

Unit dose requirements

Dr Pascal BONNABRY, CC

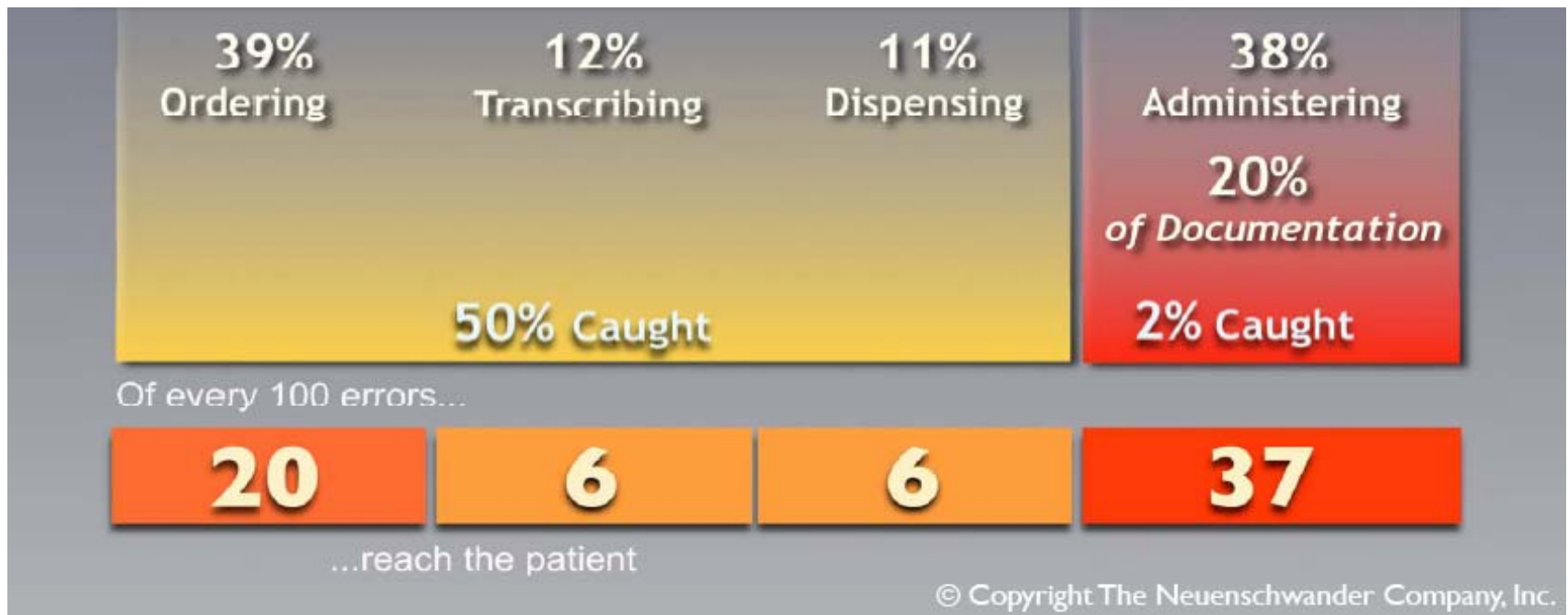
Head of pharmacy

GS1 HUG, Berlin, January 31, 2007



Where are the errors ?

Avoidable adverse events in 6.5% of hospitalizations



Human reliability

Efficacy of human-performed controls

- Introduction of errors during unit dose dispensing
- Detection ability:
 - Pharmacists: 87.7%
 - Nurses: 82.1%

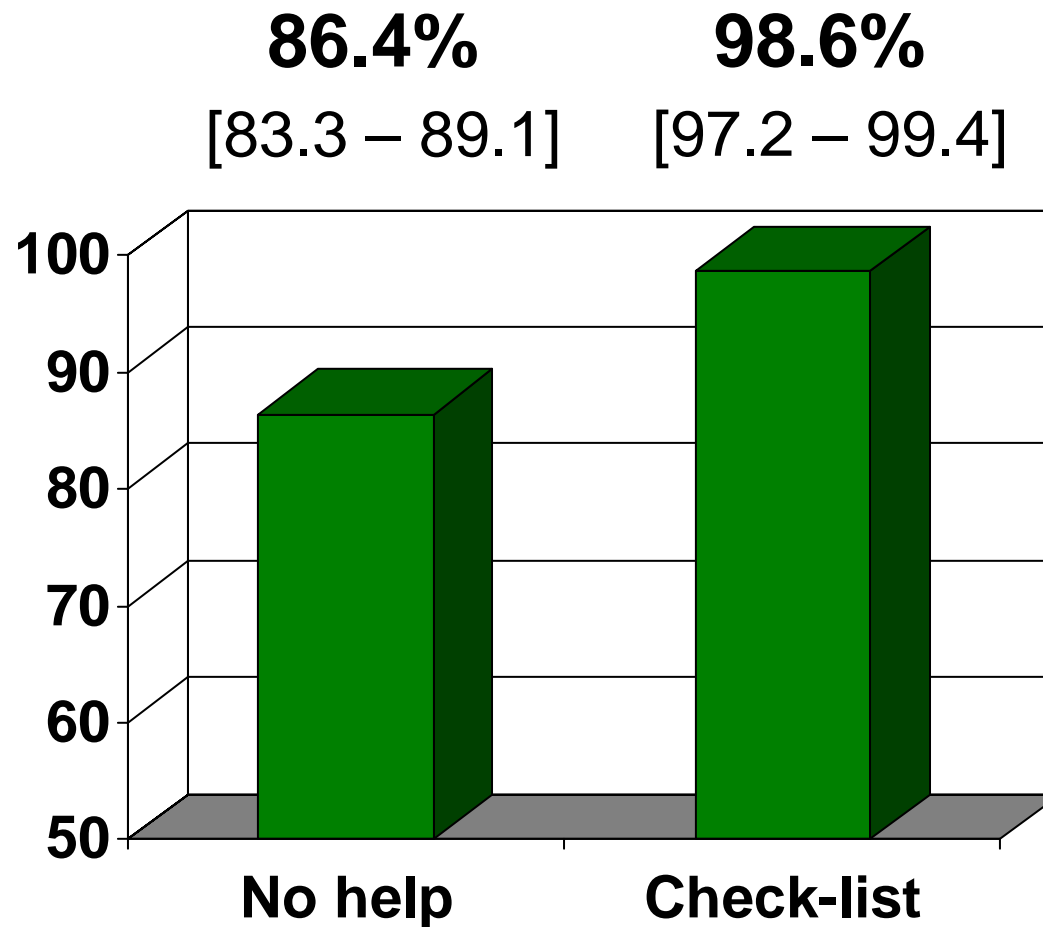
Facchinetti NJ, Med Care 1999;37:39-43

Efficacy = 85%
(known value in the industry)

Don't be too confident with the double-checks

Impact of a check-list

Experimental results



Mean
[IC 95%]

n=62

A simple story

Safety issue

- **Oral methotrexate**

- Administered **once a week** when used in auto-immune diseases
- Correct prescription
- Mistake during order retranscription
- Not used to administer drugs once a week
- Drug administered **each day**
- **Patient died 10 days later**

→ **This death could have been avoided by scanning the drug !**

A simple story

Traceability issue

- **IV immunoglobuline**

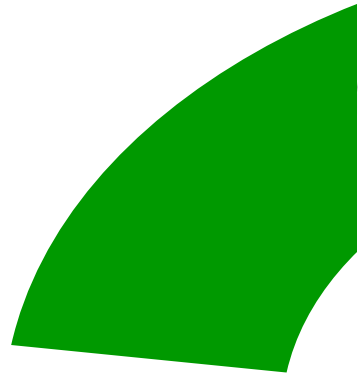
- Discovery of a possible batch contamination by HIV
- Batch recall announced by the industry
- Easy to identify the wards having received the batch of the drug
- Very difficult to identify with certainty the patients having received the product

→ **A true traceability until the patient would have been ensured by scanning the drug !**

Challenges for hospitals

- Processes of care are very complex and strongly based on human reliability
 - **Improve the safety**
- Follow-up and documentation of care is more and more required unto the patient level
 - **Improve the traceability**
- Increased need to communicate information inside and between institutions
 - **Improve the communication**

The « ideal » process ?



Automatic dispensing



Scanning at bedside



Electronic prescribing

Information technologies

Electronic patient record

Prescrire Outils

Prescrire sur la Feuille d'ordre (unité ARV)

Rechercher

lasix

- furosémide Furosémide lasix® inject
- furosémide Furosémide lasix® or
- furosémide Furosémide lasix® 250 mg/500 mg
- néphrographie isotopique avec test au Lasix
- Laboratoires
- Soins

Autres

Autre médicament

Autres ordres médicaux

furosémide-Furosémide lasix® inject

Raison du traitement : ascite

Dose par prise	Fréquence	A passer sur	Voie
20 mg	1x/j	IV lent	intraveineux
10 mg	2x/j	IV direct	intramusculaire
40 mg	3x/j	sur 24h	per os
80 mg	1x/h	sur 12h	autre
120 mg	1x/8h	sans précision	
autre	matin-midi-soir	autre	

Debut	Fin	Condition
débuter DE SUITE	jusqu'à nouvel ordre	d'office
débuter selon horaire habituel	ce jour	en Réserve
en urgence	pour demain	autre
autre début	autre durée	

⚠ ne pas dépasser une vitesse d'injection de 4mg/min (2.5 mg/min en commentaires, instructions :

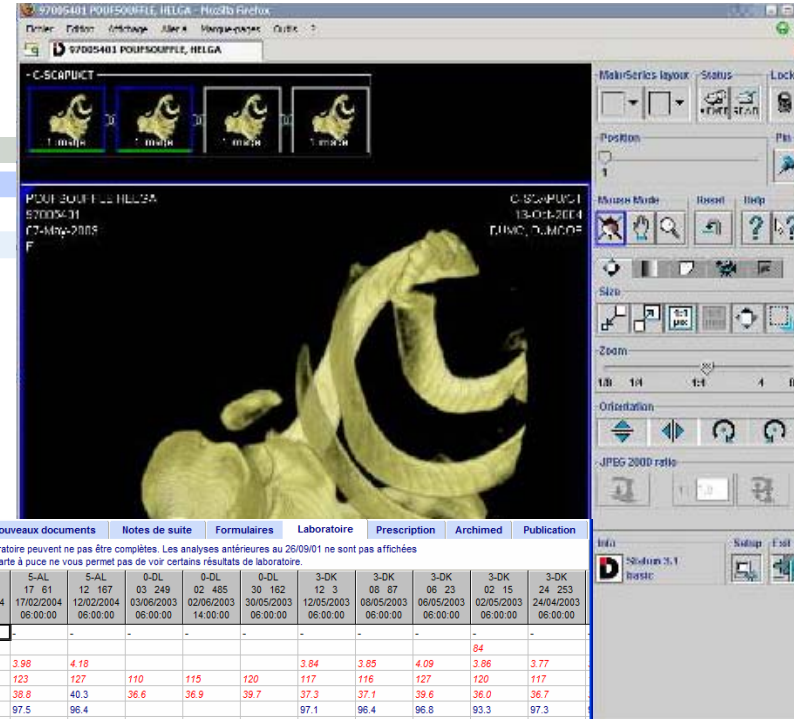
Informations

Ordre Saisi le 23.02.2004 à 14:15 par D

Résumé du dossier Document disponible Nouveaux documents Notes de suite Formulaires Laboratoire Prescription Archimed Publication

Les données de laboratoire peuvent ne pas être complètes. Les analyses antérieures au 20/09/01 ne sont pas affichées. L'absence de votre carte à puce ne vous permet pas de voir certains résultats de laboratoire.

	unité	S-AL 20 06:00:00	S-AL 54 17 06:00:00	S-AL 17 02:00:00	S-AL 12 167 03/06/2003 06:00:00	O-DL 03 249 02/06/2003 14:00:00	O-DL 02 485 30/05/2003 06:00:00	O-DL 12 3 12/05/2003 06:00:00	3-DK 06 87 09/05/2003 06:00:00	3-DK 06 23 06/05/2003 06:00:00	3-DK 02 15 02/05/2003 06:00:00	3-DK 24 253 24/04/2003 06:00:00
IMAGES												
VITESSE DE SEDIMENTATION	mm/heure 0-10											
GLOBULES ROUGES	TL 4.40-6.00	4.28	3.98	4.18				3.84	3.85	4.09	84	3.86 3.77
HEMOGLOBINE	g/L 140-180	133	123	127	110	115	120	117	116	127	120	117
HEMATOCRITE	% 40.0-52.0	40.6	38.8	40.3	36.8	36.9	39.7	37.3	37.1	39.6	36.0	36.7
MCV	fL 82.0-98.0	94.9	97.5	96.4				97.1	96.4	96.6	93.3	97.3
MCH	pg 26.0-34.0	31.1	30.9	30.4				30.5	30.1	31.1	31.1	31.0
MCHC	g/L 320-380	328	317	315	301	312	302	314	313	321	333	319
GLOBULES BLANCS	GL 4.0-11.0	9.1	6.6	7.0				10.0	10.4	9.6	10.3	6.3
Répartition leucocytaire												
Neutrophiles (%)	% 33.0-80.0			53.0								62.4
Neutrophiles segmentés	% 33.0-75.0	73.0	55.0					75.0		73.0	68.0	
Neutrophiles non segmentés	% 0.0-5.0	0.0	0.0					0.0		0.0	0.0	
Eosinophiles	% 0.0-5.0	2.0	7.0	6.9				9.0		3.0	9.0	5.6
Basophiles	% 0.0-2.0	1.0	0.0	0.7				1.0		0.0	2.0	0.6
Monocytes	% 0.0-8.0	5.0	14.0	8.6				5.0		7.0	10.0	4.5
Lymphocytes	% 15.0-60.0	19.0	24.0	30.8				10.0		17.0	11.0	26.9
Plasmocytes	% 0.0-0.0											
Metamyélocytes	% 0.0-0.0											
Cellules Réparties												
Neutrophiles Nb.Abs	GL 1.50-8.00			3.70								3.92
Neutro segmentés Nb.Abs	GL 1.50-7.50	6.63	3.64					7.46		7.02	6.97	
Lymphocytes Nb.Abs	GL 1.00-4.50	1.73	1.59	2.15				0.99		1.63	1.13	1.69
% GB	0-0											
PLAQUETTES	GL 150-350	214	203	243			290	209	237	258	212	241
Morphologie érythrocytes												
Anisocytose									PRES			
Anisochromie										PRES		PRES
Polychromasie												
Erythrocyt. en rouleaux												
Morphologie leucocytes												



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Berlin, January 31, 2007



Handwritten → Electronic traceability

C. Lovis, HUG, 2005



The 3 actors

The caregiver



The patient



The drug

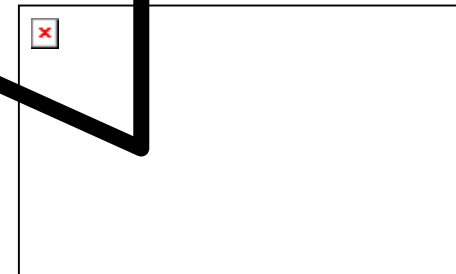
Identification ?

The 3 actors

The caregiver



The patient



The drug

Patient identification



Acceptability

Table 1 Support for identification bracelet among former patients

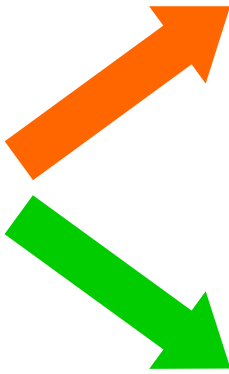
Variable	N	Hospital should introduce compulsory wearing of identification bracelet (% agree)		Would wear such a bracelet during a future hospitalisation (% agree)	
Overall	1289	83.6		90.2	
Examples of situations in which patient identification was a concern					
Given	648	87.9	(p<0.001)	92.2	(p=0.015)
Not given	641	79.2		88.1	
Means of patient identification on bracelet					
Patient name	626	83.7	(p=0.92)	90.2	(p=0.98)
Anonymous code	636	83.5		90.2	

p values based on χ^2 tests.

Unit dose identification



?



Reconditioned
by the pharmacy

Identified
by the industry



Unit dose identification

The example of the FDA



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Press Release

FOR IMMEDIATE RELEASE
Wednesday, Feb. 25, 2004

FDA Press Office
301-827-6242

**HHS Announces New Requirements for Bar Codes
on Drugs and Blood to Reduce Risks of Medication Errors**

Product identification mandatory
(batch number and expiry date encouraged)

Mandatory since April 26, 2006

Prevention of 500'000 adverse events / year ?

The scanning in the USA

	2000	2002	2004	2006	2010
Opinion leaders	++	++	++	++	
Objective results	-	+	++	+++	
Drugs	≈ 30%		FDA	≈ 80%	100%
Commercial solutions	-	-	+	+++ (≈ 30)	
Hospitals using the scanning	1%	1.5%		10%	80%?

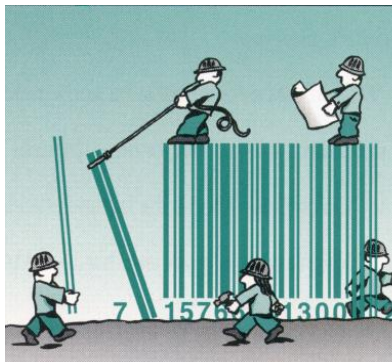
The benefit of bedside scanning

- **BPOC impact**

- Wrong drug - 75%
- Wrong dose - 62%
- Wrong patient - 93%
- Wrong administration time - 87%

Globally

- 80%



The scanning in Geneva

Pilot study with chemotherapies

Why the chemotherapies ?

1. High-risk process, with potential dramatic consequences for patients in case of error
2. Production centralised at the pharmacy, possibility to identify the final product
3. Electronic prescription implemented

The scanning in Geneva Pilot study with chemotherapies

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Berlin, January 31, 2007



Untitled - Microsoft Internet Explorer
Fichier Edition Affichage Favoris Outils ?
Précédente Recherche Favoris Média
Adresse http://spock.hcuge.ch/module/WebObjects/CytoDemande.woa/1/wo/eax:U2mRST4GZnYfdKRLw/7.6

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 Ttt** 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.

dc	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/m ² iv 250 ml sur 30 minutes	1346 mg	1346 mg	100 %	1																		
<input type="button" value="Modifier"/>	Doxorubicine 50 mg/m ² iv push	89,71 mg	89,71 mg	100 %	1																		
<input type="button" value="Modifier"/>	Vincristine 1,4 mg/m ² iv push	2,512 mg	2,512 mg	100 %	1																		
(hors pharmacie)	Prednisone 40 mg/m ² po				1	1	1	1	1														

Administration J1 heure:minute No Cycle

The scanning in Geneva

Pilot study with chemotherapies



Caregiver ID
(RFID)



Drug ID (RFID)



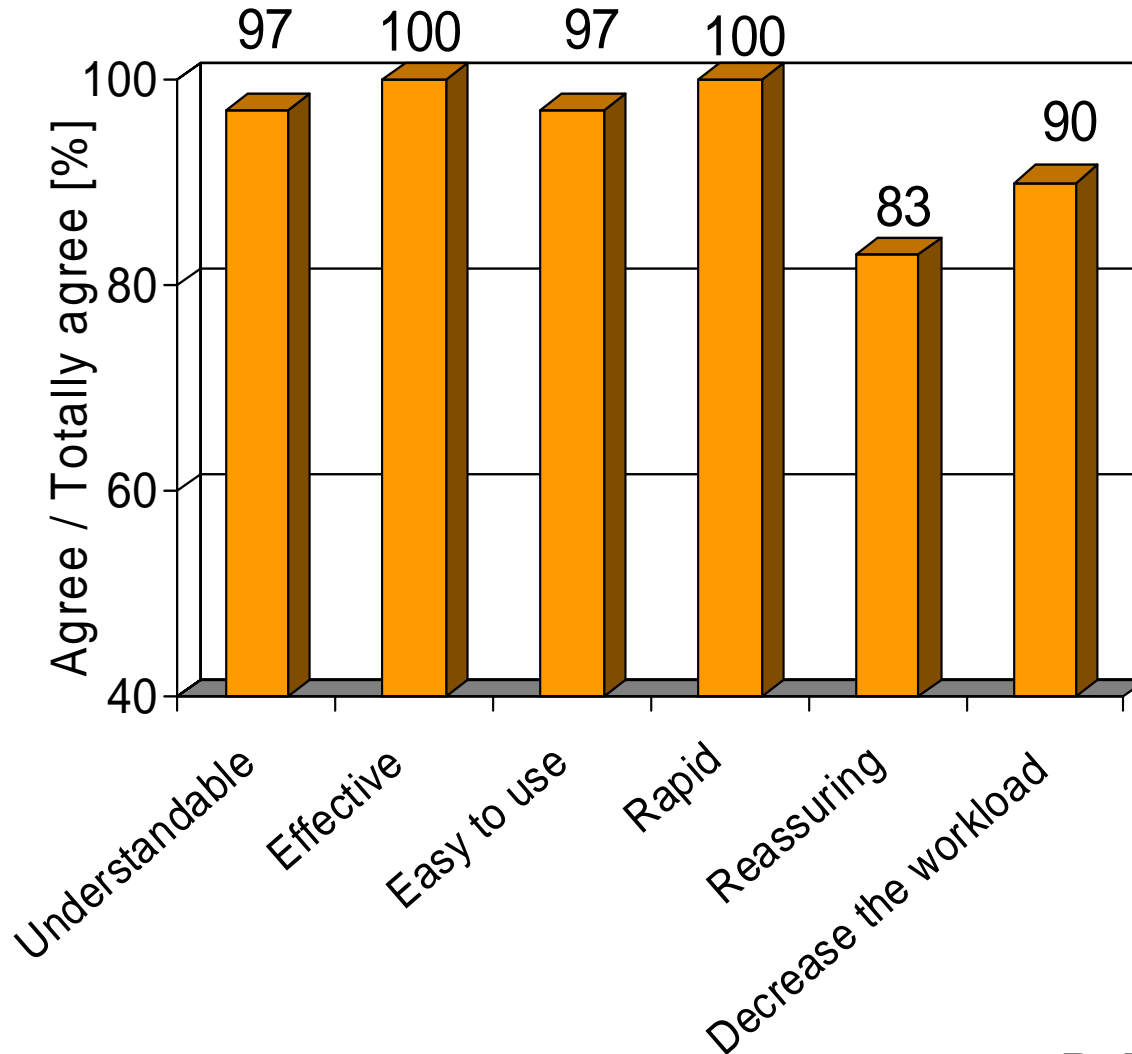
CYTOS-TRACE
(database)



Patient ID (RFID)

(actually under implementation)

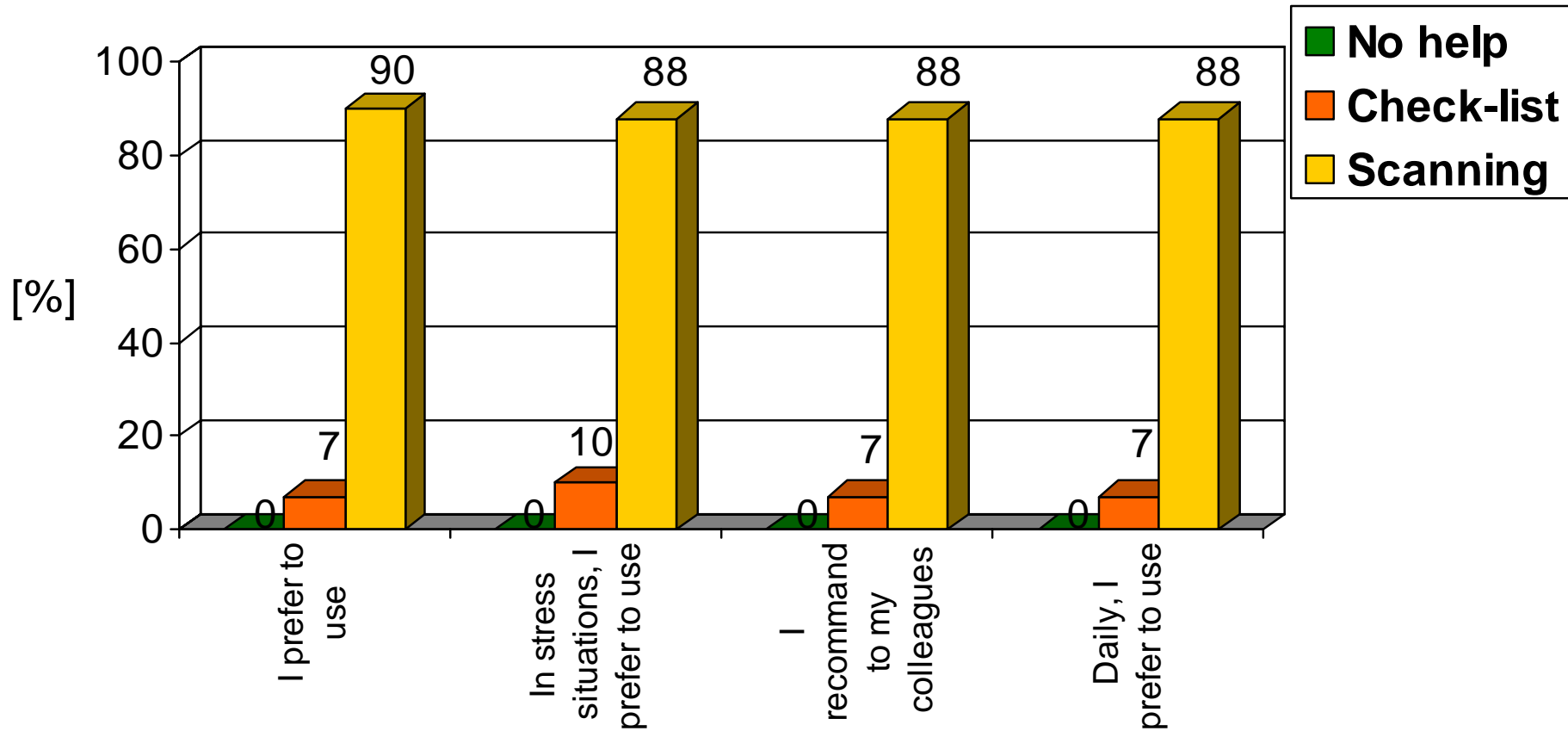
Acceptability



n=41

R. Balbaaki, HUG, 2006

Acceptability



n=41

R. Balbaaki, HUG, 2006

Time saving

	No help	Check-list	Scanning
Time for 10 controls [min]	32	18	8
Time saved / 10'000 controls [h]		220	160 Tot 380 h

→ **Time saved for patients care !**

Annual operating costs

(already existing electronic prescription)

	RFID	Datamatrix
Patient labels	1'760	0
Product labels	25'300	0
Caregiver labels	existing (badge)	0
Material renewal (25%)	11'188	5'313
TOTAL COSTS (CHF)	38'248	5'313
% of annual expenses	1.0%	0.1%
Overcost by chemotherapy (CHF)	3.48	0.48

Taxes perceived for ambulatory deliveries:
≈ CHF 300'000.- /year

Cost-efficacy analysis

(already existing electronic prescription)

Cost /avoided error [CHF]

Datamatrix	Rate of use CL/scan [%]	Scanning vs no help	Scanning vs check-list
Without error cost	100 / 100	355	3'450
With error cost	100 / 100	- 5'645	- 2'550

Conclusion

- The prescription in hospitals is more and more computerized
- The bedside scanning can improve the patient safety
- The acceptability by caregivers seem to be good, but a close support is needed during the implementation in the real-life
- **We need to have unit-doses of drugs with barcodes !**

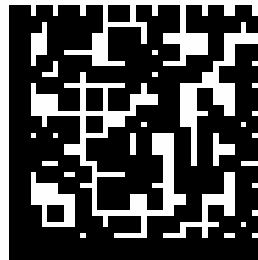
Which data in the barcode ?

- **ID product**
 - To avoid errors
 - improve the **safety**
- **Batch number / expiry date**
 - To answer efficiently to the legal requirements (vs labels to stick)
 - To facilitate searches in case of problems (batch recall)
 - improve the **traceability**

Which carrier ?

- **Datamatrix**

- Safety
- Traceability
- Product ID
- Batch number
- Expiry date



How to implement it on large scale ?

Polyvalent readers for PDA are needed !

EAHP request for unit-doses

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



European Association of Hospital Pharmacists