

Implementation of Standardized Terminology and ISBT 128 Product Codes for Ocular Tissue

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ABSTRACT

International eye bank societies have approved a joint statement encouraging the use of ISBT 128 to standardize terminology, coding, and labeling of ocular tissue products. This standard is already in use in blood banks, cellular therapy facilities, and tissue banks around the world. Such global standardization promotes patient safety through improved traceability and identification of ocular tissue products. Use of a standardized, machine-readable code, such as a linear bar code, a 2-D matrix bar code, or radio frequency identification (RFID), also permits improvements in efficiency, accuracy in data capture, and interoperability among facilities using the same coding system.

A standardized terminology for ocular tissue products has been developed, and its adoption can be the first step in implementing ISBT 128. Use of standardized terminology supports common understanding of products among eye banks and ophthalmic surgeons and permits better communication when ocular products are distributed internationally.

Full implementation of ISBT 128 is a multistep process that begins with an understanding of how information is encoded and presented on ISBT 128 product labels and follows a typical project management process.

KEYWORDS: eye bank terminology, labeling, ISBT 128, global harmonization

The implementation of globally standardized bar codes for the labeling of ocular tissue products would improve the accuracy of product descriptions and efficiency of information transfer and, through these benefits, improve traceability and patient safety. Because the information within the bar codes must have the same meaning to all who scan them, standardization of terminology and coding of information are needed. This requirement is in accord with the 2010 World Health Assembly Resolution WHA63.22, which calls on member states to “encourage the implementation of globally consistent coding systems for human cells, tissues, and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation.”¹

Representatives of international eye banking societies, namely the European Eye Bank Association, the Association of Eye Banks of Asia, the Eye Bank Association of India, the Eye Bank Association of America, the Eye Bank Association of Australia and New Zealand, and the Pan American Eye Bank Association, first met in 2010 to discuss how to move forward with standardization. This newly formed Eye Bank Technical Advisory Group (EBTAG) concluded that ISBT 128, a global standard for terminology, coding, labeling, and information transfer for medical products of human origin, was suitable for use with ocular tissue. ISBT 128 is widely used worldwide by blood establishments, transfusion services (blood banks), and some cellular therapy facilities and is also being adopted by tissue banks. The standard is managed by the International Council for Commonality in Blood

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Bank Automation (ICCBBA), a nongovernmental organization in official relations with the World Health Organization (WHO).

As a first step, the EBTAG developed an international standard terminology for ocular tissue that, after public consultation, has been published.² Based on the group’s recommendations, a joint statement was released by international eye bank societies that promoted the adoption of the ISBT 128 Standard (see Table 1 at end of article). The standardized terminology allows specific descriptions of ocular tissue products to be created from unique combinations of a class, which is a broad descriptor such as cornea or sclera, and one or more attributes to provide further information such as graft type, storage state, or method of pathogen reduction.² The terminology is flexible and may be updated as developments in ocular tissue transplantation occur.

As is true for any new technology, implementation of ISBT 128 presents operational challenges. This guidance has been prepared by the EBTAG to address some of those implementation challenges and draws on the experience gained in other fields. It should be noted that this document was written with an international audience in mind and does not provide details about specific standards or national or supranational regulatory requirements. This guidance should be used along with the ISBT 128 Technical Specification³ and other ICCBBA documents.⁴⁻⁷

PHASED IMPLEMENTATION

The ISBT 128 standard may be introduced as a full system or in progressive steps. In particular, the implementation of terminology may precede ISBT 128 coding and labeling, which means that organizations can adopt the standardized terminology developed by EBTAG at any time. This terminology should be used in the labeling of ocular tissue, within standard operating procedures, and in written and oral communications. For a complete listing of the ocular terminology, investigators should consult the ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.⁴ The subsequent pace of adoption of ISBT 128 coding and labeling will depend on financial, managerial, and technical resources and may be built into other developments within an eye bank, such as planned upgrading or renewal of computer systems.

FULL IMPLEMENTATION

Full implementation of ISBT 128 coding and labeling requires software that is able to utilize ISBT 128 data structures. This requires either purchasing software that is ISBT 128 compliant or updating existing software to utilize the codes. Detailed information about how the coding system works may be found in the ISBT 128 Technical Specification.³

If ISBT 128 is fully implemented, a globally unique donation identification number (DIN) is assigned to each tissue donation event, and a standardized product code is assigned to each product from that event. These two identifiers (DIN and product code) together create a globally unique identification for each ocular tissue.

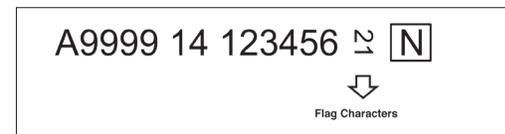


Fig. 1. ISBT 128 donation identification number (DIN). The DIN identifies all products from a single donation event using a globally unique number.

Donation Identification Number

The DIN comprises a facility identifier, which is assigned by ICCBBA to ensure it is globally unique; a two-digit year code, which provides uniqueness over a 100-year period; and a sequence number assigned by the eye bank (Fig. 1). The use of this DIN means that hospitals cannot encounter duplicate identifiers from different suppliers. Ideally, from a traceability perspective, the DIN would be assigned to a donor and used by all recovery or procurement organizations that recover tissue or procure organs from the donor. However, at least in the short term, each organization may assign its own DIN.

Product Code

ISBT 128 product codes comprise a product description code and a division/pack code.

- Product description codes are assigned to each unique combination of class and attributes, which are based on the standardized terminology developed by EBTAG.
- Division/pack codes are used to differentiate multiple “copies” of products that have the same DIN and product description code. For example, if sclera is divided such that there are two products with the description SCLERA, Part Sclera, Left, Hypothermic Storage (product description code = V0008), division codes 001 and 002 following the product description code are used to differentiate them (Fig. 2).

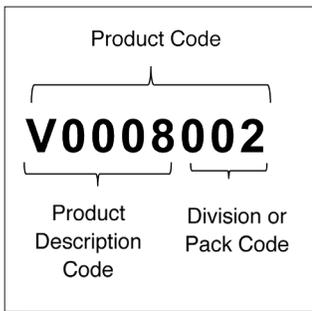


Fig. 2. ISBT 128 product code. The product code consists of a product description code and a division/pack code. The division/pack code allows traceability when more than one similar product (e.g., two partial scleras) are produced from the same donation.

Other Information

Other information, such as expiry date and time, processing date and time, and processing/labeling organization may also be encoded and appear within the 2-D matrix bar code on the product label (Fig. 3). Labeling of products with ISBT 128 bar codes requires the appropriate labeling software and printers. The choice of which software system and equipment depends on, among other things, numbers of labels produced, existing software, budget, the range of different tissue products produced, and organizational preferences.

PROJECT PLANNING STEPS

If full implementation of ISBT 128 is planned, a project plan including the following steps should be considered.

Identify the project manager. Once the decision to implement ISBT 128 is made, in all likelihood one person within the institution will coordinate the project. This project manager should be identified early in the process.

Identify the team. The project manager should recruit the appropriate multi-disciplinary team to participate in the implementation of ISBT 128.

Assemble and review educational materials. The project manager should assemble pertinent education materials regarding ISBT 128. Various resource materials are available on the ICCBBA website (<http://www.iccbba.org>). These materials may be utilized in planning, implementation, and training.

Follow standard change control measures. Change control measures should follow facility-defined policies and procedures for implementing change.

Register with ICCBBA. All facilities that apply ISBT 128 bar-coded labels or use ISBT 128 DINs are required

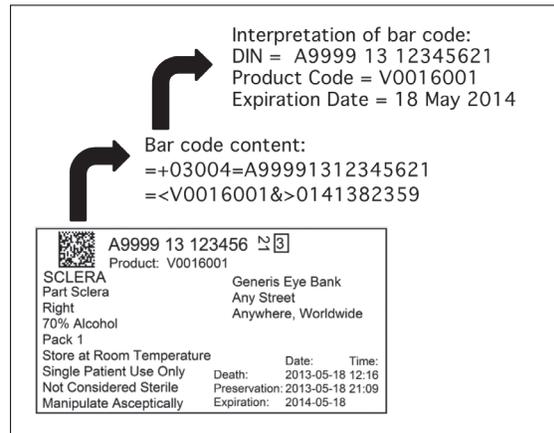


Fig. 3. ISBT 128 label. The 2-D bar code in the upper left corner includes the DIN, product code, and expiration date.

to register with ICCBBA, as are vendors whose products utilize ISBT 128 data structures. Registration information is found on the ICCBBA website.

At the time of writing (2013), the cost of registration for eye banks is US \$200 (one-time fee). Additionally, an annual licensing fee is charged based on the volume of tissue products distributed. For facilities distributing fewer than 1,000 products per year, the current annual fee is US \$213. For facilities distributing between 1,001 and 5,000 products per year, the current annual fee is US \$325. Facilities distributing more than 5,000 products per year currently pay US \$325 plus US \$0.11 per product over 5,000. All these fees apply to facilities in countries with a High Human Development Index (HDI), as defined by the United Nations. Countries with a Medium or Low HDI pay a reduced fee.

Registration and licensing provides a facility identification number to allow eye banks to assign globally unique donor identification numbers, access to the password-protected areas of the ICCBBA web site, and technical support from the ICCBBA help desk.

Learn about product terminology and coding. A current list of terms and their definitions developed by EBTAG is found in the ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.⁴ Each unique product description is assigned a five-character product description code and included in the product description code database. Product coding details are found in Implementation Guide: Use of Product Code Data Structure [003]-Ocular Tissue.⁶

Determine a label design. Label designs should comply with the requirements in ISBT 128 Standard Labeling of Ocular Tissue.⁵ The minimum information that must be bar coded on ISBT 128 labels includes the DIN (which includes the facility identification number as shown in Fig. 1), the product code, and the expiry date. Various standard-setting organizations and regulatory agencies may require additional information.

Determine costs. Costs vary significantly depending on the automation level of the facility and its complexity. The ICCBBA website maintains a list of vendors licensed to utilize ISBT 128 in their products. Vendors on this list may be contacted for specific information about products and pricing.

Select equipment, software, and supplies. Each organization should select the requisite equipment, software, and supplies.

Equipment includes:

- Scanners. Data Matrix 2-D bar codes have been recommended for ocular tissue because of the size of the labels. Therefore, imaging scanners capable of reading 2-D bar codes will be needed.
- Label Printers. Thermal transfer bar code label printers for on-demand printing are favored by vendors of on-demand label printing software. It is recommended that printers with 300 dots-per-inch resolution be used to meet high-density and small type font requirements needed on small labels.

Software includes:

- Label Printing Software. Label printing software may be purchased or developed in-house. Software may be “stand-alone,” meaning it runs independently of other systems and will require manual input of information to produce each label. It is preferable, however, to have software that may be integrated into existing systems so that information transfer is automated.

Supplies include:

- Labels. Staff should select label stock that is appropriate for the storage conditions of the products. This selection is important, as some adhesives and paper stocks may not be suitable for use on cryopreserved products or where moisture could be an issue.
- Printer Ribbons. If thermal transfer printers are used, ribbons must be matched to the printers and types of label stock.

Perform validations. All new equipment, software, supplies (including labels), and processes must be validated. Examples of valid and invalid labels that may be used for validation purposes are found on the ICCBBA website.⁷ Both valid and invalid bar codes should be used to validate the user’s system when implementing ISBT 128.

Communicate with donor testing laboratory. If donor testing services are outsourced and ISBT 128 DINs are to be used, it is important to notify the laboratory of the change in labeling. Many instruments used for infectious disease marker testing will be able to read ISBT 128 labels.

Communicate with end users. End users (e.g., hospitals, ophthalmologists) should be given advance notice and information about the new labeling system. If they want to take advantage of the benefits of bar code scanning, they may need to update their computer software. If the facility is an establishment that collects blood for transfusion, or if it has a blood bank (transfusion service), it may already have software that can scan and interpret ISBT 128 bar codes, although the software may require an update to support ISBT 128 for ocular tissue.

Develop training materials. Staff who will require training should be identified, and policies, standard operating procedures, and other relevant documentation updated. A training plan and time line should be developed to accomplish these requirements

Plan for existing inventory. Tissues already in storage should not be relabeled; rather, ISBT 128 should only be utilized for product labels on tissues processed after the implementation date.

Audit procedures. Policies and procedures should be audited to ensure that they contain information pertaining to ISBT 128.

Assess progress. As a part of a quality assurance plan, implementation progress, including problems encountered and their solutions, should be tracked.

CONCLUSION

Bar code technology is a part of daily life. It offers improved efficiency and accuracy wherever it is used. ISBT 128 is a system that provides globally standardized bar codes and terminology for medical products of human origin including ocular tissue, thus

supporting traceability and biovigilance and helping to improve patient safety. Eye bank societies around the world support the implementation of ISBT 128 for ocular products.

Standardized terminology may be implemented as a first step, allowing clear communication among professionals in the field, but it is recommended that this should be followed by full implementation to gain all the benefits of ISBT 128. Full implementation of the ISBT 128 standard requires good project management that follows existing change control policies and procedures.

The EBTAG will continue to monitor the progress of this initiative and, whenever possible, assist facilities by providing updated information, education, and training materials. The ICCBBA office also provides help desk support to facilities implementing the standard.

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Table 1. Joint Statement of Eye Bank Societies

International Eye Bank Technical Advisory Group on Terminology, Coding, and Labeling of Ocular Tissue

The Boards of the Association of Eye Banks of Asia, Eye Bank Association of Australia and New Zealand, Eye Bank Association of America, Eye Bank Association of India, European Eye Bank Association, Pan American Association of Eye Banks, and the International Council for Commonality in Blood Bank Automation:

- taking into account World Health Assembly Resolution WHA63.22, which calls for the implementation of globally consistent coding systems for human cells, tissues, and organs;
- recognizing the significant benefits of international standardization of nomenclature, coding, and labeling in clinical practice;
- recognizing the need for globally unique identification of grafts to support international traceability and biovigilance;
- acknowledging the widespread use of the international information standard ISBT 128 in the fields of transfusion and transplantation;
- recognizing the need for international management and technical co-operation for the successful maintenance and development of such standards,

have established an international advisory group for nomenclature, coding, and labeling of ocular tissue to:

- a) develop a standard terminology to describe ocular tissue grafts;
- b) provide guidance on standard labeling of ocular tissue grafts;
- c) promote the adoption of the ISBT 128 standard in eye bank facilities around the world;
- d) provide advice and support to facilities introducing the standard;
- e) advise on the ongoing development of the ISBT 128 standard to support new developments in eye banking.

An agreed nomenclature has now been developed, and the boards of the above organizations confirm their support for the international use of ISBT 128 in the coding of ocular tissue and encourage eye banks to:

- adopt this standard terminology for use in communications and in the labeling of ocular tissue grafts;
- implement ISBT 128 globally unique donation identification for ocular tissue grafts;
- move towards full implementation of ISBT 128 nomenclature, coding, and labeling in accordance with guidance published by the Eye Bank Technical Advisory Group.

For further information on this initiative, see <http://www.iccbba.org/subject-area/ocular>.

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