

Case Study: Using GS1 Standards for Tracking Blood Products



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Agenda

- Background to the Service
- Background to Haemophilia
- Issues
- Solutions
- Outcomes/ROI
- Conclusion

Ireland



- **Population:** 4,156,119
- Haemophilia (A) Affects 1 in 5,000 to 1 in 10,000 male live births

St. James's Hospital



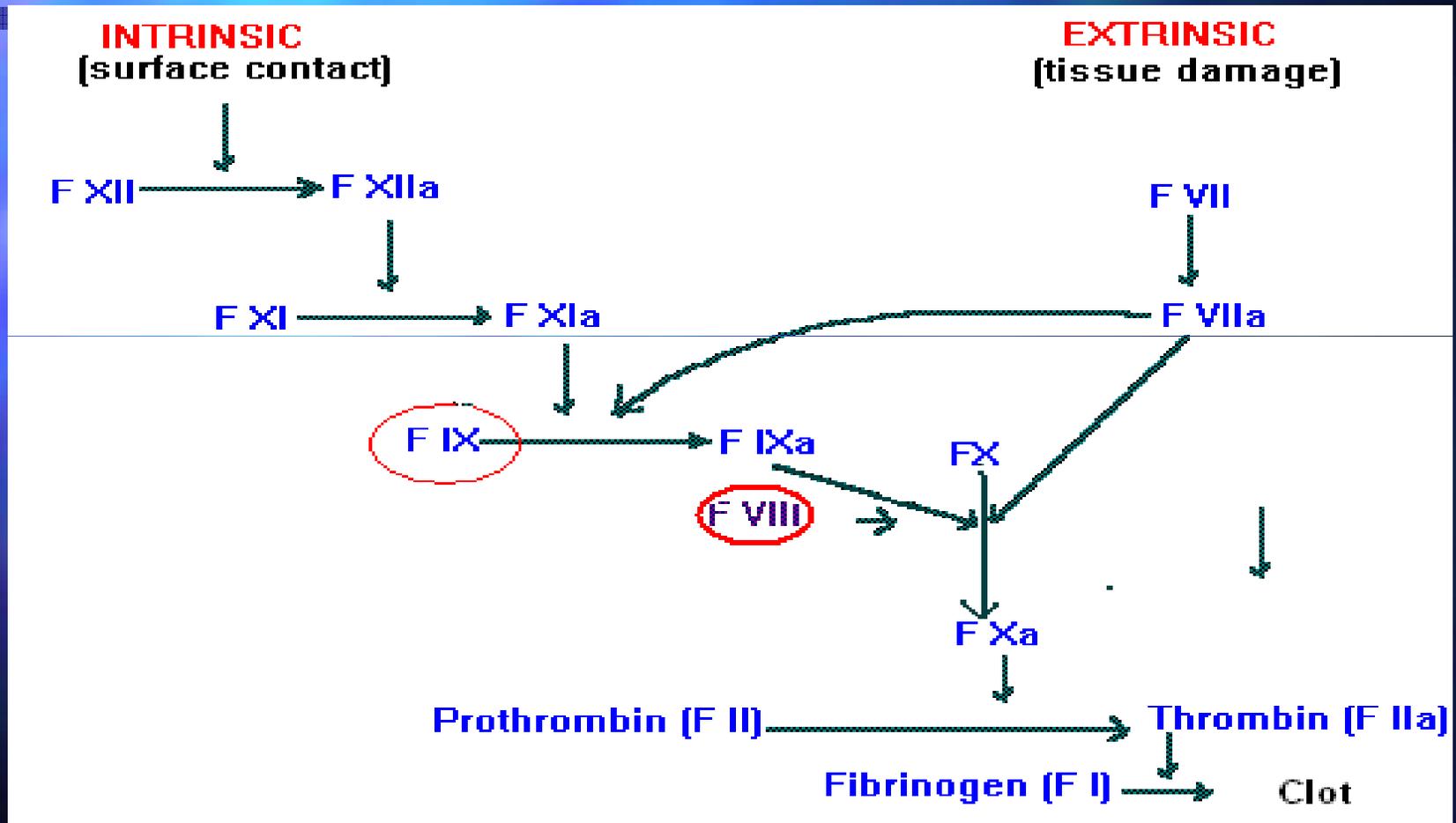
National Centre for Hereditary Coagulation Disorders (NCHCD)

- Located at St James's Hospital, Dublin
- 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 Factor deficiency self medicate at home

What is Haemophilia ?

- Haemophilia 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 blood) using a concentrated preparation "Clotting Factor Concentrate" (CFC)

The Science bit...!





What triggered the initiative ?

Healthcare

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

- Lindsay Report 2001
- EU Blood Directive 2002/98/EC

Industry

- COMBATING COUNTERFEIT DRUGS
A Report of the FDA: February 2004
- FDA Counterfeit Drug Taskforce Report: 2006 Update
- California: e- Pedigree ruling
- Turkey: Regulation on Packaging and Labelling

Business Case



No Product barcode



Incomplete/retrospective
treatment information



Non Availability



Incomplete data



Increased Risk



Non validated delivery



Wastage/
ineffective
Medication

The solutions



Unique GS1 barcoding

Encrypted Messaging

validation



Home/Hospital tracking



Comprehensive integrated care



Electronic Patient record



Validated cold chain delivery

What does Barcode Technology offer ?



- Identify patients, locations and medications uniquely
- Real-time ID and 100% track and trace of all medication
- Studies show the error rate of data entry in a skilled typist is 1 every 300 keystroke
- Error rate in B/C scanning is estimated at 1 in a million characters
- Faster data entry
- Scanned data can be transferred easily to any database

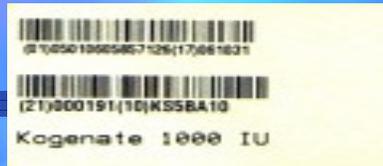
Why GS1 and Linear Barcodes ?

FDA Ruling

- Any linear symbology, including Reduced Space Symbology (RSS), can be used for the bar code
- Two-dimensional (2D) bar code symbologies are **not permissible**. This includes Data Matrix, which is already in use in the pharmaceutical industry
- RFID is not an acceptable substitute for the bar code
- **EAN.UCC** or HIBCC standards **may be used**, but neither is required.

ID Formats

Current Barcode (2 Linear)



Manufacturer allocated barcode



RFID



Product Name
(GTIN)

Batch Number

Expiry Date

Serial Number

The solutions



Unique product barcoding

Encrypted Messaging

validation



Electronic Patient record



Patient

Home/Hospital tracking



Validated cold chain delivery



National Haemophilia EPR



- Working in partnership with a local vendor (Clintech.ie) to add disease specific information capture
- Electronic Chart with up to date information *in one place*
- Accessible in any Haemophilia treatment centre throughout Ireland

Multi location deployment

National
Haemophilia
Centre



Regional Haemophilia Centers

Training Manager

File Workup Assessments Manage Tx View System Admin Window Help

Summary History Master Flow Sheet Chart Vital Signs Exam Tx Options Rx Drug Admin Prov Appr Reports BT Orders

Modify Patient

General **Patient IDs** Contacts Demographics Healthcare Professionals Referrals

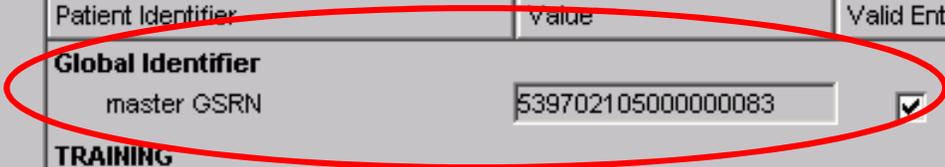
Institution: TRAINING Show History

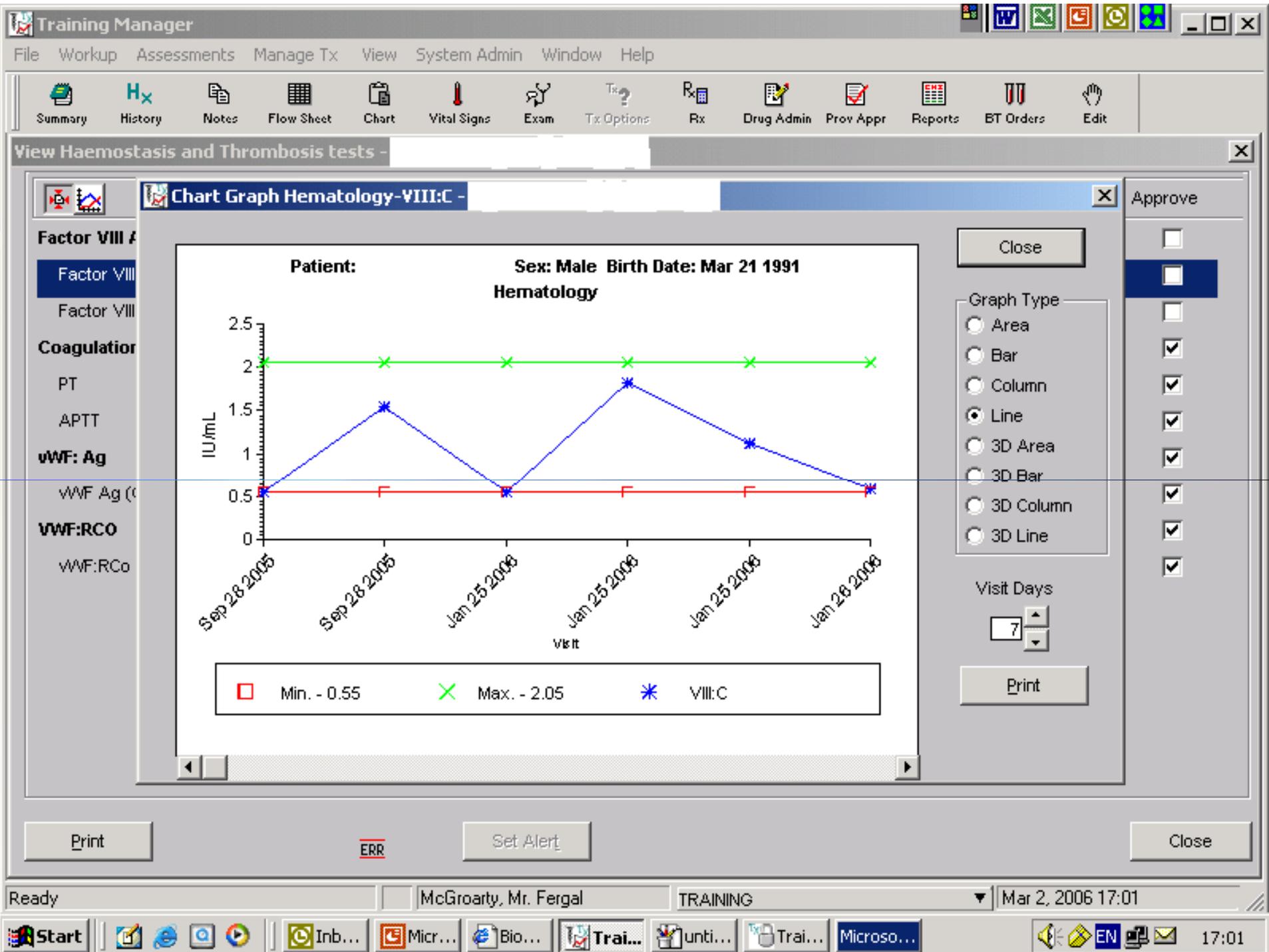
Patient Identifier	value	Valid Entry	Entered On	Expiry D
Global Identifier				
master GSRN	539702105000000083	<input checked="" type="checkbox"/>	Jun 03, 2005	Active
TRAINING				
Beaumont Hospital MRN		<input checked="" type="checkbox"/>		
Coombe Hospital MRN		<input checked="" type="checkbox"/>		
Cork University Hospital MRN		<input checked="" type="checkbox"/>		
Galway University Hospital MRN		<input checked="" type="checkbox"/>		
Holles St MRN		<input checked="" type="checkbox"/>		
Letterkenny General Hospital MRN		<input checked="" type="checkbox"/>		
Limerick Regional Hospital MRN		<input checked="" type="checkbox"/>		
NCHCD Haemophilia Number	7	<input checked="" type="checkbox"/>	Jun 03, 2005	Active

Print... OK Cancel

Ready | McGroarty, Mr. Fergal | TRAINING | Oct 10, 2005 12:08

Start | Inbox - Micr... | Clintech Ma... | Clintech Se... | Training M... | 12:09





Training Manager

File Workup Assessments Manage Tx View System Admin Window Help

Summary History Notes Flow Sheet Chart Vital Signs Exam Tx Options Rx Drug Admin Prov Appr Reports BT Orders

Modify Diagnosis / Problem -

Definition Diagnostic Tests Recommended Treatment

ICD D66.04

Desc Hereditary Factor VIII Deficiency - Severe Clinical Desc Hereditary Factor VIII Deficiency - Severe

Historic Migrated: Factor VIII Deficiency - Severe
Details Baseline function 1: < 0.01 u/ml or <1% (u/dl)

New Details

dd/mm/yyyy

Card Issued Issue Date 10/10/2005

Status Active Status Date 28/09/2005

Source Clintech-MGR

OK Cancel

Patient History | McGroarty, Mr. Fergal | TRAINING | Oct 10, 2005 13:34

Start | Inbox - Micr... | Training M... | TAGSYS RF... | Microsoft P... | 13:35



Diagram illustrating the flow of information from a patient's diagnosis to a physical card:

- The **Definition** tab in the software interface is circled in red.
- The **Issue Date** field is circled in red.
- A blue information card is shown, containing the following details:
 - Name: John Smith
 - Condition: Severe F VIII Deficiency
 - Treatment: Treatment of Choice Kogenate
 - Barcode: PM GSRN
- Blue arrows indicate the flow of information from the software interface to the physical card.

Modify Patient - Test, One

General Patient IDs Secondary GLN Contacts **Demographics** Healthcare Professionals Referrals

Race

Religion

Language

Marital Status

Occupation

Educational Level

Country of Birth

Present Employer Name

Mother's Full Name

Mother's Maiden Name

Father's Full Name

Advance Directives on File 

Health Care Durable Power of Attorney

Organ Donor

Autopsy Request

Living Will / Personal Directive

Do Not Hospitalize Status

Do Not Resuscitate Status

Feeding Restrictions

Medication Restrictions

Other Treatment Restrictions

Home Treatment

Last Issue Date:

GLN Assignments X

Active numbers only Current addresses only

Patient Identifier	Expiry Date			Address
Primary GLN				Primary 5397021015164 Phone: Bus: Mob: Fax: USA
	5397021015164	Active		
Secondary GLN				Secondary 5397021026665 Phone: Bus: Mob: Fax: USA
	5397021026665	Active		
Mobile GLN				
	5397021038224	Active		

Match

The solutions



Unique product barcoding

Encrypted Messaging

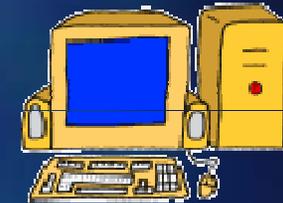
validation



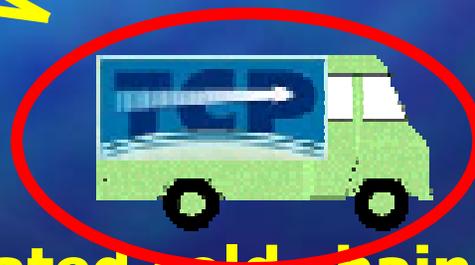
Home/Hospital tracking



Patient



Electronic Patient record



Validated cold chain delivery

Validated Cold Chain Delivery



- Over 75% of Patients with severe Factor deficiency receive product at home
- Ensure quality of product using validated scheduled cold chain delivery (Home/Pharmacy/School)
- Licensed by Irish Medicines Board
- Home Fridge management (Temperature monitoring)

How TCP manage the product

- Transport stock to warehouse from IBTS
- Pharmacist enters product info onto system (double checked)
- Serialised Bar code is produced, label attached, scanned to verify
- Stock held at validated temperature
- Order received from Hospital or Prescription for home delivery, order packed and labelled with SSCC B/C
- Patient contacted prior to delivery
- Fridge is stocked and temperature data downloaded
- All movement is confirmed using hand held scanners

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, GSRN

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

The solutions



Unique product barcoding

Encrypted Messaging

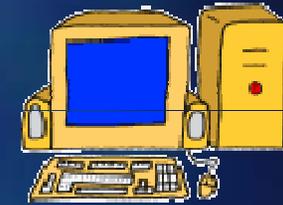
validation



Home/Hospital tracking



Patient



Electronic Patient record



Validated cold chain delivery

Solution for tracking and tracing products within the home



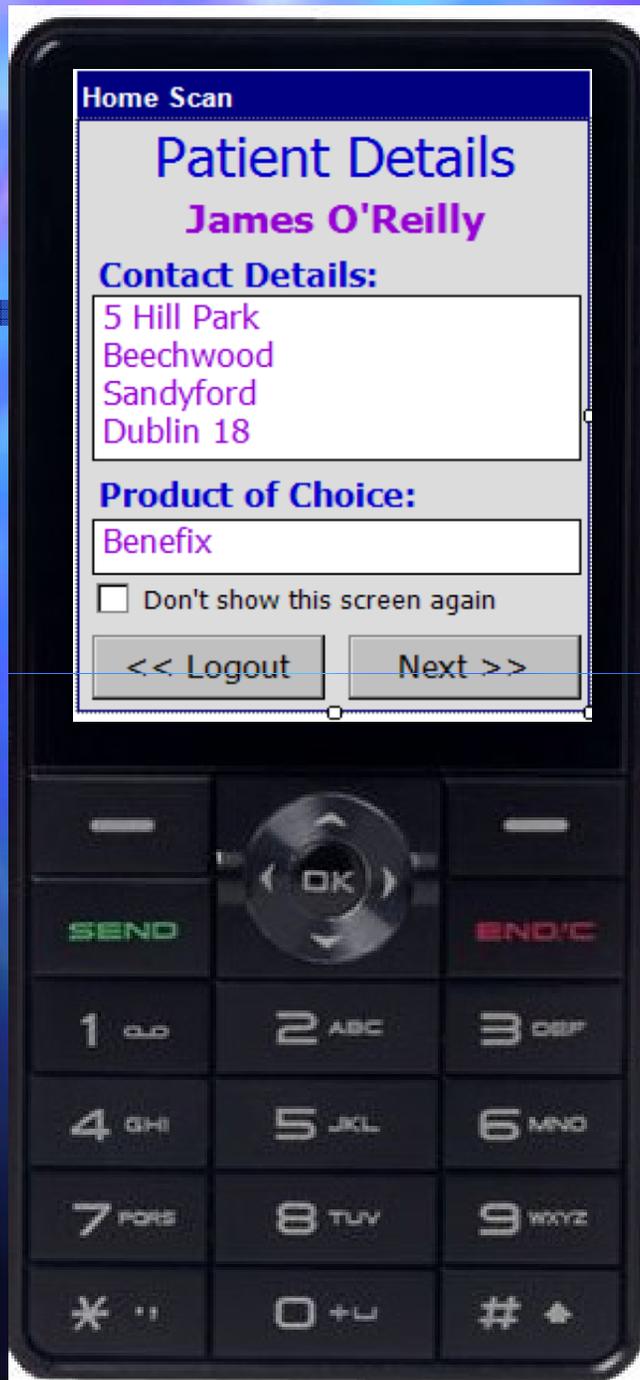
- Remove paper trail
- Reduce risk by providing a check on Patient V Product suitability
- Real time alert product recall
- Complete traceability of medication to infusion
- Added value
 - Clinical Information gathering and integration with EPR
 - Messaging

Phone with integrated B/C scanner





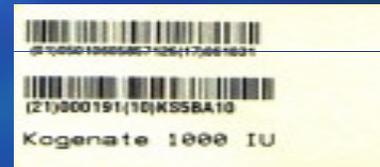
**Patient Scans ID Card
or enters Username
and password**

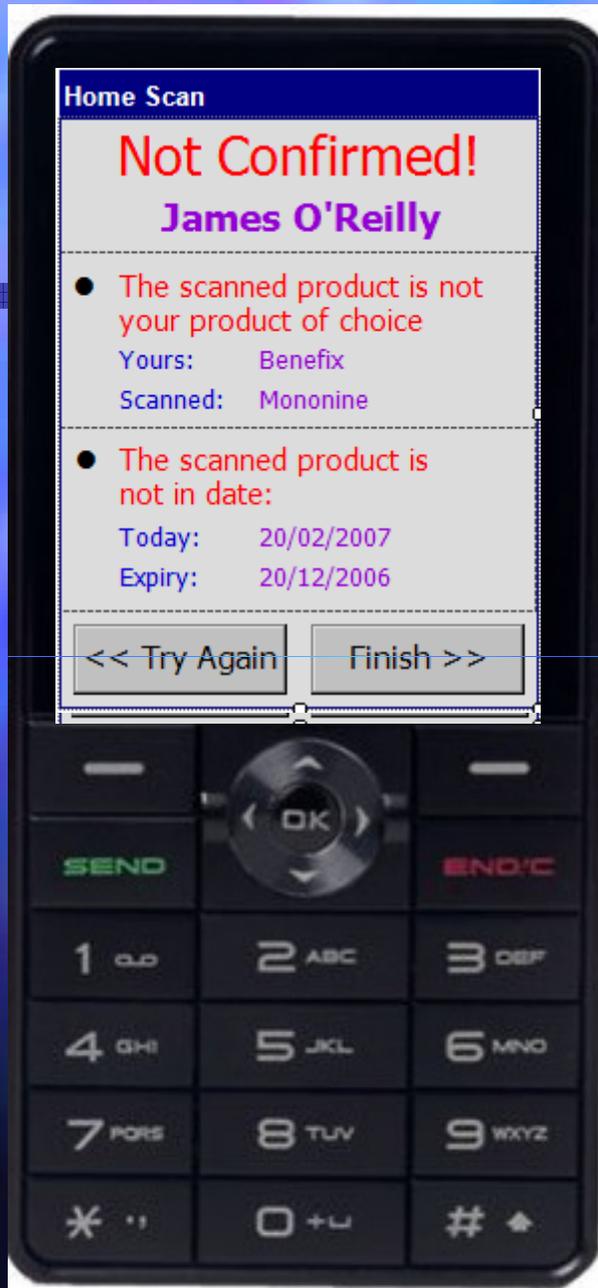


**Patient can confirm
details including
treatment of choice**

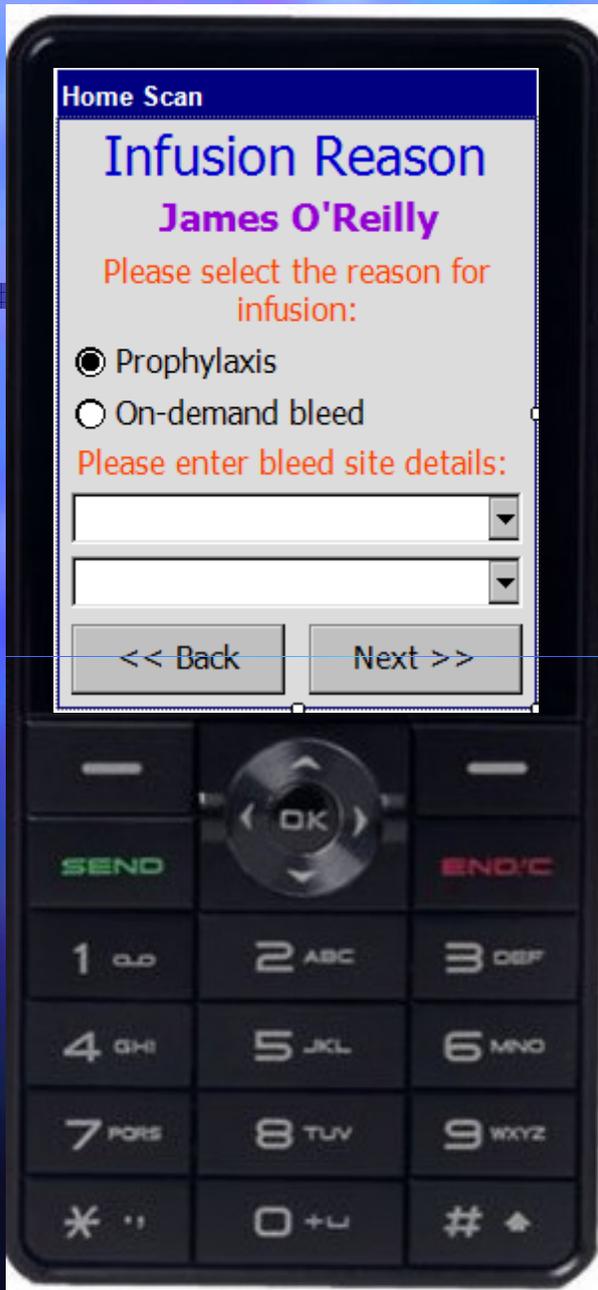


Patient scans the barcode on the box

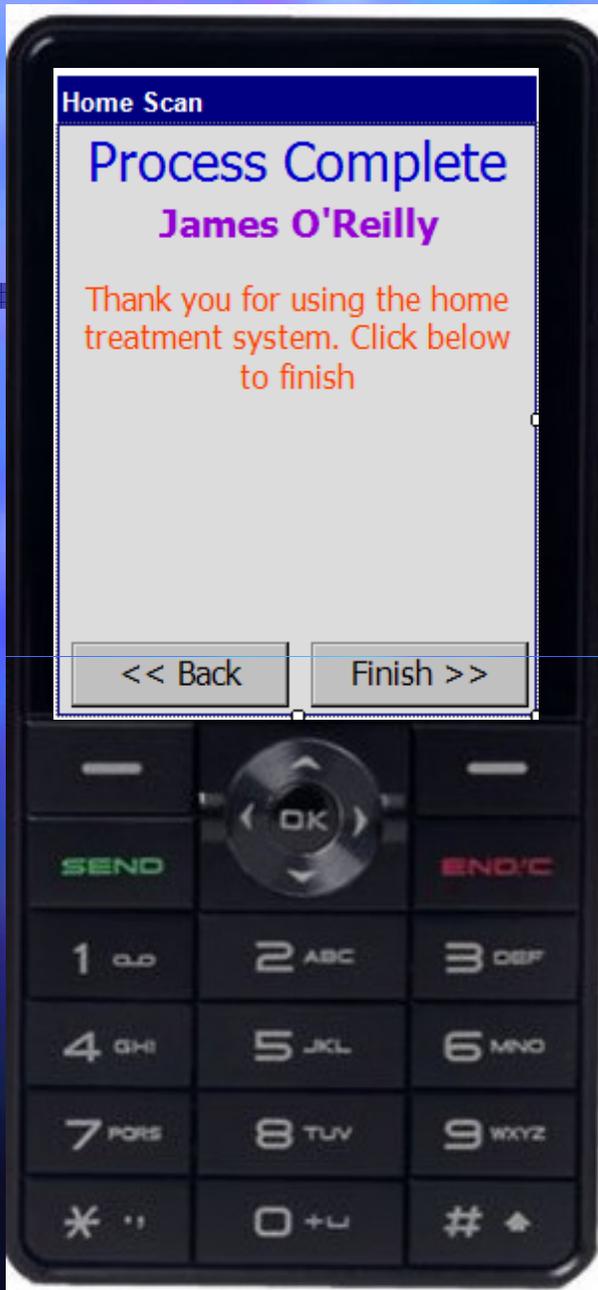




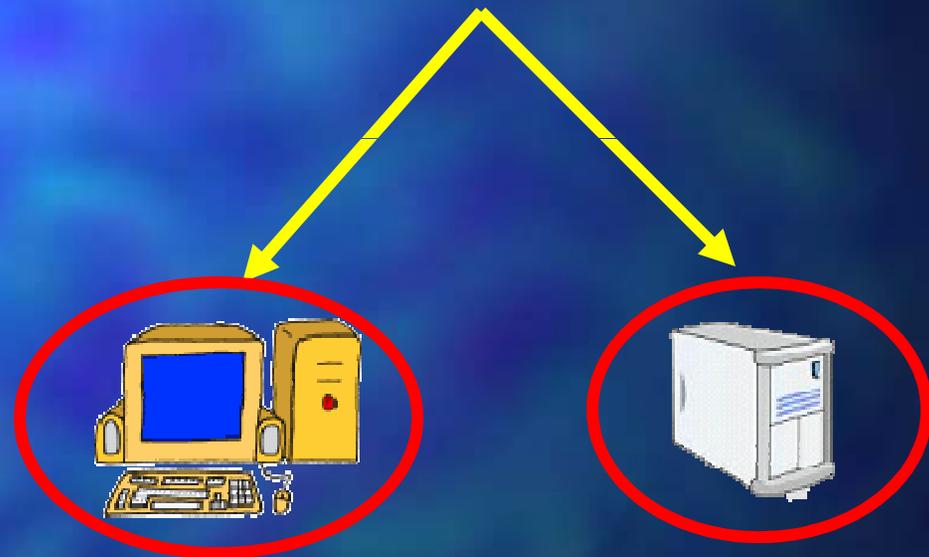
A check is performed against the product of choice and the expiry date. An audible and visible warning will appear if there is a problem



The reason for treatment can be entered



Once the patient clicks "Finish" all information will be transferred to the EPR and the stock management system



The solutions



Unique product barcoding

Encrypted Messaging

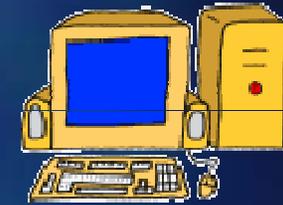
validation



Home/Hospital tracking



Patient



Electronic Patient record



Validated cold chain delivery

Solution for tracking and tracing products within the Hospital



Bar coded CFC is delivered to the Hospital by TCP



Hospital (GLN)



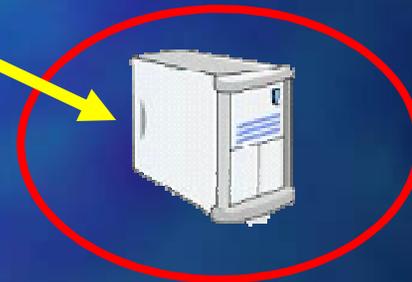
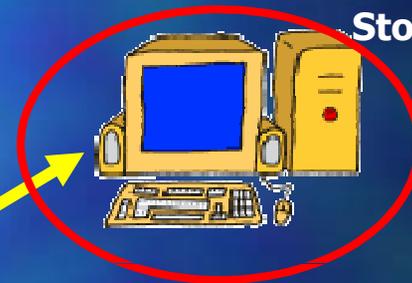
Stock Fridge (GLN)



Prepare product (GTIN)



Patient receives CFC

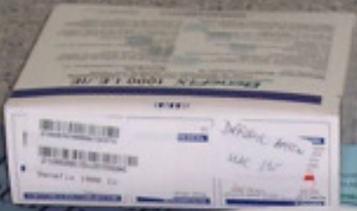


Issue Fridges (GLN)



Check Product V Patient and issue





BAYDOR PRODUCTS
OUTPATIENT / INPATIENT TREATMENT FORM

DATE	TIME	DRUG	PRODUCT NAME	DATE	TIME	DRUG	PRODUCT NAME
11/16	12:00	1	500 Melvate	11/16	12:00	2	500 Melvate
11/16	12:00	3	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	4	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	5	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	6	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	7	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	8	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	9	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	10	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	11	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	12	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	13	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	14	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	15	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	16	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	17	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	18	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	19	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	20	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	21	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	22	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	23	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	24	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	25	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	26	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	27	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	28	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	29	500 Melvate	11/16	12:00	1	500 Melvate
11/16	12:00	30	500 Melvate	11/16	12:00	1	500 Melvate



Issue Item To Patient

Patient Details

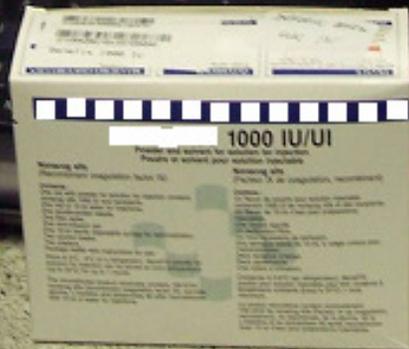
PMGSRN	Name	Address Line 1
123456789012345678	Mr Joe Bloggs	23 Happy Lane

VBSN Part 1:

VBSN Part 2:

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



Main Features of the Hospital Stock management System

- Removes paper trail
- Time and date stamp movement
- Real-time location of all medication
- Medication v Prescription check
- Rapid Recall
- Reporting suite

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

PharmaTrack (Live)

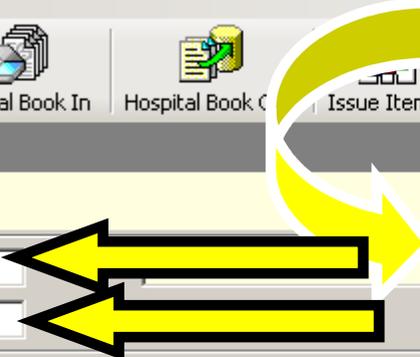
PharmaTrack Hospital Stock Patient Reports

Dashboard VBSN Info Stock Transfer In Stock Transfer Out Hospital Book In Hospital Book Out Issue Items Work Terminal

VBSN Details

Please scan or enter Part 1 and Part 2 of the VBSN to get information

Part 1 :
Part 2 :



VBSN Details Movements

Product Information

GTIN :
Group Name :
Serial #:

Batch Information

Batch #:
Date Received :
Expiry Date :
Received By :

PharmaTrack (Live)

PharmaTrack Hospital Stock Patient Reports



VBSN Details

Please scan or enter Part 1 and Part 2 of the VBSN to get information

Part 1 : VBSN :
Part 2 :

VBSN Details **Movement** Patient Details

Product Information

GTIN :
Group Name :
Serial #:

Batch Information

Batch #:
Date Received :
Expiry Date :
Received By :

Issued to Patient



VBSN Details

Please scan or enter Part 1 and Part 2 of the VBSN to get information

Part 1 : VBSN :
Part 2 :

VBSN Details | **Movements** | Patient Details

TransactionType	TransactionDate	From	To	Reference	Reason	LoginName
Booked In	16/03/2007 14:25	TCP DELIVERY VAN	CPL 05 DISPATCH		CPL Stock top up	ammcann
Transferred In	16/03/2007 14:25	CPL 05 DISPATCH	WALTER STEVENSON WARD		WSW Stock Top Up	bgraham
Issued	01/05/2007 10:52	WALTER STEVENSON WARD	(REDACTED)	AQUIRED VIII DEF WITH INHIBITORS ISS...		Feargal

Issued to Patient

Close

Recall Reports

TX Type
Product

Benifix 1000 IU

Batch Number	Expiry Date	Name	Trans-Date	Total	
LE07E055AA	31/10/2008	SJH, Blood Transfusion Lab.	06/09/2006	1	
			05/09/2006	2	
			27/09/2006	2	
			08/09/2006	1	
			15/09/2006	2	
			08/11/2007	2	
		Total issued to SJH		9	
		Total issued to OLCHC	11/09/2006	20	
		Patient name			
		Home Patient	XXXX, XXXXXXXX	11/09/2006	10
		Home Patient	XXXX, XXXXXXXX	21/09/2006	25
		Home Patient	XXXX, XXXXXXXX	01/09/2006	10
		Home Patient	XXXX, XXXXXXXX	29/09/2006	6
		Home Patient	XXXX, XXXXXXXX	21/09/2006	30
		Home Patient	XXXX, XXXXXXXX	22/09/2006	10
		Home Patient	XXXX, XXXXXXXX	06/09/2006	24
		Home Patient	XXXX, XXXXXXXX	06/09/2006	15
		Home Patient	XXXX, XXXXXXXX	02/05/2007	10
		Home Patient	XXXX, XXXXXXXX	11/09/2006	10
		Home Patient	XXXX, XXXXXXXX	21/09/2006	30
		Home Patient	XXXX, XXXXXXXX	25/09/2006	20
		Home Patient	XXXX, XXXXXXXX	28/08/2006	30
		Home Patient	XXXX, XXXXXXXX	21/09/2006	25
		Home Patient	XXXX, XXXXXXXX	14/09/2006	8
		Home Patient	XXXX, XXXXXXXX	24/08/2006	30
		Home Patient	XXXX, XXXXXXXX	08/09/2006	30
		Home Patient	XXXX, XXXXXXXX	22/09/2006	30
		Home Patient	XXXX, XXXXXXXX	01/09/2006	60
		Home Patient	XXXX, XXXXXXXX	19/09/2006	20
		Home Patient	XXXX, XXXXXXXX	19/09/2006	30
		Home Patient	XXXX, XXXXXXXX	14/09/2006	30
Grand TOTAL Issued to Patients				493	

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 Patient Name: XX XXXXXXXX	31/10/2006 15:22
	Reference : Prophylaxis	
000260	Transferred In GLN: NCHCD	29/02/2006 12:24
In Stock	Reason: NCHCD Stock Top Up	
000046	Issued Patient Name XXXXX XXXXXXXX	03/10/2006 13:02
	Reference :	
000120	Issued Patient Name XXXXX XXXXXXXX	13/09/2006 10:34
	Reference : surgical site bleed	
000121	Issued Patient Name XXXXX XXXXXXXX	14/09/2006 11:51
	Reference :	
000378	Transferred In GLN: WALTER STEVENSON WARD	12/03/2008 12:02
In Stock	Reason: WSW Stock Top Up	
000122	Issued Patient: XXXXX XXXXXXXX	03/10/2006 15:26
	Reference : right thigh bleed	
000123	Issued Patient: XXXXX XXXXXXXX	14/09/2006 11:51
	Reference :	
000134	Issued Patient: XXXXX XXXXXXXX	02/10/2006 15:31
	Reference : Right thigh bleed	

BATCH SUMMARY

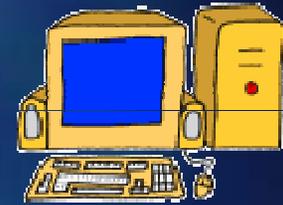
Total Booked In :	9
Issued to patients :	7
Stock in GLN(s) :	2

The solutions



Unique product barcoding

Encrypted Messaging



Electronic Patient record



Patient



Home/Hospital tracking



Validated cold chain delivery

Why is validation of Computer Systems Important?



- The FDA believes that the only way to develop validatable software is within a **"Quality Regulated Environment."**
- **SJH** choose GAMP, the validation system of choice for European pharmaceutical industry and is equivalent of
FDA CFR 21 11

Outcomes/ROI

EPR

- Standardisation of data entry (ICD 10 Coding/procedures etc) allows better reporting
- Access to key clinical information available electronically out of hours via summary screen

Hospital Product tracking system

- 100% visibility of all stock within the hospital
- Detailed reports on stock movement /issued/wastage
- Reduce errors by providing an electronic check on product V prescription before issue

Outcomes/ROI

Validated Cold Chain delivery System

- Since Cold Chain delivery started all products verifiably delivered between 2⁰-5⁰ Celsius
- Product wastage reduced from €90,216 to zero in the immediate year post service implementation
- 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
- Mock Recall identified location of all (100%) Medication within 10 minutes along with quantities of alternate stock available

What do the patients think?

- Convenience of new service – 100% satisfaction
- Privacy and confidentiality – 99% satisfaction
- Overall service satisfaction rating
 - 89% very satisfied
 - 10% satisfied
 - 1% dissatisfied

Future developments

- Continue developing the EPR (additional functionality)
- Roll out the EPR and stock management system to other Hospitals
- Move to Manufacturer allocated datamatrix B/C and EPC and eventually RFID?

Datamatrix Barcodes



European Federation of Pharmaceutical Industries (efpia) endorsed the use of datamatrix barcodes on 30th May 2007 because it was recognized that RFID is currently "more expensive and less reliable..."

20th Jan '09 - The FDA is calling for all drugs to be labelled using a standardised numerical identifier similar to the one suggested in the delayed California e-Pedigree guidelines. Another feature on the guidance is its compatibility with the serialised Global Trade Item Number (sGTIN) model set up by the international standards organisation GS1

January 2008 - Pharmaceutical Bar Coding to Improve Patient Safety Options for Technical Standards in the Canadian Environment - Roundtable Discussion Paper

"For discussion purposes, ISMP Canada proposes that the guidelines recommend two-dimensional (Data Matrix) symbology"

The data content and structure of the B/C developed by Baxter/GS1 and St. James's Hospital has become the de facto standard

Regulatory bodies

Turkey: Significant amendments were made in the Regulation on Packaging and Labelling on February 1 2008. This amendment introduced new identification and traceability requirements and stipulates that medicines must have a data matrix type 2-dimensional barcode. It is worth mentioning that a transitional period is accepted by the regulators, and licence holders of the medicinal products should start inserting 2D barcodes in their products at the latest on January 1 2009.

California: In January 2011, California was due to become the first US state to implement legislation mandating that drug manufacturers, wholesalers and distributors create electronic pedigrees (e-pedigrees) to track and trace all prescription drugs distributed within the state. Now 50% wholesalers must have system in place by 2015 with all wholesalers and retailers compliant by 2016

EU Catch up?

- European Commission consultation document issued on 11th March 2008
- Compared to 2005 seizures of counterfeit medicines at the boarder of the EU have increased by 380%
- The consultation document makes reference to Datamatrix bar codes

...dealing with product characteristics and Good Manufacturing Practices (GMP). Obligatory safety features shall allow for; identification checking, authenticity checking and tracing...

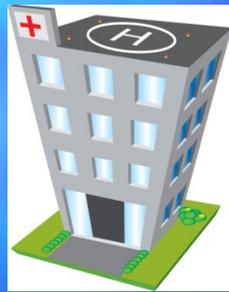
"Heparin recall only partially successful"

(4th Global Forum on Pharmaceutical AntiCounterfeiting 2008)

- Heparin recall that occurred during the spring of 2008 had only been partially successful
- Recalls had been issued by FDA and, among others, Baxter Healthcare, several times since contaminated vials of the blood treatment were found early in the year
- According to press reports, upwards of 83 patients have died nationally as a result of receiving the apparently sub-potent product—making the recall a high priority throughout the healthcare system
- Through May, upwards of 18% of the 500 hospitals in California still had unrecalled product in their stockrooms
- **Some dosages were found that had been returned to intermediate distributors—and then sent out again !**

Source: <http://www.pharmaceuticalcommerce.com>

Where we are



Conclusion

- **Measures need to be implemented to ensure patient safety**
 - **Barcodes work!**
- **Simply implementing bar code scanning can improve patient safety, increase efficiency and reduce costs**
 - **GS1 can help with technical issues (standards) and practical issues (implementation)**
 - **Medication suppliers are now moving towards barcoding**
- **Collaboration with other standards bodies will simplify processes**



Thank You

