Pervasive traceability: Improving safety in the administration of chemotherapies

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Chemotherapy…

- Often very efficient treatments but…
- Life-threatening side effects
- Dangerous products (e.g. for skin)
- Requires very high level of attention from nurses & clinicians
- Prepared at the central pharmacy
- Limited duration of usability
- High cost
“Old” Process

- Clinician prescribes a chemotherapy
  - Hand computation of doses
  - Self control of maximal doses
- Clinician confirms week per week the chemotherapy
  - Protocol is faxed to the pharmacy
- Pharmacist produces the chemotherapeutic agents
  - Recipe is completed by pharmacists (template)
  - Medication is prepared generally one by one
- Clinician or nurse administers the medication
  - Information written on the label
- Partial traceability through paper & pharmacy’s internal management application
Goals

- Electronic prescription
- Electronic transmission to the pharmacy
- No retranscription of important information
- Automation of the production of the recipe
- Support during the fabrication
- Control before / during / after the administration
- Traceability from the prescription to the administration
Full traceability

- Patient ID
- Protocol
- Preparation
- SIH
- Substances + doses
- Visas
- Workflow
- Preparation, batch numbers, etc.
- Batch numbers
- Weighter-aided control

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Prerequisites

• Description of the “ingredients”:
  • Available substances
  • Rules for preparation
  • Rules for administration
  • Stability, possible mixes, etc.

• Description of chemotherapy protocols:
  • Substances
  • Doses
  • Calendar of administration
  • Constraints

• Descriptions maintained by clinicians & pharmacists
Prescription module

- Clinicians are forced to use protocols
- Automatic computation of doses according to selected patient
- Automatic limitation of doses
- Reduction is possible
- History available
- Confirmation week per week
- Prescription & confirmation available in the patient record
- Confirmed prescription placed into the work list of the pharmacy
- Pending prescriptions visible from the pharmacy
**Demandes de préparations de chimiothérapies**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Nom</th>
<th>Prénom</th>
<th>Date de naissance</th>
<th>No Ttt</th>
<th>Unité</th>
<th>Poids (kg)</th>
<th>Taille (cm)</th>
<th>Surface corporelle (m²)</th>
<th>Créatinine</th>
<th>Clairance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Médicin</td>
<td>BIP</td>
<td></td>
<td>30.07.1963</td>
<td></td>
<td></td>
<td>70</td>
<td>170</td>
<td>1.81</td>
<td>55</td>
<td>75.1</td>
</tr>
</tbody>
</table>

**45-EP-cycle1**

Protocole de 1 cycle(s) de 28 jour(s) chacun.

<table>
<thead>
<tr>
<th>dcl</th>
<th>dose protocole</th>
<th>dose prescription</th>
<th>Pourcentage</th>
<th>J01</th>
<th>J02</th>
<th>J03</th>
<th>J04</th>
<th>J05</th>
<th>J06</th>
<th>J07</th>
<th>J08</th>
<th>J09</th>
<th>J10</th>
<th>J11</th>
<th>J12</th>
<th>J13</th>
<th>J14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modifié</td>
<td>Cisplatin 35mg/m² i.v dans NaCl 0.9% 500 ml en 60 min.</td>
<td>45 mg</td>
<td>45 mg</td>
<td>180</td>
<td>%</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modifié</td>
<td>Etoposide 100mg/m² i.v dans Glucose 5% 500 ml en 60 min.</td>
<td>101 mg</td>
<td>101 mg</td>
<td>180</td>
<td>%</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Administration**

- Date début: 01.04.2006
- heure:minute: 10:00
- No Cycle: 1
- Protocole partiel: date début = J1

**Commandes effectuées précédemment:**

<table>
<thead>
<tr>
<th>Nom protocole</th>
<th>No Cycle</th>
<th>J1</th>
<th>Date prescription</th>
<th>Visa pres.</th>
<th>Date comm.</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-EP-cycle1</td>
<td>1</td>
<td></td>
<td>01.03.2006 20:00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tamôterol + Cisplatin + RTX persistance</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Recipe production module

- Pharmacist selects preparations to be produced
- Possibility to group preparations with same substances
  - Local rule: only for the same patient!
- Production of the recipe according to rules
- Electronic archival of recipe
**FORMATION** Nouvelle, New 30/07/1963  
Utilisateur Demo  
Bip:

<table>
<thead>
<tr>
<th>J1</th>
<th>10.02.2006 20:00</th>
<th>F-CYT/06-121</th>
<th>Onco4</th>
<th>inconnu</th>
<th>00000</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>DACARBAZONE 1448 mg</th>
<th>Glucose 5% 250 ml</th>
<th>INTRA VEINEUX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poche</td>
<td></td>
<td>Durée: 30 min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nb Produit</th>
<th>Conc.</th>
<th>Matériel</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 DTIC-DOME® 200 mg</td>
<td>10 mg/ml</td>
<td>1 Aiguille</td>
</tr>
<tr>
<td>2 Eau distillée 100 ml</td>
<td></td>
<td>1 Cytosafe</td>
</tr>
<tr>
<td>1 Glucose 5% 250 ml</td>
<td></td>
<td>1 Seringue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 Tubulure opaque</td>
</tr>
</tbody>
</table>

**Mode opératoire**

<table>
<thead>
<tr>
<th>Dissoudre (cytosafe)</th>
<th>8 * [ DTIC-DOME® 200 mg + Eau distillée 19.7 ml ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retirer:</td>
<td>Glucose 5% 250 ml 94.8 ml</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prélever (cytosafe) et ajouter ce volume à la poche</th>
<th>DTIC-DOME® 10 mg/ml 144.8 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Volume final: 300 ml</td>
</tr>
</tbody>
</table>

**Stabilité:**  24 heure(s)  
Au frigo  
À l'abri de la lumière + tubulure opaque

**Remarques:**  
Stabilité: 8 h à température ambiante  
Comprimé dans une 250 ml de Glucose 5%
Workflow management @ pharmacy

- Follow-up of the status of the preparation
- Recording of exact lot numbers
- Link with software for computer aided fabrication (CATO)
- Traceability management
- Printing of labels
"Last mile"

- Administration phase is critical
- Wrong administration may cause death
  - Administration through wrong path
  - Substance no more usable
  - Wrong patient
  - Etc.
- Need for:
  - Reliable identification of patient, preparation, intervener
  - Check of adequacy
  - Information when specific controls have to be performed
Identification

- Clinicians/nurses: SC & RFID (13.56 MHz) ID card available
- Patient: wristband
  - Bar code: not really suitable (perception, readability)
  - RFID tag in the label (125 MHz)
- Medication:
  - Linear barcode: no space on the label!
  - RFID tag in the label (125 MHz)
  - 2D barcode: possible, but limited availability of readers
- Identification occurs at least:
  - Before starting the administration
  - At each change of nurse
  - At the end of the administration
- Standard identification: GS1-128 (formerly UCC/EAN)
Identification terminal

- At the bedside
- Several clinicians & nurses
- Potentially several patients & medications

→ Portable device:
  → Pocket PC
  → RFID reader
  → On-line (WLAN)
Architecture

Scanner

GS1 codes

Cache (scanned codes)

Retrieval of codes

PDA Application

Decoding of GS1 codes

GS1 codes server

Validation

Traceability Application

Web Pages (user interface)

GS1 codes

Web Page

RFID

GS1 codes

Server

Page Cache (scanned codes)

Application

GS1 codes

Retrieval of codes

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GS1 codes server

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Traceability Application

Web Pages (user interface)
Benefits

- No retranscription any more
- Recording of what has been administered & when in the electronic patient record
- Better follow-up of the preparations for the pharmacy
- Possibility to block the administration until the very last moment
- Very limited risk of error left at administration phase
- Enhanced quality control
- Global traceability
Key success factors

- Strong involvement of all partners – clinicians, nurses, pharmacists
- Modular architecture → integration step by step
- Integrated system:
  - Every patient-related data is in the patient record
  - No double capture of information
  - Central logging facility
Status of the project

- Electronic prescription, preparation & workflow management at the pharmacy in production for more than one year
  - Very good acceptance by clinicians and pharmacists
  - New departments will join the infrastructure soon

- Last mile evaluated without patients:
  - Very good acceptance by nurses
  - Better problem detection
  - Valuable support for the work (higher level of security)

- Pilot in one ward (with patients) in August 2006
Main problems encountered

- Get and formalize the knowledge form the pharmacists
- Get the resources to describe and validate chemotherapy protocols
- Technical problems:
  - Programming RF-ID chips in labels
  - Getting the right label format
  - Stability of the drivers for the PDA
  - Bi-frequencies + 1D & 2D barcodes readers
- Request for unique ids on raw substances not satisfied yet