Improved Patient Safety using GS1 Standards

Feargal Mc Groarty, Project Manager,
National Centre for Hereditary Coagulation Disorders, St James’s Hospital, Ireland
Where is Ireland?

Where is Mexico?
Ireland-Mexico Links

• The largest diaspora in USA is Irish-American; and the second largest diaspora is Mexican-American.

• Both have been colonised but gained independence.

• St Patricios” A group of about 200 mostly Irish immigrants that travelled to Mexico to fight in the Mexican-American War between 1846 and 1848.
5 other things you might not know about Mexico

• **Chocolate was invented in Mexico**
  The word itself is derived from Nahuatl, the language of the Aztecs, who drank chocolate before they ate it. Cacao has been grown in Mexico for over 3,000 years.

• **Caesar salad was invented in Mexico**
  It’s not an Italian dish, but rather the invention of an Italian-American immigrant, Caesar Cardini, who opened restaurants in Mexico City and Tijuana.

• **Mexico City is built on a lake**
  It sinks about 20cm a year. Take that, Venice. – Life jackets are under your seats!

• **62 indigenous languages are spoken throughout Mexico**
  It’s the second highest number globally, surpassed only by India.

• **Ireland is the biggest per capita consumer of Corona beer in Europe!**
  We give you Guinness, you give us Corona…a fair swap!
Sombrerero?
First Barcode

FIG. 10

NOTE: LINES 6, 7, 8, AND 9 ARE LESS REFLECTIVE THAN LINES 10.

INVENTORS:
NORMAN J. WOODLAND
BERNARD SILVER

BY THEIR ATTORNEYS

Houston

Houston
Famous Pop Group?

Juan Direction
Agenda

- Standards in the Healthcare Supply Chain
- Barcodes on medication – Why? What?
- Background to NCHCD and Haemophilia
- Why our medication Supply chain had to change
- Exploiting smartphone technology - allowing patients to scan their medication within the home
- Outcomes/ROI
- Conclusions
"Why is it when a death happens one at time, silently, it warrants less attention than when deaths happen in groups of five or 10?......"

“.....every day, a 747, two of them are crashing....we would not tolerate that degree of preventable harm in any other forum."

Peter Pronovost, MD, senior vice president for Patient Safety and Quality and director of the Armstrong Institute for Patient Safety and Quality at Johns Hopkins.
So….. let’s look at one of the reasons for these “silent” deaths…
Pharma Drug manufacturing

Overview

Process and Period of New Drug Development

It is considered that 9-17 years and ¥50 billion are required to develop a new drug.

2-3 years
3-5 years
3-7 years
1-2 years
9-17 years

Preclinical tests
Clinical trials
Examination

Creation of a new substance
Screening of candidate substances
Research on physicochemical properties
General toxicity research
Pharmacokinetic research
Pharmaceutical research
Toxicological research
General pharmacological research
Toxicological research on drug effects
Speculative toxicity research
Phase I trial
Phase II trial
Phase III trial
Application filing
Approval
Marketing
Drug development....excellent!
Quality and Validation...excellent!
Pharma Supply Chain... excellent!
And then after 17 years development what do they do…?
When the drug gets to the patient…. Not counterfeit but just as dangerous!

Would barcode scanning have prevented this? Absolutely!
How did this happen?

American College of Obstetrics and Gynaecologists – August 2012

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

• Fatigue
• Inattention
• Memory Lapse
• Lack of Knowledge
• Failure to communicate
Do these suffer from any of the causes listed?
Imagine….

• If all medication could be tracked from manufacturer to the patient
• Imagine if the patient could verify that the medication was safe to take even in their own home
• Imagine that hospitals could remotely monitor patient medication compliance
• Imagine if governments/regulators could be assured of a total medication recall
Case Study

The use of GS1 standards to enhance patient safety, improve medication recording compliance and reduce costs
National Centre for Hereditary Coagulation Disorders (NCHCD)

- Located at St James’s Hospital, Dublin, Ireland
- Manages patients with inherited and acquired bleeding disorders
- Approximately 2000 patients with Haemophilia
- Approximately 200 patients with severe haemophilia (require intensive care/treatment)
- Medication budget is ~ €45 M
- Over 75% Patients with severe Haemophilia self medicate at home
What is Haemophilia and why is traceability important?

• Haemophilia is a Chronic Disease, it is a bleeding disorder caused by a deficiency of a clotting factor

• 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 plasma) using a concentrated preparation “Clotting Factor Concentrate” (CFC)

• **Patients required to self treat at home**

• Lack of prompt response can lead to prolonged hospitalisation, decreased quality of life and misuse or wastage of expensive plasma and recombinant products
Models of Haemophilia medication treatment care

- Physician choice V National tender

- Cryoprecipitate (pooled plasma) V Recombinant Factor Concentrate (synthetic)

- Clinic Treatment V Home Treatment

- Collected at Pharmacy V Home Delivery
An economic model of Haemophilia in Mexico.


- Results indicated that treatment with **concentrate at home** compared with **cryoprecipitate at a clinic** substantially improves clinical outcomes at reduced annual cost levels.

“Patients treated at home experienced 30% less joint damage, used 13-54% less factor VIII (concentrate), had four times fewer clinic visits, and utilized half as many hospital days than those treated at a clinic.”
Medication Supply chain.....where we were
What triggered the initiative?

**Catastrophic Event**

Failure of Supply Chain - Infection of patients with Hepatitis C and HIV due to contaminated blood products. *Infected medication remained in the supply chain after recall - leading to subsequent infection*

Over 70 people died in Ireland alone
Lindsay Report 2001

Main Recommendations

– Improve communication between treatment centres
– Accurate product tracing
– Enact a validated product recall
Redesign the Supply Chain

Medication
Manufacturer
Cold Chain Supplier
Hospital
Patient Home
Patient
Piece missing!

Manufacturer

Medication

Cold Chain Supplier

Patient

Hospital

Patient Home
The Final Piece!

- Manufacturer
- Cold Chain Supplier
- Medication
- GS1 Barcodes
- Hospital
- Patient
- Patient Home
Solution – Adopt the Retail Track and Trace Model based on GS1 Standards

- Unique identification (barcode) of patient – PMGSRN
- Unique identification (barcode) of medication - Serialised GTIN
- Unique identification (barcode) of locations (Hospital/Home/Pharmacy/Transport) - GLN
Solution

IDENTIFY

CAPTURE

SHARE
Identify

- Product Name (GTIN)
- Batch Number
- Expiry Date
- Serial Number

GTIN 00314141999995
SN 10000000234
LOT 987654321GFEDCBA
Solution for tracking and tracing products within the Hospital

Bar coded medication is delivered to the Hospital by TCP

Hospital (GLN)

Stock Fridge (GLN)

Patient receives CFC

Check Product V Patient and issue

Issue Fridges (GLN)
<table>
<thead>
<tr>
<th>Product Name</th>
<th>Batch No</th>
<th>Received On</th>
<th>Expiry Date</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advate 1.1 1000iu Baxject II Ireland</td>
<td>LE01F515AC</td>
<td>23/03/2007</td>
<td>30/08/2008 23:59</td>
<td>10</td>
</tr>
<tr>
<td>Advate 1.1 1500iu Baxject II Ireland</td>
<td>LE01F942AS</td>
<td>26/02/2007</td>
<td>31/08/2008 23:59</td>
<td>6</td>
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<tr>
<td>Advate 1.1 500iu Baxject II Ireland</td>
<td>LE01E127CH</td>
<td>20/10/2006</td>
<td>30/11/2007 23:59</td>
<td>5</td>
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<tr>
<td>Benefix 500 IU</td>
<td>LE07F946AA</td>
<td>09/03/2007</td>
<td>31/03/2009 23:59</td>
<td>9</td>
</tr>
<tr>
<td>Fanthi 500 IU</td>
<td>IBVB6MRNT1</td>
<td>23/03/2007</td>
<td>28/02/2008 23:59</td>
<td>4</td>
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<tr>
<td>Novo Seven 2.4mg (120 KIU)</td>
<td>SU60351</td>
<td>05/09/2006</td>
<td>30/06/2008 23:59</td>
<td>1</td>
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<tr>
<td>Novo Seven 4.8mg (240 KIU)</td>
<td>SU61573</td>
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<td>SU60724</td>
<td>16/03/2007</td>
<td>30/09/2008 23:59</td>
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<td>VNP2F002</td>
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<td>31/05/2008 23:59</td>
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**Single unit tracing**

![Vbsninfo Interface]

<table>
<thead>
<tr>
<th>Date</th>
<th>Depot/Location</th>
<th>By</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Aug 2011</td>
<td>CPL 05 DISPATCH</td>
<td>Liam Byrne</td>
</tr>
<tr>
<td>25 Aug 2011</td>
<td>OUT OF FRIDGE</td>
<td>Brian Graham</td>
</tr>
<tr>
<td>25 Aug 2011</td>
<td>NCHCD</td>
<td>Helen Shiel</td>
</tr>
<tr>
<td>01 Sep 2011</td>
<td>LOGERIDMAUGH</td>
<td>Eadaoin O Shea</td>
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</table>
Batch Recall

1. Select Product & Batch

Product: Advate 100 IU

Batch Number: LCB208Y

<table>
<thead>
<tr>
<th>Batch No</th>
<th>Expiry Date</th>
<th>Received</th>
<th>Awaiting Supply</th>
<th>Issued</th>
<th>Allocated</th>
<th>On Van</th>
<th>In Stock</th>
<th>Used</th>
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<tbody>
<tr>
<td>LCB208Y</td>
<td>13/02/2012</td>
<td>140</td>
<td>30</td>
<td>70</td>
<td>10</td>
<td>5</td>
<td>60</td>
<td>21</td>
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</table>

2. Select Recall Level

- Batch Allocation & Order Packing Process
- Batch Processing in Goods Receiving Process
- Patient Home Usage
- Order Delivery By Driver
- Hospital Usage
- Include / Exclude Certain Patients & Hospitals

Generate Recall Report
Include / Exclude Patients & Hospitals
Recall Reports

5. Batch Recall Report

- **Product:** Advate 1000 IU
- **Patients:** 56
- **Recalled By:** Hilary Mooney
- **Hospital:** 21
- **Recall Date & Time:** 22 May 2011 1200
- **Expiry Date:** 13/02/2012
- **Total:** 77

<table>
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<th>Patient / Hospital</th>
<th>Issued</th>
<th>Used</th>
<th>Mobile</th>
<th>Phone</th>
<th>Address Line 1</th>
<th>Address Line 2</th>
<th>Address Line 3</th>
<th>County</th>
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<td>7</td>
<td>086 3235812</td>
<td>01 410 3000</td>
<td></td>
<td></td>
<td></td>
<td>Dublin 8</td>
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<td>086 3235812</td>
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<td>Cavan</td>
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<td></td>
<td></td>
<td></td>
<td>086 3235833</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Co. Cork</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>086 3235815</td>
<td>01 410 4211</td>
<td></td>
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<td>Carrigaline</td>
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<td></td>
<td></td>
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<td>01 410 2414</td>
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<td></td>
<td></td>
<td>086 3235813</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Co. Kerry</td>
</tr>
</tbody>
</table>

6. Confirm & Execute Batch Recall Process

- **Recall Type:** Simulation Only
- **Enter Password:** *******

[Execute Batch Recall Process]
## Recall Reports

### PharmaTrack Batch Recall Report

<table>
<thead>
<tr>
<th>Batch No</th>
<th>Serial No</th>
<th>Transaction Type</th>
<th>Reference</th>
<th>GLN:</th>
<th>Reason:</th>
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</thead>
<tbody>
<tr>
<td>LE07E055AA</td>
<td>000035</td>
<td>Issued</td>
<td>Prophylaxis</td>
<td>NCHCD</td>
<td>NCHCD Stock Top Up</td>
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<tr>
<td>LE07E055AA</td>
<td>000260</td>
<td>Transferred In</td>
<td>29/02/2006 12:24</td>
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<td>XXXX XXXXXXXX</td>
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</tr>
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<td>Issued</td>
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<td>LE07E055AA</td>
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<td>Issued</td>
<td>right thigh bleed</td>
<td></td>
<td></td>
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<tr>
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<td>XXXX XXXXXXXX</td>
<td></td>
<td></td>
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<tr>
<td>LE07E055AA</td>
<td>000134</td>
<td>Issued</td>
<td>Right thigh bleed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**BATCH SUMMARY**

- Total Booked In: 9
- Issued to patients: 7
- Stock in GLN(s): 2
Delivery to the home and “In home” usage

- Electronic prescription

Data sent to the EPR and stock management system with product usage information

Patient scans product. Verification received from EPR

Details of all movements are sent to the stock management system

Cold Chain Supplier verifies Order at dispatch - recording batch and expiry dates - GLNs, GTIN

Cold Chain Supplier verifies delivery of product to Patient - recording batch and expiry details GLN, GTIN

Cold Chain receives home patient orders with GTIN & delivery location details GLNs

Electronic prescription
Smartphones with scanning App
How it works

The system is designed to be simple to use but comprehensive – designed in consultation with patient focus group.
Log-in

Secure Login by
• Username/Password
or
• Scanning unique GS1 ID on Card
Patient Details

Patient detail confirmation includes product of choice
Scan Product

Barcode on Vial box is scanned to check …..

• product detail (prescription)
• expiry date
• Recall status
• Check for “older” stock in Fridge
Validation – FAIL!

If incorrect product or product out of date or RECALLED, system will alert using a visible and audible alarm
Validation – OK!

If the Product passes the validation checks then the user is prompted to continue.

There is also the ability to retrospectively record treatment.
Infusion Detail

User records reason for infusion
Specific bleed sites can be used to trigger e-mail alerts to the treatment centre

- Head Injury
- Iliopsoas Bleed
- Haematuria
- Haemoptysis
- Haematemesis
- PR Bleed
Infusion Authorisation

Again, the app prompts the patient to proceed.
Process Complete

Process concludes, system synchronises data wirelessly to web application
## Bleed Report

**Home Scan System**

**Surname:** Test  
**DOB:** 01/01/1940  
**First Name:** Seven

**Bleed Report 23/06/2010 - 23/06/2010**

<table>
<thead>
<tr>
<th>Treatment Date</th>
<th>Prophylaxis</th>
<th>Bleed Site Details</th>
<th>Products Name</th>
<th>Batch No.(s)</th>
<th>Units</th>
<th>Vials</th>
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<tbody>
<tr>
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<td></td>
<td>Advate</td>
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<td>1000</td>
<td>1</td>
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<td>LE01H546AB</td>
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<td>1</td>
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<tr>
<td>23/06/2010</td>
<td>No</td>
<td>Blood in bowel motion (PR bleed)/N/A</td>
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<td>LE01J025AY</td>
<td>1500</td>
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<td>LE01J025AY</td>
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</table>

**TOTAL:** 16500 12
Share
Outcomes/ROI

Validated Cold Chain delivery Service using GS1 Datamatrix Bar coding on medication packaging

• Since Cold Chain delivery started all products verifiably delivered between $2^0$-$5^0$ Celsius
• Documentation errors reduced from 12 to zero in the year post service implementation
• € 5 Million worth of medication stock has been removed from the supply chain
• Stock rotation in 2011 saved €600,000 worth of stock
• Mock Recall identified location of all (100%) Medication within 10 minutes along with quantities of alternate stock available
Initial Outcomes from smartphones

- 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 or 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’s Next?

• Built in alert for the patient to use oldest dated stock (€50K in 2013 expired)
• Built in alert for staff if patient has not scanned medication in 4 days (compliance)
• Built in Quality of Life survey
• Use the Haemophilia model for other disease groups such as
  ✓ Vaccines
  ✓ Orphan Drugs
  ✓ Clinical trials
‘…Track and Trace provides a level of visibility on the journey of a vial which we currently don’t have. The information it can provide in the event of a recall is invaluable…’
Recommendations

- Bar coded batch/bar coded serialisation should be introduced for all vaccines
- Data entry of serialised/batch details should be captured real-time using bar code scanning
- Bar coded technology for all immunisation information systems should be used to capture serialised/batch number and product details, patient identifiers, administration and location identifiers
- Provision of bar coded vaccines (2D) should be a weighted selection criteria in all future vaccine tenders
- Priority should be given to the introduction of a national information system supporting the capture of all vaccination events in Ireland (both public and private)
Conclusions

- Measures need to be implemented to ensure patient safety
- Measures need to be implemented to improve Supply Chain efficiency
- Barcodes work!
- Technology and standards already exist to help improve patient safety and reduce supply chain costs
Our patients....your Customers!
Acknowledgements

All staff in National Centre for Hereditary Coagulation Disorders, in particular…..

• Dr. Barry White (Clinical Director)

• Evelyn Singleton (National Co-ordinator for CFC)

• Rachel Bird (National Haemophilia system data manager)

• Vincent Callan (Director of Facilities Management)
Thank you for listening
Any Questions?

fmcgroarty@stjames.ie