Implementing traceability cytostatics projects

Global GS1 Healthcare Conference Geneva, June 22 - 24 2010
Mag. Elfriede Dolinar
Head of Pharmacy Department
Vienna General Hospital
Medical University
Vienna General Hospital
„Traceability in Compounding of Cytotoxic Drugs from Vendor to Patient“
Content

• Pharmacy department
• Current situation
• Project: 2 parts
• Goals
• Expected improvements
• Beyond our own nose
Pharmacy Department
Vienna General Hospital

- 2009 app. 57,000 ready to use preparations of cytotoxic drugs, virustatics and monoclonal antibodies
- Including service for St. Anna Kinderspital (children's hospital with focus on oncology - 7,500 units)
- Number of different substances used: 68
- Software used:
  - SAP for merchandise management
  - CATO:
    - Oncology software for compounding
    - Working according gravimetric principle using a balance in the clean bench (weighing control)
    - Computerised physician order entry
Current Situation in Austria

• Linear barcodes on registered drugs including the Austrian product specification code
• Mainly on secondary package
• Some blisters with product name and expiry date
• No 2 dimensional barcodes
DataMatrix

- The more advanced bar codes like
  - GS1-128
  - GS1 DataBar
  - GS1 DataMatrix
- allow attribute information such as
  - batch numbers
  - expiration dates
- to be encoded using the GS1 Application identifier
Goals Part I: Traceability from vendor to production

Increase patient safety - right drug, right dose, right

- Using DataMatrix on primary and secondary packages of cytotoxic drugs and solutions for reconstitution
- Identification of product, batch number and expiry date
  - Scan at point of delivery to pharmacy
  - Scan at point of storage in compounding unit
  - Scan before compounding
- Reduce manual interventions
Supply to pharmacy

Identification, expiration date and batch number are documented by scan

Storage

Data transfer from SAP to CATO

CATO id, batch nr exp. date

Future: from vendor to production

Storage

Scan + balance: specific weight

Identification

Compounding
Project team

- GS1 Austria Health Care
- Vienna General Hospital
- 6 Pharmaceutical companies: cytotoxic drugs and solutions for reconstitution
- CATO
GS1 Austria

• Gives Information about global standards for product identification
• Link to pharmaceutical industry
• Looking for network partners
  – Hôpitaux Universitaire Genève
  – Projects in Germany and Belgium
Vienna General Hospital

- Pharmacy department
  - Project leader: Head of Pharmacy department
  - Oncology pharmacist
- IT- Department
  - Implementation of scanning at point of receipt using 2-dimensional barcode in SAP
  - Identification, documentation of batch number and expiry date
  - Creating an interface with SAP/Cato
    - Inventory – same inventory in SAP and CATO
    - Cost centre accounting
- Oncologist and head nurse of Oncology Department

GS1 Healthcare Conference Geneva
June 22-24, 2010
Industry

- Currently implementation of 2-dimensional barcodes on pharmaceuticals in a few countries
- DataMatrix on pharmaceuticals expected in whole Europe in about 5 years
- Production mainly centralized Europe/whole world
- Public procurement - advantage in competition
CATO

• Oncology software used
  – for CPOE
  – for compounding

• Scan of DataMatrix on original packages

• Scan of unique identification number during transport and administration
Goals part II: Traceability from Preparation to Patient

To ensure the 5 “Rs”

• Print of an unique identification number on label
  - linear barcode GTIN + serial number
• Scan at point of dispensing in pharmacy
  - Identification of hospital
• Scan at point of delivery to ward
  - Identification of drug and ward
• Scan at point of administration
  - Identification of drug and patient (case number)
From production to patient

- Compounding
- Label print
- Transport
- Supply to ward
- Storage
- Administration

Right Drug? Right ward?

Right Drug? Right Patient?
From production to patient

Compounding

Label print

Transport

Supply to ward

Storage

Administration

Right Hospital 😊

Right Drug 😊
Right Ward 😊

Right Drug 😊
Right Patient 😊
Further goals

- Reimbursement in Austria – Austrian DRG system
- ICD 10 International Statistical Classification of Diseases and Related Health Problems
- Coding at point of administration
Timeline

- Idea during Global GS1 Health Care Conference in Vienna in March 2009
- First contacts with CATO and some pharmaceutical companies at EAHP Congress in Barcelona in March 2009
- Kick off meeting end of August 2009
- Visit to Geneva University Hospital beginning of September 2009
- GS1 first contacts to industry
- Kick off meeting with all partners in November 2009
- Trial period September 2010
Transition period

Handling of products without DataMatrix

- Identification per double check
- Documentation of expiry date and batch number manually in SAP and Cato
- Goal: to make this period as short as possible
- Information to other companies which are not part of the project in due time
EAHP- Working group
Unit dose identification

- Unit doses blisters, with each single dose containing the whole information
  - Trade name
  - Active substance
  - Dosage
  - Expiration date
  - Batch number
  - Barcode
    - Including product ID, expiry date and batch number
    - Use of a recognized international standard (i.e. GS1)
    - DataMatrix

EAHP, 2007
HUG: Cytotoxic treatment and bedside scanning: Improving patient healthcare

Prof. Pascal Bonnabry

• Risk analysis to find the best and most efficient solution of cytotoxics

• Strategic approach built on three pillars
  – Prevention
  – Diagnosis
  – Treatment

• Goals: reduction of criticality at patients bedside

• Implementing barcode system GS1 Datamatrix
Global process management

Preparation with weighing control

Electronic prescription

Bedside scanning

Source: Pascal Bonnaby
Electronic prescription

| Mode of Administration | dc1 (dose per cycle) | dose per prescription | prescription/protocol | J01 | J02 | J03 | J04 | J05 | J06 | J07 | J08 | J09 | J10 | J11 | J12 | J13 | J14 | J15 | J16 | J17 | J18 | J19 | J20 |
|------------------------|----------------------|-----------------------|----------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Moduler               | Cyclophosphamide 750 mg/m² x 260 ml sur 50 minutes | 1346 mg | 1346 mg | 100 % | 1   |
| Moduler               | Doxorubicine 50 mg/m² x push | 89.71 mg | 89.71 mg | 100 % | 1   |
| Moduler               | Vincristine 1.4 mg/m² x push | 2,512 mg | 2,512 mg | 100 % | 1   |
| (b)ors pharmacie      | Prednisone 40 mg/m² po | | | | |

Administration: J1 [heure:minute] No Cycle
Production with weighing system

- Cytostatics – CATO®
  - Direct calculation from the prescription
  - Operator guided step by step
  - Weighing control
  - Identity control by barcode (version 2)
  - Traceability

Need to have a barcode on the primary package

www.cato.eu

Source Pascal Bonnabry
Bedside scanning

Physician

Database

Nurse

Stop

Drug

Patient

Source Pascal Bonnabry
Traceability

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<th>Quantity</th>
<th>Nom</th>
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<th>No Lot</th>
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Visas:

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<td>FARE</td>
<td>Préparé par CATO</td>
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Préparation effectuée dans: Isolateur 2

When? What? Who?
Perspective

Will we be able to be as effective as supermarkets?

Pascal Bonnabry

Yes, we scan!