

# Traceability – implementation and benefits for hospitals and retail pharmacies

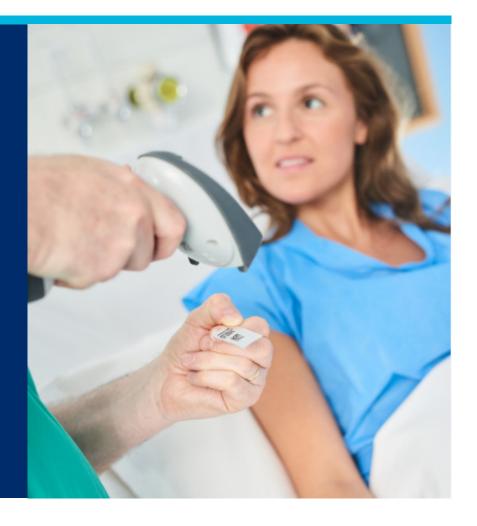
Jean-Michel Descoutures, Hospital Pharmacist, Centre Hospitalier Victor Dupouy

October 2016



"Take care of the patient and everything else will follow."

Dr. Thomas Frist Sr. Founder of the Hospital Corporation of America





# Healthcare challenges **Changing landscape**











Aging population

New high-cost advanced medical treatments

Intense performance scrutiny

Increasing patient empowerment



#### Some challenges hospitals face



Lack of traceability due to absence of product identification and patient ID



Risk of medication errors Errors due to manual processes Excess clinical time spent ordering and managing stock



Lack of inventory visibility and stock control

Wastage and costs associated with disposal and reordering



Ineffective and inefficient product recalls





# Why GSI standards?



#### Why do mistakes happen?



"The main causes (of medication error) are human factors including...

- Fatigue
- Inattention
- Memory Lapse
- Lack of Knowledge
- Failure to communicate"

**Source:** American College of Obstetrics and Gynaecologists – August 2012



# Do barcodes and scanners suffer from any of the causes listed?





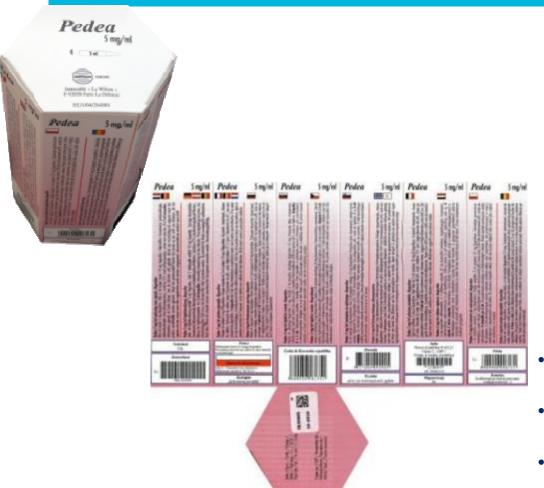
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- Multiple bar codes on one package which one to scan?
- Different types of bar codes inconsistency; incompatibility
- No bar code need to bar code; repackage; re-label



#### How can standards help?



GS1 standards enable identification, automatic data capture and with that traceability across borders

Identify and mark the product once with a globally unique number and barcode...





# New McKinsey & Company report quantifies supply chain issues in Healthcare





New McKinsey report "Strength in unity: The promise of global standards in healthcare"

Highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in healthcare

Available at:

http://www.gs1.org/healthcare/mckinsey

Source: http://www.mckinsey.com



# Huge cost savings and patient safety benefits when adopting a single global standard in healthcare



"Implementing **global standards** across the entire healthcare supply chain **could save 22,000-43,000 lives** and avert 0.7 million to 1.4 million patient disabilities"

"Rolling out such standards-based systems globally **could prevent tens of millions of dollars' worth of counterfeit drugs** from entering the legitimate supply chain"

[We] "estimate that healthcare cost could be reduced by \$40 billion-\$100 billion globally" from the implementation of global standards

"Adopting a single set of global standards will cost significantly less than two" (between 10-25% less cost to stakeholders)

# Our speakers... learn from those who have implemented



- Justin Bitter, Business Manager, Bernhoven Hospital
- Peter Helmbaek, Senior Consultant, Amgros I/S
- Feargal Mc Groarty, National Haemophilia System Project Manager, St. James's Hospital, Ireland

The Global Language of Business







**Justin Bitter** Bernhoven Hospital the Netherlands



#### Justin Bitter MSc



Medical- and business administration background

Strategic Business Manager at Bernhoven Hospital, the Netherlands

➤ Member of the GS1 Healthcare Leadership Team since July 2014



# The journey of traceability

- 1. The need for traceability for hospitals
- 2. Searching for help
- 3. Exploring opportunities
- 4. Selection process
- 5. Decision-making process
- 6. Implementation
- 7. First use of scanning barcodes



# The need for traceability



#### Improving patient safety

- Recall procedure
- Waste of time: search/find process
- One uniform process for the supply chain
- Risc of counterfeiting
- Risc of missing needed materials



## The need for traceability



#### Creating efficiency in cost management

- Amplifying balance sheet of the hospital
- Reduction of stock levels (25%)
- Reduction of expired products (80%)
- Lowering high indirect costs of staff



### Searching for help...



Where to start?

Where to go?

Who should be involved?













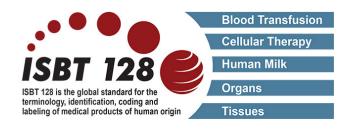


# Exploring opportunities

 Determine the main problem(s) you want to improve in your processes

#### Solutions by scanning are:

- GS1
- HIBCC
- ISBT 128 (ICCBBA)





# The selection process (©



- ➤ Which IT-infrastructure is there already in the hospital?
- >1D/2D scanners
- ➤ Are interfaces easy to build (businesscase!)
- ➤ How to work with GS1 and non-GS1 compliant items?



## The decision-making process

- Start underpinning the need with a quick scan (10-15 days in total)
- At first, involve members of the board
- Take a decision based on a business case (ROI) including the output of the quick scan
- Take care of the promises of the business case and measure.....



# Implementation



- ✓ Involve your employees (engagement!)
- ✓ Secure training and facilitate!
- ✓ Start at only one department at a time (first progress some results)
- Make use of evaluations and monitor continuously!
- ✓ Check the (technical) conformance of GS1

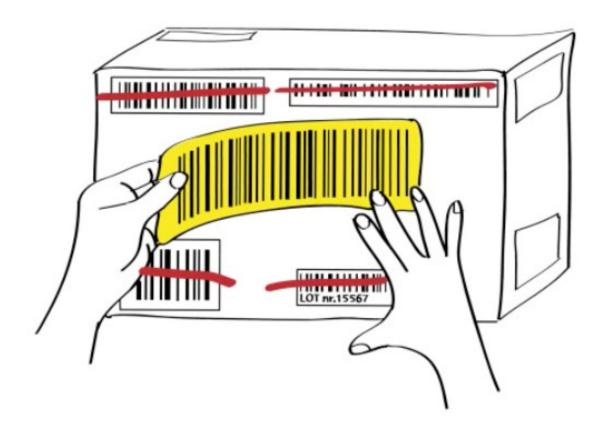


## First use of scanning barcodes

- Kick-off meeting with the team
- Explain abbreviations!! (GTIN,GLN etc)
- Training users before start (link supermarket)
- Support on the workplace
- Facilitate and listen to your staff
- Celebrate successes!



## Bernhoven Hospital, The Netherlands



Medical devices (OR- and Radiology Department)



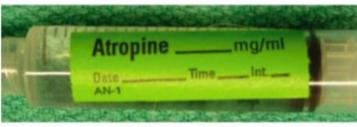
#### High Risk Medication in the OR -proof of concept-



(A) No Labeling Elements



(C) Propofol without Expiration

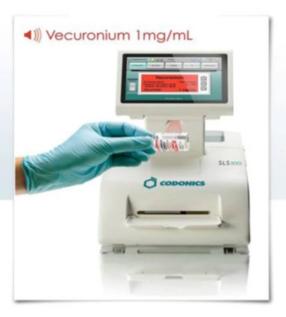


(B) Name Only



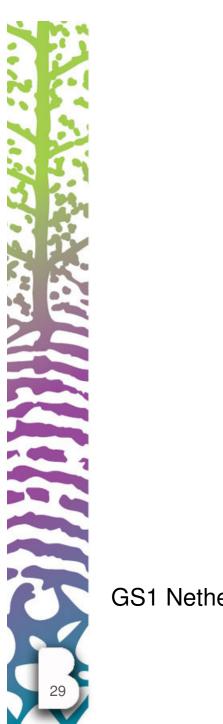
(D) JC Compliant

#### The chosen solution during the proof of concept











GS1 Netherlands described a step-by-step implementation guide for hospitals





The Global Language of Business

#### **GS1** Healthcare Reference Book 2015-2016

Successful implementations of GS1 standards







#### The Netherlands



## Bernhoven: the first dutch hospital with a unique barcode on all medical devices

Bernhoven is the first hospital in the Netherlands that operates according to the GS1 Global Traceability Standard for Healthcare. An extensive international audit has shown that the hospital has a unique GS1 barcode on each medical device in the operating room (OR). The result is complete traceability, from the time a product enters the hospital to the point of use, thus improving patient safety and supply chain efficiency. All of this is accomplished via the support and cooperation of all stakeholders throughout the chain within the hospital, from management to purchasing, finance and IT departments.

By Justin Bitter and Erik van Ark



#### bernhoven

#### Background

Improving patient safety and adequate management were the motives for starting a project on traceability in Bernhoven, a 380bed hospital located in Uden, The Netherlands. The goal was to achieve 100 % visibility in the internal process flow for medical devices, including better management of product recalls, improved inventory management and reduced manual processes.

Bernhoven decided first to focus on traceability of medical devices in the operating room (OR), starting with orthopsedic implants, because 40 % of medical products used at Bernhoven support this speciality. Orthopsedic implants are also characterised by a high value; showing quick results was important to lower any institutional resistance to implementing standards and provide confidence to all stakeholders of the potential benefits of traceability.



Hospital staff checking status of medical devices internal distribuses

Next, Berhoven started implementing the traceability process in the instrument sterilisation department and on high-risk medication in the OP.

As a starting point, Bernhoven used the business case "Patient Safety and Efficiency at the OR" (2012) which demonstrated that the investments had a return of investment within one year. This convinced the Board of Directors of Bernhoven as well as other management and key personnel



## Hospital implementations



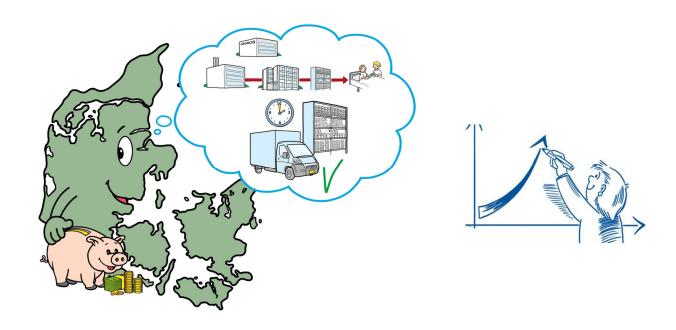


# THANKS





#### **Traceability** of Medication in Danish Hospitals



Peter Helmbaek, Senior Specilist, Amgros I/S, Denmark October 2016 Beijing











#### Peter Helmbaek, Amgros I/S



M.Sc. & EconomicSenior Specialist, Amgros,Tendering and procurement supply of drugs and medical devices

- Amgros is the pharmaceutical procurement service for regional authorities in Denmark



Denmark

Worked at Amgros since July 1996

Work experience:

- IT development & Economy





#### Amgros I/S

Amgros is responsible for 99 % of the pharmaceuticals used in public hospitals

Turnover 2015: 1.270m €

Savings in 2015 : 312m €

- Number of orders in 2015: > 130,000 total number of packages 8.9m (162m DDD)
- ▶ In 2015, Amgros published 293 EU tenders in 749 ATC codes, with 1,116 sub-tenders, which included around 3,000 different item numbers
- Amgros plays a key role in the supply of pharmaceuticals to all Danish hospitals in close collaboration with hospital pharmacies





## Procurement in Amgros



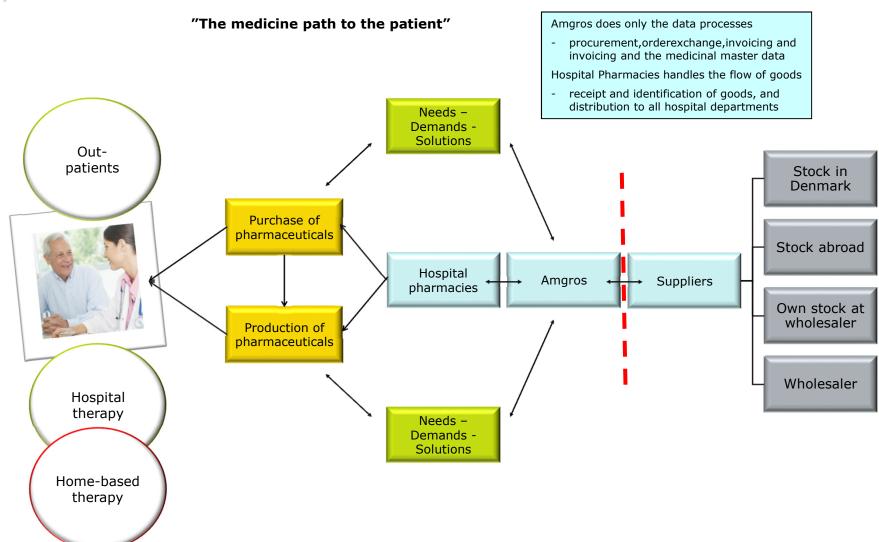
Amgros organizes tenders, in order to cover hospital pharmacies/hospitals needs for medicine, and concurrently increase competition as much as possible, without compromising treatment efficacy and patient safety!







## Supply chain for medicines to Hospitals



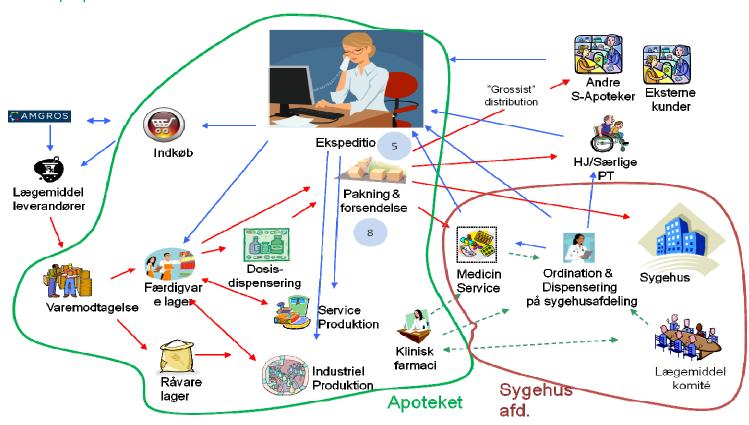


## Complex business processes

Proces-relationer mellem involverede interessenter

Blå pil: ordre Rød pil: vareflow Grøn stiplet pil: viden





Through the last 16 years the collaboration between the 5 regions and Amgros in the development of the Pharmasystem ApoVision has shown its value





## Traceability is about *patient safety*



- Medication errors has been a matter of growing attention
- ► Together with hospital pharmacies and members of the pharmaceutical industri Amgros started to analyse how to reduce medication errors in November 2006
- ► The results was presented in a report June 2008 and 'The Health Authority' was introduced to 'The Green Report'.





# Medication Errors During Dispensing are Estimated to Have a Significant Impact

Errors in

1,8-4,1%

of all dispensing according to Danish studies

An estimated

23-35%

of all these errors are severe

Affecting an estimated

11-17.000

hospitalizations each year in Denmark







## Our Vision for Primary Packaging Barcodes

- was to comply with The 5 Rights of safe medication practices

The right medication
... in the right dose
... at the right time

... via the right route
... to the right patient





Definition: Primary packaging is the material that first envelops the product and holds it. This usually is the smallest unit of distribution or use and is the package which is in direct contact with the contents.





## Why scanning barcodes?



# SILENT ZONE

Working in the medicine Dispensing both the secundary and primary packages of drugs!







## Barcode scanning of all packages of drugs

#### Benefit:

- Avoid medication related errors
- Reduce time and cost (included stocking)
- Traceability withdrawal

#### Requirements:

- ▶ Implemented i Capital Region in 2010 according to the Joint Commision Accreditation
- Barcode requirements on both secundary and primary packages of drugs since 2011







## From then on GS1 was part of the processes

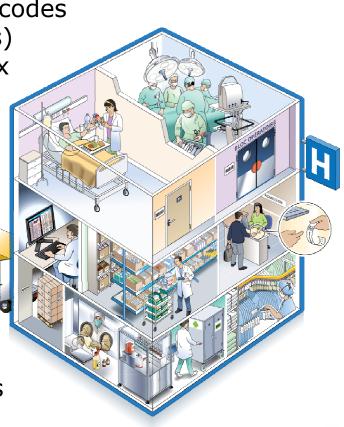
GS1 standars for barcodes

• EAN-13 (continues)

GS1 2D DataMatrix

GS1 formalized technical guidance for suppliers and hospital staff

GS1 has since supportet the implementation of barcode applications through all processes









# Amgros requires barcodes on both secondary and primary packages of drugs from 2011

Category	Туре	2011/12	2012/13	2014	2015			
High risk	IV / Infusion / Injection	EAN 13 or 2D DataMatrix						
Medium risk	Unlicensed Phamaceutical							
	Tablets, capsules etc. (not blister and single dose)	2D DataMatrix						
Lov risk	Surface use							
	Orale liquid							
	Bed-side medicine / inhalators							

<sup>-</sup> The barcode requirements are only the GTIN for the pharmaceuticals.

It is required that primary package barcodes are applied by the manufacturers





# Barcodes on Medications Also Have the Potential to Create Logistics Improvements

Inventory management in

2,000

dispensing rooms may be simplified

More than

100

Withdrawals each year may be less of an administrative task

Early warnings for

>100

Order backlogs each year in Denmark

The software to do this must be developed and implemented





## Amgros webside for suppliers

- Suppliers can inspect there products
- > Suppliers can inspect there Amgros agreement products
- ➤ The productlist shows for each product if a primary package barcode is required
- > The barcode data is shown if it is assigned
- When there is no barcode and it is required, the supplier can enter the barcode data and it will be verified











### Du er logget ind som:

Peter Helmbæk

Amgros I/S

#### Log ud

Serverens tid: 17-10-2015 17:18:58

## Stregkodemærkning - (Mine vare)

	 1		
ATC-kode:	Varenavn:	Varenummer:	Søg

Gem ændringer (Alt+S)

Eksporter til Excel

ATC Code	Varenavn	Varenummer	Vareform	Styrke	Pakning	Prim. Embl.	Aftalevare	Krav om stregkode	Stregkode
V08CA09	Gadovist	001337	INJVSKO	1 mmol/ml	10 x 30 ml	7046260013377		Χ	
G03AA12	Yasmin	002391	TABFILM	3 mg+30 mikrogram	3 x 21 stk. (blister)				
G03AA12	Yasmin 28	002413	TABFILM	3 mg + 30 mikrogram	3 x 28 stk. (blister)				
V08CA09	Gadovist	003298	INJVSKO	1 mmol/ml	10 x 15 ml	7046260032989		Х	
G03AA07	Microgyn	005538	TABOTR	0,15 + 0,03 mg	63 stk. (3x21)			Х	
L01BB05	Fludara	005782	TABFILM	10 mg	15 stk. (blister)				
L01BB05	Fludara	005836	TABFILM	10 mg	20 stk. (blister)				
V08CA09	Gadovist	006008	INJVOIS	1,0 millimol/ml	5 x 10 ml	7046260060081		Χ	





Amgros I/S Aftaler

Tidligere tilbud | Stregkodemærkning ▼ |

Restordre

#### Du er logget ind som:

Peter Helmbæk Amgros I/S

#### Log ud

Serverens tid: 17-10-2015 17:23:58

### **Stregkodemærkning** - (Mine aftalevarer)

ATC-kode:	Varenavn:	Varenummer:	Søg

Gem ændringer (Alt+S)

Eksporter til Excel

ATC Code	Varenavn	Varenummer	Vareform	Styrke	Pakning	Prim. Embl.	Aftalevare	Krav om stregkode	Stregkode
B02BD02	Kogenate "Bayer" BIO-SET	074502	INJPSOS	250 IE	1 sæt	7350074000042	Ja	Х	
B02BD02	Kogenate "Bayer" BIO-SET	086002	INJPSOS	1000 IE	1 sæt	7350074000066	Ja	Х	
S01LA05	Eylea	126803	INJVSKO	40 mg/ml	1 stk.	7350074000035	Ja	Х	
B01AF01	Xarelto	126926	TABFILM	15 mg	100 stk. (blister)	7046261269261	Ja	Х	
B01AC11	Ventavis	131014	INHVNEO	10 mikrogram/ml	168 x 1 ml	7350074000097	Ja		
V08AB05	Ultravist	168082	INVSKO	370 mg iod/ml	10 x 200 ml	7350074000110	Ja	Х	
B01AF01	Xarelto	178223	TABFILM	10 mg	100 stk. (blister)	7046261782234	Ja		
B01AC11	Ilomedin	371057	KONCINF	20 mikrogram/ml	5 x 2,5 ml	7350074000172	Ja	Х	
B02BD02	Kogenate "Bayer" BIO-SET	398605	INJPSOS	3000 IE	1 sæt	7350074000080	Ja	Х	



## Barriers to the use of barcode systems (2012)

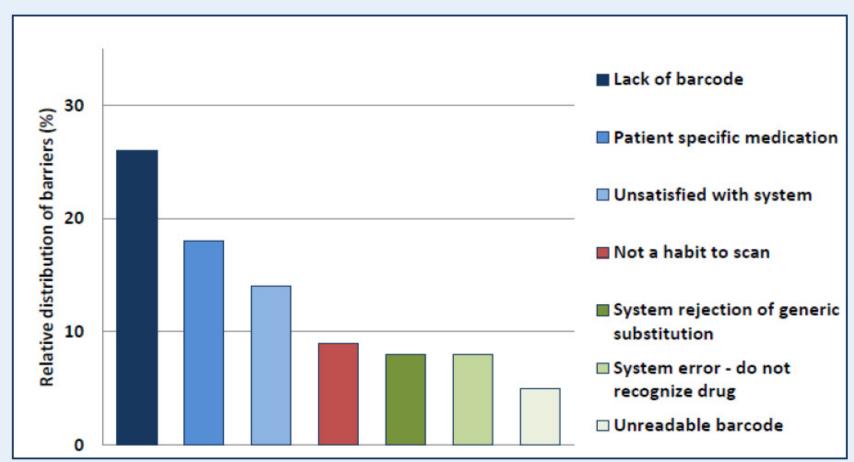


Figure 2. Relative distribution of main barriers identified by observation. Relative distribution (%) is calculated as the number of times a barrier was observed relative to total number of drugs that were not scanned (N=224).





### Where are we now?

Challenges in implementing barcodescanning in all part af the medication chain have been overcome

A new IT Healthcareplatform controlling patient medication have been introduced







## Dispensation in the medicine room



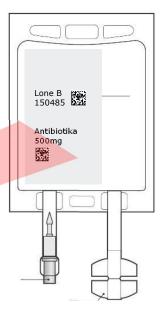




## Administration - bedsite and drug scanning















## Perspectives from executive leaders

"The NHS (National Health Service) recognises the direct impact standards have on patient safety. They are now conducting demonstrations and calling on trusts to 'scan for safety."

The Rt Hon Lord Philip Hunt PC OBE. Shadow Deputy Leader, House of Lords, Labour spokesperson for Health

administrative processes,

and reducing risks

we are preventing errors

by reducing human intervention. At the same

time, we are increasing

the time our caregivers

spend with patients

matters most."

Universitätsklinikum

Carl Gustav Carus

"Throughout our

"For me, the choice is clear: Using standards should no longer be a choice. The benefits are tangible and the potential enormous as we expand our use of standards to other parts of the hospital."



## bernhoven

- Dr. Erik van Ark. Executive Director of Medical Staff, Chairman of Operating Rooms, Bernhoven Hospital, Netherlands

"The business case to invest in GS1 standards was obvious to us. The processes supporting where human intervention traceability were very paper based and presented significant risk for our clinical environment. Starting the journey to adopt standards was Wilfried E. B. Winze the natural next step to manage risk and further support our hospital's mission to deliver best-inclass care for our patients."

> OSPIDÉAL NAOMH SÉAMAS ST. JAMES'S HOSPITAL

- Vincent Callan, Director of Facilities Management, St. James's Hospital

GS1 standards." Radboudumc - Alex van der Putten ~ inply Chain Manager, "By using our collective Medical Centre buying power via our GPO and asking our suppliers to comply with our needs, about 95 percent of our top suppliers use GS1 barcodes, and 80 percent of all primary packages now carry them." The Hospital

"Patient safety is the number one driver of changes in our stock management processes. One way to measure this is the availability of stock for procedures and care. My target is 100 percent, which is possible with





Safer, more efficient care starts with a simple scan Perspectives from executive leaders

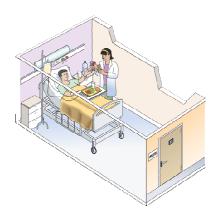


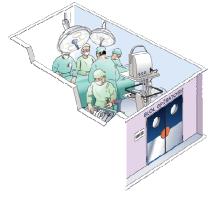
The Global Language of Business





# GS1 has continously supported Danish hospitals Hospital clinical processes









Bedside scanning— Scanning staff, patient and produkt and verification

Elektronic patient (medical)journal

**Implant Register** 

Management and tracking of instruments and equipment

Withdrowal of products

Traceability

Preparing for patient specific infusions and dispensation of drugs





## Perspectives on future requirements for European barcode labeling serialization

Challenges with application of dynamic data in barcodes to be resolved before februar 9, 2019.







Product Name (GTIN)

**Expiry Date** 

Batch/lot Number

**Serial Number** 





## Questions







# Use of GS1 standards to improve patient safety in the home

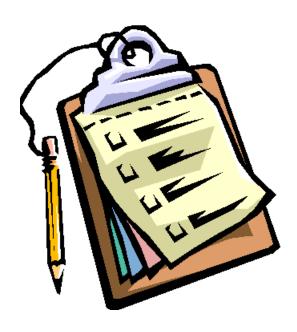


Feargal Mc Groarty, Project Manager,

National Centre for Hereditary Coagulation Disorders, St James's Hospital, Ireland

## Agenda

- Why we did it! (issue)
- How did we hear about GS1
- What role did GS1 Play
- Where is GS1 used in our system(s)
- How did we undertake implementation
- Outcomes What worked/didn't, what we would do differently
- Advice for others





# What is Haemophilia?



- Haemophilia is a hereditary bleeding disorder caused by a deficiency of a clotting factor (protein)
- Characterised by excessive bleeding even after minor injury
- Incidence is between 1:5,000 and 1: 10,000 Males
- The treatment of haemophilia involves the replacement of the clotting factor (previously prepared from pooled blood) using a concentrated preparation "Clotting Factor Concentrate" (CFC)
- Very expensive medication
- Patients self medicate in the home (Prophylaxis)



# **ISSUE**What triggered the initiative?



## **Catastrophic Event**

- Infection of patients with Hepatitis C and HIV due to contaminated blood products. Infected products remained in the supply chain after recall leading to subsequent infection
- Over 100 patients died
- Lindsey Tribunal



## Lindsa

## Ma

 Improv treatme

The block
 haemo
 the safe

#### Report

of the

Tribunal of Inquiry

into the

Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters



ons

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN TSOLÁTHAIR
le ceannach díreach ón
OFIFIG DHÍOLTA FOILSEACHÁN RIALTAIS.
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
4-5 BÓTHAR FHEARCHAIR, BAILE ÁTHA CLIATH 2,
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# Medication delivery – Where we were







# How did we hear about GS1



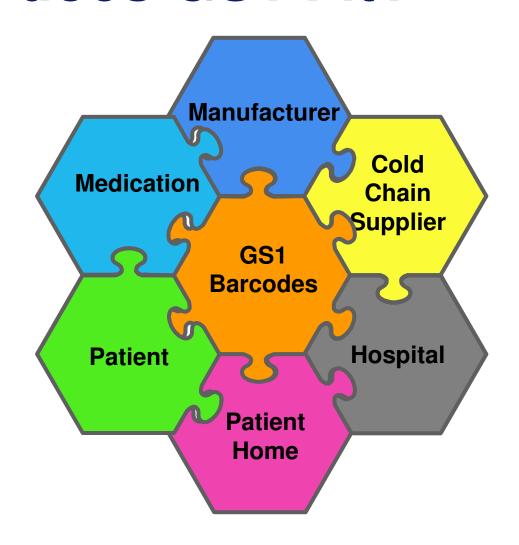
In 2003 we were approached by GS1 Ireland regarding how GS1 standards could assist in the medication delivery process

- Unique identification (barcode) of patient PMGSRN
- Unique identification (barcode) of medication Serialised GTIN (+Lot + Expiry)
- Unique identification (barcode) of locations (Hospital/Home/Pharmacy/Transport) - GLN



## Where does GS1 Fit?







# Where is GS1 in our systems?





GS1 standard barcode on medication (serialised GTIN)



EPR modified to produce
GS1 identifiers
(PMGSRN,GLN)
T&T system built to track
medication through
Hospital



All medication has **GS1** barcode either labelled at source or overlabelled



Each patient home identified with a **GS1** GLN



Rewrote their WMS to accept **GS1** identifiers and produce GS1 barcode for medication where necessary



Mobile Phone (cellphone) App used to scan **GS1** barcode and record medication compliance



# What role did GS1 play?



- Reviewed our processes and indicated where GS1 standards could add value
- Educated medication suppliers and system solution providers about why and how to implement GS1 standards
- Provided on going advice throughout the implementation and beyond
- Worked with solution providers to embed GS1 identifier capture and generation in their systems





# Once in place, how do we use GS1 standards?













SHARE





## Identify



Product Name (GTIN)

**Expiry Date** 

Batch/lot Number

**Serial Number** 



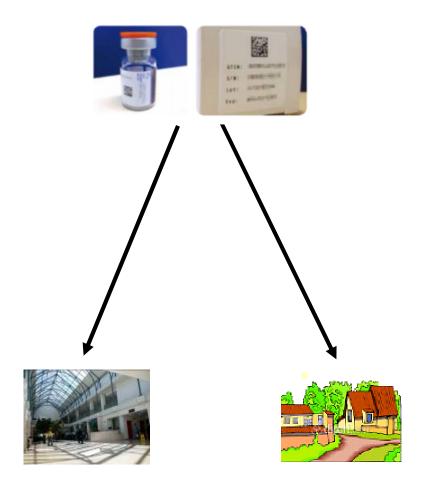






# Capture











## **Smartphones with scanning App**





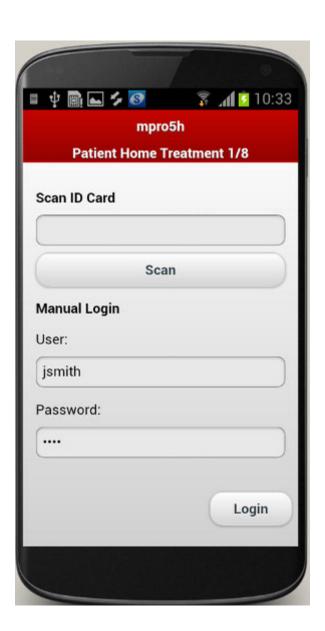


#### Log-in

#### Secure Login by

- Username/Password or
- Scanning unique GS1 ID on Card





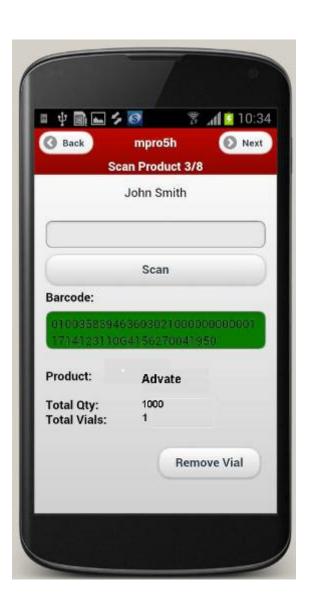


#### **Scan Product**

Barcode on Vial box is scanned to check

- Product detail (prescription)
- Expiry date
- Recall status

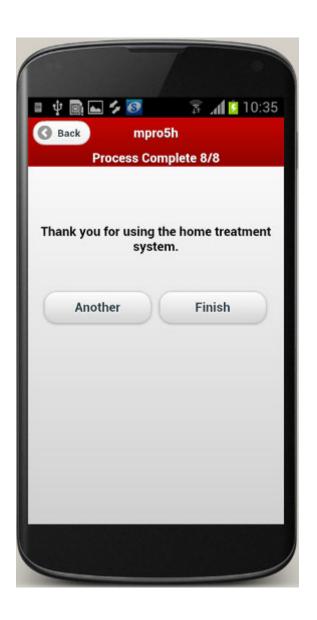






#### **Process Complete**

Process concludes, system synchronises data wirelessly to web application

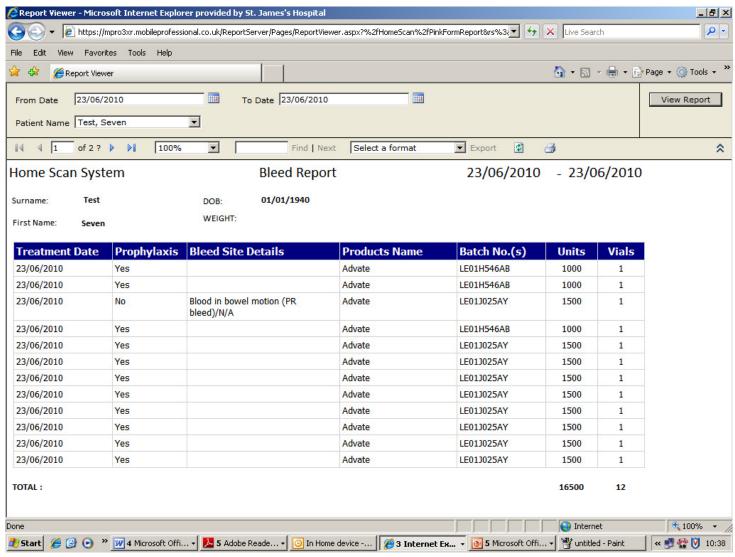




#### **Share**



SHARE

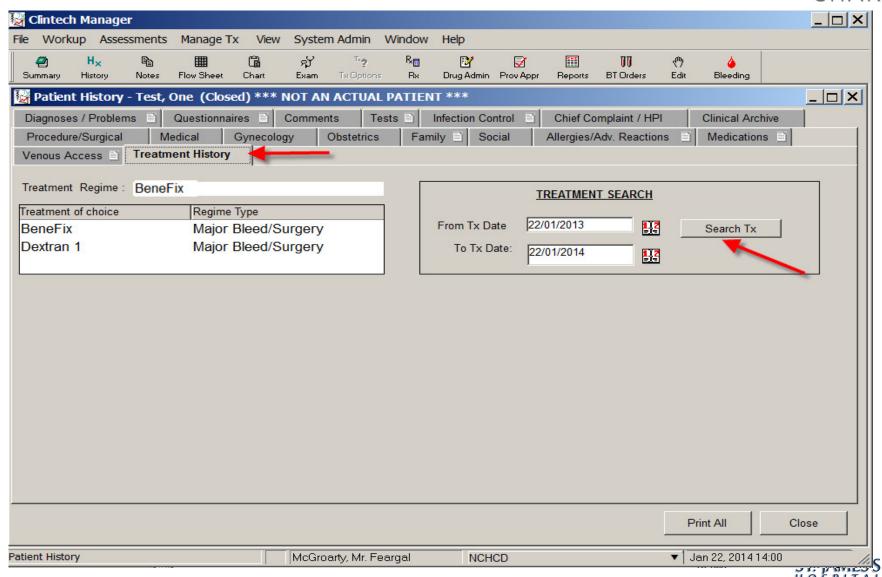




#### **Share**



SHARE



### Haemophilia Project Timeline



Cold Chain distribution service for medication commenced Haer

Haemophilia EPR implemented

#### Datamatrix barcodes

Start of migration from linear to GS1 2D (Datamatrix) barcodes on medication

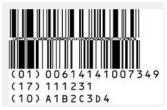
#### Smartphone App

First 20 patients commence scanning with smartphone App



#### GS1 Barcodes

barcodes (linear) implementation on medication and embedded in Cold Chain delivery service



#### Hospital tracking

Hospital track and trace of haemophilia medication using barcode scanning implemented

#### Patient data integration

Patient home treatment data from App fully integrated with EPR







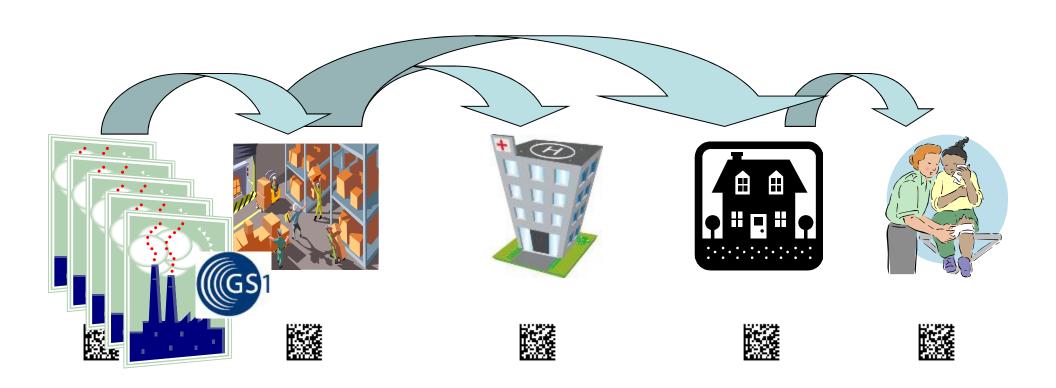
(launched June 2010)

- Real-time recall alert
- Timeliness of infusion
- Prescription compliance (2000iu instead of recommended 1750iu)
- Automatic compliance (no manual record keeping)
- Compliance > 90% (for those with phone App)
- Real-time Alerts for specific bleeds
- Patient empowerment
- Significant savings (over €70,000 within first 3 months with only 20 users)





#### Where we are





## What worked, what didn't?



- Still over labelling for some medications
- Still lack of understanding by Solution Providers of what "GS1 compliance" means
- The hospital was required to pay for 3<sup>rd</sup> party system modifications
- Even with the documented outcomes and learnings, the template has not been adopted by other disease groups such as Orphan Drugs and Vaccines

#### Why?

- Lack of strong clinical sponsorship/leadership
- Lack of funding
- Lack of awareness of GS1 (HC professionals and Solution Providers)
- Cost of system modifications (solution providers)
- Priorities



#### Advice....



- Use GS1 as a resource
- When going to tender for any system, build GS1 standards into the requirement specifications
- Add your GS1 MO to your system tender team
- Look at GS1 reference books for examples of implementations
- Find a strong clinical advocate
- Use the FMD, UDI and US DSCSA legislation as a business case
- Quick wins are always good!



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# Remember, GS1 standards are just a tool.....





## Thank you for listening!





#### Questions and discussion



