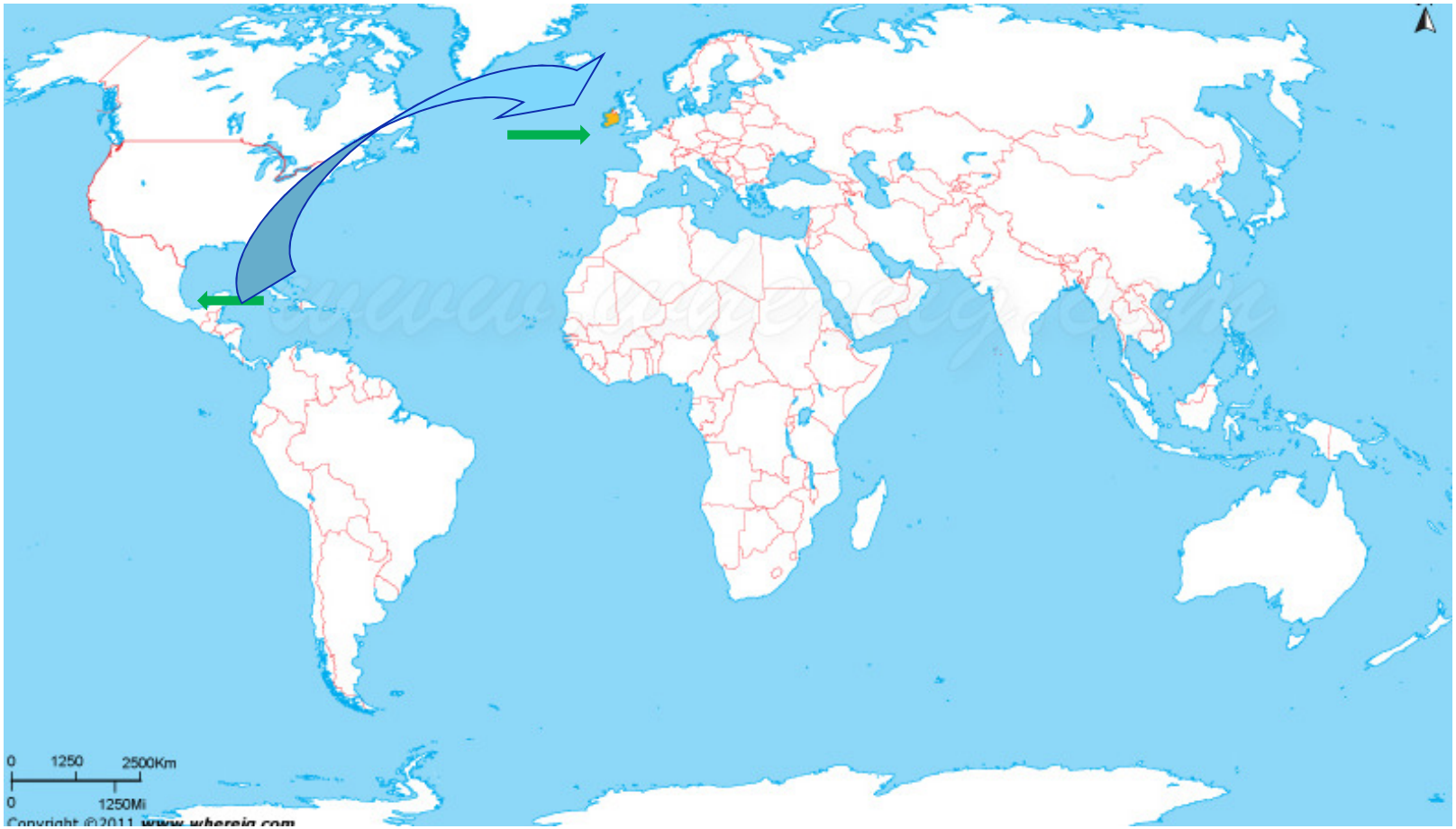
Improved Patient Safety using GS1 Standards

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 larg…erican; and the secc…American
- Both ha… indepen…
- **St Patr**…*cios*" A group o…its that travelle…n-Americ…

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.

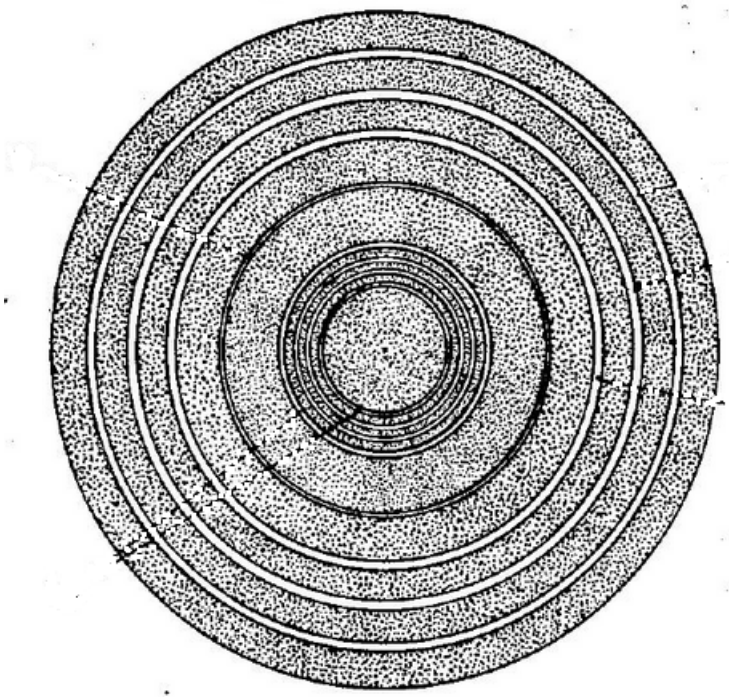
- **Caesar salad was invented in Mexico**
  It's not an Italian dish, but rather the invention of an Italian-American immigrant, Caesar Cardini, who opened restaurants in Mexico City and Tijuana.

- **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!

Sombrero?



First Barcode

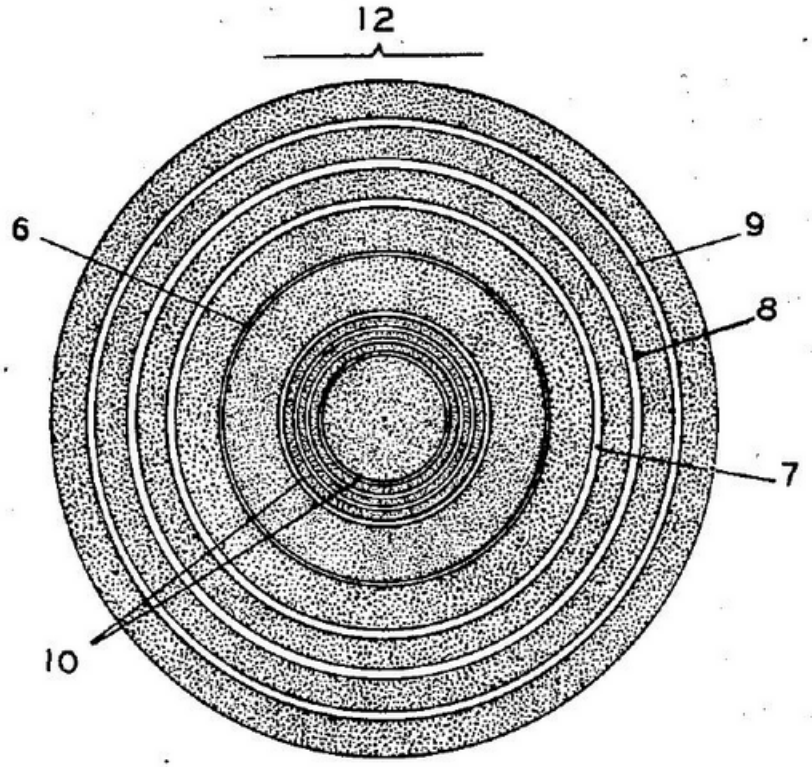


FIG. 10

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

INVENTORS:
NORMAN J. WOODLAND
BERNARD SILVER
BY THEIR ATTORNEYS
Howson & Howson

Famous Pop Group?

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.

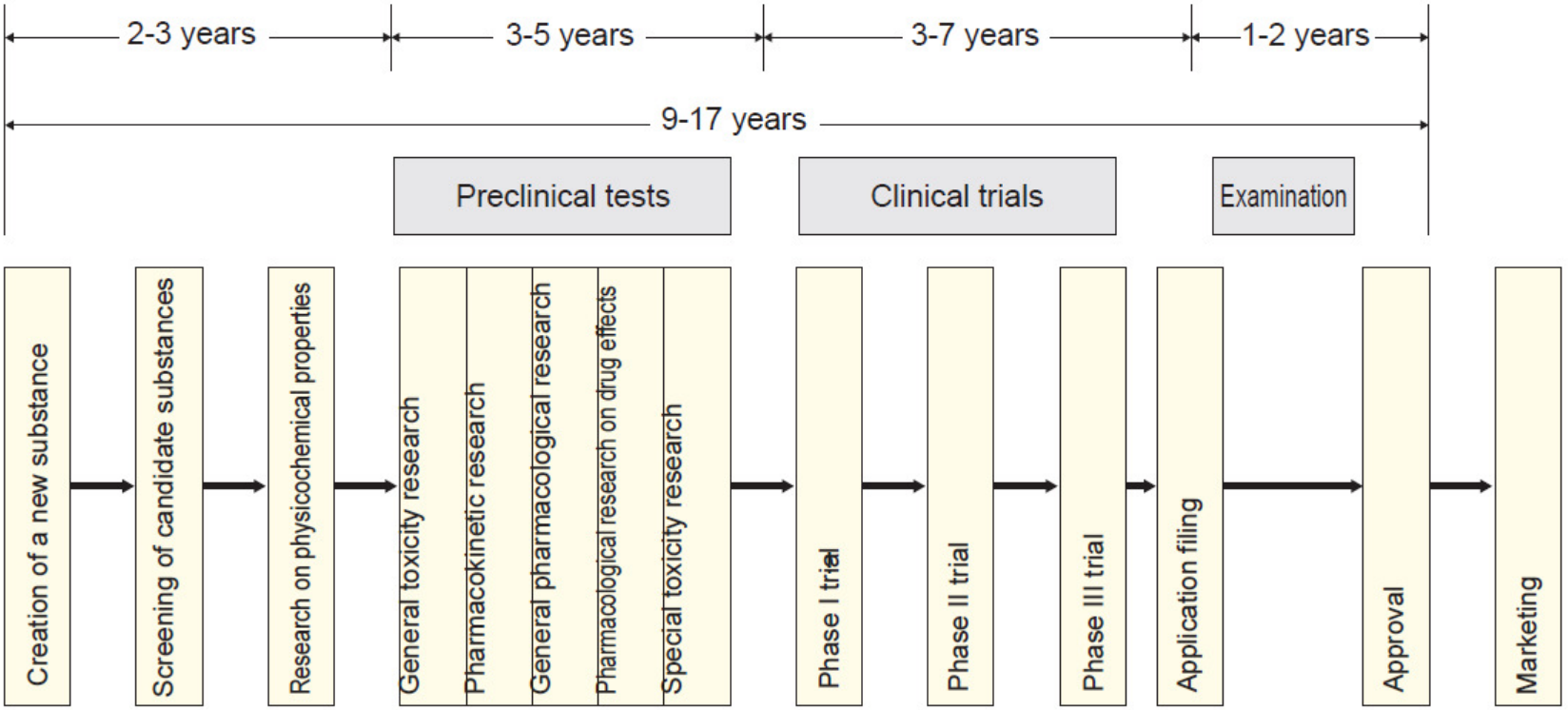
So….. let's look at one of the reasons for these "silent" deaths…

Pharma Drug manufacturing

Overview

Process and Period of New Drug Development

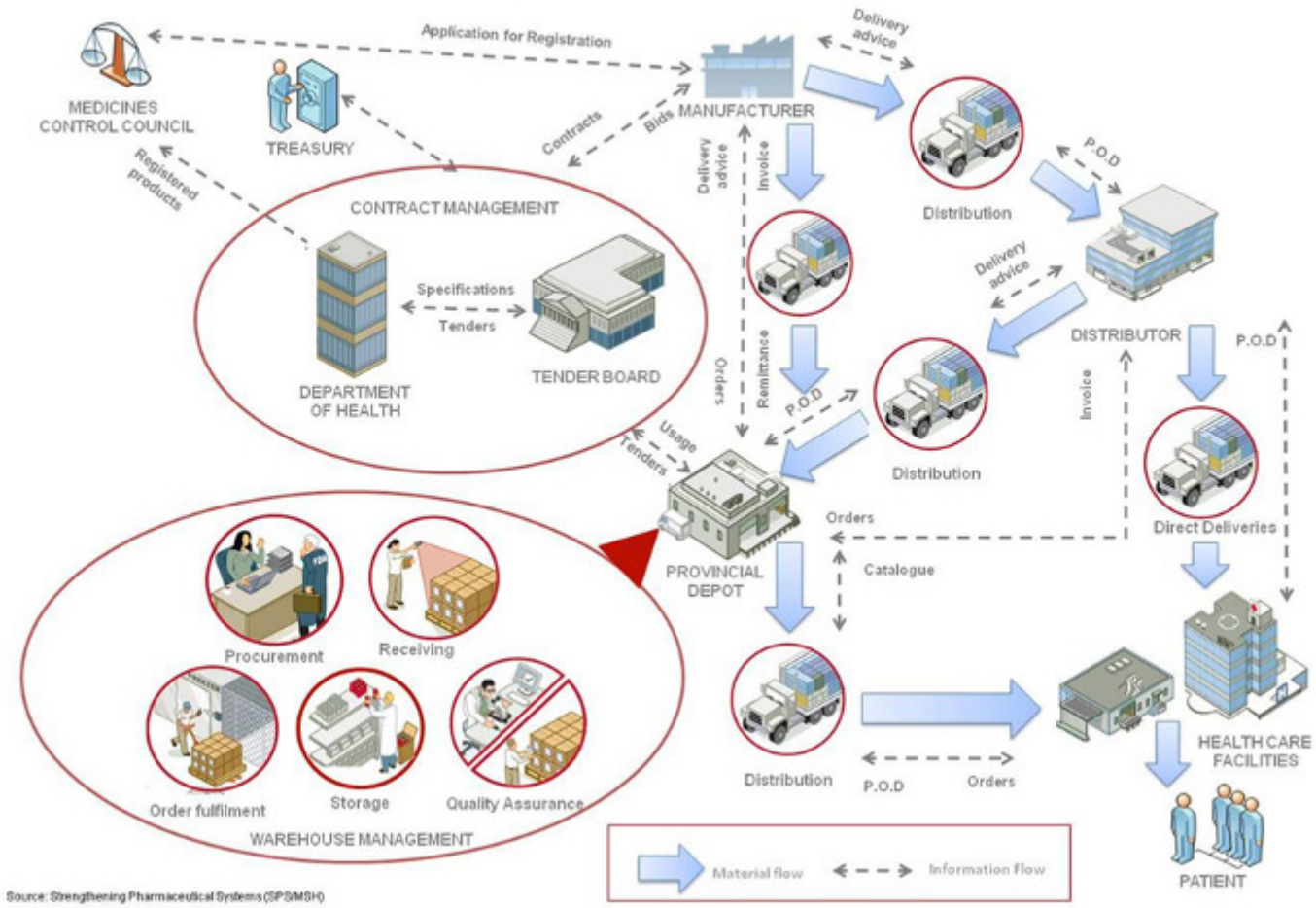
It is considered that 9-17 years and ¥50 billion are required to develop a new drug.



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!

Spot the difference

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?

(01)07612345678900(17)100503
(10)AC345G3

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.

Haemophilia. 2004 Jan;10(1):9-17.

- 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***

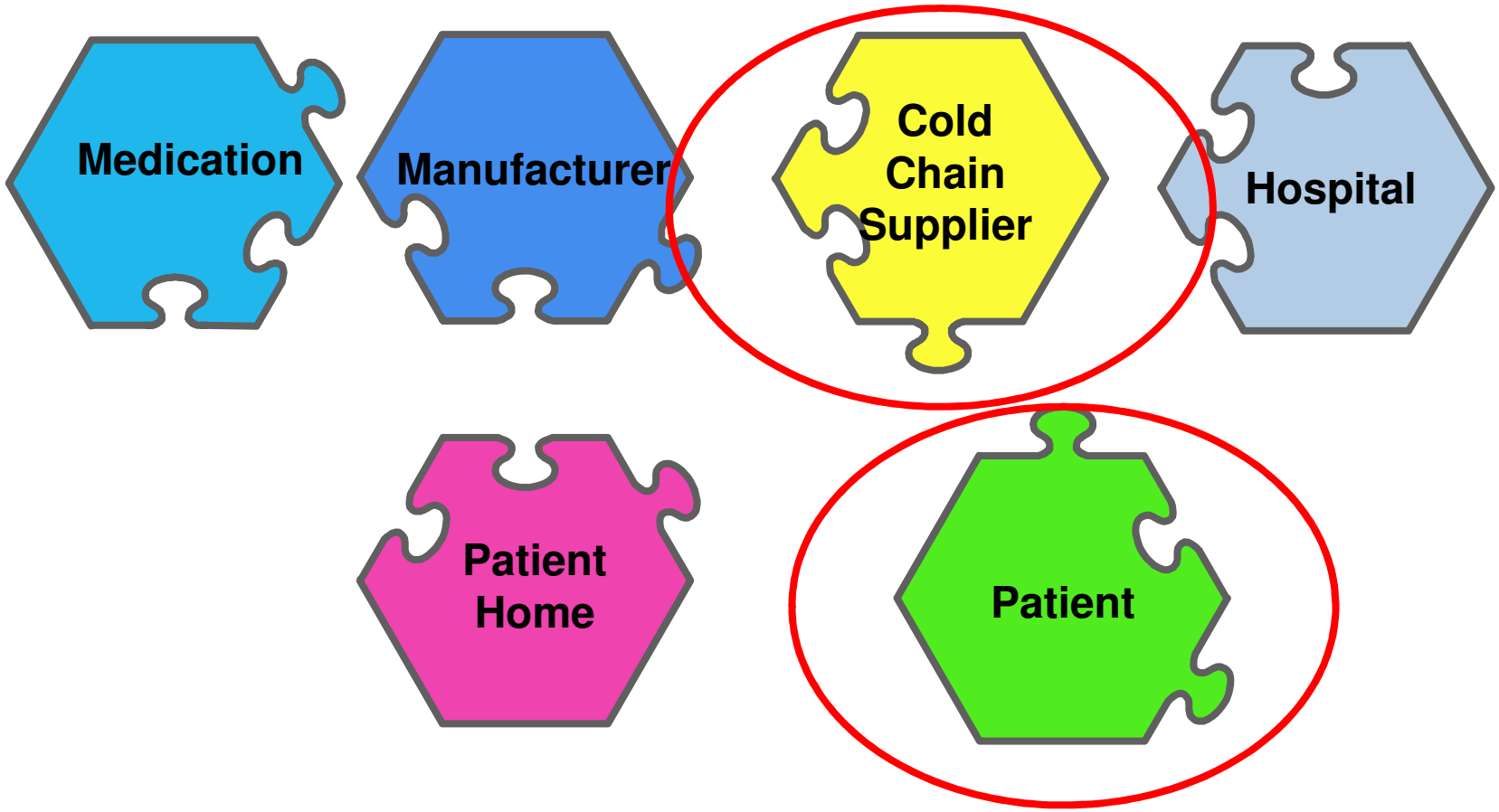
Over 70 people died in Ireland alone

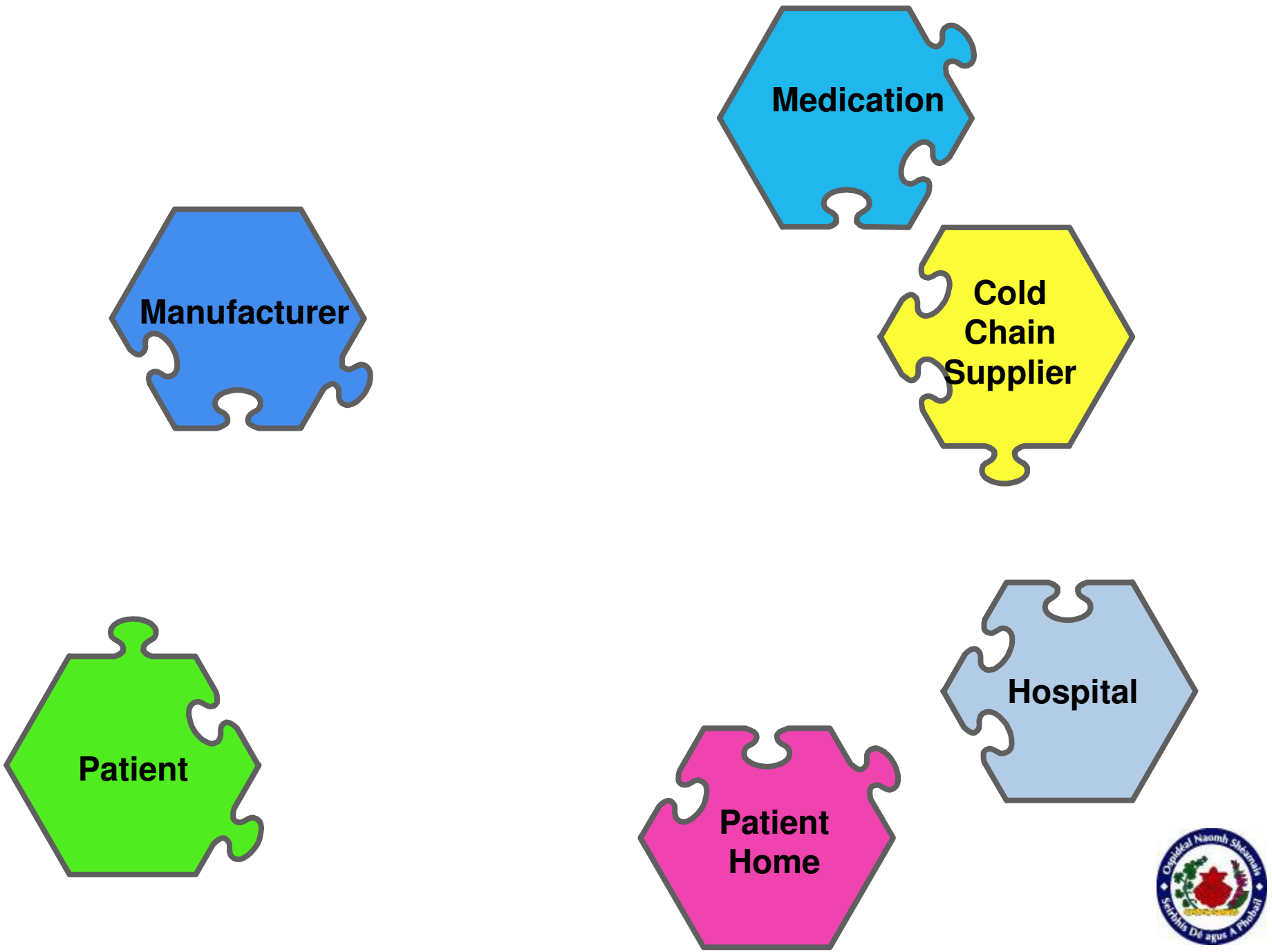
Lindsay Report 2001

Main Recommendations

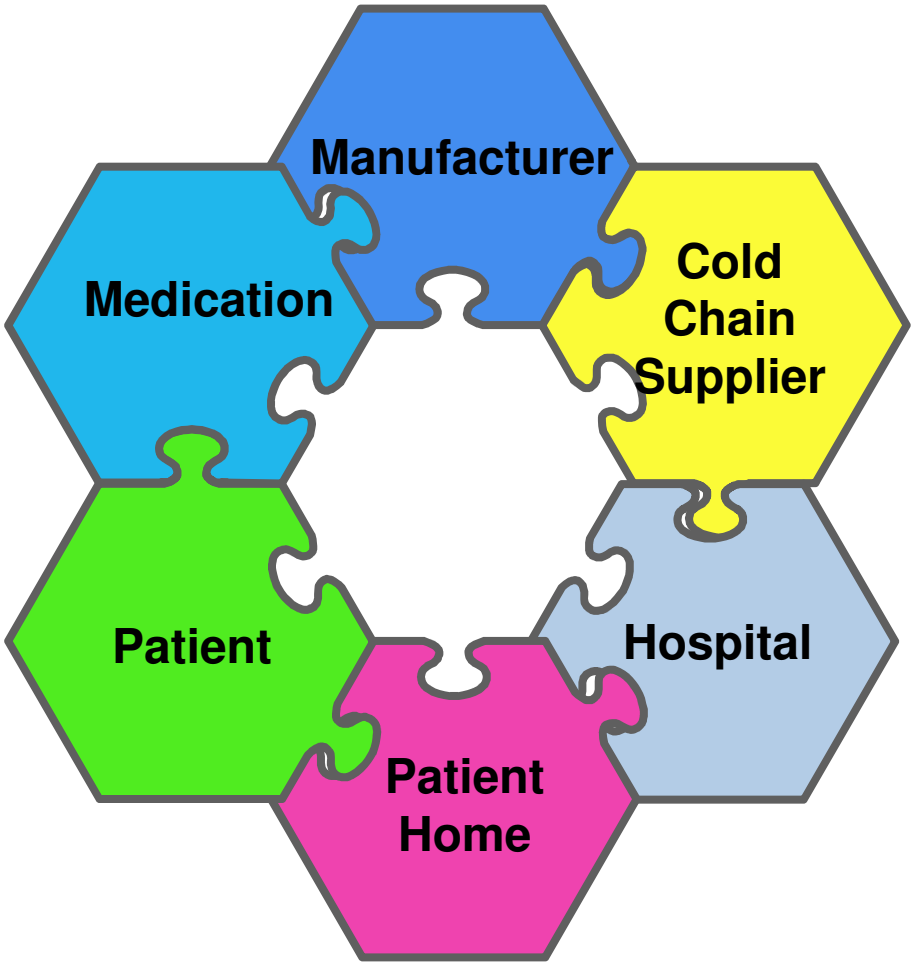
- Improve communication between treatment centres
- Accurate product tracing
- Enact a validated product recall

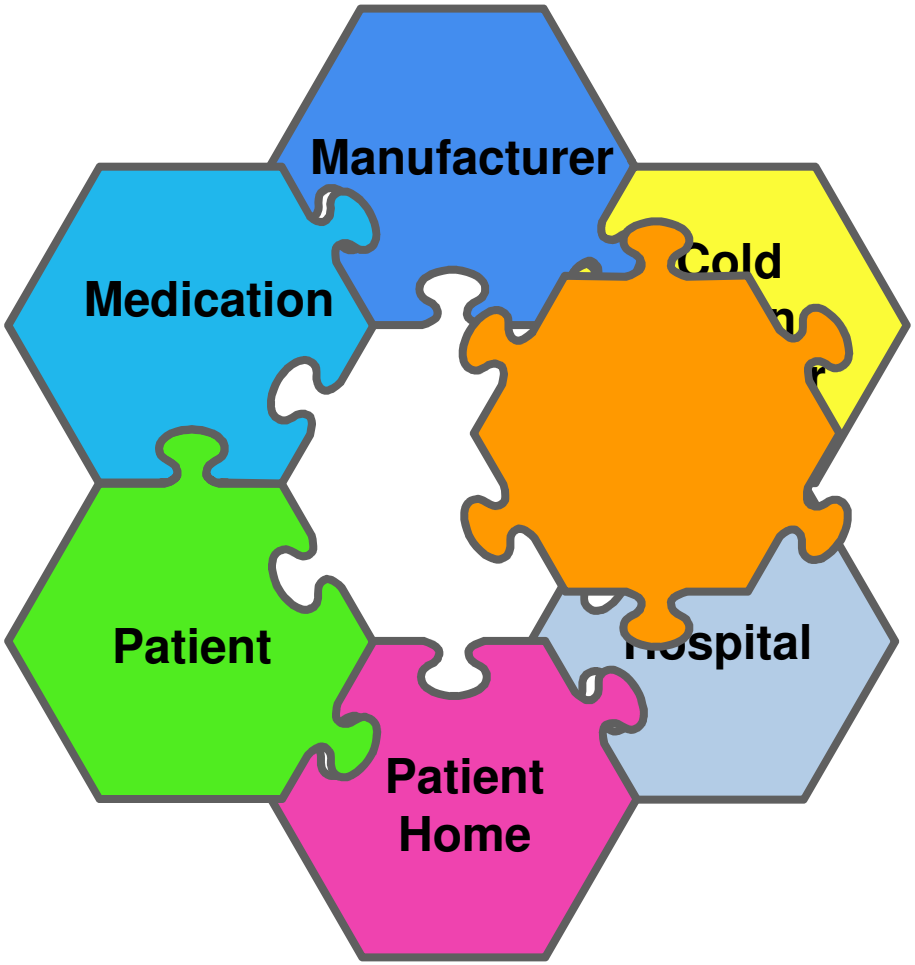
Redesign the Supply Chain

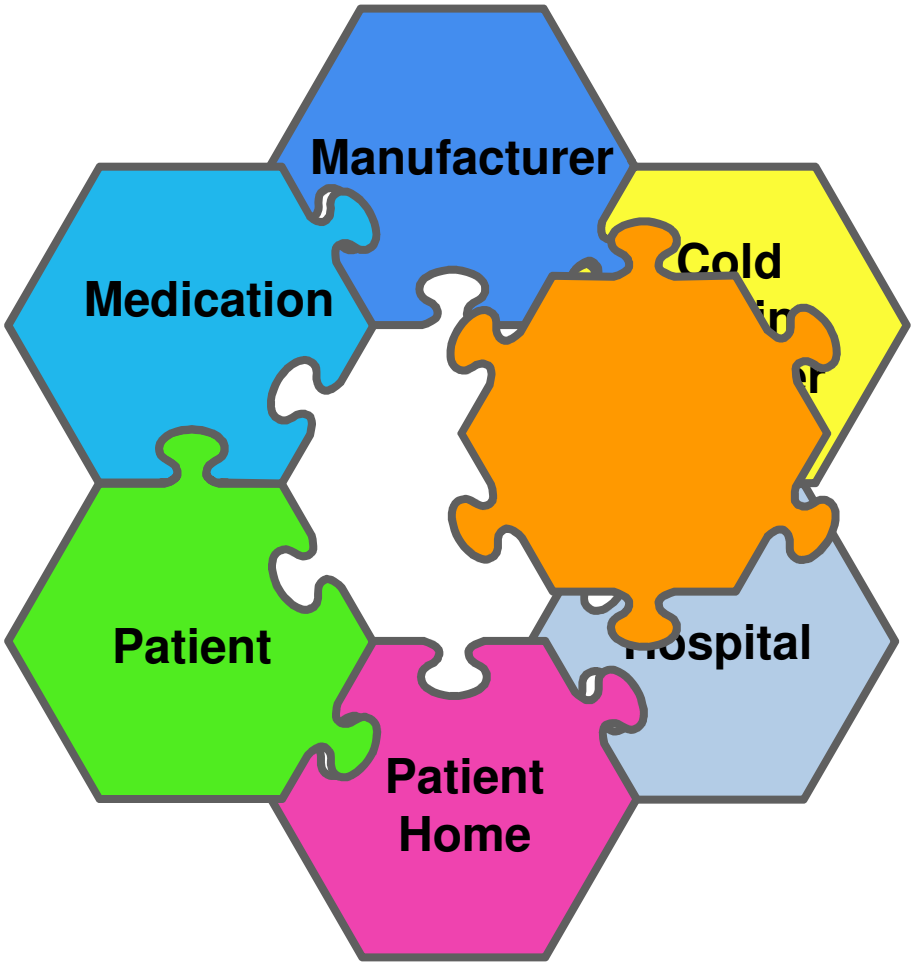



Medication
Manufacturer
Cold Chain Supplier
Patient
Hospital
Patient Home

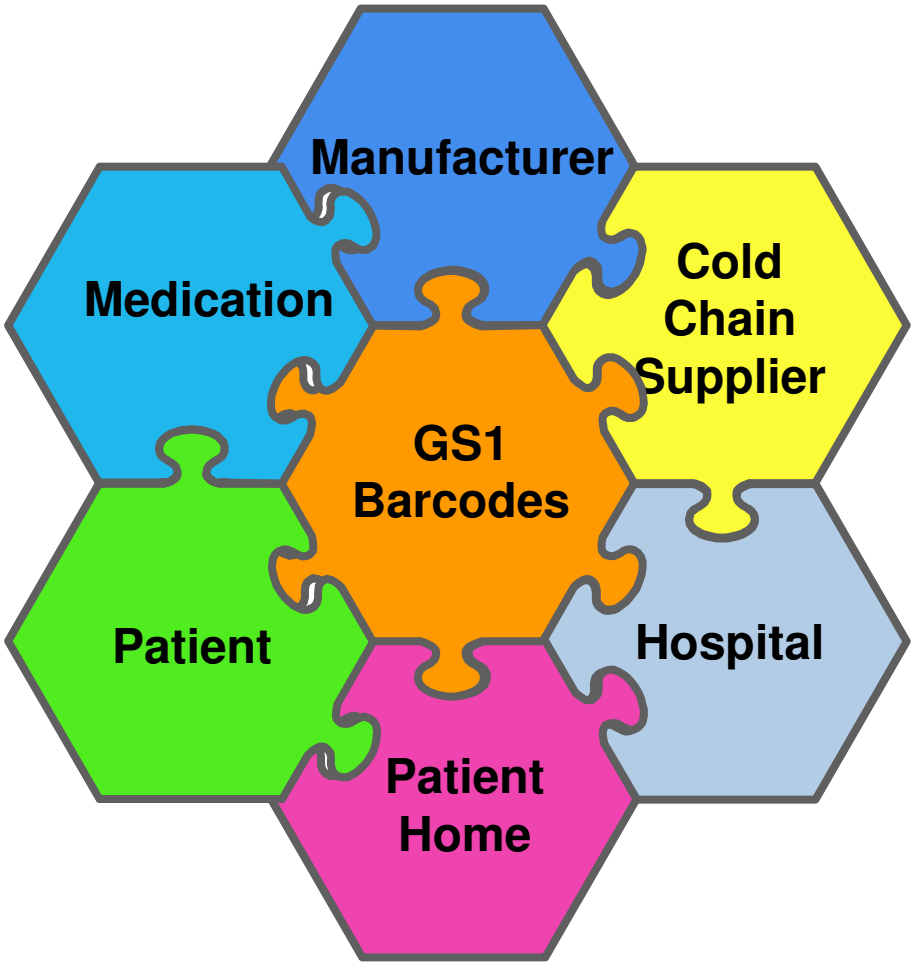
Piece missing!




Manufacturer
Medication
Cold
Patient
Hospital
Patient
Home


Manufacturer
Medication
Cold
Patient
Hospital
Patient
Home

The Final Piece!



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

GTIN 00314141999995
SN 10000000234
LOT 987654321GFEDCBA

Product Name

(GTIN)

Batch Number

Expiry Date

Serial Number

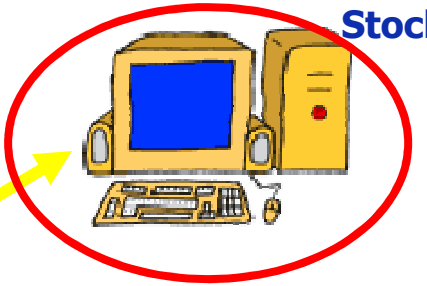
Capture

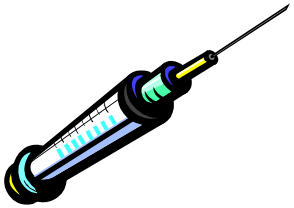
Solution for tracking and tracing products within the Hospital

Bar coded medication is delivered to the Hospital by TCP

Hospital (GLN)

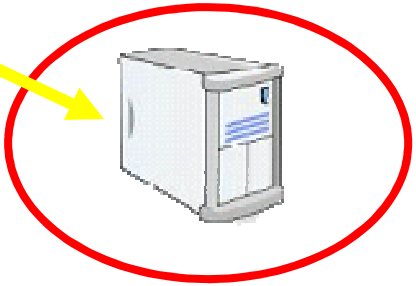
Stock Fridge (GLN)





Prepare product (GTIN)

Patient receives CFC



Issue Fridges (GLN)

Check Product V Patient and issue

Share

Company: **St. James Hospital**
Source: **PharmaTrack**
Criteria: **(GLN = NCHCD)**

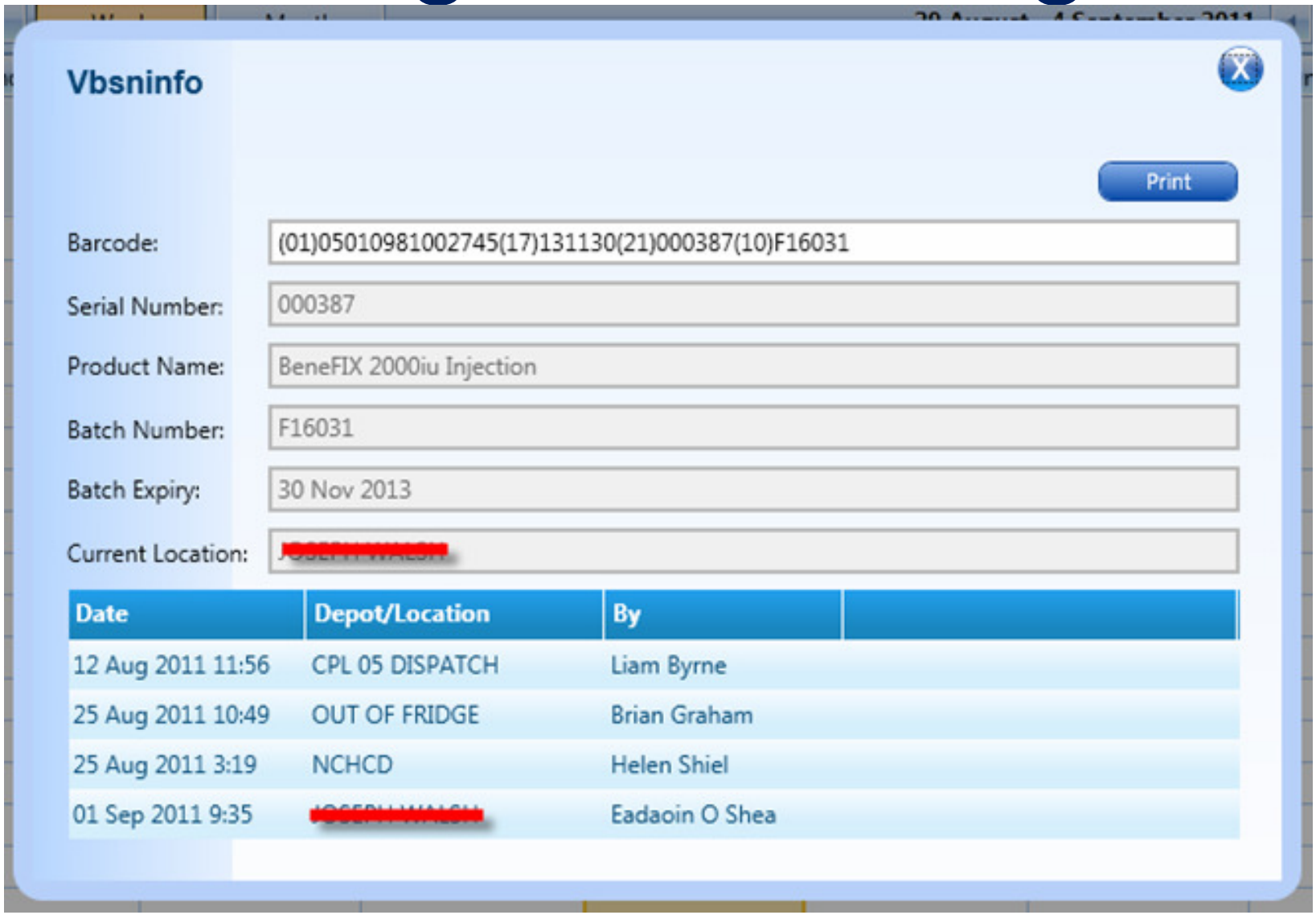
Stock Report By Location

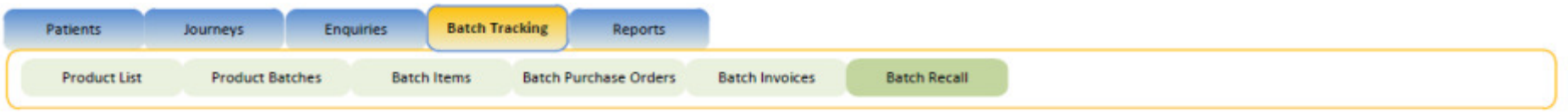
Owner: **Feargal**
Date: **02/05/07 16:28**

NCHCD

ProductName	Batch No	Received On	Expiry Date	Quantity
Advate 1.1 1000iu Baxject II Ireland				
	LE01F515AC	23/03/2007	30/08/2008 23:59	10
Advate 1.1 1500iu Baxject II Ireland				
	LE01F042AS	26/02/2007	31/08/2008 23:59	6
Advate 1.1 500iu Baxject II Ireland				
	LE01E127CH	20/10/2006	30/11/2007 23:59	5
Benefix 1000 IU				
	LE07F021AA	11/04/2007	31/07/2009 23:59	17
Benefix 500 IU				
	LE07F046AA	09/03/2007	31/03/2009 23:59	9
Fandhi 500 IU				
	IBVB6MRNT1	23/03/2007	28/02/2008 23:59	4
Novo Seven 2.4mg (120 KIU)				
	SU60351	05/09/2006	30/06/2008 23:59	1
	SU61573	08/03/2007	31/03/2009 23:59	3
Novo Seven 4.8mg (240 KIU)				
	SU60724	16/03/2007	30/09/2008 23:59	3
Novo Seven 1.2 mg (60 KIU)				
	SU60350	16/03/2007	31/03/2008 23:59	2
	SU60785	19/09/2006	28/02/2008 23:59	3
Prothromplex 600 IU				
	VNP2F001	11/10/2006	31/12/2007 23:59	2
	VNP2F002	02/11/2006	31/05/2008 23:59	4

Single unit tracing





Batch Recall

Close

1. Select Product & Batch

Product: Advate 100 IU ... Batch Number: LC8208Y Go

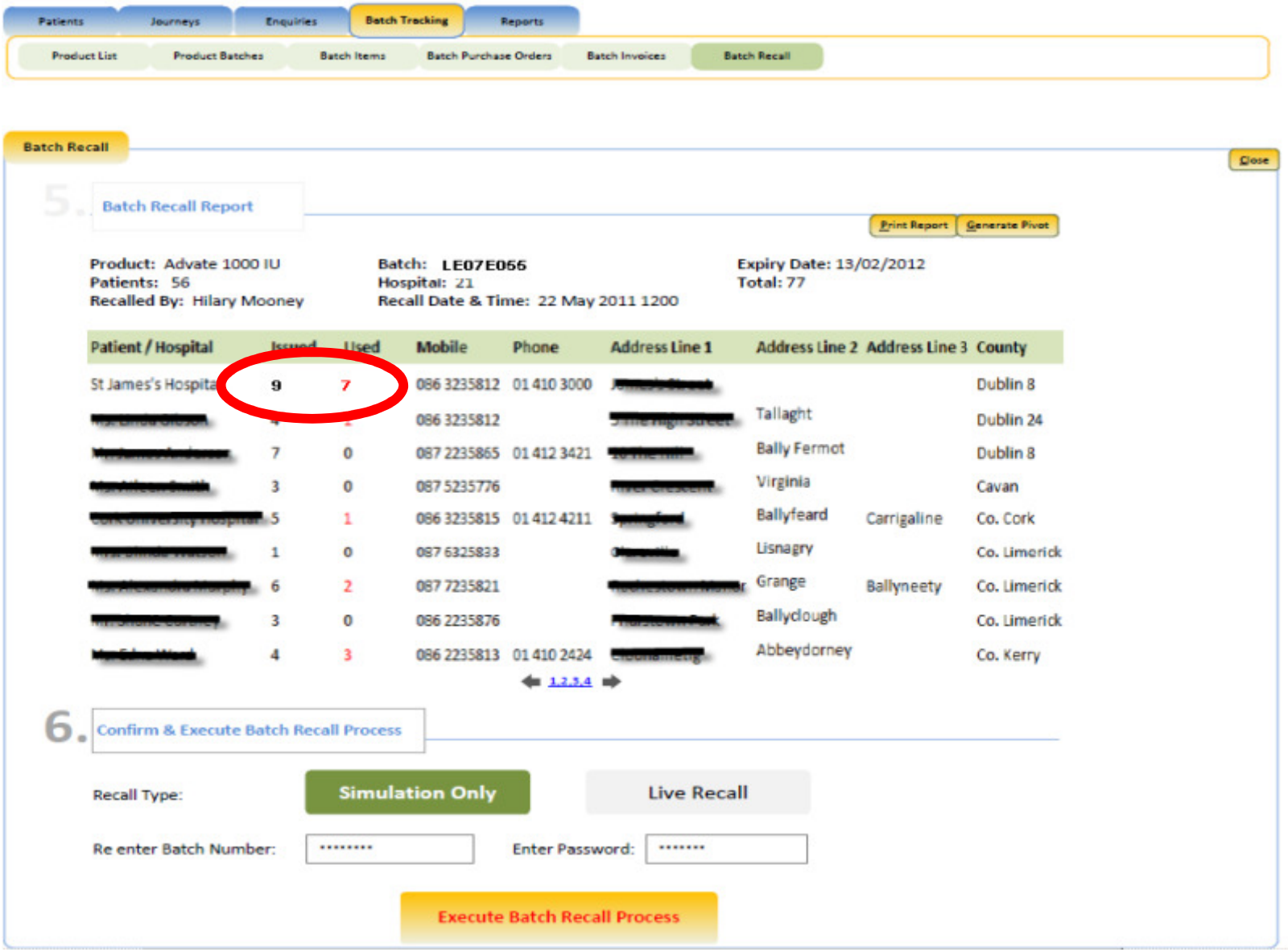
Batch No	Expiry Date	Received	Awaiting Supply	Issued	Allocated	On Van	In Stock	Used
LC8208Y	13/02/2012	140	30	70	10	5	60	21

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



Recall Reports

PharmaTrack Batch Recall Report

Company: **St. James Hospital**

Batch Recall Report

Source: **PharmaTrack**

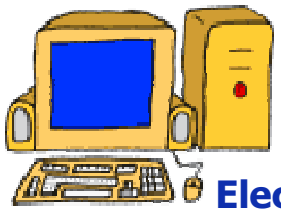
Criteria: **(Batch No = LE07E055AA)**

Batch No :	LE07E055AA		**Benefix 1000 IU**
Serial No	**Transaction Type**		**Transaction Date**
000035	Issued		31/10/2006 15:22
	Patient Name:	XX XXXXXXX	
Reference :	*Prophylaxis*		
000260	Transfered In		29/02/2006 12:24
In Stock	**GLN:**	**NCHCD**	
Reference :			
Reason:	*NCHCD Stock Top Up*		
000046	Issued		03/10/2006 13:02
	Patient Name	XXXXX XXXXXXX	
Reference :			
000120	Issued		13/09/2006 10:34
	Patient Name	XXXXX XXXXXXX	
Reference :	*surgical site bleed*		
000121	Issued		14/09/2006 11:51
	Patient Name	XXXXX XXXXXXX	
000378	Transfered In		12/03/2008 12:02
In Stock	**GLN:**	**WALTER STEVENSON WARD**	
Reference :			
Reason:	*WSW Stock Top Up*		
Reference :			
000122	Issued		03/10/2006 15:26
	Patient:	XXXXX XXXXXXX	
Reference :	*right thigh bleed*		
000123	Issued		14/09/2006 11:51
	Patient:	XXXXX XXXXXXX	
Reference :			
000134	Issued		02/10/2006 15:31
	Patient:	XXXXX XXXXXXX	
Reference :	*Right thigh bleed*		

BATCH SUMMARY

Total Booked In :	**9**
Issued to patients :	**7**
Stock in GLN(s) :	**2**

Delivery to the home and "In home" usage

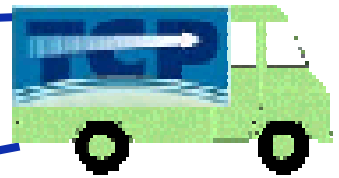


Electronic prescription

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

Details of all movements are sent to the stock management system

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

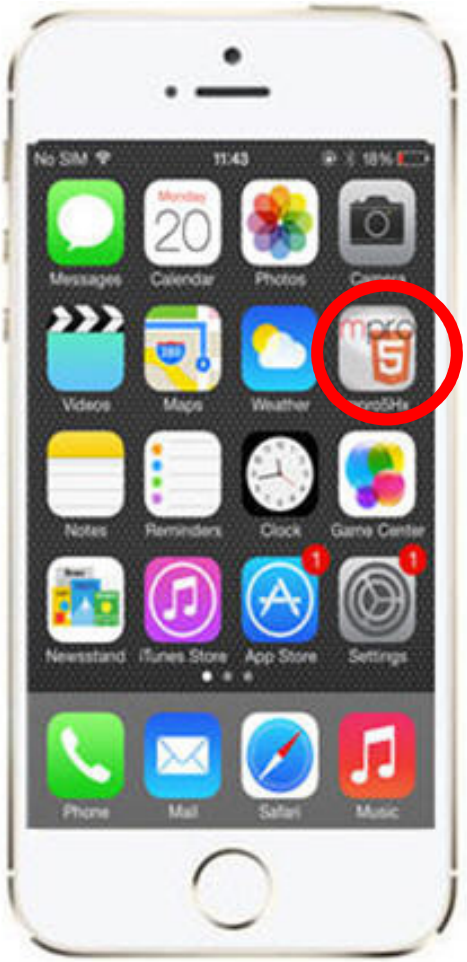


Patient scans product. Verification received from EPR

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

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

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

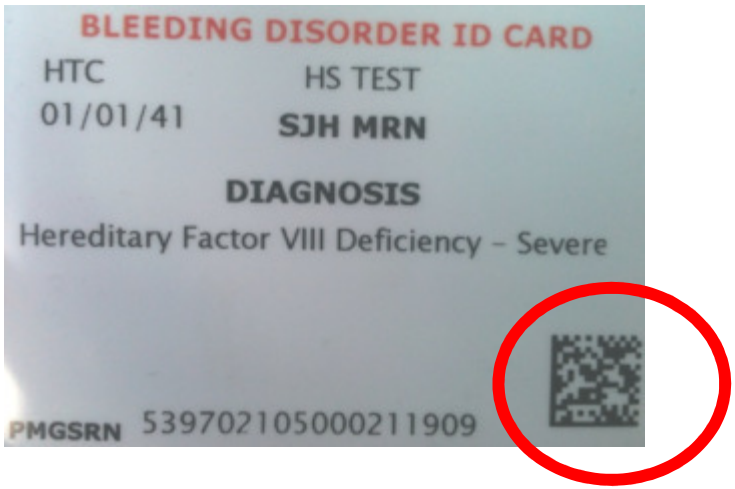
Log-in

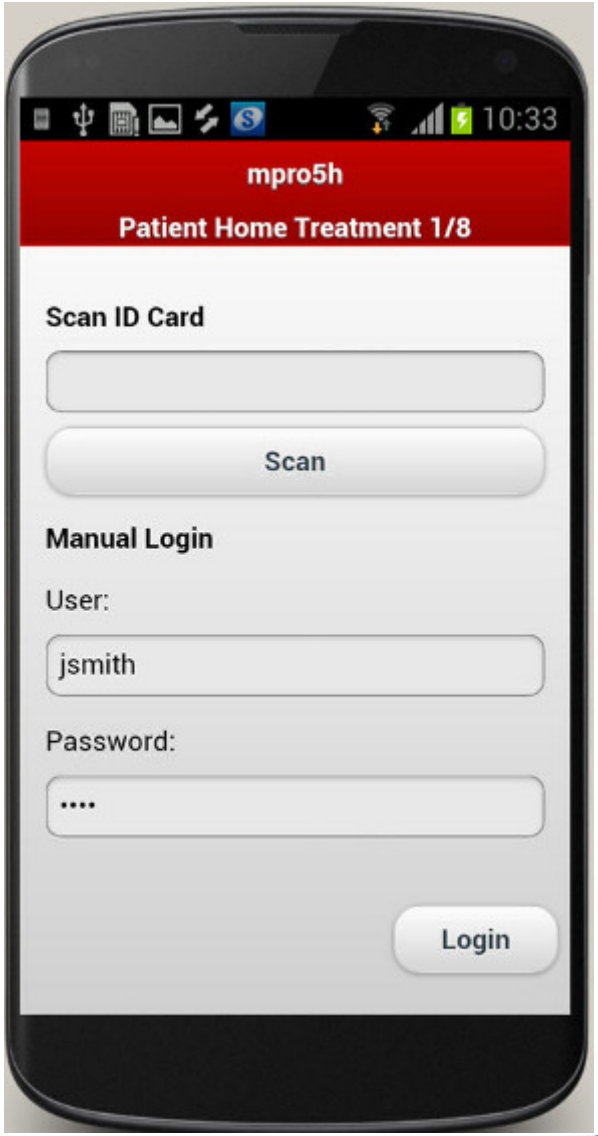
Secure Login by

- Username/Password

or

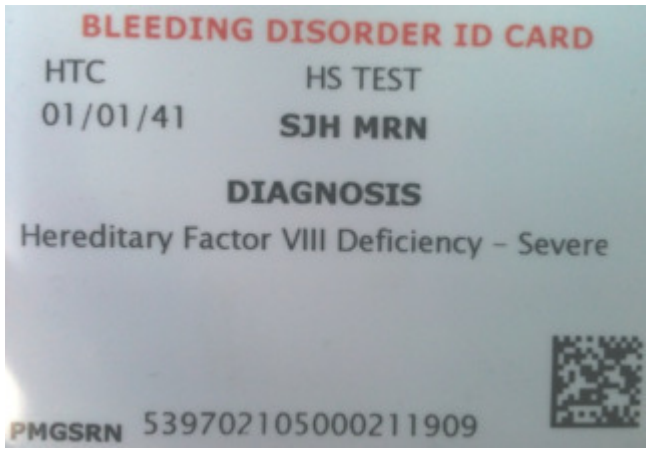
- Scanning unique GS1 ID on Card

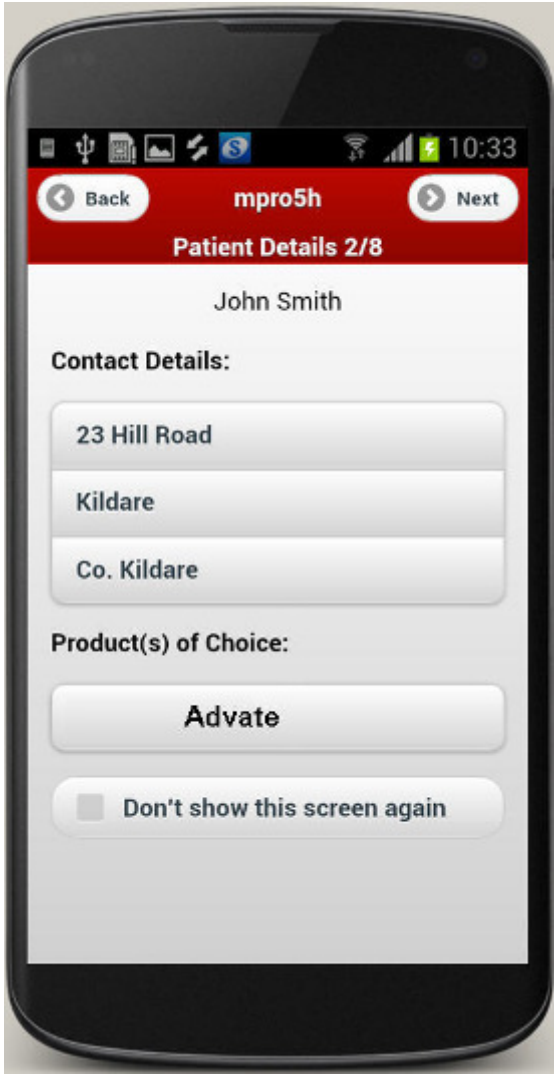




Patient Details

Patient detail confirmation includes product of choice

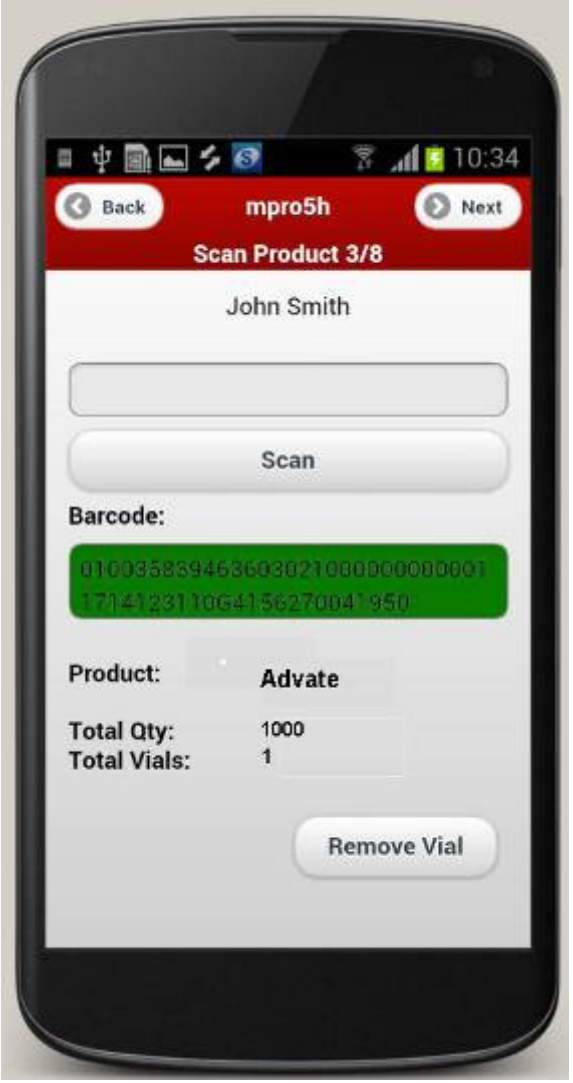




Scan Product

Barcode on Vial box is scanned to check …..

- product detail (prescription)
- expiry date
- Recall status
- **Check for "older" stock in Fridge**



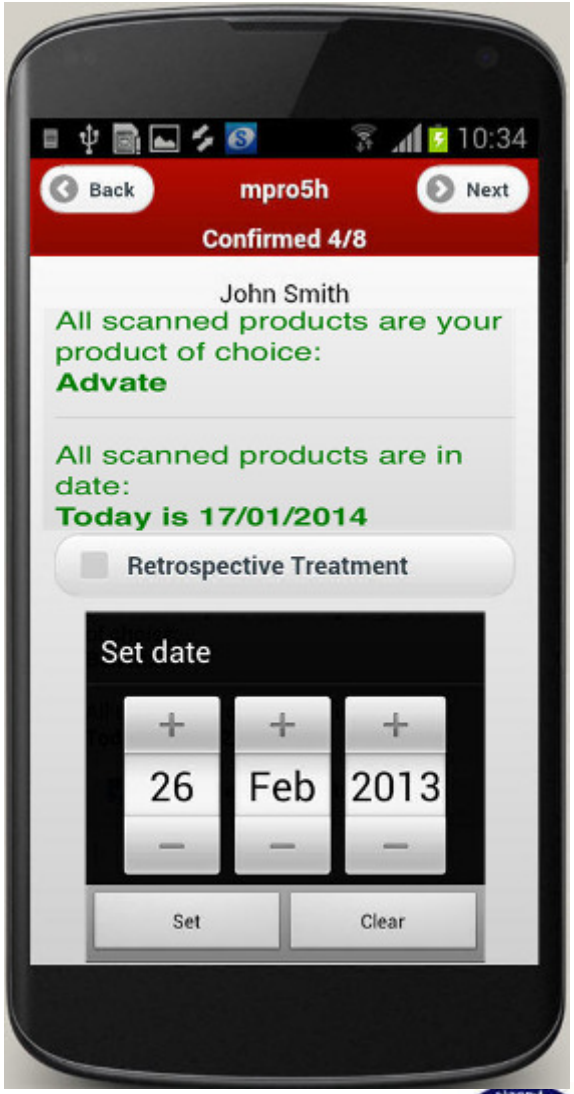
Validation – FAIL!

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

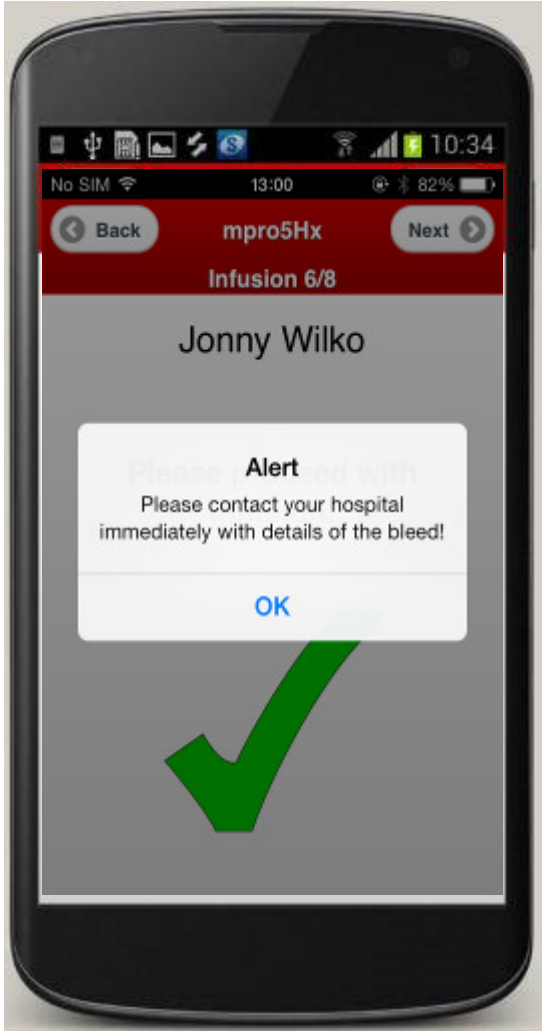


Infusion Detail

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

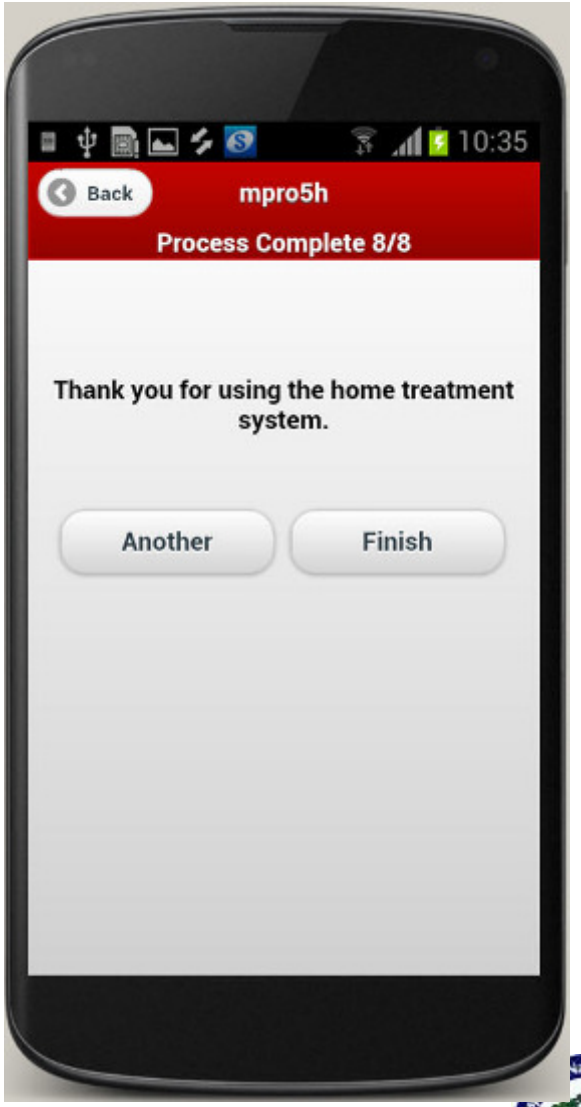


Infusion Authorisation

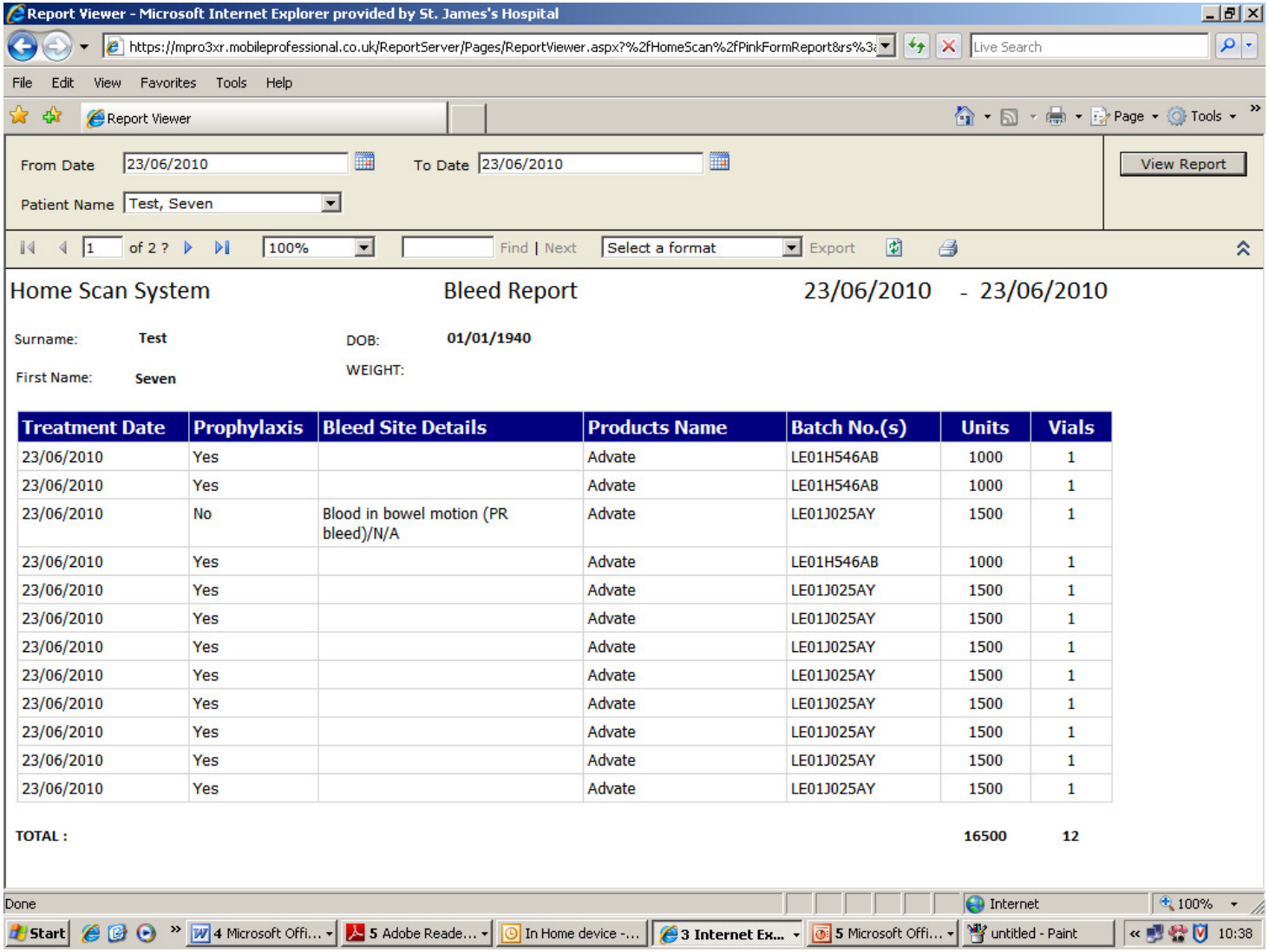
Again, the app prompts the patient to proceed.

Process Complete

Process concludes, system synchronises data wirelessly to **web application**



Share


Report Viewer - Microsoft Internet Explorer provided by St. James's Hospital
https://mpro3xr.mobileprofessional.co.uk/ReportServer/Pages/ReportViewer.aspx?%2fHomeScan%2fPinkFormReport&rs%3a
File Edit View Favorites Tools Help
Report Viewer
From Date 23/06/2010
To Date 23/06/2010
View Report
Patient Name Test, Seven
1 of 2 ?
100%
Find | Next
Select a format
Export
Home Scan System
Bleed Report
23/06/2010 - 23/06/2010
Surname: Test
DOB: 01/01/1940
First Name: Seven
WEIGHT:
Treatment Date | Prophylaxis | Bleed Site Details | Products Name | Batch No.(s) | Units | Vials
23/06/2010 | Yes | | Advate | LE01H546AB | 1000 | 1
23/06/2010 | Yes | | Advate | LE01H546AB | 1000 | 1
23/06/2010 | No | Blood in bowel motion (PR bleed)/N/A | Advate | LE01J025AY | 1500 | 1
23/06/2010 | Yes | | Advate | LE01H546AB | 1000 | 1
23/06/2010 | Yes | | Advate | LE01J025AY | 1500 | 1
23/06/2010 | Yes | | Advate | LE01J025AY | 1500 | 1
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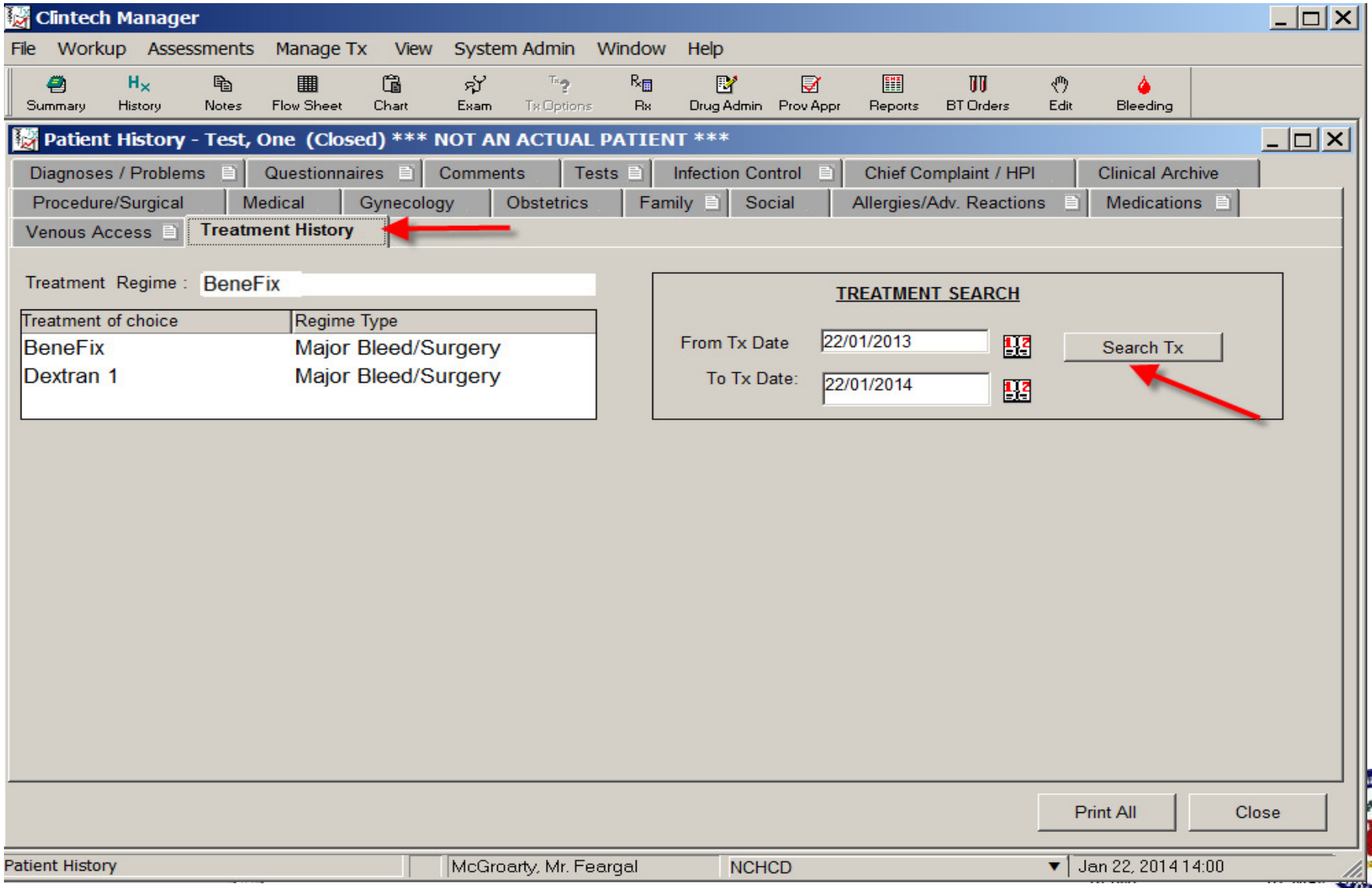
23/06/2010 | Yes | | Advate | LE01J025AY | 1500 | 1
TOTAL : 16500 12
Done
Internet
100%
Start
4 Microsoft Offi...
5 Adobe Reade...
In Home device -...
3 Internet Ex...
5 Microsoft Offi...
untitled - Paint
10:38

Share


Clintech Manager
File Workup Assessments Manage Tx View System Admin Window Help
Summary History Notes Flow Sheet Chart Exam Tx Options Rx Drug Admin Prov Appr Reports BT Orders Edit Bleeding
Patient History - Test, One (Closed) *** NOT AN ACTUAL PATIENT ***
Diagnoses / Problems Questionnaires Comments Tests Infection Control Chief Complaint / HPI Clinical Archive
Procedure/Surgical Medical Gynecology Obstetrics Family Social Allergies/Adv. Reactions Medications
Venous Access Treatment History
Treatment Regime : BeneFix
Treatment of choice Regime Type
BeneFix Major Bleed/Surgery
Dextran 1 Major Bleed/Surgery
TREATMENT SEARCH
From Tx Date 22/01/2013
To Tx Date: 22/01/2014
Search Tx
Print All
Close
Patient History
McGroarty, Mr. Feargal
NCHCD
Jan 22, 2014 14:00

Outcomes/ROI

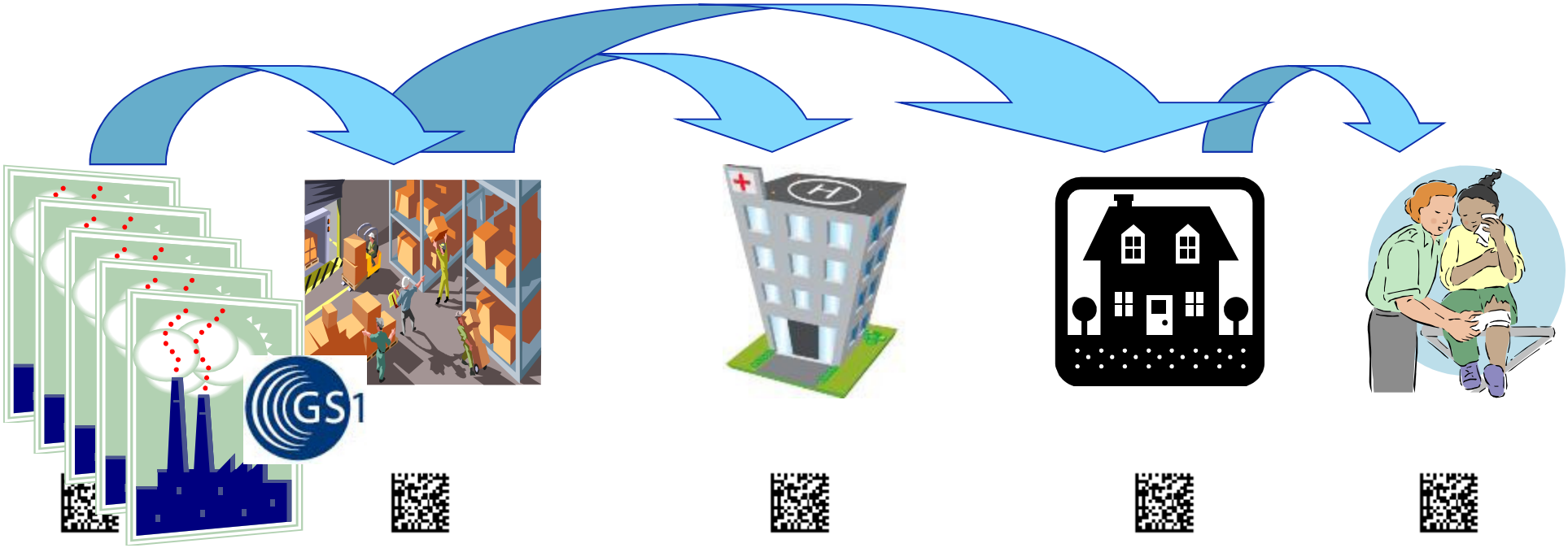
Validated Cold Chain delivery Service using GS1 Datamatrix Bar coding on medication packaging

- 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

HSE Track and Trace Pilot for Vaccines… 18th February 2014

THE IRISH TIMES
Tuesday, February 18, 2014

Medical Notes

Tracking system for vaccines: A pilot of a "track and trace" system for the distribution of vaccines within the health system has found it could have significant impact on the safety and efficiency of vaccination programmes. The trial, which used 1,800 individually barcoded flu vaccinations, was carried out by UDG Healthcare and the HSE National Immunisation Office.

"The correct implementation of immunisation programmes requires complex specialist distribution systems. Track and trace provides a level of visibility on the journey of a vial which we don't currently have," said Cliona Kiersey, chief pharmacist at the HSE National Immunisation Office.

more individual and personalised treatment of patients with metastatic prostate cancer.

'…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…'

HSE Track and Trace Pilot for Vaccines… 18th February 2014

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…..

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- **Rachel Bird** (National Haemophilia system data manager)
- **Vincent Callan (**Director of Facilities Management)

Thank you for listening

Any Questions ?

fmcgroarty@stjames.ie