

EXPANSION OF ISBT 128 TERMINOLOGY TO REGENERATED AND SOURCE PRODUCTS

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BACKGROUND

In 2006, the International Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) was formed by ICCBBA with support of professional organizations including ISCT. A goal of this group was to standardize terminology used in Cellular Therapy (CT). In 2007, the output of this group was published and thereafter AABB, FACT, JACIE, and NMDP required use of this terminology. New terminology has been developed for regenerated products and source organs used for regenerated products. Once standardized terminology is agreed, assignment of ISBT 128 computer codes follows, supporting bar coding and electronic transmission of information.

METHODS

In addition to CTCLAG, the ICCBBA Tissue Engineered Products Technical Advisory Group and Tissue Technical Advisory Groups worked through a consensus process to develop additional terminology. Drafts of terminology were distributed to relevant professional societies for comment and were published on the ICCBBA website for public comment.

RESULTS

CT terminology was updated in 2013 to follow a standard format for the class name: Cell Type, Source (e.g., MNC, Apheresis).

More recently, the class name of regenerated products was agreed to have the format "Regenerated" followed by the tissue type (e.g., REGENERATED EPIDERMIS). Additional details such as cell type, delivery mechanism, ancillary substances, excipients, and storage temperature, were added as attributes. An example description is: REGENERATED EPIDERMIS, from keratinocytes, in the form of a sheet, with ancillary substances present.

The format for class names of organs used as a source of cells for production of cell and tissue products is the organ name followed by the word "Tissue" in parentheses, for example, HEART (TISSUE). The word "Tissue" was added to distinguish organs intended for transplant from those intended for further processing. Organs for transplant have just the organ name (e.g., HEART).

CONCLUSIONS

Through the efforts of experts in the fields of cellular therapy, tissues, and regenerated products working in advisory groups, terminology for medical products of human origin have been developed for CT, tissue, and regenerated products. This terminology is available publicly through the ICCBBA website (www.iccbba.org) and its use for communication and labeling is encouraged.



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