Cell Tissue Bank (2010) 11:375–378
DOI 10.1007/s10561-010-9218-0

ORIGINAL PAPER

ISBT 128 coding and labeling for cellular therapy products

Ineke Slaper-Cortenbach

Received: 1 July 2010 / Accepted: 14 August 2010 / Published online: 21 September 2010

Abstract This paper describes the development of the ISBT 128 coding and labeling for cellular therapy products. It is published on behalf of the international Cellular Therapy Coding and Labeling Advisory Group (see www.ICCBBA.org)

Keywords Cellular therapy · Terminology · Coding · Labeling

Abbreviations

AABB	American Association of Blood Banks
ASBMT	American Society for Blood and Marrow Transplantation
ASFA	American Society for Apheresis
APBMT	Asia Pacific Blood and Marrow Transplantation Group
CT	Cellular Therapy
CTCLAG	Cellular Therapy Coding and Labeling Advisory Group
EBMT	The European group for Blood and Marrow Transplantation
EU	European Union
ISCT	International Society for Cellular Therapy
FACT	Foundation for the Accreditation of Cellular Therapy
FDA	Food and Drug Administration
JACIE	Joint Accreditation Committee of ISCT and EBMT
NMDP	National Marrow Donor Program
WHO	World Health Organization
WMDA	World Marrow Donor Association

This report is done on behalf of the international Cellular Therapy Coding and Labeling Advisory Group (see www.ICCBBA.org).

I. Slaper-Cortenbach (✉)
UMC Utrecht, Utrecht, The Netherlands
e-mail: i.slaper@umcutrecht.nl

Introduction

ISBT 128 is a coding and labeling system which was developed for blood and blood products to improve quality, safety and traceability in blood banking by the International Society of Blood Transfusion (ISBT). It was launched at the meeting of the ISBT in Amsterdam in 1994 and since then, the system has been integrated in blood banks all over the world. Today the standard is managed by ICCBBA.

Cellular therapy (CT) started with stem cell transplantation using bone marrow as a source of hematopoietic progenitor cells (HPC, bone marrow) in the early 1980s. This field has been rapidly expanding in the last two decades, because other sources like mobilised progenitor cells harvested by apheresis machines (HPC, Apheresis) and HPC from cord blood (HPC, Cord Blood) have proved to be excellent sources of HPCs for stem cell transplantation. Since then, the treatment of patients with matched unrelated donor transplants has improved considerably and now

a worldwide exchange of CT-products has become evident. The World Marrow Donor Association (WMDA) published their data on export and import, showing that nearly 50% of the HPC products for matched untreated donor transplantation are exchanged internationally (WMDA 2008).

This exchange caused an urgent need within the Regulatory Agencies worldwide and in Europe in particular to develop an unified regulatory framework to ensure high standards of quality and safety of tissues and cells. This led to the publication of the European Directive 2004/23/EC in 2004, entitled: 'Setting standards on quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells'.

In this EU-Directive the following issues for coding and labeling were addressed:

- 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

At that time the emerging role of coding and labeling of CT products to support worldwide exchange was recognized by ICCBBA. Following the EBMT-meeting in Prague in 2005, the ICCBBA executive director arranged a meeting with technical experts and representatives of the major organisations in the field: International Society for Cellular Therapy (ISCT), the European group for Blood and Marrow Transplantation (EBMT), and the accreditation organisations for stem cell transplant centers: the Foundation for the Accreditation of Cellular Therapy (FACT) in the USA and the Joint Accreditation Committee of ISCT and EBMT (JACIE) in Europe. It was discussed and decided to use ISBT 128 for all "cellular therapy" products to provide an uniform coding and labeling system worldwide. This system provides:

- a globally unique donation identification number
- international product description list with definitions and codes
- standard data structures for donation numbers, product descriptions and other information for CT products

This decision was then brought before the members of the ISCT at the ISCT meeting in Vancouver in 2005 and was fully supported by the leadership of the organisations involved and their members. To accomplish the work in the field of CT, a Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) was launched. The first face-to-face meeting was organized in Athens in 2005. The decision making meeting on the new terminology and labeling was held in October 2006 at the headquarters of the American Association of Blood Banks (AABB) in Bethesda, USA.

To date most of the worldwide operating organisations in CT support the group and sent representatives to face-to-face meetings and on the teleconferences. Participants in the group include AABB, Asia Pacific Blood and Marrow Transplantation (APBMT), American Society for Blood and Marrow Transplantation (ASBMT), American Society for Apheresis (ASFA), EBMT, FACT, FACT-Netcord, ISCT, ISCT-Europe, JACIE, National Marrow Donor Program (NMDP), WMDA and observers from the Food and Drug Administration (FDA).

The activities of the CTCLAG

Since the start of the CTCLAG in 2005 its role has been defined as follows:

- review existing regulation regarding labeling;
- design CT product specific 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.

In 2007, the group published two papers on CT products simultaneously in Transfusion, Bone Marrow Transplantation and the Journal for Clinical Apheresis, one paper on CT terminology and labeling (Ashford et al. 2007a, b, c) and the related paper on the implementation plan for cellular therapy products (Ashford et al. 2007d, e, f).

As foreseen, terminology has more recently been extended towards the newer CT-products like Therapeutic Cells, Mesenchymal Stromal Cells (TC-MSC)

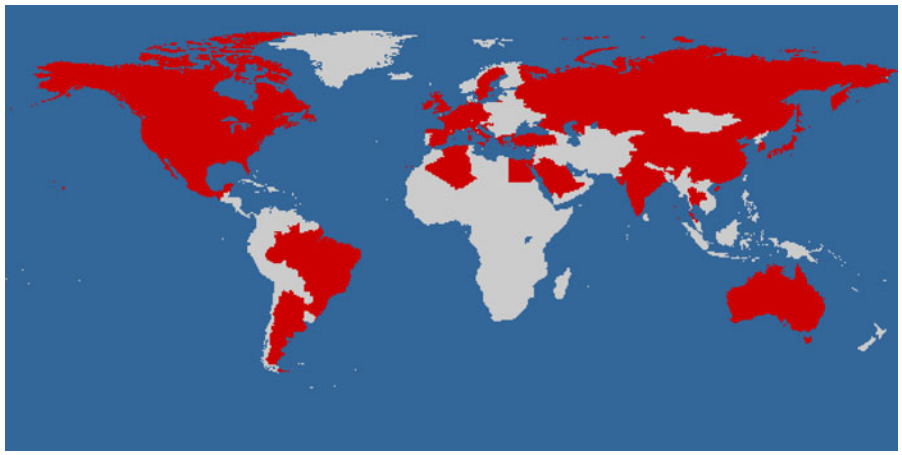

Fig. 1 Registered CT-facilities with ICCBBA (2009)

or TC-Dendritic Cells which fall under the regulation for advanced therapy medicinal products (Regulation (EC) no 1394/2007). The intention of this regulation was to unify the regulatory framework for medical devices, tissue engineering and medicinal products including cellular and gene therapeutic products. This initiative was required due to the regulatory gap for tissue-engineered products as well as the rather broad spectrum of legal and regulatory implementation in the different EU member states.

In the meantime the European Commission (DG Sanco) established a working group to establish guidelines and to make specific recommendations on the single European coding system. An international CEN/ISSS workshop was held in Brussels from November 2007–April 2008 in which the CTCLAG and ICCBBA actively participated.

Although other Member States had set up national coding systems, it was recognized that ISBT 128 fulfills all requirements for the globally unique donation code and provides international product codes, which are being maintained by professionals in the CTCLAG.

The Regulatory Committee of the EU however, decided that an impact assessment was necessary and so far no major decisions in Europe have been made.

In 2008, the accreditation bodies JACIE, FACT and AABB published versions of their standards in which ISBT 128 terminology became mandatory. Currently the organisations are working on the new version of their standards, in which it is foreseen that the transition to ISBT 128 coding and labeling will be gradually moving forward, firstly by requiring an implementation plan for ISBT 128 for CT products, followed by a later requirement for full implementation.

In Summary

During the 5 years since the inception of the 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 (see Fig. 1). In the year 2009, 25 new CT facilities registered with ICCBBA. The CT-terminology has been updated by adding new classes and product codes.

Organisations involved in Cellular Therapy worldwide are participating in the CTCLAG[1] including representation from regulatory bodies like the US FDA. The next step for CTCLAG will be to cooperate with WHO. The 63rd World Health Assembly on May 21, 2010 discussed the situation regarding human organ and tissue transplantation. WHO was requested "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".

[1] ICCBA cellular therapy home page: http://www.iccbba.org/cellulartherapy_home.html

References

Ashford P, Distler P, Gee A, Lankester A, Larsson S, Feller I, Loper K, Pamphilon D, Poston L, Rabe F, Slaper-Cortenbach I, Szczepiorkowski Z, Warkentin P (2007a) Standards for the terminology and labeling of cellular therapy products. Transfusion 47(7):1319–1327

Ashford P, Distler P, Gee A, Lankester A, Larsson S, Feller I, Loper K, Pamphilon D, Poston L, Rabe F, Slaper-Cortenbach I, Szczepiorkowski Z, Warkentin P (2007b) Standards for the terminology and labeling of cellular therapy products. J Clin Apher 22(5):249–257

Ashford P, Distler P, Gee A, Lankester A, Larsson S, Feller I, Loper K, Pamphilon D, Poston L, Rabe F, Slaper-Cortenbach I, Szczepiorkowski Z, Warkentin P (2007c) Terminology and labeling of cellular products: 1. Standards. Bone Marrow Transpl 40(11):1075–1083

Ashford P, Distler P, Gee A, Lankester A, Larsson S, Feller I, Loper K, Pamphilon D, Poston L, Rabe F, Slaper-Cortenbach I, Szczepiorkowski Z, Warkentin P (2007d) ISBT 128 implementation plan for cellular therapy products. Transfusion 47(7):1312–1318

Ashford P, Distler P, Gee A, Lankester A, Larsson S, Feller I, Loper K, Pamphilon D, Poston L, Rabe F, Slaper-Cortenbach I, Szczepiorkowski Z, Warkentin P (2007e) ISBT 128 implementation plan for cellular therapy products. J Clin Apher 22(5):258–264

Ashford P, Distler P, Gee A, Lankester A, Larsson S, Feller I, Loper K, Pamphilon D, Poston L, Rabe F, Slaper-Cortenbach I, Szczepiorkowski Z, Warkentin P (2007f) Terminology and labeling of cellular products: 2. implementation plan. Bone Marrow Transpl 40(11):1085–1090