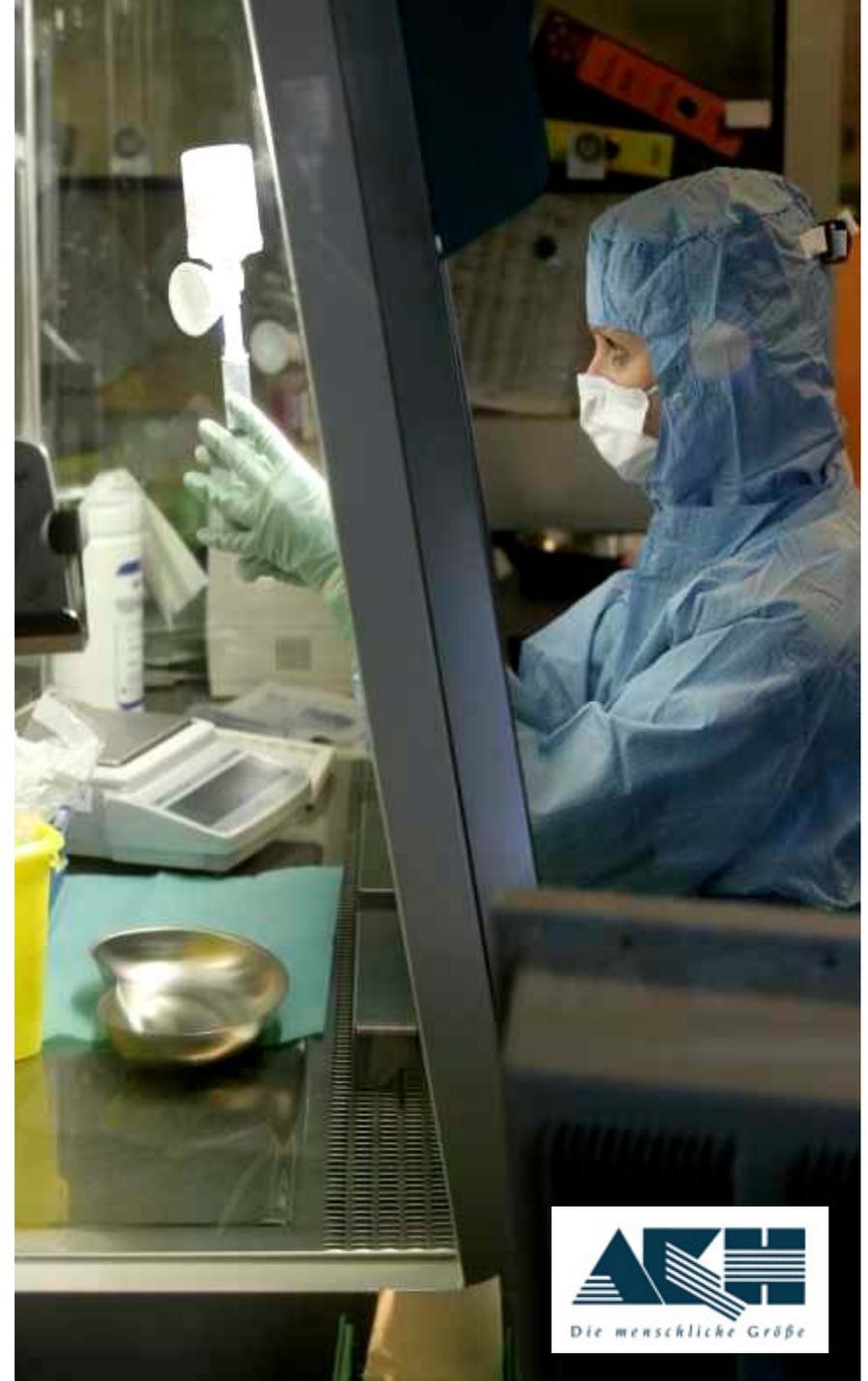


Implementing traceability cytostatics projects



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

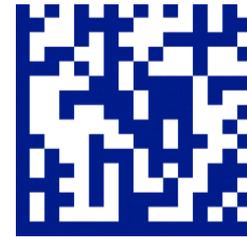
- 2009 app. 57.000 ready to use preparations of
- cytotoxic drugs, virustatics and monoclonal antibodies
- Including service for St. Anna Kinderspital (childrens hospital with focus on oncology - 7.500 units)
- Number of different substances used: 68
- Software used:
 - SAP for merchandise management
 - 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

Storage

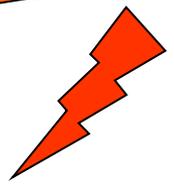
CATO id, batch nr exp. date

Storage

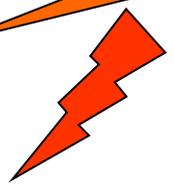
Identification

Compounding

2 eyes check expiration date, batch number not documented, no bar code scan

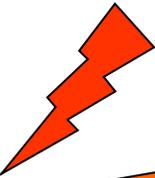


4 eyes check no bar code scan



From vendor to production

4 eyes check balance: specific weight no bar code scan



Supply to pharmacy

Identification
expiration date

Storage

CATO
id, batch nr
exp. date

Storage

Identification

Compounding

Identification, expiry date and batch number are documented by scan



Data transfer from SAP to CATO



Future:
from vendor
to production

Scan + balance:
specific weight





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

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

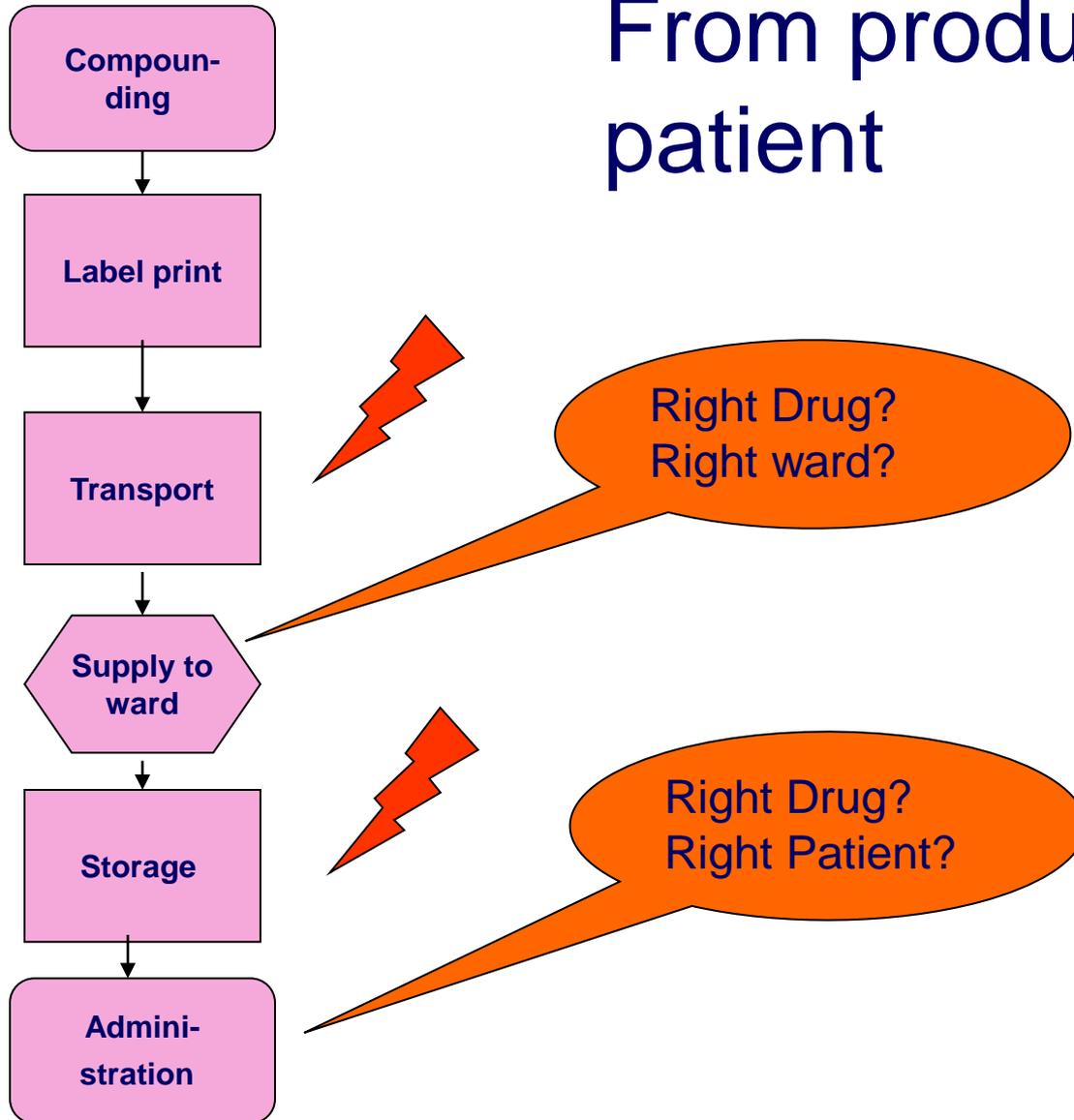
Goals part II: Traceability from Preparation to Patient

To ensure the 5 “Rs”

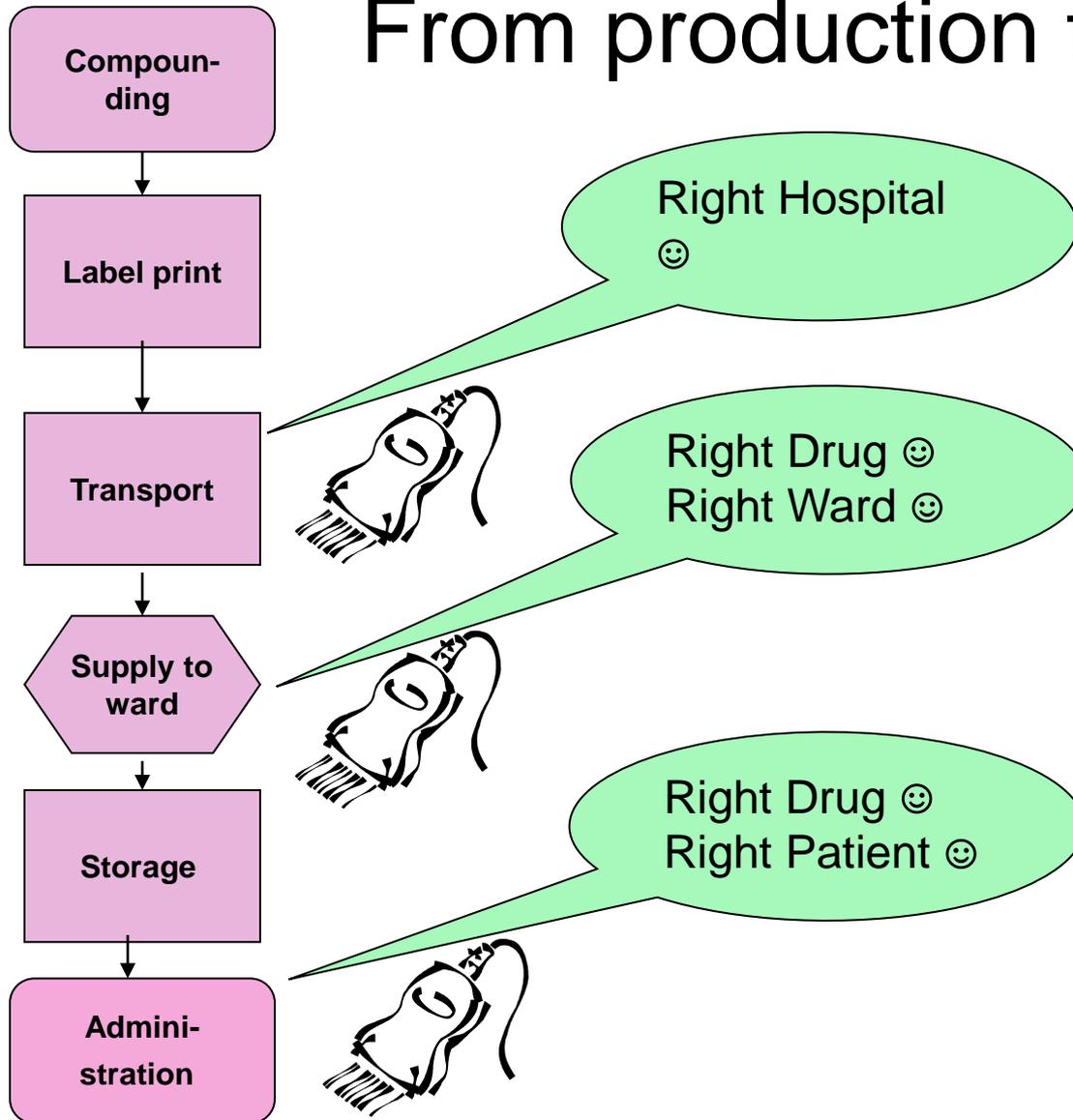
- Print of an unique identification number on label
 - linear barcode GTIN + serial number
- Scan at point of dispensing in pharmacy
 - Identification of hospital
- Scan at point of delivery to ward
 - Identification of drug and ward
- Scan at point of administration
 - Identification of drug and patient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



From production to patient



From production to 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

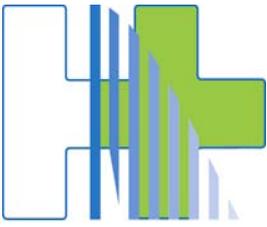


EAHP, 2007

HUG: Cytotoxic treatment and bedside scanning: Improving patient healthcare

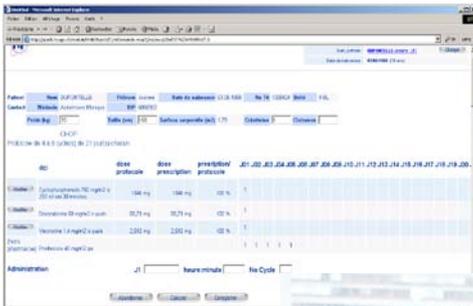
Prof. Pascal Bonnabry

- 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

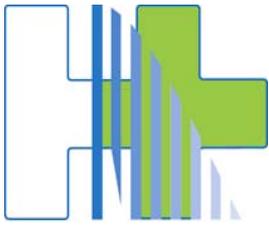


Electronic prescription



Bedside scanning





Electronic prescription

Untitled - Microsoft Internet Explorer

Fichier Edition Affichage Favoris Outils ?

Précédente → → Recherche Favoris Média

Adresse <http://spock.hcuge.ch/module/WebObjects/CytoDemande.woa/1/wo/ea:JU2mRST4GZnYfdKRlw/7.6> OK Liens »

Nom, prénom: **DUPONTELLE Jeanine (F)**

Date de naissance: **03.06/1968** (36 ans)

Patient **Nom** DUPONTELLE **Prénom** Jeanine **Date de naissance** 03.06.1968 **No Tit** 1008424 **Unité** 4-BL

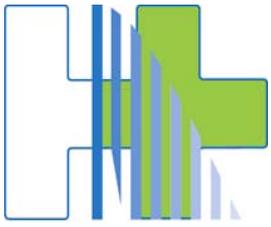
Contact **Médecin** Ackermann Monique **BIP** 6859363

Poids (kg) **Taille (cm)** **Surface corporelle (m2)** 1,79 **Créatinine** **Clairance**

CHOP
Protocole de 4 à 8 cycle(s) de 21 jour(s) chacun.

dcj	dose protocole	dose prescription	prescription/ protocole	J01	J02	J03	J04	J05	J06	J07	J08	J09	J10	J11	J12	J13	J14	J15	J16	J17	J18	J19	J20
<input type="button" value="Modifier"/> Cyclophosphamide 750 mg/m2 iv 250 ml sur 30 minutes	1346 mg	1346 mg	100 %	1																			
<input type="button" value="Modifier"/> Doxorubicine 50 mg/m2 iv push	89,71 mg	89,71 mg	100 %	1																			
<input type="button" value="Modifier"/> Vincristine 1,4 mg/m2 iv push	2,512 mg	2,512 mg	100 %	1																			
(hors pharmacie) Prednisone 40 mg/m2 po				1	1	1	1	1															

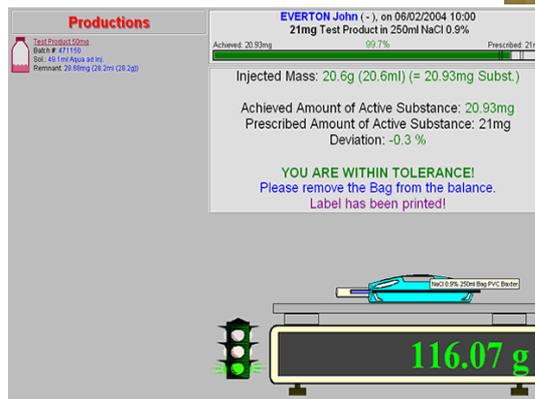
Administration **J1** **heure:minute** **No Cycle**



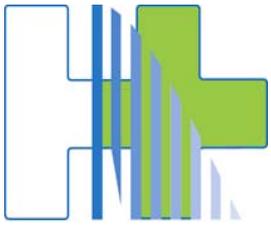
Production with weighing system

- **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



Bedside scanning

Physician



Nurse



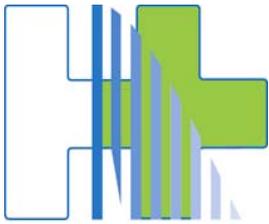
Drug



Database



Patient



Traceability

Tracabilité des préparations de chimiothérapies

HUG ChimioTrace, 2009

Pascal Bonnabry connecté depuis 16:37 jusqu'à 17:40

Pharmacien/ne / Pharmacie

Affichage du matériel utilisé pour la préparation

Préparation no cyt/09-68373 - ETOPOSIDE PHOSPHATE 191 mg

Patient: Nom, Prénom, Date de naissance, No Ttt, Unité, 6-EL
 Administration: Date, No Cycle, No Jour, Durée, 15 minute
 Contact: Médecin, BIP, Etude

Préparations liées: cyt/09-68374 à cyt/09-68377

Modifier Produits Viser Etiquettes Fermer Dupliquer

Produits utilisés:

Quantité	Nom	Type	No Diogène	No Lot	No reste CATO
1	Etopophos® 1000 mg	poudre	111714	9D54487-31/07/11	306
1	Eau distillée 100 ml	solutionPreteAEmploiDiluant	4608	1490209-28/02/12	
5	NaCl 0,9% 100 ml	solutionPreteAEmploiDiluant	7726	09062138-30/06/12	

Visas:

Date visa	Date opération	Type	Initiales	Remarques
07.09.2009 09:19:24	07.09.2009 09:16	prescription BEP chir (190)	acge	
07.09.2009 09:19:24	07.09.2009 09:19	sortie matériel	fage	
07.09.2009 09:49:10	07.09.2009 09:49	mat+etiq	isgt	
07.09.2009 09:49:13	07.09.2009 09:49	envoyé à Cato	isgt	
07.09.2009 09:50:03	07.09.2009 09:50	Annonce J1	isgt	
07.09.2009 11:01:02	07.09.2009 10:44	cato	FAGE	Préparation terminée correctement (isolateur 2/DANE-0089).
07.09.2009 11:01:02	07.09.2009 10:44	cato	FAGE	Etopophos 20 mg/ml 190 mg (99.57%)
07.09.2009 11:01:02	07.09.2009 10:44	preparation	FAGE	Préparé par CATO
07.09.2009 11:01:02	07.09.2009 10:44	à facturer	FAGE	Préparé par CATO
07.09.2009 16:01:37	07.09.2009 16:01	debutAdmin	mhai	
07.09.2009 16:22:41	07.09.2009 16:22	finAdmin	mhai	

Préparation effectuée dans: isolateur 2

When ? What ? Who ?

Perspective

Will we be able to be as effective as supermarkets?

Pascal Bonnabry

Yes, we scan !

