The importance of FMD and barcoding for patient safety

Feargal McGroarty, SJH

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The importance of FMD and barcoding for patient safety

Feargal Mc Groarty, Project Manager,
St James’s’s Hospital, Ireland
Agenda

- Why do we need standards in the medication supply chain?
- How can we leverage the impending FMD?
- The Irish haemophilia story
- Exploiting smartphone technology - allowing patients to scan their medication within the home
- Outcomes/ROI
- Conclusions
WHY?
Counterfeit medicines may look the part......
But they are manufactured in squalid conditions...
...and are have been found to contain harmful ingredients
Let's look at the legitimate supply chain
Sounds obvious?

Medicines are supposed to save lives…

Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable.

(Lepakhin V. Geneva 2005)
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
General pharmacological research
Pharmacological research on drug effects
Special 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....

Quaids Settle for $750K in Babies' Overdose

By Neal Colgrass, Newser Staff
Posted Dec 15, 2008 8:00 PM CST

(NEWSER) – Dennis Quaid has settled a wrongful death lawsuit for $750,000 with a Los Angeles hospital after its nurses overdosed their newborn twins with heparin, People reports. The twins, who were born after Quaid called a hospital “harassers,” are now in critical condition after receiving the wrong medication. The doctors also filed suit against the man, saying he was gathering information about pediatric and adult doses in an attempt to steal the patents for the drug.
How did this happen?

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

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

*American College of Obstetrics and Gynaecologists – August 2012
Do these suffer from any of the causes listed?
Benefits for Patient Safety

• Reduction of medical errors
• Improved recall procedure and adverse event reporting
• Documentation of product/patient relationship – in Electronic Health Records (EHR) and registries
• Visibility of inventory – availability of devices
• Supply chain security/anti-counterfeiting
Case Study

The use of GS1 standards to enhance patient safety, improve medication recording compliance and reduce costs
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
- Approximately 200 patients with severe form
- Patients self medicate in the home (Prophylaxis)
Issue
What triggered the initiative?

Catastrophic Event

- Infection of patients with Hepatitis C and HIV (late 1970’s – 1985) due to contaminated blood products. Infected products remained in the supply chain after recall leading to subsequent infection

- Over 100 patients suffering from haemophilia died

- Lindsey Tribunal 1999 - 2002
Main Recommendations

• Improve communication between treatment centres.

• The blood products supplied to persons with haemophilia should be of the highest standard and of the safest nature available.
Medication delivery – Where we were
Where does medication barcoding fit in our process?
Where is GS1 in our systems?

**Manufacturer**

**GS1** standard barcode on medication (serialised GTIN)

**Medication**

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

**Cold Chain Supplier**

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

**Hospital**

EPR modified to produce **GS1** identifiers (PMGSRN,GLN)

T&T system built to track medication through Hospital

**Patient Home**

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

**Patient**

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

**St. James's Hospital**

Dublin, Ireland
Once in place, how do we use GS1 barcodes?
Identify

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

(01) 20887511007364
(17) 150331
(10) A1B2C3D4E5
(21) 123456789
Solution for tracking and tracing products within the Hospital

Bar coded medication is delivered to the Hospital by TCP

Hospital (GLN)

Stock Fridge (GLN)

Prepare product (GTIN)

Patient receives CFC

Check Product V Patient and issue

Issue Fridges (GLN)
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Solution for tracking and tracing medication to the home
Smartphones with scanning App
Log-in

Secure Login by

• Username/Password

or

• Scanning unique GS1 ID on Card
Advate 250 IU (2ml)
Vial Size: 250 IU
9

Advate 500 IU (2ml)
Vial Size: 500 IU
2

Advate 250 IU (2ml)
Barcode: (01)05413760427355(17)/70731(19)0000000...
Batch: LE01L543AQ
Date: 31/07/2017

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Batch: LE01L543AQ
Date: 31/07/2017

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Batch: LE01L543AQ
Date: 31/07/2017

Barcode: (01)05413760427355(17)/70731(19)0000000...
Batch: LE01L543AQ
Date: 31/07/2017
Scan Product

Barcode on Vial box is scanned to check

• Product detail (prescription)
• Expiry date
• Recall status
• Shorter dated stock
Scanning Process

Jonny Wilko

Please proceed with infusion.

Thank you for using the home treatment system.

Another
Finish

Uploading On-demand
### Home Scan System

**Bleed Report**

**Date:** 23/06/2010 - 23/06/2010

**Surname:** Test

**First Name:** Seven

**DOB:** 01/01/1940

**Weight:**

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**TOTAL:**

- Units: 16500
- Vials: 12
Share
Haemophilia Project Timeline

- **2003**: Cold Chain distribution service for medication commenced
- **2004**: Haemophilia EPR implemented
- **2006**: Datamatrix barcodes
  - Start of migration from linear to GS1 2D (Datamatrix) barcodes on medication
- **2007**: Smartphone App
  - First 20 patients commence scanning with smartphone App
- **2010**: GS1 Barcodes
  - Barcodes (linear) implementation on medication and embedded in Cold Chain delivery service
- **2014**: Hospital tracking
  - Hospital track and trace of haemophilia medication using barcode scanning implemented
- **2014**: Patient data integration
  - Patient home treatment data from App fully integrated with EPR
Immediate outcomes post implementation of smartphone App
(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
Conclusions

• Measures need to be implemented to ensure patient safety
  • Measures need to be implemented to help Anti counterfeiting
  • Measures need to be implemented to improve Supply Chain efficiency (reduce costs)
    • Barcodes work!
    • Standards are the key
  • Standards and technology already exists to help improve patient safety and reduce supply chain costs
  • The FMD and USDCA will allow the widespread adoption of processes that use medication barcodes
What’s Next?

• Use the Haemophilia model for other disease groups and medications such as
  ✓ Vaccines
  ✓ Orphan Drugs
  ✓ Clinical trials
Acknowledgements

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• Rachel Bird (National Haemophilia system data manager)

• Vincent Callan (Director of Facilities Management)
Thank you for listening!

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