CYTOTOXIC TRACEABILITY AND PATIENT WRISTBANDS

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Introduction

- A full traceability of the medication process is the final objective to reach
- The implementation should be progressive, as a puzzle
- To make the proof of concept, it is important to select
  - Pilot processes
  - Pilot products
  - Pilot persons (patients, healthcare workers)

Why cytotoxic as pilot process ?

- High-risk process, with potentially dramatic consequences for patients in case of error
- Critical and costly drugs, a full traceability has a clear added value
- Last check at bedside complex and time consuming
- Product preparation centralized at the pharmacy, with a possibility to identify the final container
- Computerized prescription already implemented

Control complexity

- **10 points to check before the administration**

CHECK-LIST pour le contrôle des concordances d'information lors de l'administration des cytostatiques

Mettre un + dans le carré (+) lorsqu'il y a concordance entre deux informations provenant de deux sources différentes. Mettre un – dans le cas inverse (–).

Sources / Vérifications	Patient	Protocole	Préparation	Calendrier	Conservation
Identité patient	●	□ ●	□ ●		
Nom du produit		●	□ ●		
Dose totale		●	□ ●		
Voie d'administration	●	□ ●	□ ●		
Date du jour de l'administration		●	□ ●	□ ●	
Produit non périmé avant la fin de l'administration			●	□ ●	
Mode de conservation			●		□ ●

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Balbaaki R, HUG, 2006

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Errors during cytotoxic preparation

- **Detected errors**
  - **Total:** **0.45 %**
  - **Major:** **0.19 %**
  - **High workload** (>60/day) **increase the risk** (Odds-Ratio = 2)

n=30’819

Error category	*Nº of errors (%)*	
Major errors		
Wrong dose (confirmed or doubt)	39	(27.9%)
Labeling (name, drug or dose error)	11	(7.9%)
Unauthorized drug	4	(2.9%)
Incompatible diluent	3	(2.1%)
Incompatible set or bag	2	(1.4%)
Sub-total	59	(42.1%)
Minor errors		
Wrong set of infusion (without incompatibility)	31	(22.1%)
Final volume	22	(15.7%)
Wrong diluent (without incompatibility)	21	(15%)
Final presentation (e.g. bag instead of syringe)	6	(4.3%)
Solvent of reconstitution (without incompatibility)	1	(0.7%)
Sub-total	81	(57.9%)
Overall	**140**	**(100%)**

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Limat S, Pharm World Sci 2001;23:102

Failure during verification and administration

Task	Number of nurses committing error (%)		
	Preintervention experiment		
	Condition 1: uninterrupted (n=18)	Condition 2: interrupted (n=18)	Significance (Condition 1 vs 2)*
Medication verification tasks (assessment of error detection)			
1. Verifying medication name	3 (17%)	6 (33%)	No (p=0.160)
2. Verifying medication dosage	4 (22%)	4 (22%)	No (p=0.595)
3. Verifying medication volume in syringe	9 (50%)	16 (89%)	Yes (p=0.003)
4. Verifying medication volume in AIP	10 (56%)	17 (94%)	Yes (p=0.002)
5. Verifying patient ID	7 (39%)	6 (33%)	No (p=0.591)
Medication administration tasks (assessment of error commission)			
6. Intravenous push	8 (44%)	16 (89%)	Yes (p=0.02)
7. Pump programming and infusion initiation	0 (0%)	7 (39%)	Yes (p=0.03)

*McNemar's χ^2 test (within-subjects analysis).
†Fisher's exact test (between-subjects analysis).

Simulation study

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Prakash V, BMJ Qual Saf 2014;23:884

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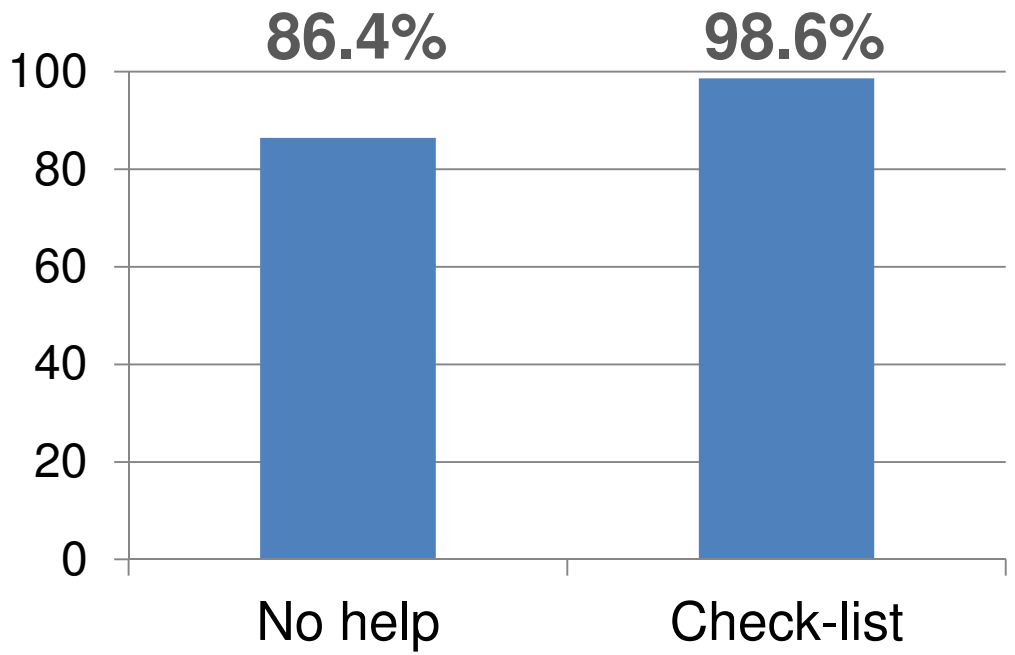
Impact of a check-list

- **Error detection in a simulation setting**



n=62

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Balbaaki R, HUG, 2006

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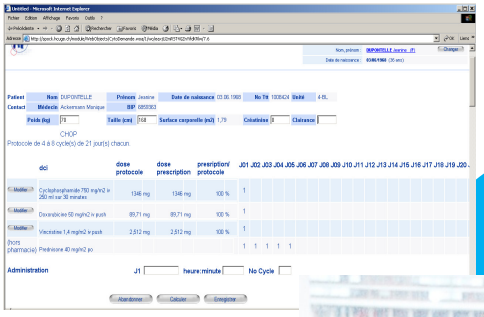
Check-list in real life

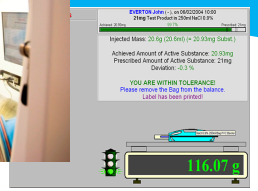
- The impact of a paper check-list in the real life is certainly lower
  - Compliance rate
  - Efficacy of the control (time constraints, interruptions)
- The paper check-list is not a traceability tool

- **Need for an efficient electronic process**

IT in the cytotoxic process

Automated preparations (2015)

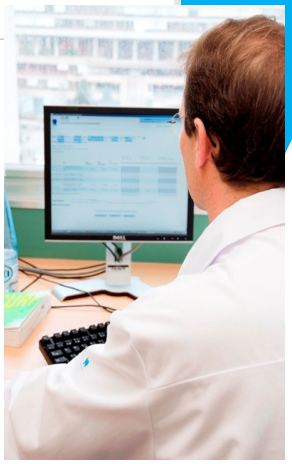




Electronic prescription

+

Dose-banding (2016)



Preparation with gravimetric control

Bedside scanning

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Bedside scanning
Organisation

Nurse

Cytotoxic

Physician

Database

Patient

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Bedside scanning
Objectives

- Increase patient safety
- Increase patient satisfaction (safety feeling)
- Increase efficiency (documentation, stock management, invoicing,…)
- Increase nurses satisfaction
- Reduce costs (especially related to errors)

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Foote SO, Nursing Economics 2008;26:207

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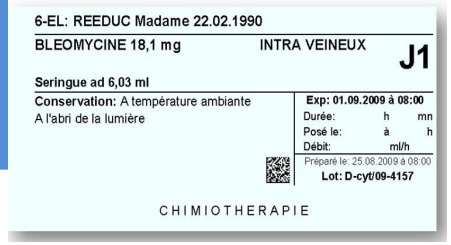
Traceability as a side effect

- **Safety first**
- **Efficiency**
  - Documenting
  - Invoicing
  - ...
- **Traceability**
  - Tracing
  - Tracking

Actors identification

Patient

Caregiver



Drug

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YOUR IDENTITY
IS YOUR SECURITY

Become an actor of your own security

Immediately after your admission, you will receive an ID bracelet with your name, surname, gender and date of birth. By keeping it at your wrist (or at your child's wrist) throughout your stay, you will contribute to the safety of your health care. It helps controlling that you receive the treatment that you were prescribed. This procedure also applies to the children followed up in Pediatrics.

Fewer errors thanks to wearing the bracelet

With an ID bracelet for all patients, the HUG intend to improve your health care and reduce errors. That is why, during your stay, your identity (or that of your child) is verified several times. Your participation is essential.

Patient identification

ANONYME
Fille
0dm – 29/10/1983

GSRN (with hospital ID encapsulated)

8018 7613167 80009627382

GCP **HUG ID**

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Product identification (cytotoxic)

0-GM: ANONYME Fille 29.10.1983

ASPARAGINASE E.COLI 8000 UI INTRA VEINEUX

Poche NaCl 0.9% ad 503 ml **J1**

Conservation: Au frigo
A l'abri de la lumière

Exp: 16.03.2011 à 14:00
Durée: h mn
Posé le: à h
Débit: ml/h

Préparé le: 15.03.2011 à 14:00
Lot: cyt/11-198499

Formulation magistrale
CHIMIOTHERAPIE

GTIN - cytos	**EXP (date and time)**	**Serial # HUG**
01 07613167000009	**7003** 1103161400	**21** cyt-11198499

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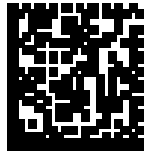
Why GS1?

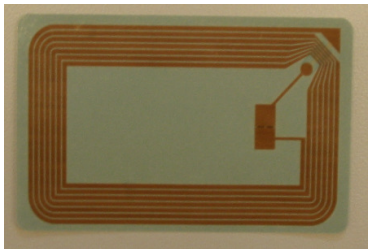
- Need to have a standardized system to identify objects, persons and places
- GS1 is an international standard, recognized in the fields of logistic and health
- GS1 is the dominant standard for drug identification around the world
- Increasing interoperability needs in and between hospitals, important to abandon proprietary systems

Data carrier (drug and patient)

- **Datamatrix**
  - Simple to print and to read
  - Robust
  - Need a service to calculate the image from the alphanumerical sequence



- **RFID** (initial choice)
  - Scan at distance, under bed sheet, …
  - More costly
  - Need specific labels and printers
  - Encoding problems (suboptimal reliability)
  - Practical problems (syringes, liquids)



Readers

- **Computer on wheel (COW) and scanner**
  - Platform already working for physicians
  - Full access to the electronic patient record
  - Can manage all nurses activities
  - Cumbersome at bedside

- **PDA** (initial choice)
  - Mobile and accessible (in the pocket)
  - Specific to a single/few task(s)
  - Connectivity problems (Wi-Fi deconnexion)

Electronic traceability of a cytotoxic

Préparation cyt/16-408119 GEMCITABINE 1920 mg

Patient	Nom		Prénom		Date de naissance	05/06/1942	No Ttt / Unité	OH-NOR
Administration	Date	04.04.2016 08:00	No Cycle	1	No Jour	1	Durée	30 minute
Contact	Médecin		BIP		Etude			

Visas: **When ?** **What ?** **Who?**

Date visa	Date opération	Type	Initiales	Remarques
01.04.2016 13:56:03	01.04.2016 13:56	prescription Gemcitabine; Oxaliplatine (GEMOX) (1086)	auvr	
01.04.2016 14:21:29	01.04.2016 14:21	Fiche de fabrication	edls	
01.04.2016 14:21:32	01.04.2016 14:21	sortie matériel	edls	
01.04.2016 14:30:17	01.04.2016 14:30	mat+etiq	kery	
01.04.2016 14:30:19	01.04.2016 14:30	envoyé à Cato	kery	
01.04.2016 14:30:50	01.04.2016 14:30	information	kery	Etiquette imprimée, date de péremption : 14.04.2016 08:00, préparation : 04.04.2016 08:00
04.04.2016 07:39:09	04.04.2016 07:37	cato	vrcs	Préparation terminée correctement (isolateur 1/PHAR-7013).
04.04.2016 07:39:09	04.04.2016 07:37	cato	vrcs	Gemcitabin 40 mg/ml_SANDOZ 1924 mg (100.21%)
04.04.2016 07:39:09	04.04.2016 07:37	preparation	vrcs	Préparé par CATO
04.04.2016 07:39:09	04.04.2016 07:37	à facturer	vrcs	Préparé par CATO
04.04.2016 09:05:20	04.04.2016 09:05	Livraison	mjrm	
04.04.2016 09:10:45	04.04.2016 09:10	debutAdmin	naju	
04.04.2016 09:49:10	04.04.2016 09:49	finAdmin	naju	

Produits utilisés :

Quantité	Nom	Type	No Diogène	No Lot	No reste CATO
1	Gemcitabin Sandoz® 2000mg = 50ml	solutionPreteAEmploi	450113	FR6661-30/06/18	
1	NaCl 0,9% 250/500 ml	solutionPreteAEmploiDiluant	97803	15102234A-31/10/18	

Préparation effectuée dans: Isolateur 1

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Tracking of cytotoxics

Libellé produit:		Nom patient:	
Composant:		Date protocole:	(JJ.MM.AAAA)
Préparé entre le:	(JJ.MM.AAAA)	et le:	(JJ.MM.AAAA)
Numéro lot:	null	Lot spécifique:	FR6661-30/06/18
Isolateur:		Mnémo unité:	
Seulement prép. annulées:	☐	Seulement prép. bloquées:	☐

Chercher Annuler

Préparations correspondant aux critères:

No préparation	Nom Patient	Unité	Libellé	Date protocole	Date préparation	Isolateur	% Cato
cyt/16-408483		OH-INF	GEMCITABINE 1560 mg	06.04.16 16:00			
cyt/16-408390		7BL-US	GEMCITABINE 2100 mg	05.04.16 16:00	06.04.16 10:19	Isolateur 1	101.42
cyt/16-408362		OH-INF	GEMCITABINE 1600 mg	05.04.16 12:16	05.04.16 14:56	Isolateur 1	95.92
cyt/16-408285		OH-NOR	GEMCITABINE 1700 mg	04.04.16 14:07	05.04.16 11:01	Isolateur 1	101.62
cyt/16-408278		OH-NOR	GEMCITABINE 1450 mg	04.04.16 13:47	05.04.16 10:52	Isolateur 1	98.21
cyt/16-408258		OH-INF	GEMCITABINE 400 mg	04.04.16 11:34	04.04.16 14:41	Isolateur 2	97.74
cyt/16-408119		OH-NOR	GEMCITABINE 1920 mg	01.04.16 13:56	04.04.16 07:37	Isolateur 1	100.21
cyt/16-408116		OH-INF	GEMCITABINE 1450 mg	01.04.16 13:47	04.04.16 11:00	Isolateur 1	
cyt/16-408053		ONCPEL-CS	GEMCITABINE 1100 mg	31.03.16 16:47			
cyt/16-407978		OH-INF	GEMCITABINE 1560 mg	30.03.16 17:04	31.03.16 08:12	Isolateur 2	99.89
cyt/16-407866		ONCPEL-CS	GEMCITABINE 1128 mg	29.03.16 17:29			
cyt/16-407819		OH-NOR	GEMCITABINE 1050 mg	29.03.16 10:39	30.03.16 08:41	Isolateur 1	103.71
cyt/16-407631		OH-NOR	GEMCITABINE 1450 mg	24.03.16 12:01	29.03.16 10:41	Isolateur 2	101.19
cyt/16-407576		ONCPEL-CS	GEMCITABINE 1760 mg	23.03.16 17:46	24.03.16 08:00	Isolateur 1	
cyt/16-407569		OH-NOR	GEMCITABINE 1500 mg	23.03.16 16:58	24.03.16 08:49	Isolateur 2	101.29
cyt/16-407561		OH-INF	GEMCITABINE 1800 mg	23.03.16 16:20	24.03.16 08:17	Isolateur 2	96.89
cyt/16-407453		OH-NOR	GEMCITABINE 1050 mg	22.03.16 12:22	23.03.16 10:42	Isolateur 1	101.01
cyt/16-407392		OH-NOR	GEMCITABINE 1700 mg	21.03.16 16:44	22.03.16 08:13	Isolateur 2	102.5
cyt/16-407382		OH-NOR	GEMCITABINE 1700 mg	21.03.16 15:43	22.03.16 10:50	Isolateur 2	101.23
cyt/16-407293		7BL-US	GEMCITABINE 2238 mg	20.03.16 18:50			
cyt/16-407179		OH-INF	GEMCITABINE 1550 mg	18.03.16 12:08	21.03.16 07:33	Isolateur 2	102.24

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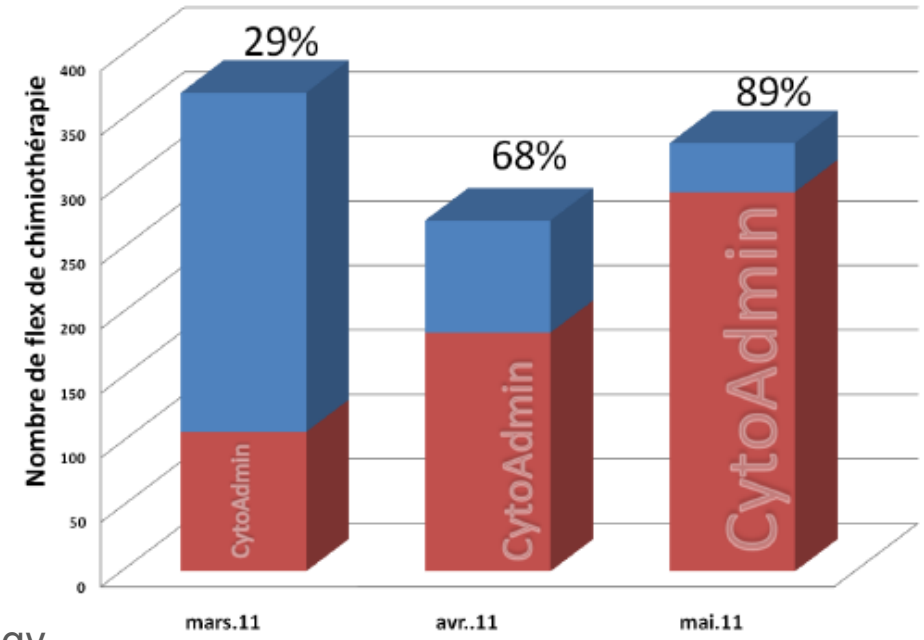
Follow the implementation

- **Scanning rates** during the first months



Outpatient medical oncology

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Fleury M, HUG, 2012

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Consider users

	Résistant	Fonctionnel	Expert
Usages TIC	Cite 0 à 2 usages Peu ou pas d'outils. Usages basiques.	Cite 3 à 6 usages Outils et leurs fonctionnalités. Usages autonomes.	Cite 7 et plus usages Maîtrise du hardware comme du software.
Oncogynécologie ambulatoire	0	3	2
Onco-hématologie	1	4	3
Oncologie ambulatoire	2	6	4
Oncologie stationnaire	0	6	0
Totaux	3	18	9

Consider environment

- 31h observation (onco-gynaecology, outpatient clinic)
- 89 stressors (2.7/h), 27 unplanned movements
- 24% related to the bedside scanning software

Type de stresseur	Sommes par types de stresseurs	Pourcentage cumulé
Sonnerie téléphone	13	15%
Besoin d'un médecin pour supervision	9	10%
CytoAdmin, problème de disponibilité de l'ordinateur mobile	8	9%
Panne informatique, hors CytoAdmin (logiciel, redémarrage de l'ordi)	8	9%
CytoAdmin, problème technique avec l'ordinateur mobile	5	6%
Problème voie d'administration (DAVI sans reflux, etc.)	5	6%
Patiente non programmée, sur le pas de la porte	3	3%
Patient non francophone	3	3%
Sonnerie non identifiée	3	3%
CytoAdmin, problème avec le bracelet du patient (impression impossible)	2	2%
CytoAdmin, problème de processus (pas stoppé l'administration, etc.)	2	2%
CytoAdmin, problème de lecture du Data Matrix (étiquette chimio pliée, etc.)	2	2%
CytoAdmin, bracelet à poser sur la patiente (emplacement alternatif cheville)	2	2%
Péjoration de la clinique de la patiente	2	2%

Advices

- Use standard identification system
- Involve specialists of standards
- Use robust technologies (data carrier, readers…)
- Have a strategy, but…
- Start small and scale-up (selected processes and areas)
- Involve the users and identify the workarounds
- Do not re-invent the wheel

Next steps

- Blood transfusion
- Drugs, starting with
  - Biologicals (traceability)
  - High-risk drugs (safety)
- Implantable medical devices
- Patient transportation
- …

Thank you for your attention

Tom Thumb - Traceability by Charles Perrault

The presentation can be downloaded
http://pharmacie.hug-ge.ch/ens/conferences.html

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