Symbol

-

Bar Code Readers

- GS1 Scanner Selection Guide

http://www.gs1ca.org/files/AIDC_-_Selecting_Bar_Code_Scanning_Equipment_Eng.pdf

Data Model Terminology

Next Steps

The following slides provide suggestions for next steps to advance GS1 standards

Organizational Commitment

- Align standards adoption with key quality, patient safety and operational efficiency projects within your organization
- Taking a standards-based approach is a core principle within our organization
  - Executive Team
  - Patient Safety / Quality
  - IT / Infrastructure
- Identify internal team members who require orientation, training and engagement
- Communicate expectations to solution providers and suppliers

Working with our Partners

Solution Providers

Supplier

- Champion and communicate a supplier mandate based on patient safety and health system quality
- Communicate expectations to supplier partners
- Explain readiness plans, so suppliers are assured that the standards and data will be used
- In alignment with community roadmap, issue deadline expectations for packaging and data requirements

Solution Provider:

- Champion and communicate a solution provider mandate based on patient safety and health system quality
- Request solution provider integration of the standards – include in RFP specifications
- Develop and share your roadmap and timelines with your solution provider(s) and obtain their commitment to support your strategy

Useful Links

- **Traceability:**

  http://www.gs1.org/traceability

- **Anti-counterfeiting whitepaper:**

  http://www.gs1.org/docs/GS1_Anti-Counterfeiting_White_Paper.pdf

- **GS1 US 2015 readiness:**

  http://www.gs1us.org/industries/healthcare/tools-and-resources/implementation-resources/2015-readiness

Useful Links

- **The GS1 Egypt YouTube video**

  http://youtu.be/LgwNdVX2Cr0

- **The GS1 Brazil YouTube video**

  http://www.youtube.com/watch?feature=player_detailpage&v=cAeSjQvAjW8&list=UUguZ7G2g6CMuBN1C9wdk57Q

- **The GS1 Ireland – Feargal McGroarty YouTube video**

  http://youtu.be/yigUs4AaMBo

Thank *you!*

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