Implementation of ISBT 128 through the development of an ISBT 128-compliant software

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ISBT 128, some reminders

- launched in 1994
- first implemented in 1997
- 2010
  - ~ 70 countries
  - more than 3 500 facility identifiers assigned
- several technical advisory groups ensure that terminology meets the needs of users
- ISBT 128 is managed by ICCBBA, a not-for-profit organisation
Why switching to ISBT 128-compliant terminology? General reasons

- international exchange of cells and tissues is continuously growing: around 50% of stem cell donations are shipped internationally

- WHO, 2010: “[…] encourages the implementation of globally consistent coding systems for human cells, tissues and organs […]”

- harmonized denominations are easier to deal with
  - communication between centers
  - elimination of language barriers
Why switching to ISBT 128-compliant terminology? FACT/JACIE accreditation

- **current 4th edition of FACT/JACIE standards**
  - require the use of ISBT 128 terminology
  - “cellular therapy products shall be identified according to the proper name of the product, including appropriate modifiers, manipulations, and attributes, as defined by ISBT 128”

- **5th edition of FACT/JACIE standards**
  - require an implementation plan for the usage of ISBT 128

- **6th edition of FACT/JACIE standards**
  - will require full implementation of ISBT 128
Why switching to ISBT 128-compliant terminology?
5th edition of FACT/JACIE standards

- “cellular therapy products shall be identified according to the proper name of the product, including appropriate modifiers, manipulations, and attributes, as defined by in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions”

- “if the collection/processing facility has not fully implemented ISBT 128 technology, an implementation plan for the usage of ISBT 128 coding and labeling shall be in place”

- open to public comment until July 14, 2011
- final 5th edition of the standards
  - will be published on March 1, 2012
  - will become effective on May 30, 2012
Why switching to ISBT 128-compliant terminology?

Local reasons

- **fits your needs**
  - ISBT 128 coding and labeling is flexible
  - labelling still compliant with national regulations

- **improves safety**
  - the receiving facility can have access to detailed product characteristics regardless of the language on the label

- **improves efficiency**
  - use of bar codes allows for scanned entry of product codes, identification, etc
  - saves time
    - what’s the type of anticoagulant in your BM harvest?
    - what’s the GMT time you harvested the product?
    - ...

ISCT meeting 2011, Rotterdam
Why switching to ISBT 128-compliant labels? Our reasons

- on-site transplantation program
  - apheresis unit
  - cell therapy facility
  - cord blood bank
  - transplant units

- JACIE-accredited program since 2008

- level of activity (per year)
  - 150 allos-HSCT, 250 autos-HSCT
  - 1 600 bags labelled
Why switching to ISBT 128-compliant labels? Our reasons

- **staff motivation**!

- **historical & illogical product coding system**
  - 07051
    - HPC, apheresis
    - cryopreserved HPC, apheresis
    - thawed and washed HPC, apheresis
  - limited to Marseille geographical area!

- **lack of national coding system**

- **manual labeling system**
  - thermal printer
  - hand-made labels
## Modifications majeures : codes produits

<table>
<thead>
<tr>
<th></th>
<th>cssp auto prélevées</th>
<th>cssp auto congelées</th>
<th>cssp auto décongelées</th>
</tr>
</thead>
<tbody>
<tr>
<td>système actuel</td>
<td>07051</td>
<td>07051</td>
<td>07051</td>
</tr>
<tr>
<td>système ISBT128</td>
<td>S1128</td>
<td>S1521</td>
<td>S1523</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>S1524</td>
</tr>
</tbody>
</table>

Institut Paoli-Calmettes
I’ve decided to move on: where do I start from?

1. **register your facility with ICCBBA**
   - full access to educational material and FAQ
     @ [http://www.iccbba.org/home](http://www.iccbba.org/home)

2. **take time to understand ISBT 128 basics**
   - read (and understand!) ISBT 128 documentation
   - ask ICCBBA staff -> *very responsive and helpful*

3. **establish a correspondence list between current product codes and ISBT 128 codes**
   - find the corresponding ISBT 128 codes among existing ones
   - request new codes if necessary

4. **for non english-speaking countries**
   - try to set up a workgroup to establish national-level translations
### Cellular Therapy Product Description Code Request Form

Form for use by facilities making requests to the ICCBBA office. Please see instructions here.

<table>
<thead>
<tr>
<th>Facility Identification Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Name</td>
<td></td>
</tr>
<tr>
<td>Contact Email Address</td>
<td></td>
</tr>
<tr>
<td>Component Class</td>
<td></td>
</tr>
<tr>
<td>Modifier</td>
<td></td>
</tr>
<tr>
<td>Anticoagulant Type</td>
<td></td>
</tr>
<tr>
<td>Volume</td>
<td></td>
</tr>
<tr>
<td>Storage Temperature</td>
<td></td>
</tr>
<tr>
<td>Intended Use</td>
<td></td>
</tr>
<tr>
<td>Manipulation</td>
<td></td>
</tr>
<tr>
<td>Preparation: Cryoprotectant</td>
<td></td>
</tr>
<tr>
<td>Preparation: Blood Component From Third Party Donor</td>
<td></td>
</tr>
<tr>
<td>Preparation: Other Additives</td>
<td></td>
</tr>
<tr>
<td>Genetically Modified</td>
<td></td>
</tr>
</tbody>
</table>

- HPC, Apheresis
- Cryopreserved
- Citrate
- XX
- <= -150C
- Default For administration
- Default No manipulation
- 7.5% DMSO
- Default 3rd party comp: NO
- Other additives: YES
- Default Genetically Modified: NO

[Submit to ICCBBA] [Reset]
I’ve decided to move on: implementation calendar

5. define what you have and what you need
   – adequate labels, barcode readers, thermal printers ...
   – software
     • basic (pre-defined codes)
     • advanced (ability to generate all existing ISBT 128 product codes)

6. set up an implementation calendar
   – purchase and/or develop a labelling software
   – validate software and labels with your codes
   – review institutional documents that need to be revised
   – prepare educational material
   – plan meetings with your staff
I’ve decided to move on: labels and printers

- **labels**
  - at least FDA 175.105-compliant adhesive
  - liquid-nitrogen resistant

- **printers**
  - thermal transfer technology
  - compliant with ISBT 128-recommended label sizes

- **printer and label validation**
I’ve decided to move on: what will be the costs associated with ISBT 128 transition?

- $ prescription forms
- $ traceability forms (if not electronic)
- $ labels (if size not ISBT 128 compliant)
- $$ label printers
- $$$-$$$$ software
Development of an ISBT 128-compliant software

- **context**
  - previous development of a storage management software
  - successful collaboration with the company (Modul-Bio)
  - lack of flexible « multilingual » ISBT 128-compliant software
  - willingness to limit the number of softwares

- **software development**
  - appropriation of ISBT 128 specificities
  - test phase and production phase

- **benefits**
  - complementary expertises
  - custom-made software
### Mode de conservation

<table>
<thead>
<tr>
<th>English</th>
<th>French</th>
</tr>
</thead>
<tbody>
<tr>
<td>Store at -120 C or colder</td>
<td>A conserver à -120°C minimum</td>
</tr>
<tr>
<td>Store at -150 C or colder</td>
<td>A conserver à -150°C minimum</td>
</tr>
<tr>
<td>4-14 C to 14-8 C</td>
<td>A conserver entre +4°C et +8°C</td>
</tr>
<tr>
<td>Store at Room Temperature</td>
<td>A conserver entre +20°C et +24°C</td>
</tr>
<tr>
<td>Store at -80 C or colder</td>
<td>A conserver à -80°C minimum</td>
</tr>
</tbody>
</table>

### Nature des produits cellulaires

<table>
<thead>
<tr>
<th>English</th>
<th>French</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryopreserved HPC, APHERESIS</td>
<td>CSF d’aphérèse, cryopréservée</td>
</tr>
<tr>
<td>Cryopreserved HPC, CORD BLOOD</td>
<td>CSF du sang placentaire, cryopréservée</td>
</tr>
<tr>
<td>Cryopreserved HPC, MARROW</td>
<td>CSF de moelle osseuse, cryopréservée</td>
</tr>
<tr>
<td>Cryopreserved TC-T CELLS</td>
<td>Lymphocytes T, cryopréservés</td>
</tr>
<tr>
<td>HPC, APHERESIS</td>
<td>CSF d’aphérèse</td>
</tr>
<tr>
<td>HPC, CORD BLOOD</td>
<td>CSF du sang placentaire</td>
</tr>
<tr>
<td>HPC, MARROW</td>
<td>CSF de moelle osseuse</td>
</tr>
<tr>
<td>Pooled, Single Donor Thawed Washed HPC, APHERESIS</td>
<td>CSF d’aphérèse, poolées, décongelées et lavées</td>
</tr>
<tr>
<td>TC, APHERESIS</td>
<td>Leucocytes d’aphérèse</td>
</tr>
<tr>
<td>TC-T CELLS</td>
<td>Lymphocytes T</td>
</tr>
<tr>
<td>Thawed HPC, CORD BLOOD</td>
<td>CSF du sang placentaire, décongelée</td>
</tr>
<tr>
<td>Thawed Washed HPC, APHERESIS</td>
<td>CSF d’aphérèse, décongelée et lavée</td>
</tr>
<tr>
<td>Thawed Washed HPC, CORD BLOOD</td>
<td>CSF du sang placentaire, décongelée et lavée</td>
</tr>
<tr>
<td>Thawed Washed HPC, MARROW</td>
<td>CSF de moelle osseuse, décongelée et lavée</td>
</tr>
<tr>
<td>Thawed Washed TC-T CELLS</td>
<td>Lymphocytes T, décongelée et lavée</td>
</tr>
</tbody>
</table>

### Types d’attributs

<table>
<thead>
<tr>
<th>English</th>
<th>French</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Conditions</td>
<td>conditions de conservation</td>
</tr>
<tr>
<td>Manipulation</td>
<td>type de transformation</td>
</tr>
<tr>
<td>Cryoprotectant</td>
<td>cryoprotecteur</td>
</tr>
<tr>
<td>Blood Component from 3rd Party Donor</td>
<td>produit sanguin homologue</td>
</tr>
<tr>
<td>Other Additives</td>
<td>autres additifs ou RTA</td>
</tr>
<tr>
<td>Actifs</td>
<td>Inactifs</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>CSH d’aphérèse, cryopréservées</td>
<td>CONCURRENT PLASMA, APHERESIS</td>
</tr>
<tr>
<td>CSH du sang placentaire, cryopréservées</td>
<td>Cryopreserved HPC, WHOLE BLOOD</td>
</tr>
<tr>
<td>CSH de moelle osseuse, cryopréservées</td>
<td>Cryopreserved NC ADIPOSE CELLS</td>
</tr>
<tr>
<td>Lymphocytes T, cryopréservées</td>
<td>Cryopreserved Non-Mobilized HPC, WHOLE BLOOD</td>
</tr>
<tr>
<td>CSH d’aphérèse</td>
<td>Cryopreserved TC APHERESIS</td>
</tr>
<tr>
<td>CSH du sang placentaire</td>
<td>Cryopreserved TC-CTL</td>
</tr>
<tr>
<td>CSH de moelle osseuse</td>
<td>Cryopreserved TC-IDC</td>
</tr>
<tr>
<td>CSH d’aphérèse, polées, décongelées et lavées</td>
<td>Cryopreserved TC-MSC</td>
</tr>
<tr>
<td>Leucocytes d’aphérèse</td>
<td>Cryopreserved TC-MSC- MD</td>
</tr>
<tr>
<td>Lymphocytes T</td>
<td>Frozen CONCURRENT PLASMA, APHERESIS</td>
</tr>
<tr>
<td>CSH du sang placentaire, décongelées</td>
<td>HPC, WHOLE BLOOD</td>
</tr>
<tr>
<td>CSH d’aphérèse, décongelées et lavées</td>
<td>Mobilized HPC, MARROW</td>
</tr>
</tbody>
</table>
### Informations relatives au produit cellulaire

<table>
<thead>
<tr>
<th>Nature du produit cellulaire</th>
<th>Lymphocytes T, décongelés et lavés</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attribut 1</td>
<td></td>
</tr>
<tr>
<td>conditions de conservation</td>
<td>non précisé/XX/26-24°C</td>
</tr>
<tr>
<td>Attribut 2</td>
<td></td>
</tr>
<tr>
<td>produit sanguin homologue</td>
<td></td>
</tr>
<tr>
<td>type de transformation</td>
<td>déplié en plasma</td>
</tr>
<tr>
<td>Attribut 3</td>
<td></td>
</tr>
</tbody>
</table>

### Informations relatives à la personne prélevée

- **Groupe sanguin**
  - A

- **Rhésus**
  - Positif
  - Négatif

- **Risque biologique**
  - Oui
  - Non
  - Dérogation médicale (bilan séro incomplet, ...)

- **Type de don**
  - Autoalgique
  - Allergique (don dirigé)

- **Donneur apparenté**
  - Oui
  - Non
Informations relatives au prélèvement

- Centre de collection: Unel d'Epalinges IPC
- Date de collection: 26/04/2011
- Heure de fin de collection: 12:50
- N° du don: 1234567
- Ident. de la personne préllevée: FRANCAEL
- Date de naissance: 02/05/1938

Informations relatives au patient receveur

- IPP: 110021
- Nom de naissance: COLLOT
- Date de naissance: 06/11/1945

Informations relatives au produit cellulaire distribué

- Volume: 135 ml

Information complémentaire

- Mode de conservation: A conserver entre +20°C et +24°C
- Centre de transformation: Centre de Thérapie Cellul.
Information
- Le ou les numéro(s) d'identification des dons sont:
  - F0001 11 1234567 00 9 associé au code produit S1541400

Aperçu avant impression

<table>
<thead>
<tr>
<th>Modèle d'étiquettes</th>
<th>Langue</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mm x 100 mm</td>
<td></td>
</tr>
</tbody>
</table>

Impression

F0001 11 1234567 00 9
Collection center
Maternité Saint-Louis
Saint-Louis Cord Blood Bank
Saint-Louis USA
Collection date and time
01 APR 2011 16:00
(01 APR 2011 10:00 PM GMT)

S1541 4 00
Designated
Thawed Washed HPC, CORD BLOOD
Volume: 175 ml
Store at Room Temperature
DO NOT IRRADIATE
Transformation center
Centre de Thérapie Cellulaire
Institut Paoli-Calmettes
Marseille France

Ri negative

For Use by Intended Recipient Only
Unintended Recipient Only
Donor
US1232239570US282329857
SP 05/4/2011 1111277

Expiration date and time
06 MAY 2011 16:15
(06 MAY 2011 5:15 PM GMT)
Receiver
CRT
SER
05/05/2006

Admission Center
Unite d'Hematologie Fédérative
Assistance Publique Hôpitaux de Marseille
Marseille France

ISCT meeting 2011, Rotterdam
ISCT meeting 2011, Rotterdam
Before and after!

- **before ISBT 128 implementation**
  - 10 product codes

- **after ISBT 128 implementation**
  - 35 product codes

Before ISBT 128 implementation – 10 product codes

- ISCT meeting 2011, Rotterdam
What are, IMHO, the keys to succeed in transition?

- prepare staff way in advance to transition
- keep staff informed about the implementation calendar
- implicate staff in the process
  - translation
  - equipment choice and validation
  - problems anticipation
  - ...

ISCT meeting 2011, Rotterdam
What are, IMHO, the keys to succeed in transition?

- plan short meetings with specific supports
  - with transplant MDs
  - with transplant nurses
  - with apheresis nurses
  - with cell therapy technician

- plan dedicated meetings
  - one for explaining what is ISBT 128 and why it is important to implement
  - one for reviewing the key steps for the laboratory

- take time to explain
  - it’s not just a new label!
  - it will improve patient safety
  - it’s mandatory for being FACT/JACIE compliant
S1xxx 100 : autologue, séros négatives

S1xxx E00 : autologue, séros non connues

S1xxx X00 : autologue, séros positives
What are, IMHO, the keys to succeed in transition?

- prepare dedicated training materials and ISBT 128 memos to post
  - cell therapy lab
  - apheresis unit
  - transplant unit

- send label examples to transplant units that will use your products

- prepare SOPs modification but wait until ISBT 128 is fully implemented to update SOPs

- have a dedicated phone number for the first weeks!
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ISCT meeting 2011, Rotterdam
yes, you can!