Enabling AIDC solutions in healthcare worldwide

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Alcon Laboratories, Inc.

Topics

- Background

- Where we are going

- Where we are today

- What this means to you

- Questions

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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 those data** directly into computer systems (i.e., without human involvement)."
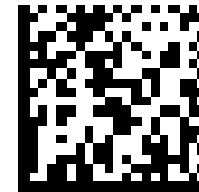
Wikipedia, 2009

AIDC Application Standards

Defines

the **data** to carry

using specific **data carriers**

for every healthcare **product**

at every **packaging level**

GS1 Healthcare Scope: Data

Data – a few examples:

✓ Global Trade Item Number (GTIN)

✓ Expiry Date

✓ Batch / Lot

✓ Serial Number

(01)07612345678900(17)100503

(10)AC3453G3 (21)123

Scope: Data carriers

**GS1-128 &
GS1 DataBar**

(01) 0 0012345 67890 5

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

GS1 DataMatrix

EPC / RFID

Of course, UPC and EAN formats will continue for retail channels

Scope: All healthcare products

GS1 Healthcare

Pharma / Vaccine / Nutritional

Medical devices

Retail

Non-retail

Scope: All packaging levels

| Pallet | Case / Shipper | Secondary package | Primary package | Directly on the item |
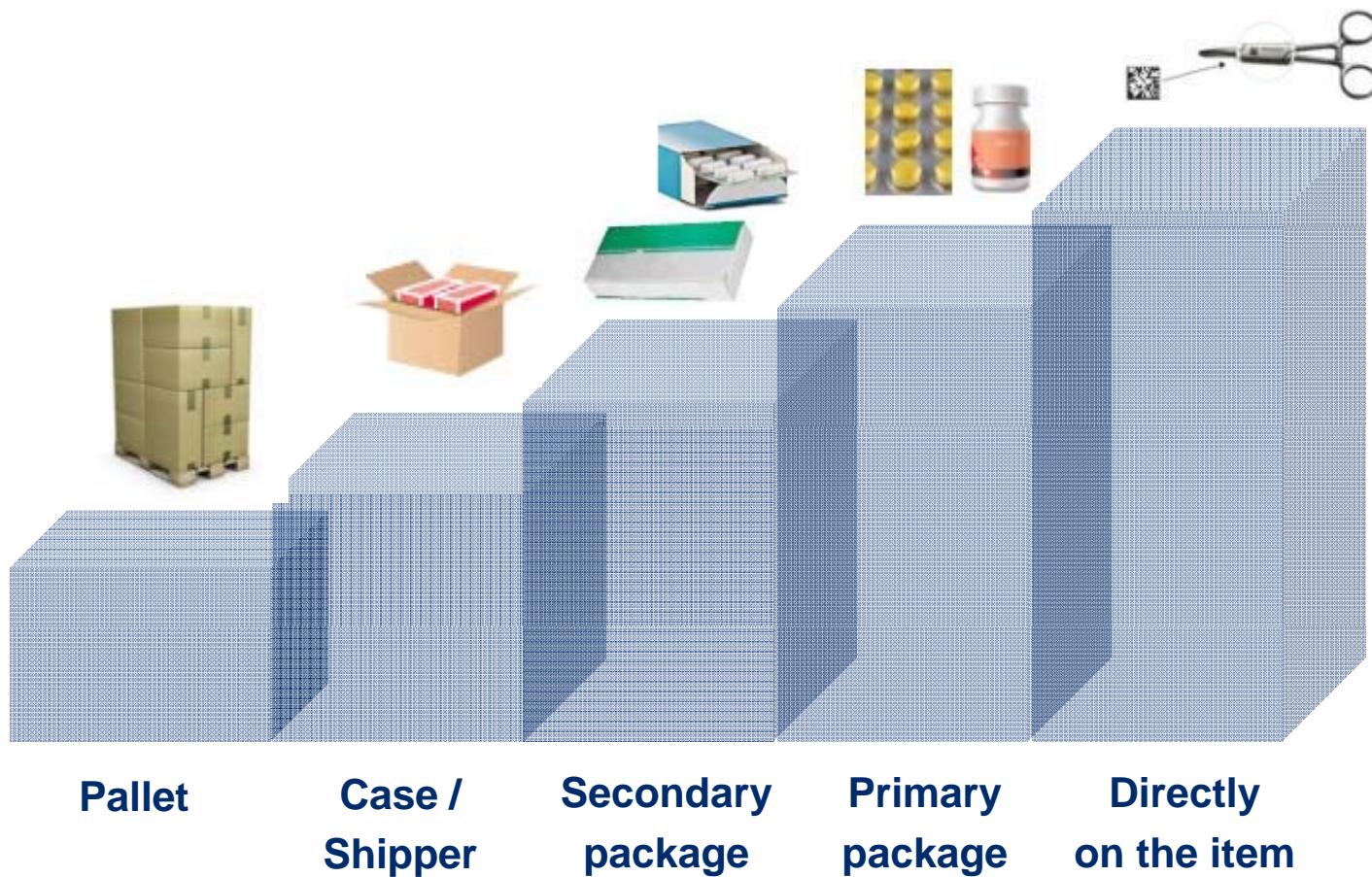
Scope: Risk-based solutions

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AIDC Marking requirements

Highest

Enhanced

Minimum

Pacemakers, hip replacements, …

Catheters, needles, …

Cotton balls, bandages, patient exam gloves, …

AIDC and the "*5 Patient Rights*"

The *right* patient

The *right* product

The *right* route

The *right* dose

The *right* time
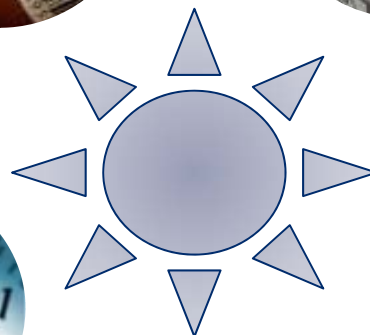
GS1 Healthcare

AIDC and the "*8 Patient Rights*"
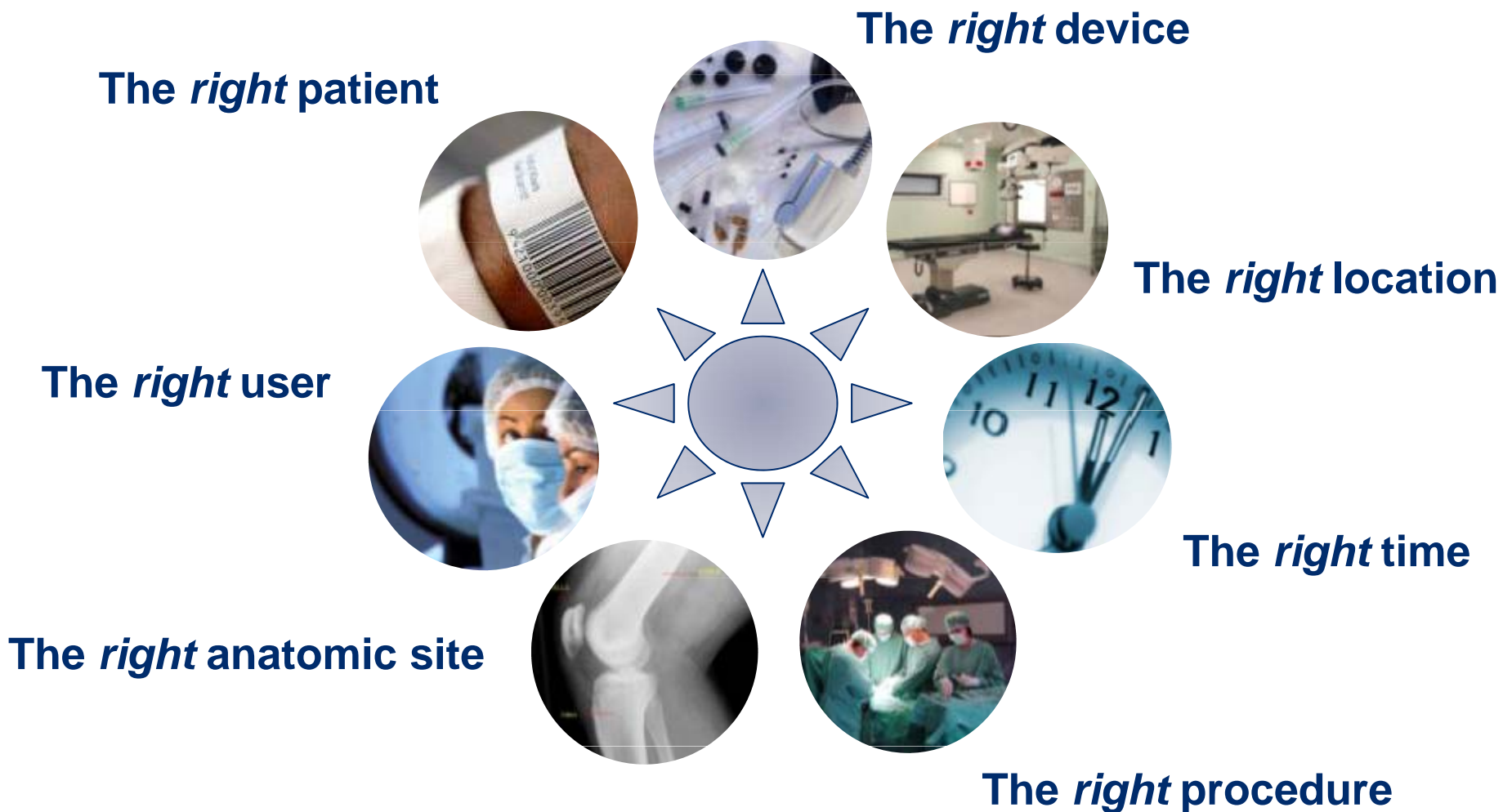
The *right* patient

The *right* device

The *right* location

The *right* user

The *right* time

The *right* anatomic site

The *right* procedure

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AIDC for Healthcare…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…

AIDC for Healthcare…Why?

- **To improve patient safety**
  - Achieve the "5 Patient Rights" or "8 Patient Rights"
  - Reduce errors
  - Ensure needed information is instantly available to the healthcare practitioner
- **To increase efficiency in supply chain and treatment chain**

My twin nephews, 11 weeks premature, in NICU…Mar. 1

Baby Brennan

Baby Collin

Putting it all together

It often takes items from many companies,
sourced from all over the world,
to effectively treat ONE patient (or in this case, TWO)

Now, imagine a world where:

- EVERY item is uniquely identified

- ONE data carrier contained all the key identification information

- ONE globally accessible repository provides data describing the item

- Picking, receiving, dispensing, billing, invoicing—all completed electronically and without human error

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GS1 Healthcare

Roadmap to global standards

| | 2010 | 2011 | 2012 |

GTIN Allocation Rules

AIDC Application Standard Phase 1 (90% of medical products)

AIDC Application Standard Small instrument marking

Key standards are completed!!

Addresses ~90% of healthcare products

Implementation guidelines

Location & legal entity ID

Plasma derivatives

Others nearing completion…

Multiple bar codes

AIDC Application Standards Phase 2 (Scope TBD)

Ratified standard | **Work finalised or near closure** | **Work in progress or planned**

Version 1.12 – January 2010

© 2010 GS1

GS1 General Specifications

Revised!

The core standards document of the GS1 System

Now including AIDC Application Standards for Healthcare

And specific standards for marking re-usable surgical instruments

Contact your GS1 Member Organisation for your copy!

GS1 General Specifications
Version 10

Issue 1, Jan-2010

Blood & plasma derivatives

Requirements Analysis

Conclusions:

✓ No gaps in standards

✓ Guidelines needed

Implementation Guide

AIDC Marking

✓ Plasma Derivatives

✓ Recombinant Products

AIDC Implementation Guide

In final draft!

How to implement AIDC for EVERY healthcare participant

Coming soon!!
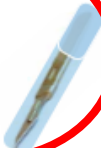
AIDC Healthcare
Implementation Guide

Issue 1, Draft 10, 28-Jan-2010

AIDC Application Standards for Healthcare and Product Marking Grid

	MINIMUM Level of AIDC Marking (Retail)		MINIMUM Level of AIDC Marking (Non-Retail)		ENHANCED Level of AIDC Marking		HIGHEST Level of AIDC Marking	
	Pharmaceuticals Distributed and/or Sold Primarily Via Retail Channels	**Medical Devices** Distributed and/or Sold Primarily Via Retail Channels	**Pharmaceuticals** Distributed and/or Sold Primarily Via Non-Retail Channels	**Medical Devices** Distributed and/or Sold Primarily Via Non-Retail Channels	**Medical Devices** Distributed and/or Sold Primarily Via Retail Channels	**Medical Devices** Distributed and/or Sold Primarily Via Non-Retail Channels	**Pharmaceuticals** Distributed and/or Sold Via Retail and/or Non-Retail Channels	**Medical Devices** Distributed and/or Sold Primarily Via Non-Retail Channels
Description of the Example Product Hierarchy	**DPM:** 1 pill **Primary Package:** 1 pill in blisterpack of 12 pills **Secondary Package:** 3 blisterpacks of 36 pills in one carton **Case:** 24 cartons (864 pills) **Pallet:** 200 cases (172,800 pills)	**DPM:** 1 consumer bandage **Primary Package:** 1 bandage in pouch **Secondary Package:** 12 pouched bandages in one carton **Case:** 12 cartons (144 bandages) **Pallet:** 200 cases (28,800 bandages)	**DPM:** 1 pill **Primary Package:** 1 pill in blisterpack of 12 pills **Secondary Package:** 3 blisterpacks of 36 pills in one carton **Case:** 24 cartons (864 pills) **Pallet:** 200 cases (172,800 pills)	**DPM:** 1 empty syringe **Primary Package:** 1 empty syringe in blisterpack **Secondary Package:** 12 empty blisterpacked syringes in one carton **Case:** 12 cartons (144 syringes) **Pallet:** 200 cases (28,800 syringes)	**DPM:** 1 contact lens **Primary Package:** 1 contact lens in vial **Secondary Package:** 2 vials of 1 contact lens each in one carton **Case:** 12 cartons (24 contact lenses) **Pallet:** 100 cases (2,400 lenses)	**DPM:** 1 catheter (temporary) **Primary Package:** 1 catheter in blisterpack **Secondary Package:** 6 blisterpacked catheters in one carton **Case:** 24 cartons (144 catheters) **Pallet:** 200 cases (28,800 catheters)	**DPM:** 1 pill **Primary Package:** 1 pill in blisterpack of 12 pills **Secondary Package:** 3 blisterpacks of 36 pills in one carton **Case:** 24 cartons (864 pills) **Pallet:** 200 cases (172,800 pills)	**DPM:** 1 re-usable scalpel handle **Primary Package:** 1 re-usable scalpel handle in pouch **Secondary Package:** 6 pouched re-usable scalpel handles in one carton **Case:** 15 cartons (90 scalpel handles) **Pallet:** 200 cases (18,000 handles)
Direct Part Mark (AIDC marked directly onto a single, unpackaged, unlabeled item)	No marking	No marking	No marking	No marking	No marking	No marking	No marking	GTIN Serial No. - Not for Implants Hospital: - 8003/8004 - optional
Primary Package (AIDC marked onto the first level of packaging, either on the packaging or on a label affixed to packaging. May consist of 1 single item, or a group of items for a single therapy such as a Kit.)	No marking (mark with GTIN if no Secondary Package)	No marking (mark with GTIN if no Secondary Package)	GTIN	No marking (mark with GTIN if no Secondary Package)	No marking (mark with GTIN if no Secondary Package)	GTIN Lot Expiry	GTIN Hospital: AI(01)+AI(21)+AI(7003)	GTIN Lot Expiry Serial No. Potency (kits) Hospital: - 8003/8004 - optional
Secondary Packaging (AIDC marked onto the next level of packaging, containing one or more single items in their Primary Packaging)	GTIN	GTIN	GTIN Lot Expiry	GTIN Lot Expiry	GTIN	GTIN Lot Expiry	[Need 2 marks] GTIN / Hospital: Lot / AI(01)+AI(21) Expiry / + AI(7003) Serial No. Potency	GTIN Lot Expiry Serial No. Potency (kits) Hospital: - 8003/8004 - optional
Case / Shipper (AIDC marked onto a shipping container. May contain one or more items in their Primary Packaging and/or Secondary Packaging.)	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry - Serial No. - Potency Logistics: - SSCC Hospital: AI(01)+AI(21) +AI(7003)	Trade Item: - GTIN - Lot - Expiry - Serial No. - Potency Logistics: - SSCC
Pallet (AIDC marked onto a pallet. May contain one or more Case / Shippers.)	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry - Serial No. Logistics: - SSC	Trade Item: - GTIN - Lot - Expiry - Serial No. Logistics: - SSCC

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ONE global standard for AIDC in healthcare
now available

Many countries have already adopted
GS1 Standards
We anticipate many more…

Putting the standards at work…

How Alcon got started

- **Participated** in work groups to understand the issues
- Started a **gap analysis** of key items
  - Focused on medical devices for UDI compliance
  - And for pharma / devices in areas with active regulations (Brasil, France, Serbia, Korea, Turkey, etc)
- Preparing **action plan** by mfg. facility based on gaps
- Reviewing results with Auto-ID Steering Committee
- Requesting 2011 – 2015 **funding**
- Starting pathfinder projects to '**learn by doing**'
- Continuously improving our approach

Changing our world…ONE item at a time…

How YOU can get started

1. Contact your local **GS1 Member Organisation** for guidance

2. **Get familiar** with the standards / guidelines
   - Attend breakout sessions this week!
   - Participate on GS1 implementation projects / team

3. Do a **gap analysis**…your items vs. GS1 Standards
   - Focus on key items and facilities…don't 'boil the ocean'
   - Build action plans, budgets, management approval

4. Implement your **action plan**
   - Start small, conduct Pilot Projects, "learn by doing", "crawl before you walk / run"…

AIDC sessions this week

This Week:

- ### Wednesday, 11:00 - 12:30   (breakout sessions)
  - AIDC Introduction Session—new application standard
  - Blood / Plasma Derivatives Work Group

- ### Wednesday, 15:30 – 17:00   (breakout sessions)
  - AIDC Patient and Caregiver ID Work Group

- ### Thursday, 11:00 – 12:30   (breakout sessions)
  - AIDC Implementation Guideline Work Group

GS1 Healthcare   Join us!!!

Global teams

- Implementation Guideline
- Blood / Plasma Derivatives
- Location and Legal Entity ID
- Patient and Caregiver ID
- Multiple Barcodes
- Barcode / EPC Interoperability
- Serialization
- Phase 2: AIDC Application Standards

Local teams

- Contact your local Member Organisation representative

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