CASE STUDY:
The Business Case for Haemophilia Product Traceability

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

Agenda

- Background to NCHCD and Haemophilia
- How to build a Business Case!
- Barcodes for Recall management, patient safety and cost containment
- Exploiting smartphone technology - allowing patients to scan their medication within the home
- Outcomes/ROI
- Conclusion

Facts

- Chronic diseases are the leading cause of mortality and morbidity in Europe - accounting for 86% of total premature deaths

"Tackling chronic disease in Europe
The European Observatory on Health Systems "

Realities

- Chronically ill persons have to deal with numerous difficulties in everyday medication management on their own.
- Patients are often overwhelmed by problems related to both their medication regimen and their routines in medication (self-) management.
- From the perspective of people with chronic conditions, the main challenge in everyday medication management is to develop, maintain, and adjust routines

"Chronic Illness - September 2009 vol.5 no3 184-196"

Finally….

Medicines are supposed to save lives

Dying from a disease is sometimes unavoidable;

dying from a medicine is unacceptable.

Lepakhin V. Geneva 2005

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)
- Over 75% Patients with severe Haemophilia self medicate at home

What is Haemophilia and why is Medication traceability important?

- Haemophilia is a Chronic Disease, it is a bleeding disorder caused by a deficiency of a clotting factor
- Incidence of 1:5,000 – 1:10,000 live male births
- 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

Healthcare Business Case?

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 and over 80 deaths

Lindsay Report 2001

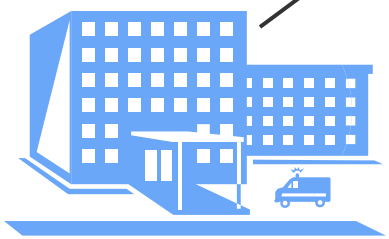
Main Recommendations

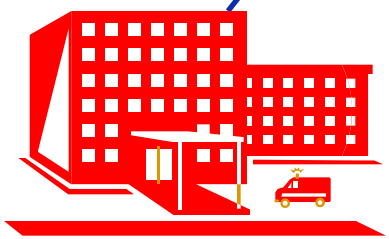
- Improve communication between treatment centres
- Accurate product tracing
- Enact a validated product recall

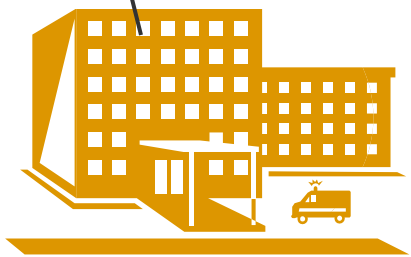
Multi location EPR (Electronic Patient Record) deployment

National Haemophilia Center

Care provider
Home access



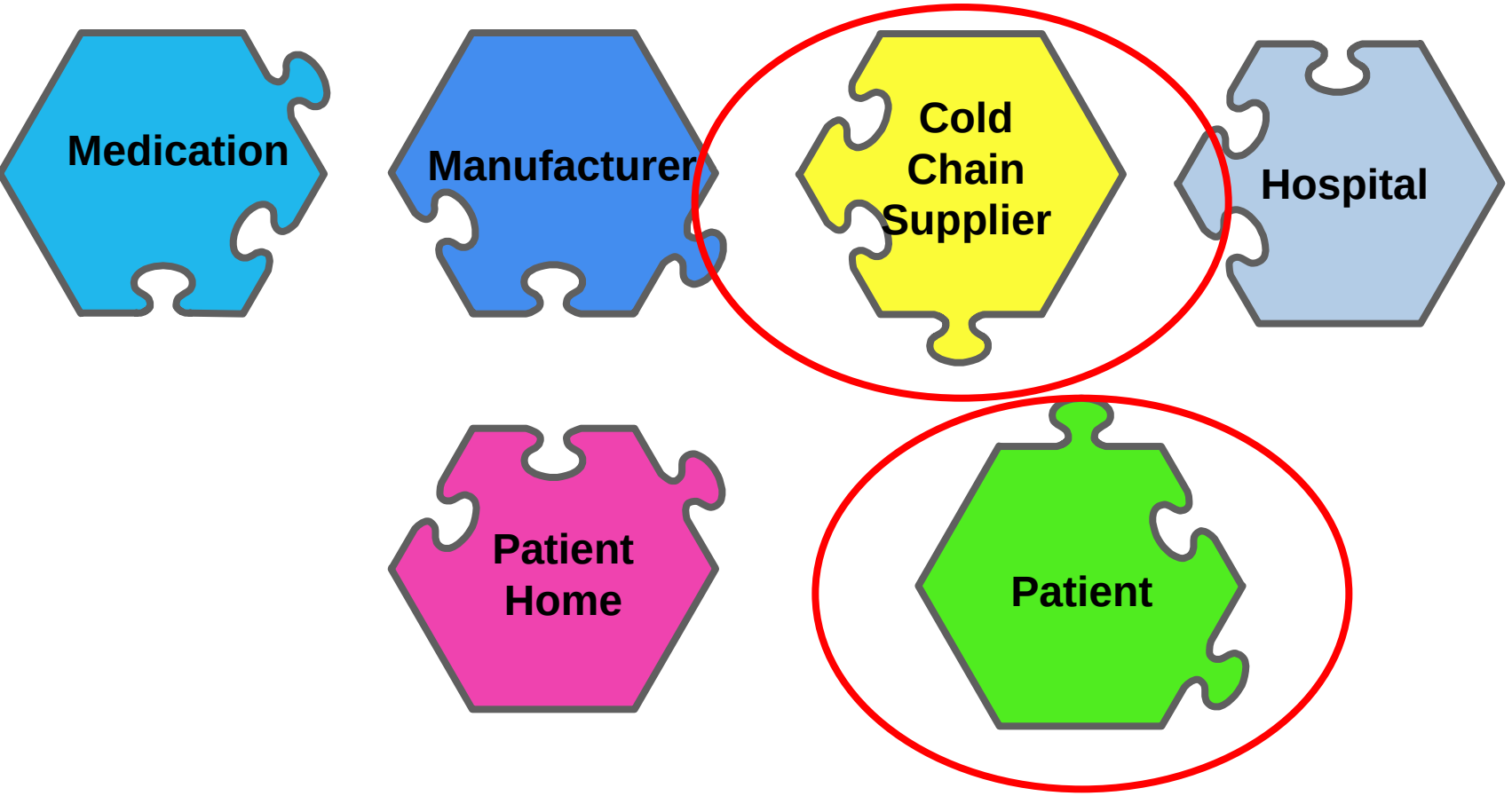


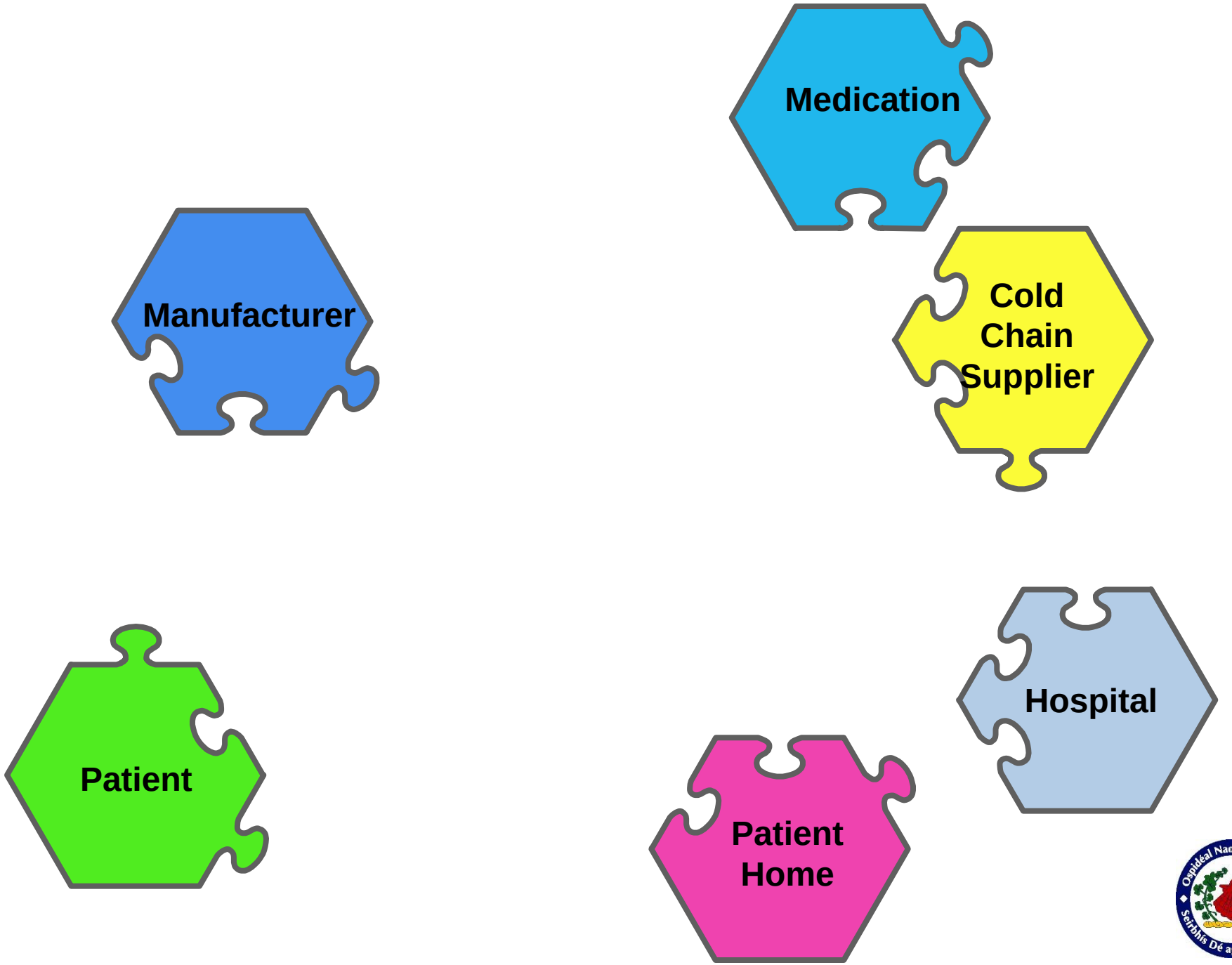


Regional Haemophilia Centres

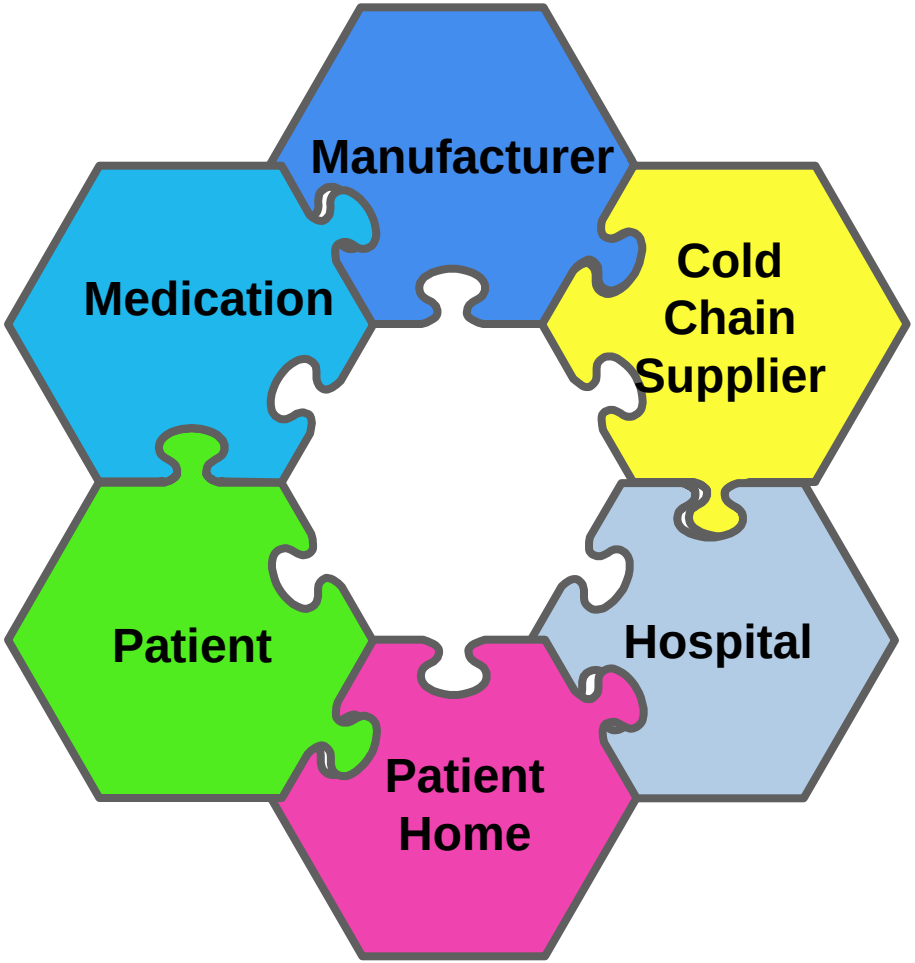
Medication delivery -Where we were

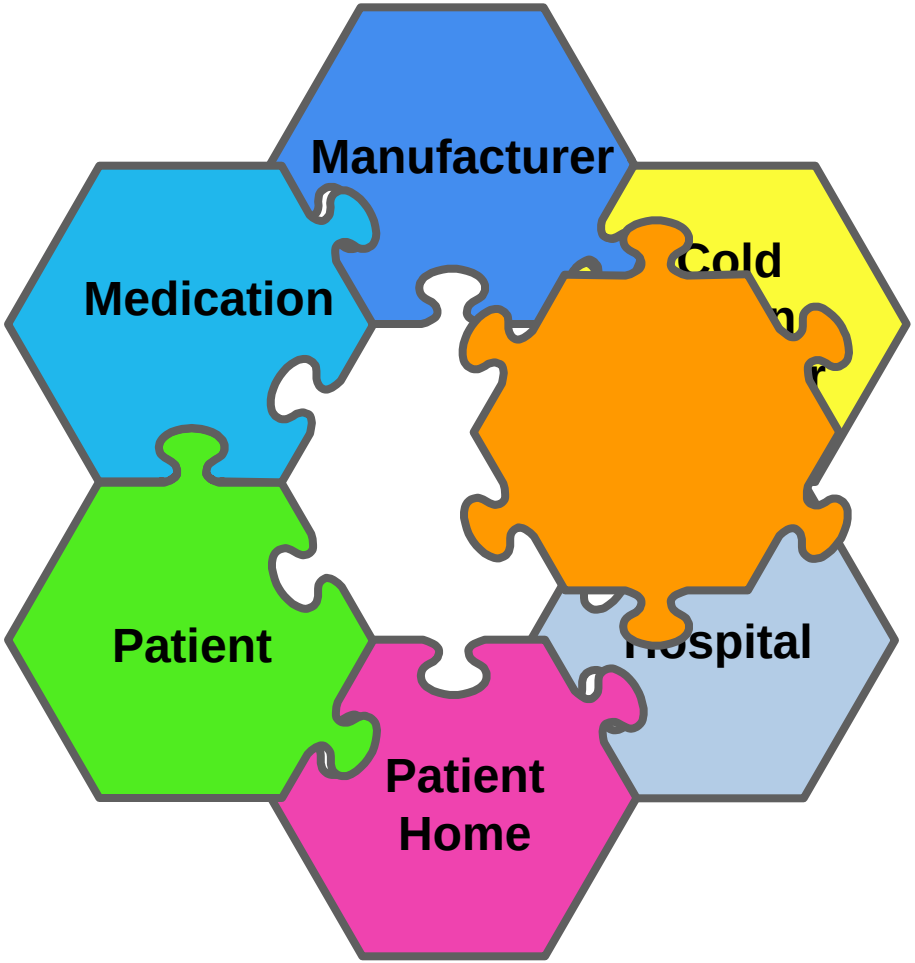
Redesign the Supply Chain

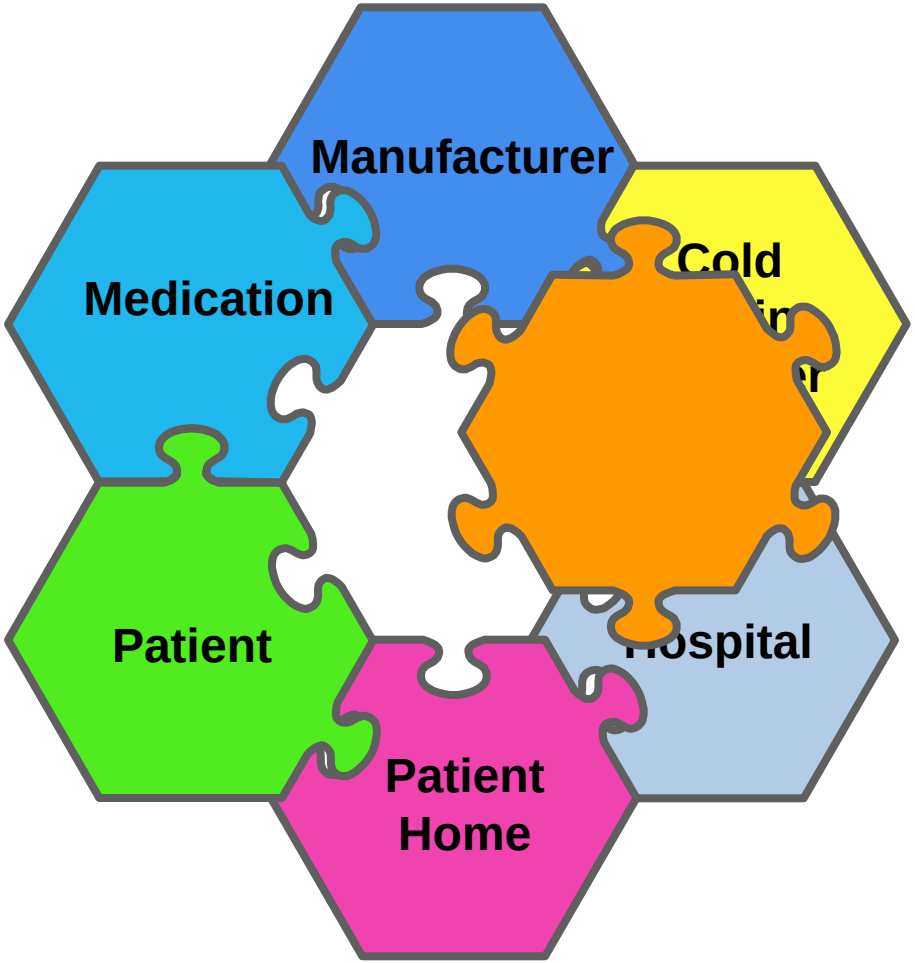



Medication
Manufacturer
Cold Chain Supplier
Patient
Hospital
Patient Home

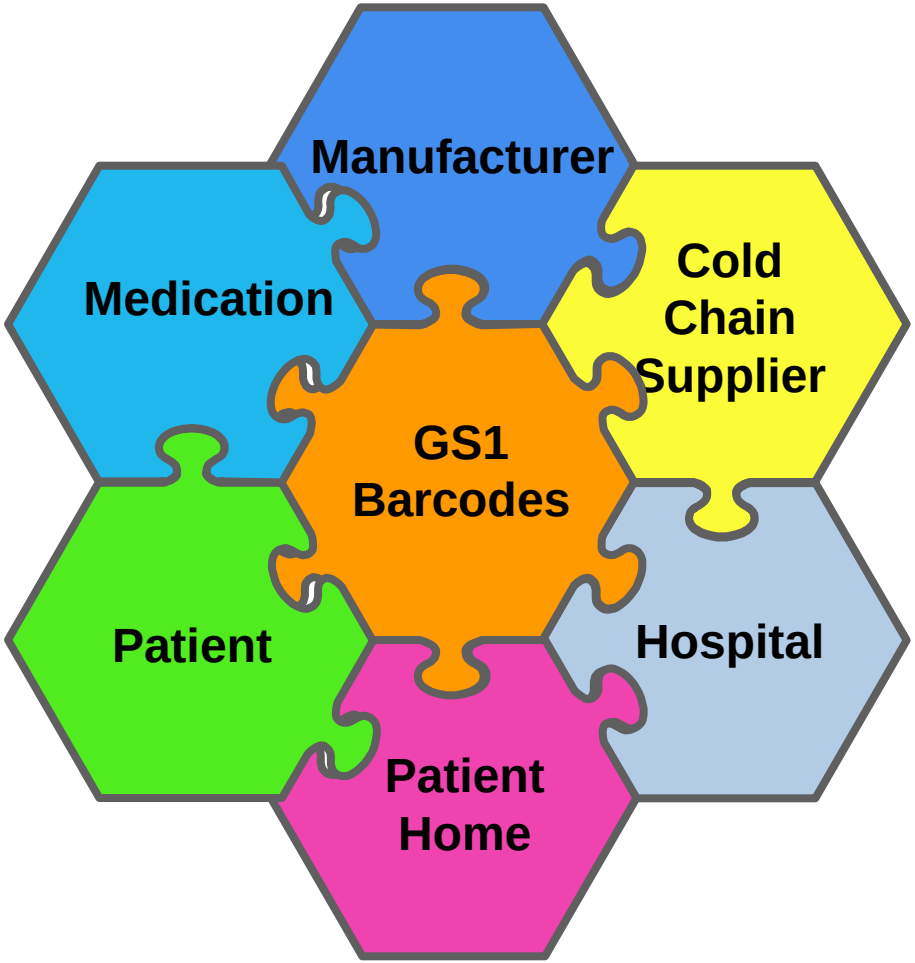
Piece missing!




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 (+Lot + Expiry)
- Unique identification (barcode) of locations (Hospital/Home/Pharmacy/Transport) - GLN

ID Formats

Previous Barcode (2 Linear)

Hospital allocated Datamatrix barcodes

Manufacturer allocated barcode

Product Name

(GTIN)

Batch Number

Expiry Date

Serial Number

St. James's Hospital

crimson tide

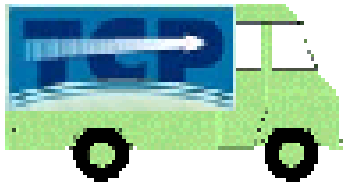
GS1 Compliant UMI Specification

Wednesday, 10th August 2011

Status:

"Approved"

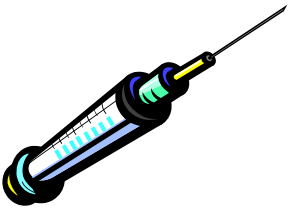
Solution for tracking and tracing products within the Hospital



Bar coded CFC is delivered to the Hospital by TCP

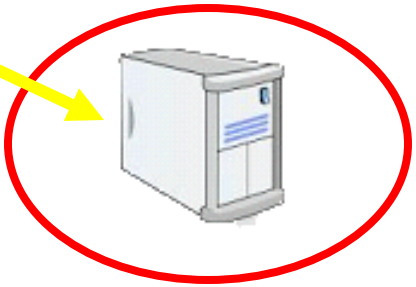
Hospital (GLN)

Stock Fridge (GLN)



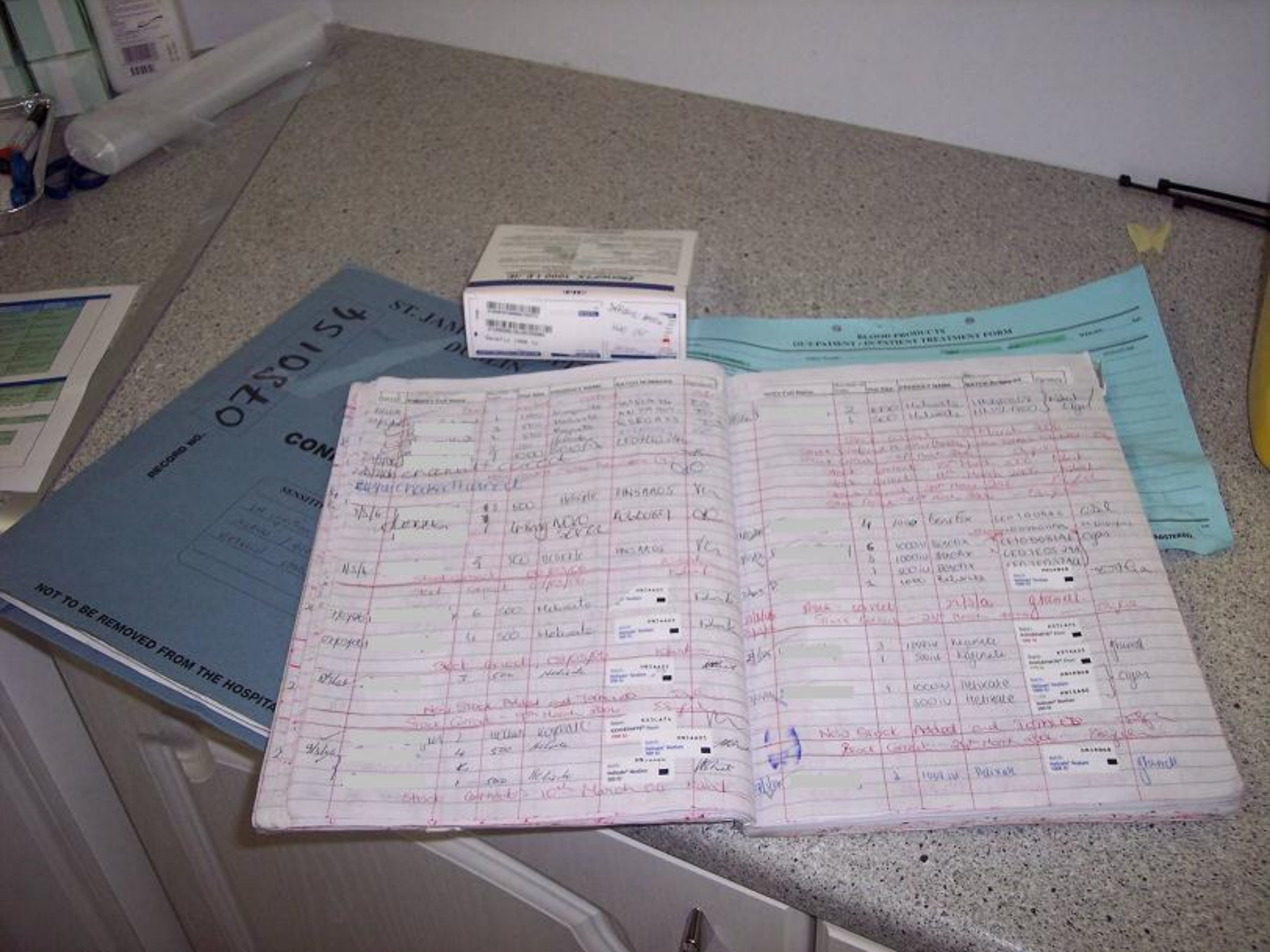
Prepare product (GTIN)

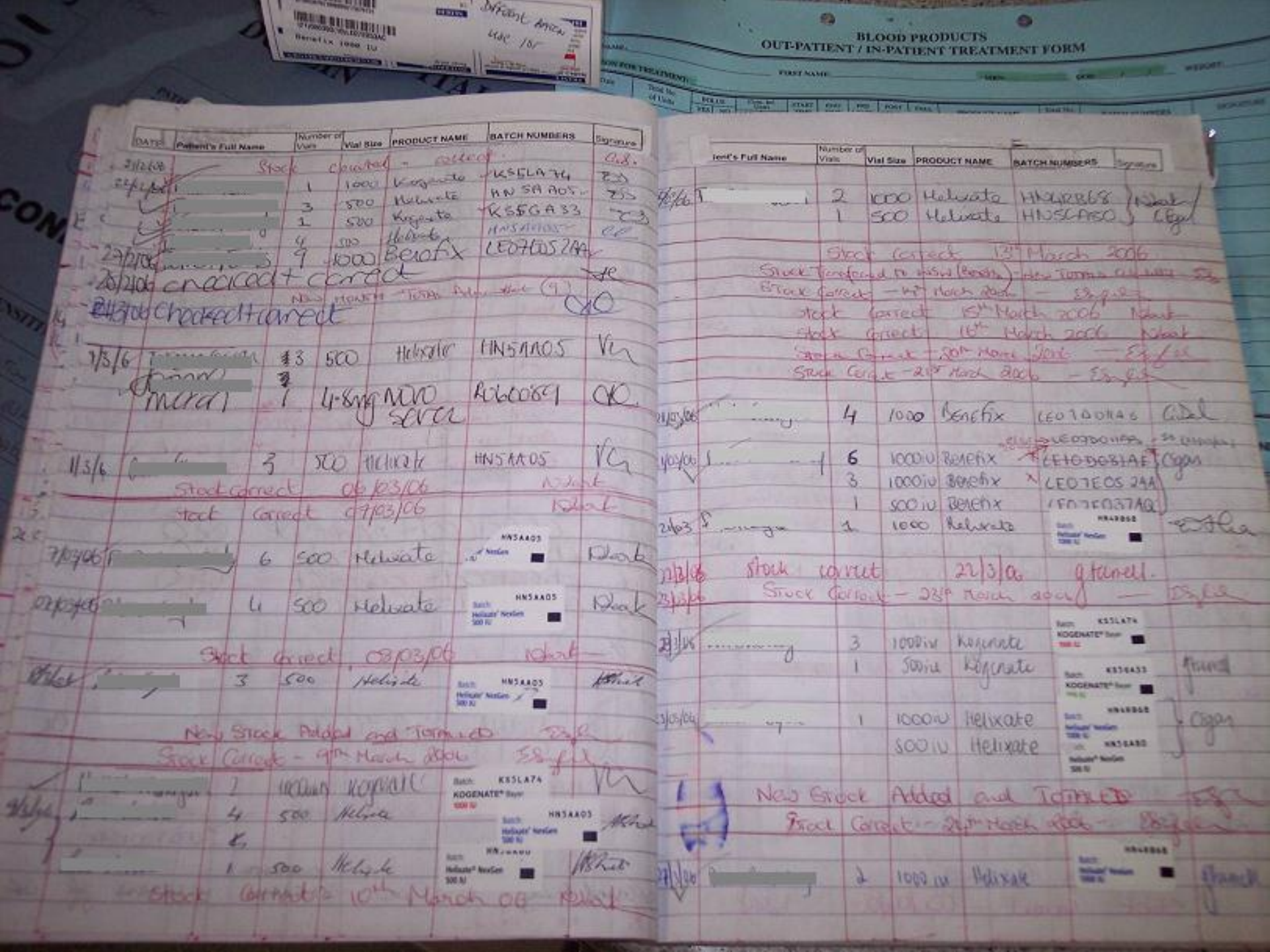
Patient receives CFC



Issue Fridges (GLN)

Check Product V Patient and issue

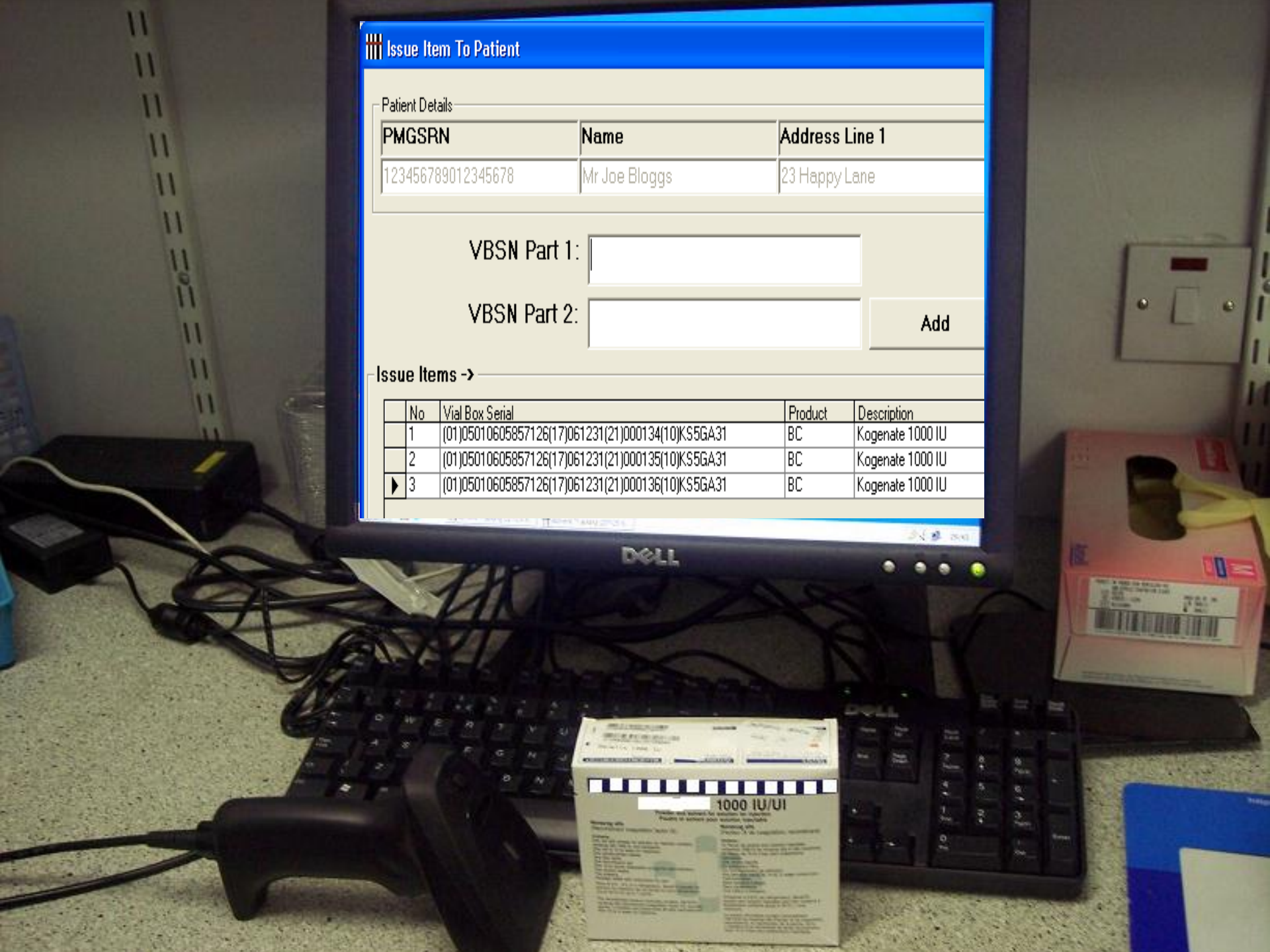

RECORD NO.
NOT TO BE REMOVED FROM THE HOSPITA
BLOOD PRODUCTS



BLOOD PRODUCTS
OUT-PATIENT / IN-PATIENT TREATMENT FORM

DATE	Patient's Full Name	Number of Vials	Vial Size	PRODUCT NAME	BATCH NUMBERS	Signature
21/2/06	Stock checked - correct					GdB.
22/2/06		1	1000	Kogenate	KS5LA74	RD
		3	500	Helixate	HN5AA05	RD
		1	500	Kogenate	KS5GA33	RD
		4	500	Helixate	HN5AA05	RD
27/2/06		4	1000	Benefix	LE07E05ZAA	RD
28/2/06	checked + correct					RD
2/3/06	checked + correct					RD
3/3/6		3	500	Helixate	HN5AA05	VG
		1	4-8ml	NOVO SEVEN	RC600851	OK
11/3/6		3	500	Helixate	HN5AA05	VG
	Stock correct 06/03/06					Nicht
	Stock Correct 07/03/06					Nicht
7/3/06		6	500	Helixate	HN5AA05	Nicht
8/3/06		4	500	Helixate	HN5AA05	Nicht
	Stock Correct 09/03/06					Nicht
9/3/06		3	500	Helixate	HN5AA05	Nicht
	New Stock Added and Totalled					RD
	Stock Correct - 9th March 2006					RD
		1	1000iu	KOGENATE	KS5LA74	VG
9/3/06		4	500	Helixate	HN5AA05	Nicht
		6				
		1	500	Helixate	HN5AA05	Nicht
	Stock Correct 10th March 06					Nicht

Patient's Full Name	Number of Vials	Vial Size	PRODUCT NAME	BATCH NUMBERS	Signature
6/3/06	2	1000	Helixate	HN5AA68	Nicht
	1	500	Helixate	HN5CA80	CEgan
	Stock Correct 13th March 2006				
	Stock Transferred to NSW (Beatrix) - New Totals				RD
	Stock Correct - 14th March 2006 - RD/GdB				
	Stock Correct 15th March 2006 Nicht				
	Stock Correct 16th March 2006 Nicht				
	Stock Check - 20th March 2006 - RD/GdB				
	Stock Correct - 21st March 2006 - RD/GdB				
21/3/06	4	1000	Benefix	LE07005A6	GdB
20/3/06	6	1000iu	Benefix	LE10D6B1AE	Cegan
	3	1000iu	Benefix	LE07E05 29A	
	1	500iu	Benefix	LE07E037AQ	
24/03	1	1000	Helixate		Esther
22/3/06	Stock correct 22/3/06				gtennell.
23/3/06	Stock Correct - 23rd March 2006 - RD/GdB				
23/3/06	3	1000iu	Kogenate	KS5LA74	
	1	500iu	Kogenate	KS5GA33	Nicht
23/3/06	1	1000iu	Helixate	HN5AB68	
		500iu	Helixate	HN5AB80	Cegan
	New Stock Added and Totalled				RD
	Stock Correct - 24th March 2006 - RD/GdB				
24/3/06	2	1000iu	Helixate		Nicht


Issue Item To Patient
Patient Details
PMGSRN
Name
Address Line 1
12345678901234567 8
Mr Joe Bloggs
23 Happy Lane
VBSN Part 1:
VBSN Part 2:
Add
Issue Items ->
No
Vial Box Serial
Product
Description
1
(01)05010605857126(17)061231(21)000134(10)KS5GA31
BC
Kogenate 1000 IU
2
(01)05010605857126(17)061231(21)000135(10)KS5GA31
BC
Kogenate 1000 IU
3
(01)05010605857126(17)061231(21)000136(10)KS5GA31
BC
Kogenate 1000 IU
DELL
1000 IU/UI

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

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

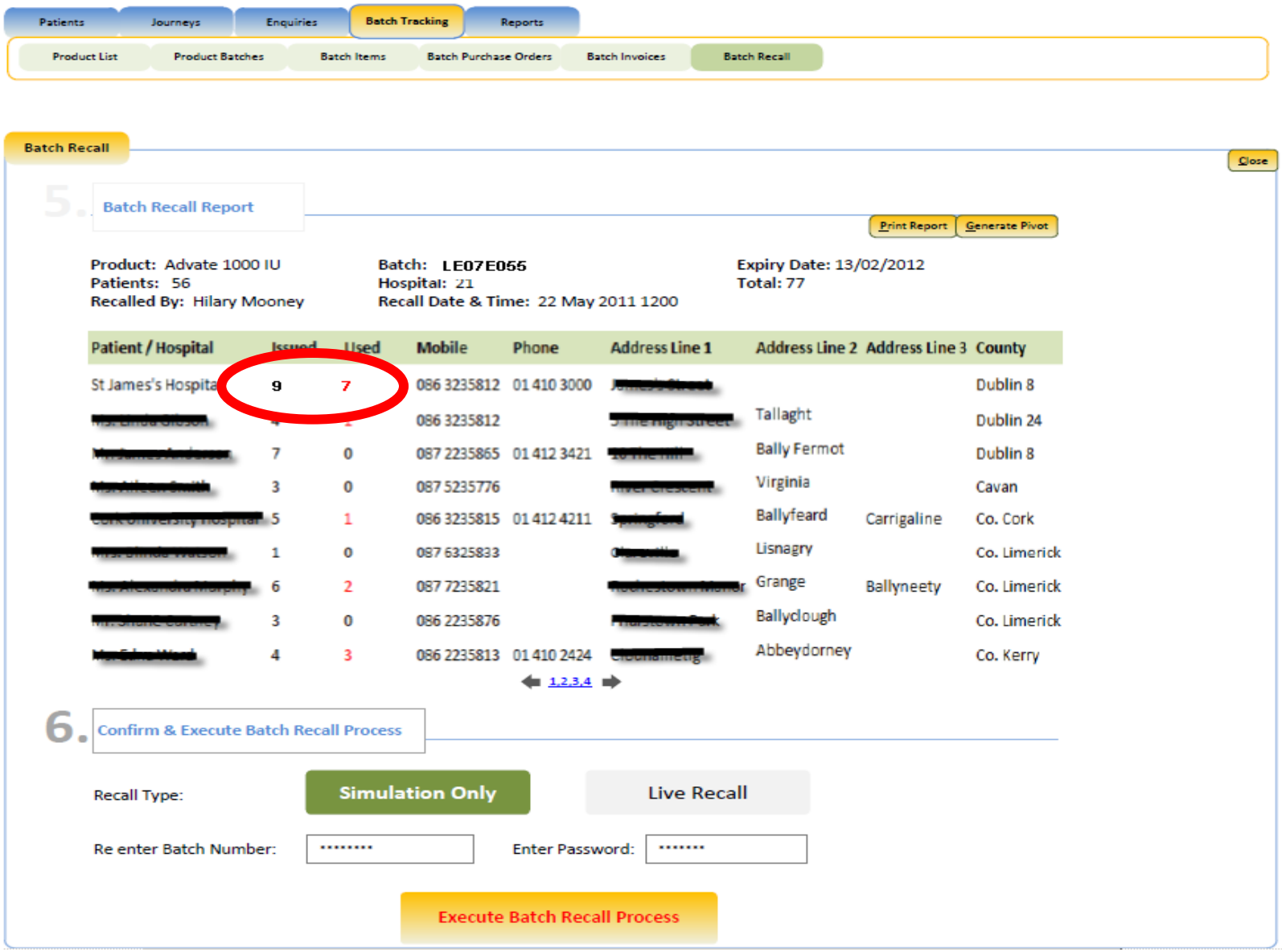
2. Select Recall Level

- [x] Batch Allocation & Order Packing Process
- [x] Batch Processing in Goods Receiving Process
- [x] Patient Home Usage
- [x] Order Delivery By Driver
- [x] Hospital Usage
- [x] 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**

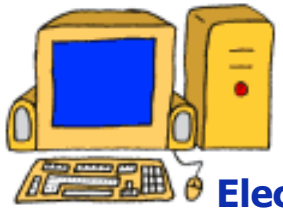
Criteria: **(Batch No = LE07E055AA)**

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	
0[illegible]378	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

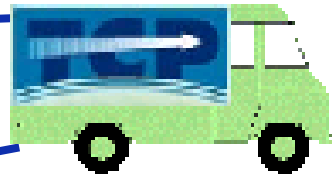


Electronic prescription

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

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

Details of all movements are sent to the stock management system



Patient scans product. Verification received from EPR

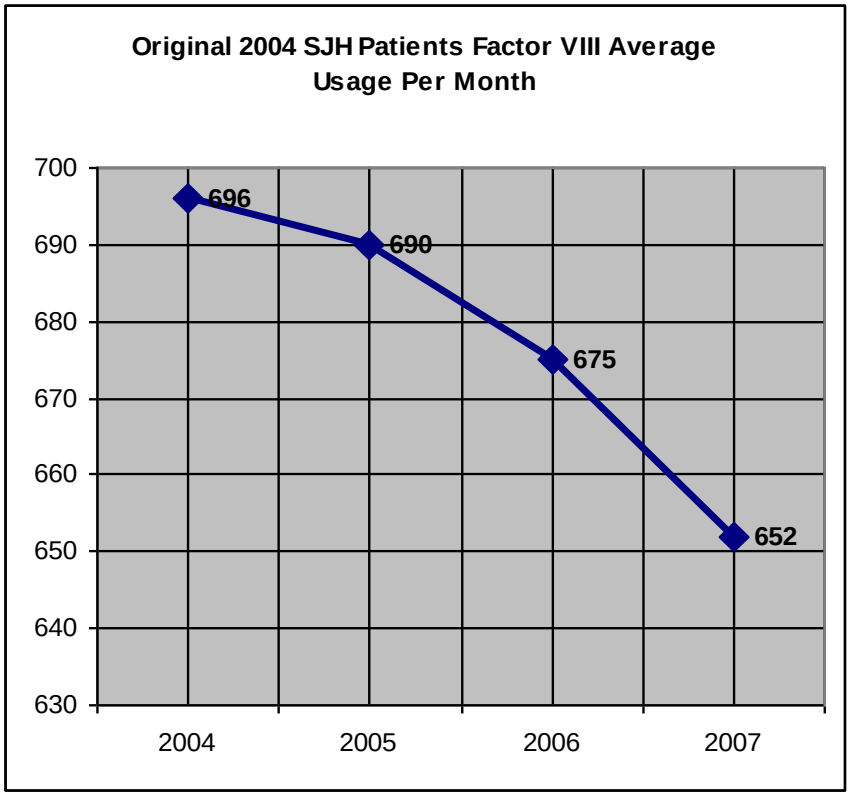
Cold Chain Supplier verifies delivery of product to Patient - recording batch and expiry details GLN, GTIN

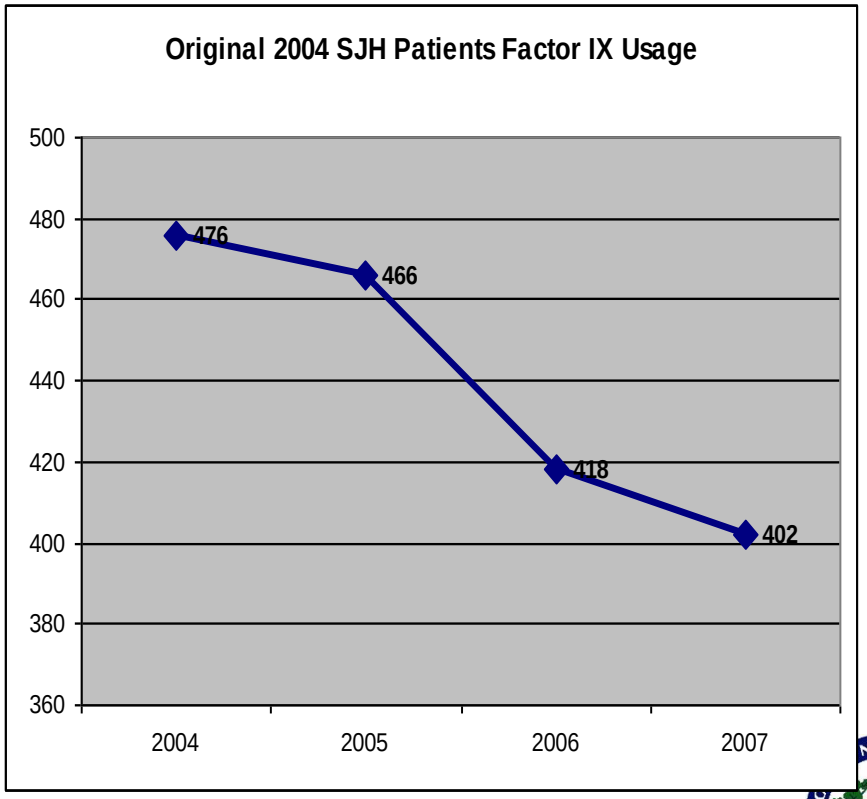
Cold Chain Supplier verifies Order at dispatch - recording batch and expiry dates - GLNs, GTIN

Outcomes (ROI) for validated Cold Chain delivery system

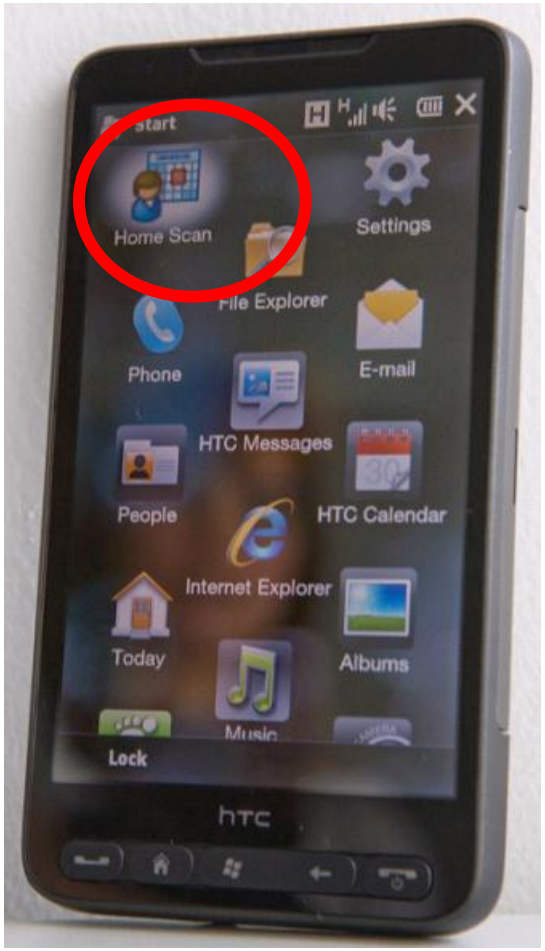
- Since Cold Chain delivery started all products verifiably delivered between 2^0-5^0 Celsius
- Product wastage reduced from €90,216 to zero in the year post service implementation
- Documentation errors reduced from 12 to zero in the year post service implementation
- Over € 5 Million worth of medication stock has been removed from the supply chain
- In 2010 € 426,000 worth of stock rotated between Hospitals and NCHCD
- Mock Recall identified location of all (100%) Medication within 10 minutes

Patient usage trends





Smartphones with scanning App

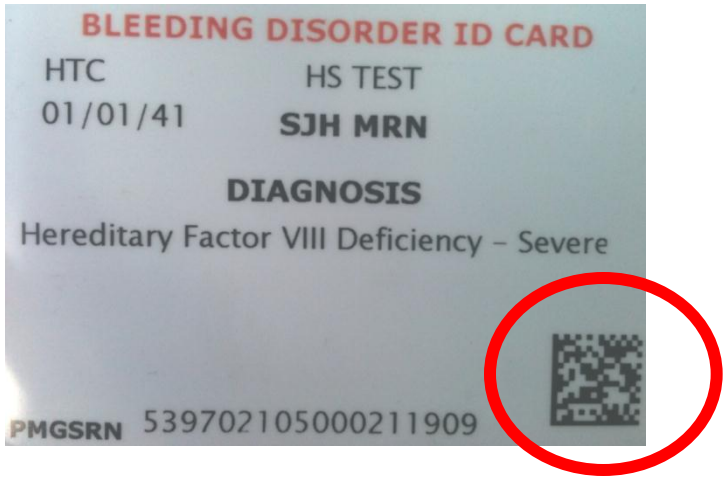


How it works

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

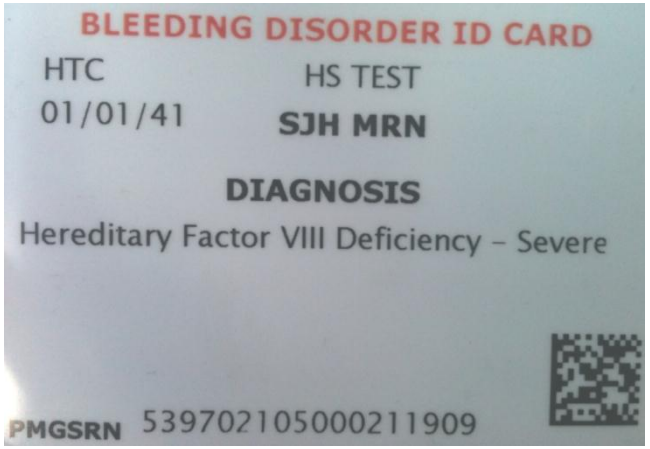
Log-in

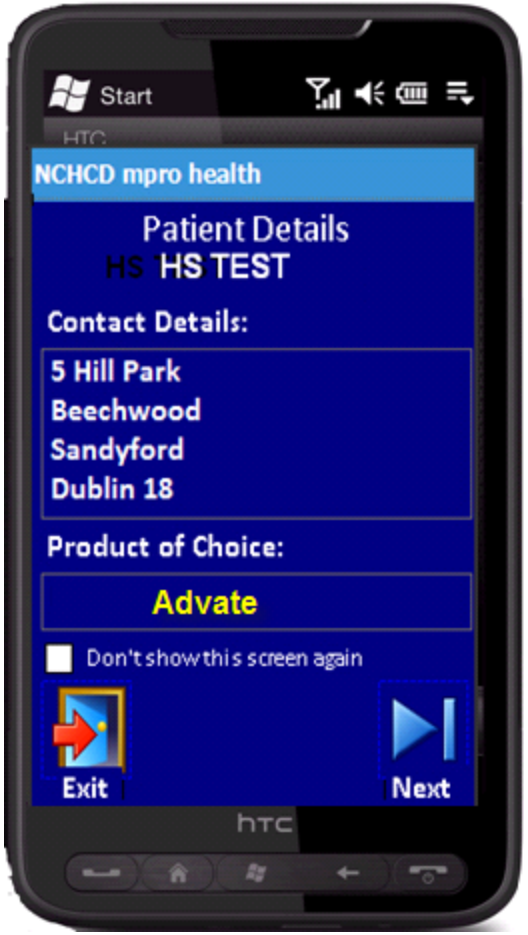
Secure Login by Username, Password or Scanning unique GS1 ID on Card Card



Patient Details

Patient detail confirmation includes product of choice



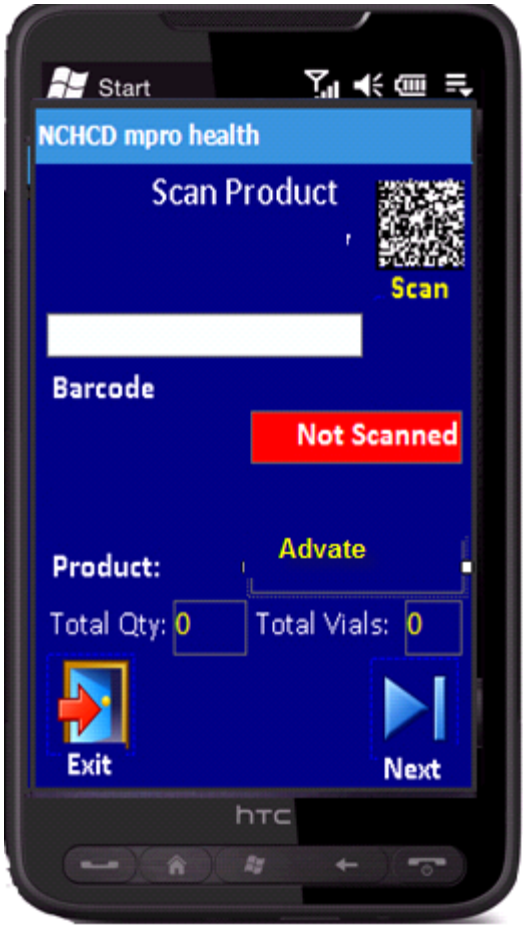


The product of choice will eventually be taken from the EPR

Scan Product

Barcode on Vial box is scanned to confirm

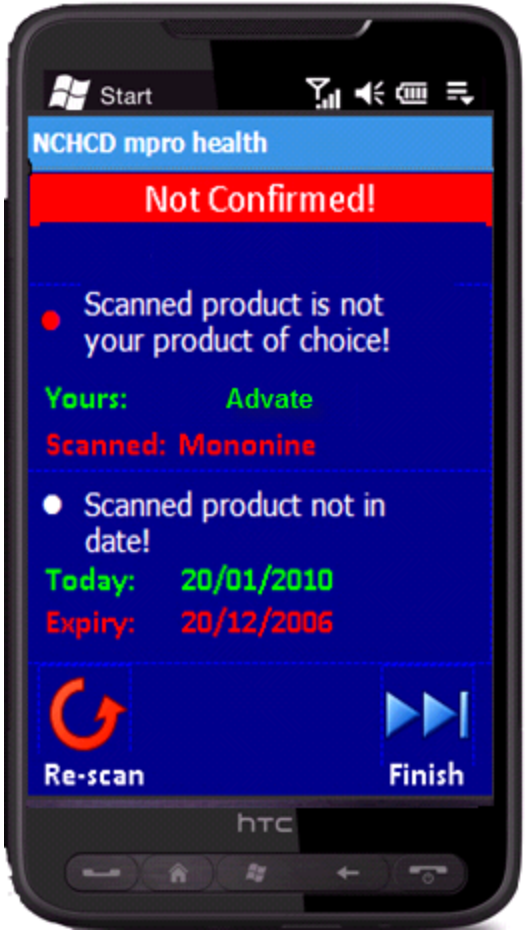
- product detail
- expiry date
- Recall status



Validation – FAIL!

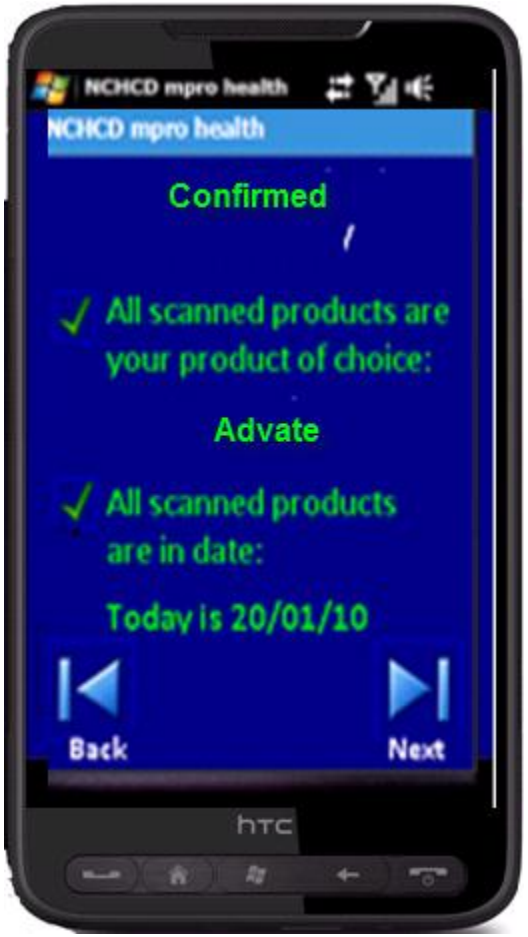
If incorrect product or product out of date or RECALLED, system will display a visible and audible alarm

A re-scan is required or exit is forced.



Validation – OK !

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



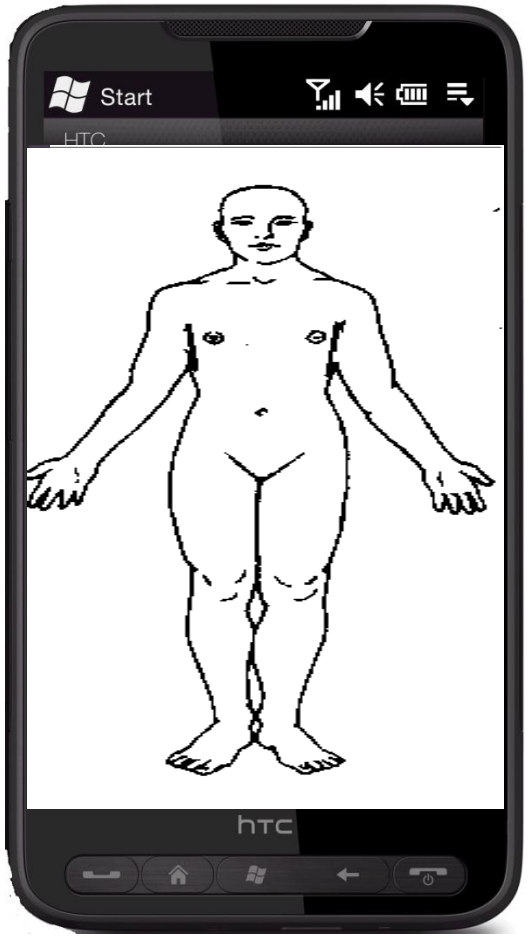
Infusion Detail

User records reason for infusion

Specific bleed sites can be used to trigger e-mail alerts to the treatment centre

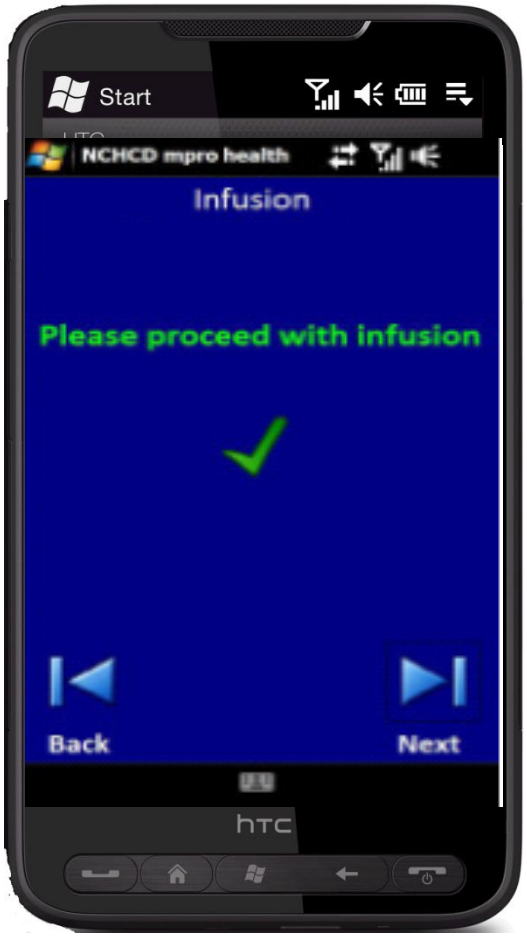
- Head Injury
- Ileopsoas Bleed
- Haematuria
- Haemoptysis
- Haematemesis
- PR Bleed

Currently dropdown menu but…..



Infusion Authorisation

Again, the app prompts the patient to proceed.



Process Complete

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

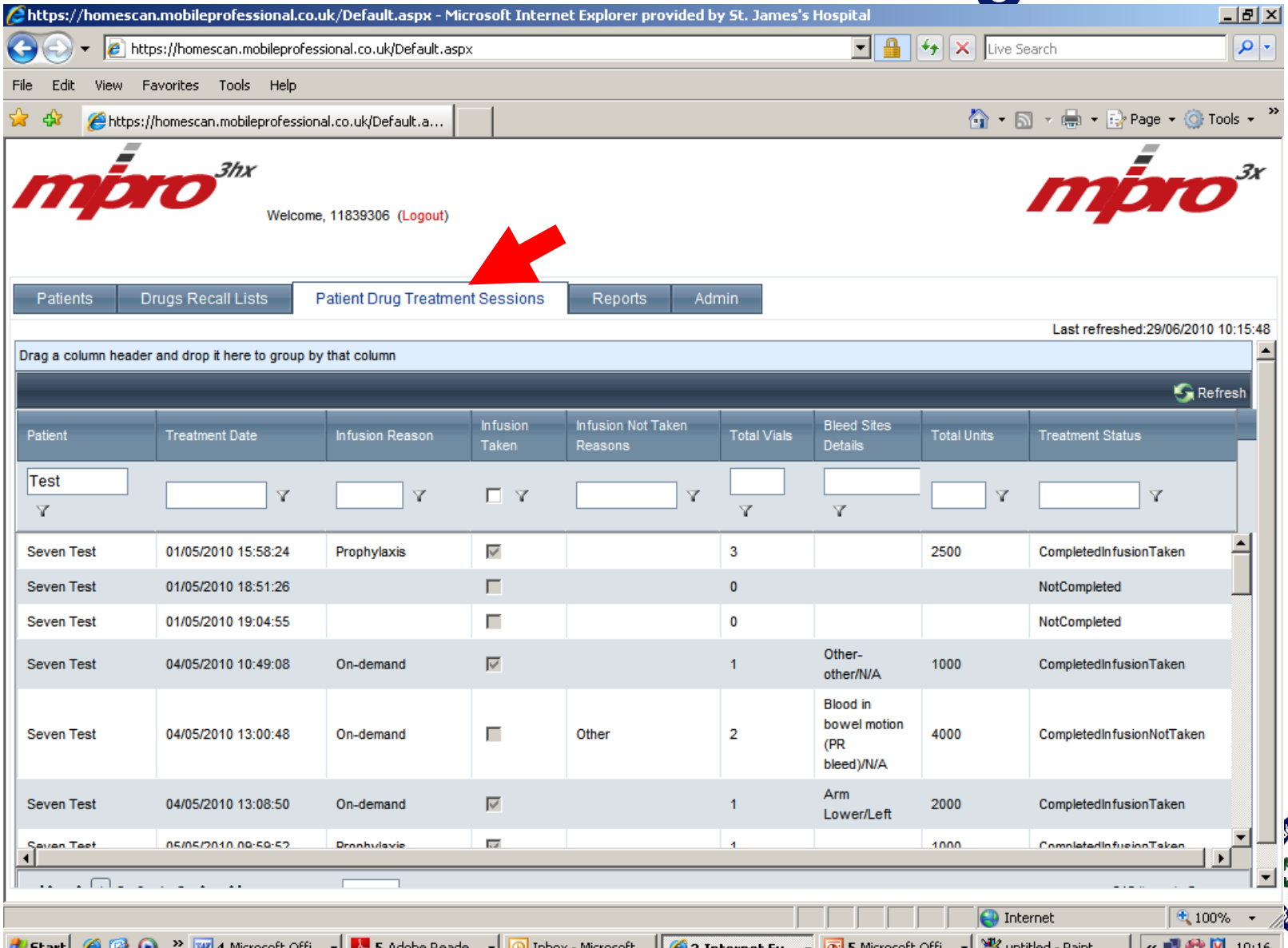
Eventually data will be transmitted to

•Warehouse Management system

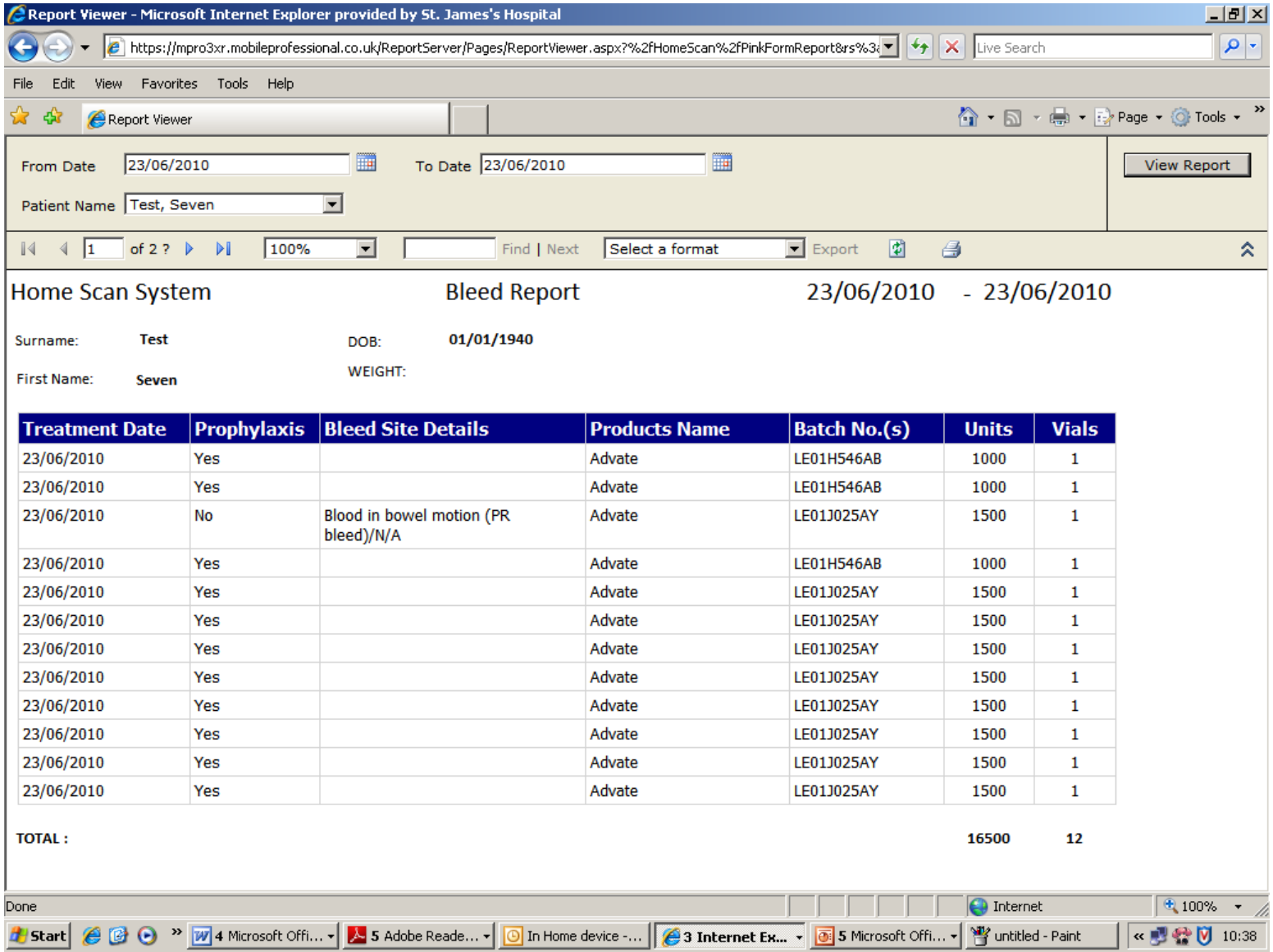
•EPR

Web Application – log on

Patient infusion logs



Patient self treatment report



Home Scan System — Bleed Report — 23/06/2010 - 23/06/2010

Surname: **Test** DOB: **01/01/1940**

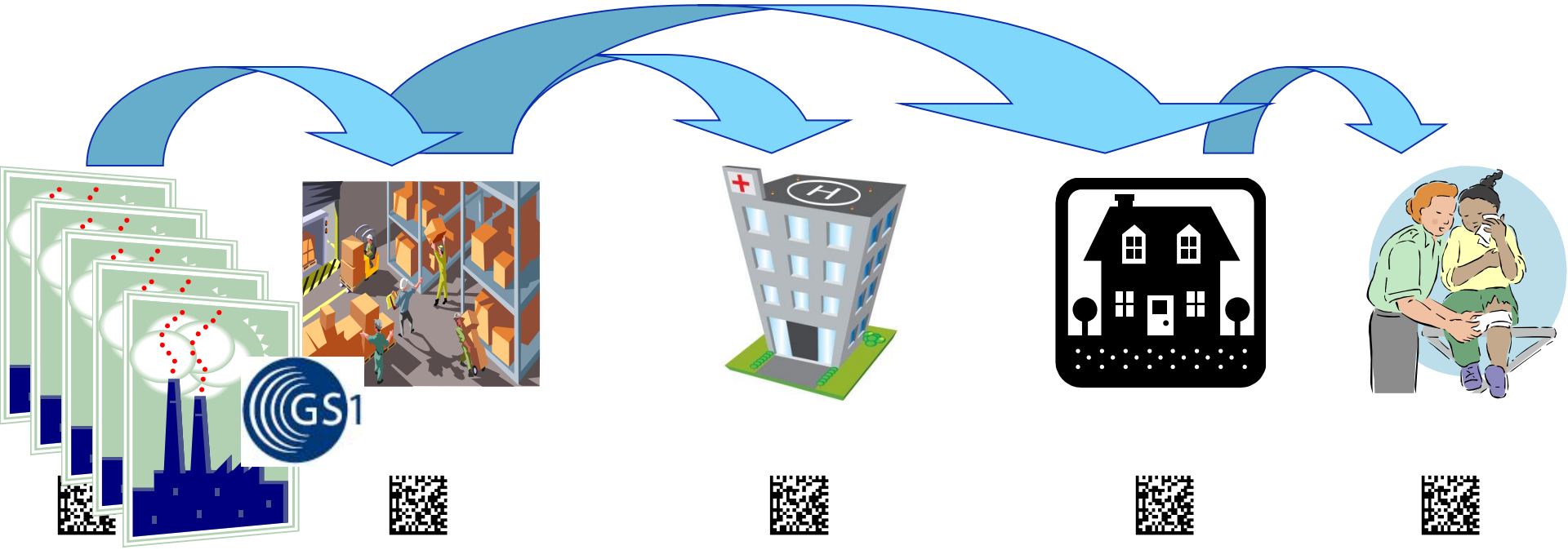
First Name: **Seven** WEIGHT:

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
23/06/2010	Yes		Advate	LE01J025AY	1500	1
23/06/2010	Yes		Advate	LE01J025AY	1500	1
23/06/2010	Yes		Advate	LE01J025AY	1500	1
23/06/2010	Yes		Advate	LE01J025AY	1500	1
23/06/2010	Yes		Advate	LE01J025AY	1500	1
23/06/2010	Yes		Advate	LE01J025AY	1500	1
23/06/2010	Yes		Advate	LE01J025AY	1500	1
TOTAL :					**16500**	**12**

Initial Outcomes from smartphones

- Realtime recall alert
- Timeliness of infusion
- Prescription compliance (2000iu instead of recommended 1750iu)
- Automatic compliance (no manual record keeping)
- Electronic diary
- Realtime Alerts for specific bleeds
- Patient empowerment

Where we are



Conclusions

- Healthcare Business cases are notoriously difficult to make
- This project proves that Technology and standards already exists today to greatly assist the care of patients living with chronic conditions
- We have removed €5 million from the supply chain and continue to make savings
- In the event of a recall we can identify the location of ALL medication (100%) anywhere in Ireland within 10 minutes
- Standardised Medication coding is the key
- Barcode standards and telehealth have the capacity to increase patient safety, improve quality of life and reduce the cost of healthcare delivery

07

THANK YOU
your barcode is
1 26007 70149 5

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