

ISBT 128 coding and labeling of cellular therapy products worldwide

Ineke Slaper-Cortenbach

i.slaper@umcutrecht.nl

Chair of CTCLAG

Why ISBT 128 coding for cellular therapy products

- ISBT 128 is a coding and labeling system, developed in 1994 for blood and blood products
- In 2004: EU Directive on safety and quality of tissues and cells was published
- At EBMT in Prague (2005) a meeting was arranged between:
 - ICCBBA: Paul Ashford
 - JACIE: Eoin McGrath, Diana Samson, Derwood Pamphilon and Ineke Slaper-Cortenbach (ISCT Europe);
 - FACT/ISCT: Adrian Gee
 - Experts: Alan Lankester and Stella Larson

EU Directive 2004/23/EC: *Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*

- Establishment of a register of entities operating in the field
- Designation of the competent authority (ies) in Member States
- Implementation of a quality system for tissue establishments (SOPs, guidelines, training & reference manuals, reporting forms, donor records etc.)
- Introduction of a system of accreditation of tissue establishments by Member States and a system for notification of adverse events and reactions
- Organisation of inspections and control measures within Member States
- **Ensurance of data protection and confidentiality.**
- **Assurance of traceability of tissues and cells** through laboratory identification procedures, record maintenance and an appropriate labelling system
- **Design of a single European coding system**

Why ISBT 128 coding for cellular therapy products

- ***Decided to use ISBT 128 for all “cellular therapy” products to provide an uniform coding and labeling system worldwide***
 - **Globally unique donation identification number**
 - **International product description list with definitions and codes**
 - **Standard data structures for donation numbers, product descriptions and other information**



Activities of the Cellular Therapy Coding & Labeling Advisory Group

Cellular Therapy Coding & Labeling Advisory Group

- review existing regulation regarding labeling
- design product label templates that satisfy regulatory requirements
- provide a focus for the standardization of terminology and product naming
- promote the adoption of the *ISBT 128* standard in cellular therapy facilities around the world
- provide advice and support to facilities introducing the standard
- advise on the ongoing development of the *ISBT 128* standard to support new developments in cellular therapy

Cellular Therapy Coding & Labeling Advisory Group



Cellular Therapy Coding & Labeling Advisory Group

Members:

- Slaper-Cortenbach, Ineke (Chair person)
- Allman, Sallie
- Ashford, Paul
- Distler, Pat (Secretary)
- Feller, Irene
- Gee, Adrian
- Lankester, Alan
- Larsson, Stella
- Lazarus, Ellen/ Yong Fan
- Loper, Kathy
- Pamphilon, Derwood
- Sims Poston, Leigh
- Szczepiorkowski, Zbigniew
- Warkentin, Phyllis
- Koh, Mickey & Takaue, Yoichi

Affiliation

- JACIE / ISCT Europe representative
- NMDP representative
- ICCBBA representative
- ICCBBA representative
- Technical expert
- Technical expert
- Technical expert
- Technical expert
- Technical expert
- FDA Liaison
- AABB representative
- EBMT and WMDA representative
- ISCT representative
- ASFA representative
- FACT representative
- APBMT representative

International Cellular Therapy Coding and Labelling Advisory Group

- **Two papers for cellular therapy products:**
 - **cellular therapy terminology and labelling;**
 - **implementation plan for cellular therapy products**
- **Published in Transfusion, BMT and J.Clin. Apher. 2007**
- **See www.iccbba.org for more information**
- **Participation with EU in CEN open workshop in 2008/2009 on the Single European coding system**



Product Codes developed by ICCBA with EU support

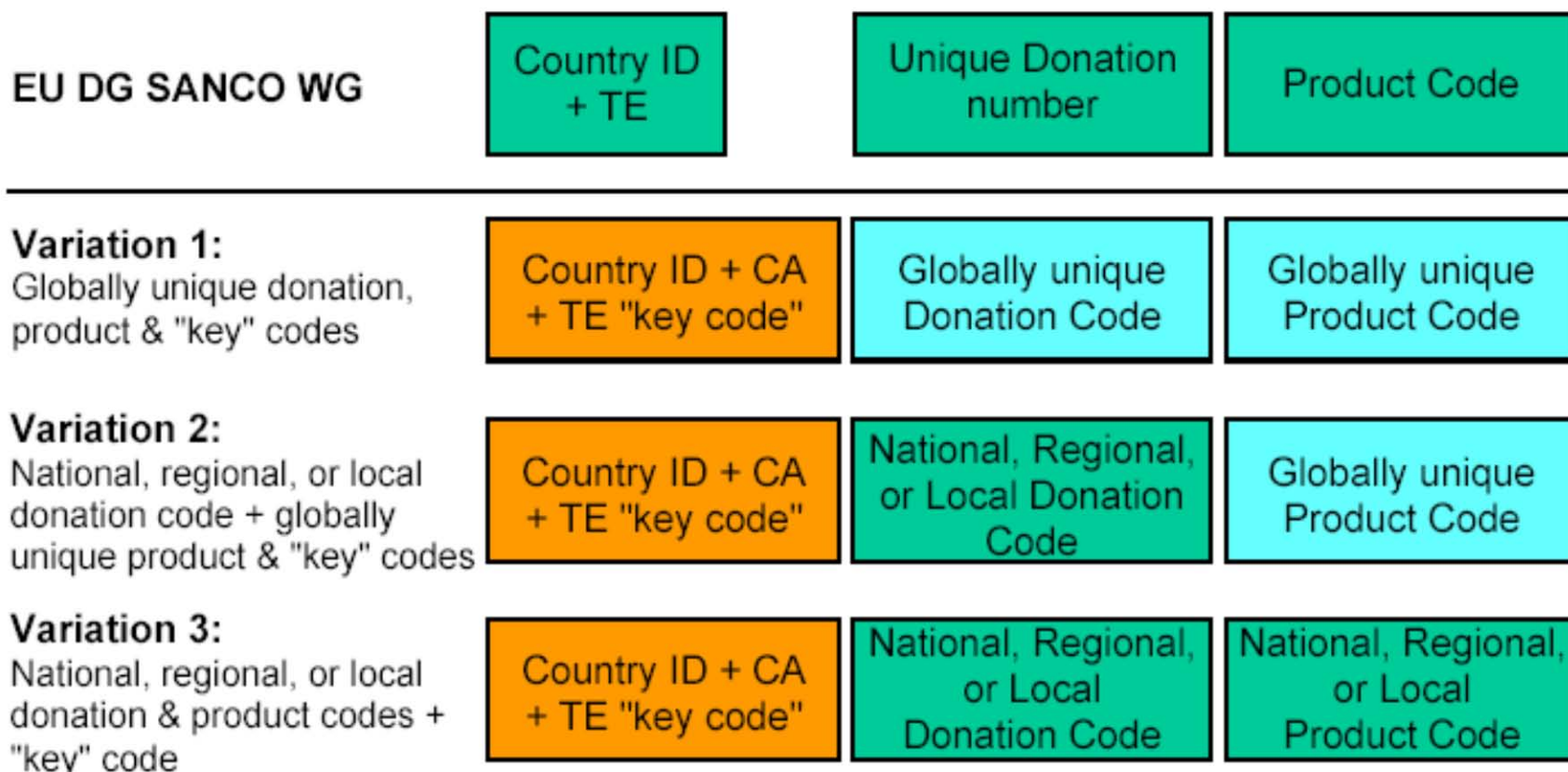


Figure 11.2: Proposed EU code structure Variations



ISBT 128 coding and labeling of cellular therapy products

ISBT 128 Structure of Terminology

- **Classes**
 - Classes are broad definitions of products: HPC, Cord Blood; HPC, Marrow; TC, Apheresis; and TC-MS, TC-DC and TC-T cells for processed products.
- **Modifiers**
 - Modifiers are applied to Classes in order to provide the next step in the categorization of the product.
 - Examples are Cryopreserved, Thawed, Washed, and Mobilized
- **Attributes**
 - Attributes provide the means to uniquely define products.
 - Core conditions (anticoagulant type, volume and temperature)
 - Groups and variables (intended use, manipulation, additives etc)

Cellular Therapy Coding & Labeling Advisory Group

Product Class: Comma vs. Hyphen

- Category 1: Comma
 - At collection, the product code will describe the intended purpose of the collection (HPC or TC) and the source material (e.g., TC, Apheresis). These products can be collected for direct infusion without further manipulation or undergo manipulation such as cryopreservation. The class doesn't change but the modifier is added into the product code (e.g., Cryopreserved HPC, Apheresis).
 - This category is identified by a comma in the full name.
- Category 2: Hyphen
 - After manufacture/processing, the intention of the product can be identified by its active component (TC-T Cells). These class names are based on function followed by a further more specific delineation of the type of cells thought to predominate in the product. After processing, the class name will describe the intended active component (e.g., a donor lymphocyte infusion identified as TC-T Cells).
 - This category is identified by a hyphen in the full name

Cellular Therapy Coding & Labeling Advisory Group

Abbreviations:

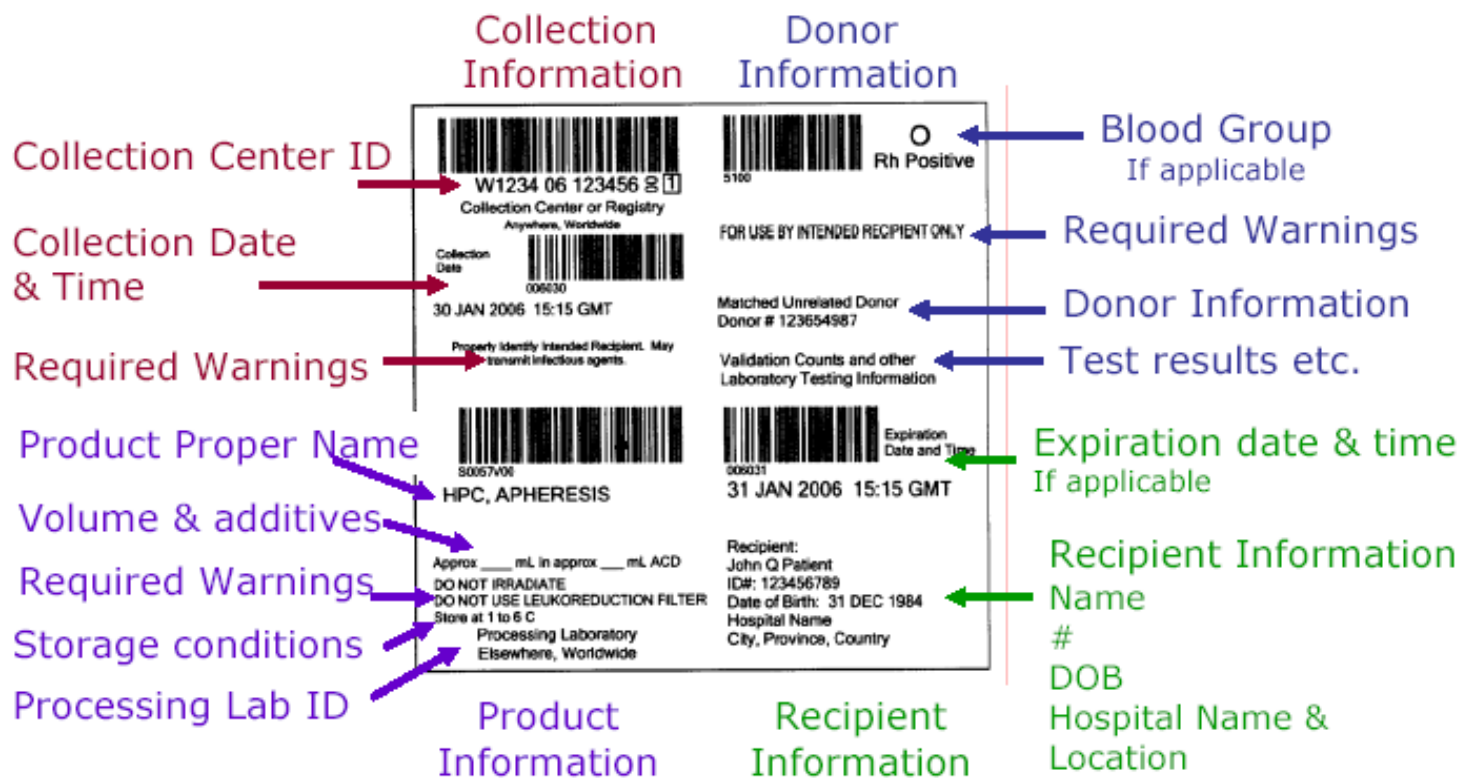
Abbreviations are sometimes needed in documents (published papers, SOPs, etc.). The following abbreviations may be used for this purpose, but should not be used in the labeling of products.

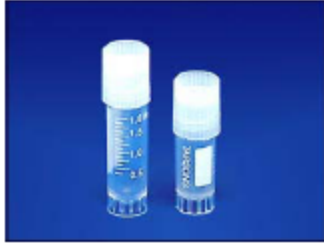
- HPC(A) for HPC, Apheresis
- HPC(CB) for HPC, Cord Blood
- HPC(M) for HPC, Marrow
- HPC(WB) for HPC, Whole Blood

No spaces should be present before the parentheses in these abbreviations.

Transfer Pack Label

Apheresis





Vial Label

2 Dimensional
barcode



Component #: C1234567
Therapeutic Cells, T-cells
Recipient: SMITH, John
TCH MRN #: 98705324

Information required on
Partial Label

Unique identifier of product
Proper name of product
Recipient name & Identifier



Cellular Therapy Coding & Labeling Advisory Group

Review and Summary of Activities:

- Standardized Abbreviations
- Create new product classes
- Revise existing class definitions
- Retire duplicate or obsolete terms

Cellular Therapy Coding & Labeling Advisory Group

Revised Class Definitions:

- TC-INV
 - Therapeutic cell product for an investigational study that is accompanied by appropriate identifying study information. This class is used for a specific product, not a product that is part of a blinded comparison study. Throughout the study, products labeled as TC-INV will be the same product, although the dose may vary within a specified range defined by the study.
- TC,TUMOR DERIVED
 - A product containing malignant cells or elements derived from them.

Cellular Therapy Coding & Labeling Advisory Group

New Classes of Products:

- TC-TIL
 - Therapeutic cells consisting of autologous tumor infiltrating lymphocytes (TIL) which have been isolated from the excised patient's tumor and cultured with lymphokines.
- TC-BLINDED STUDY
 - This class is reserved for use only in blinded studies of therapeutic cells that is accompanied by appropriate identifying study information. Products labeled as TC-Blinded Study may include different doses or may include an active product and a placebo.

Cellular Therapy Coding & Labeling Advisory Group

New Class Definitions:

- NC, Menstrual Blood: Nucleated cells collected from menstrual blood, with undefined therapeutic use at the time of collection.
- NC, Adipose Cells: Nucleated cells collected from adipose tissue, with undefined therapeutic use at the time of collection.

Terms and definitions

All terms and definitions for ISBT 128 are included in the document:

“ISBT 128: Standard Terminology for Blood, Cellular Therapy, and Tissue Product descriptions”

available on the ICCBBA Website,

<http://www.iccbba.org/standardterminology.pdf>



Cellular Therapy Coding & Labeling Advisory Group

How can you possibly keep up with all of the additions / changes?

Improve Communication

Subscribe to the ICCBBA Mailing List
found on the Cellular Therapy Home Page

– You will receive notification of all updates.

Ongoing Issues / Points To Consider

- Facility Confidentiality
 - Several concerns center around this issue with respect to registry products.
- applying a facility confidentiality label after checking but prior to hanging the product at the bedside



Ongoing Issues / Points To Consider

- Assignment of Product Expiration Date
 - Concerns center around the fact that there is no reliable sources for expiration date assignment.
- Regulatory requirements for partial labels
 - License Number, Key Code, Processing Facility
- Working with TERMIS-EU on terminology for tissue engineered products



ISBT 128 coding and labeling for CT products worldwide

FACT-JACIE standards: 4th version

INTERNATIONAL STANDARDS FOR CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION ACCREDITATION MANUAL



Guidance to Accompany the
FACT-JACIE International Standards for Cellular Therapy Product
Collection, Processing, and Administration, Fourth Edition

Fourth Edition
October 2008

NOTICE

These Standards are designed to provide minimum guidelines for programs, facilities, and individuals performing cell transplantation and therapy or providing support services for such procedures. These Standards are not intended to establish best practices or include all procedures and practices that a program, facility, or individual should implement if the standard of practice in the community or governmental laws or regulations establish additional requirements. Each program, facility, and individual should analyze its practices and procedures to determine whether additional standards apply. The Foundation for the Accreditation of Cellular Therapy and the Joint Accreditation Committee – ISCT and EBMT disclaim any responsibility for setting maximum standards and expressly do not represent or warrant that compliance with the Standards is an exclusive means of complying with the standard of care in the industry or community.

© COPYRIGHT © 2008
FOUNDATION FOR THE ACCREDITATION
OF CELLULAR THERAPY (FACT)

© COPYRIGHT © 2008
JOINT ACCREDITATION COMMITTEE -
ISCT and EBMT (JACIE)

“Standards” committee realised that:

- the ISBT CT coding and labelling is for most facilities in an implementation phase;
- decided that ISBT 128 terminology is mandatory for FACT-JACIE accredited facilities
- Implementation plan for ISBT 128 coding and labelling will be mandatory in **the fifth version** of the standards



APPENDIX I

CELLULAR THERAPY PRODUCT LABELING

Each label shall include at least the elements detailed in the following table:

Element	Partial label	Label at completion of collection	Label at completion of processing	Label at distribution for administration
Unique numeric or alphanumeric identifier	AF	AF	AF	AF
Proper name of product	AF	AF	AF	AF
Product modifiers and manipulations	AF		AF	AF
Recipient name and identifier	AF (If applicable)	AT (If applicable)	AT (If applicable)	AT
Identity and address of collection facility or donor registry		AT	AC	AC
Date, time collection ends, and (if applicable) time zone		AT	AC	AC
Approximate volume		AT	AT	AT
Name and volume or concentration of anticoagulant and other additives		AT	AT	AT
Donor identifier and (if applicable) name		AT	AT	AT
Recommended storage temperature		AT	AT	AT
Biohazard and/or Warning Labels (as applicable, see C7.3, D7.3 and Appendix IV).		AT	AT	AT
If applicable: Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"		AT	AT	AT
Statement "WARNING: Advise Patient of Communicable Disease Risks"		AT	AT	AT
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT	AT	AT
Identity and address of processing and distribution facility(ies)			AT	AT
Statement "Do Not Irradiate"			AT	AT
Expiration Date (if applicable)			AC	AT
Expiration Time (if applicable)			AC	AT
ABO and Rh of donor (if applicable)			AC	AT
RBC compatibility testing results (if applicable)				AT
Statement "Properly Identify Intended Recipient and Product"				AT
Statement indicating that leukoreduction filters should not be used.				AT
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT
Statement "For Use By Intended Recipient Only" (if for allogeneic recipient)				AT
Statement "For Nonclinical Use Only" (if applicable)				AT
Date of distribution				AC

AF=Affix, AT=Attach or Affix, AC=Accompany, Attach or Affix

Facilities registered with ICCBBA, Inc. who have fully implemented *ISBT128* labeling should follow the *ISBT128* Standard for the location of information on the label and/or the accompanying documentation.

Requirements are now easier to comply with using ISBT 128

Terminology is identical to ISBT 128 for CT products

63th World Health Assembly

- 21 May 2010 agenda item 11.21 on ***Human organ and tissue transplantation***
- Requests the Director-General:
 - “to provide, in response to requests from MS, technical support and regulation on, and suitable and traceable coding systems for, donation and transplantation of human cells, tissue or organs, in particular by facilitating international cooperation”

Cellular Therapy Coding & Labeling Advisory Group Annual Report

During the four years since the inception of CTCLAG, a great deal of progress has been made.

- At the end of 2009, 205 Facility identification numbers (FIN) assigned to Cellular Therapy Facilities in 37 countries
- In 2009: 25 new facilities registered



Country	FIN to CT Facilities of December 31, 2009	Country	FIN to CT Facilities of December 31, 2009
Algeria	1	Kazakhstan	1
Argentina	1	Mexico	2
Australia	3	The Netherlands	2
Austria	4	People's Republic of China	2
Belgium	5	Poland	19
Brazil	2	Portugal	1
Canada	11	Republic of China	4
Croatia	1	Russian Federation	3
Czech Republik	1	Saudi Arabia	2
Denmark	1	Singapore	2
Egypt	1	South Korea	1
France	5	Spain	8
Germany	1	Sweden	6
Greece	2	Switzerland	1
India	1	Thailand	2
Ireland	1	Turkey	3
Israel	3	United Kingdom	6
India	2	United States of America	94
Japan	1		



Implementation in the UMC Utrecht, the Netherlands



Implementation in UMC Utrecht

- Stem Cell Transplantation Laboratory
 - JACIE accredited since 2006
 - Tissue establishment license
- Gene and Cell Therapy Facility
 - GMP-accredited



Implementation strategy



University Medical Center
Utrecht

- Currently ± 350 cellular products/per year.
- Unique product identification was done manually, whereas data management is performed via MS Access dBases, developed and validated in-house.
- to improve quality, safety and traceability, implementation of ISBT 128 barcode labeling for our products, compliant with the JACIE standards.
- Awaiting General Laboratory Information Management System (GLIMS), we're using our current dBases as datasource.



Implementation strategy



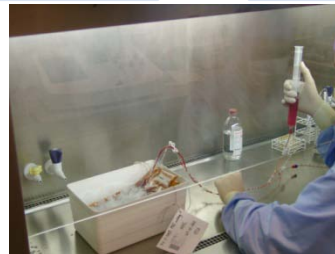
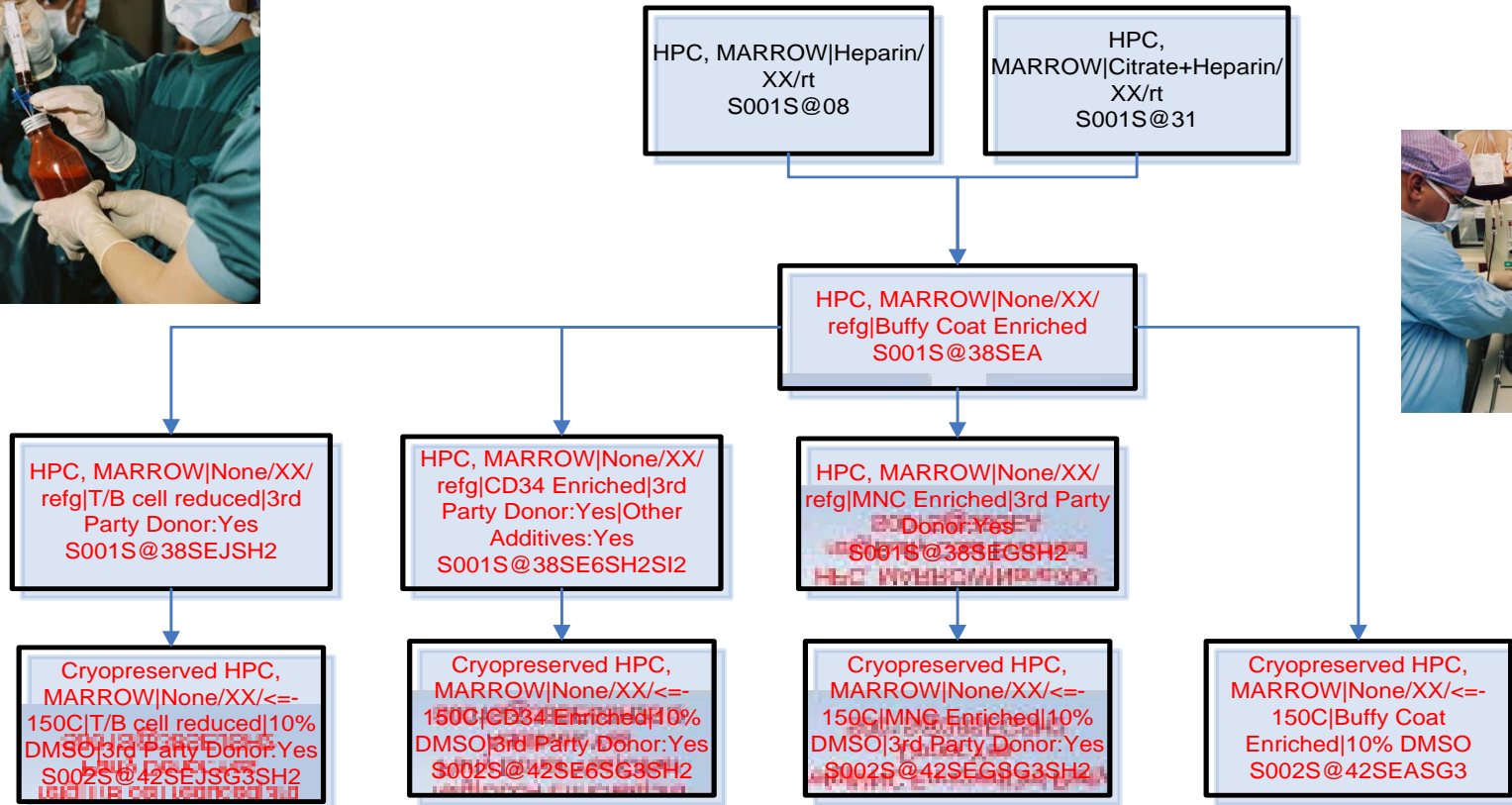
University Medical Center
Utrecht

- Labels: LabelShopUltra 6 (Intermec), which provides database connectivity.
 - The non-cryopreservation final labels (100 mm x 100 mm) and partial labels (100 mm x 40 mm) are printed on blood bag labels with certified adhesive (GraphicAll), using the Intermec Easycoder PD41 (200dpi) label printer.
 - The cryopreservation labels (40 mm x 19,8 mm) are printed on Zebra CryoCool 8000T labels using the Intermec Easycoder PD41 (300dpi) label printer.

Understand Technical issues



Generation of product codes: HPC,marrow



Implementation strategy



University Medical Center
Utrecht

- Sanquin is using ISBT 128 for all apheresis products;
 - We requested 26 new codes for HPC, Marrow; HPC, Apheresis and TC-T cells;
 - TC-MSC, TC-DC coding and labelling still to be implemented;
 - waiting for GLIMS updates for further implementation
- In general: 106 new Cellular Therapy product codes were added in 2009 at the request of facilities in Australia, Brazil, Canada, Croatia, Germany, the Netherlands, Serbia, Singapore, Sweden and the USA.*



Inside this Section



Cellular Therapy Home Page

[Cellular Therapy Home](#)[CTCLAG](#)[Joint Statement](#)[Terms of Reference](#)[Circular of Info](#)[Members](#)[Work Program](#)[Meeting Summaries](#)[Technical Specification](#)[Standard Terminology](#)[Frequently Asked Questions](#)[Educational Material](#)**Subscribe to the ICCBBA Mailing List!**

Advancing Transfusion and Cellular Therapies Worldwide



What's New

Version 3.38.0 of the *ISBT 128* product code database is now available to licensed facilities. Updates are listed in the version control sheet. The new database can be downloaded as an Access database or as text file tables. New product codes that were added are **S1481 to S1485** requested by Canada and The United States.

07 Jun 2010

ISBT 128 Cellular Therapy Letter- ICCBBA would like to ask your help in assessing the *ISBT 128* implementation status for cellular therapy facilities around the world. Please follow this [link](#) to see how you can help the cellular therapy community by participating in a short survey. Since this is a joint effort with various cellular therapy governing bodies, you may receive this notification more than once. However, please complete the survey only once for your organization.

03 Jun 2010

Cellular Therapy Annual Report - ICCBBA has published its first CT annual report. It contains the progress made by the CTCLAG group in 2009, survey results, events and activities ICCBBA participated in, and a list of frequently asked questions. Read it [here!](#)

Foundation for the Accreditation of Cellular Therapy



International Society for Cellular Therapy



ICCBBA enhances safety for patients by managing the *ISBT 128* international information standard for use in transfusion and transplantation.



ISBT 128

For Cellular Therapy

An Introduction



More information:

WWW.ICCBBA.org

Cellular therapy page

