Transitioning to ISBT128 – The Experience of The Eye-Bank for Sight Restoration

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ABSTRACT

ISBT 128 is the global standard for the terminology, identification, labeling, and information transfer of medical products of human origin across international borders and disparate health care systems. In 2014, The Eye Bank Association of America revised its Medical Standards to require its members to implement ISBT 128 labeling in a three phase process. The Eye-Bank for Sight Restoration chose to integrate ISBT 128 with its database as a means to establish an in-house tissue tracking system, in addition to meeting compliance with EBAA Medical Standards. As a result, ISBT 128 has helped provide a computerized history, including dates, times, and technician identification involved in the processes that occur once tissue is received in the ocular laboratory. Use of ISBT 128 labels and readable scanners provides more accurate data and eliminates illegibility in documentation, and is a key step towards achieving complete electronic laboratory records.

INTRODUCTION

ICCBBA[1] defines ISBT 128[2] as the global standard for the terminology, identification, labeling, and information transfer of medical products of human origin (including blood, cells, tissues, milk, and organ products) across international borders and disparate health care systems. In 2004, members of Eye Bank Association of America (EBAA) began meeting with ICCBBA to consider the process of developing standardized terminology for the purpose of labeling and tracking ocular tissue distributed worldwide. ICCBBA formed an international committee of eye bankers, known as EBTAG[3] (eye bank technical advisory group), in 2010 to develop definitions for transplant ocular tissue distributed for transplant (and later including for research purposes) using a combination of a class as a broad descriptor such as cornea or whole eye, along with one or more attributes to provide further information such as graft type, storage solution and storage state. The terminology was published in *Cornea* in 2012[4] and is a continually evolving document with additions requested as needed.

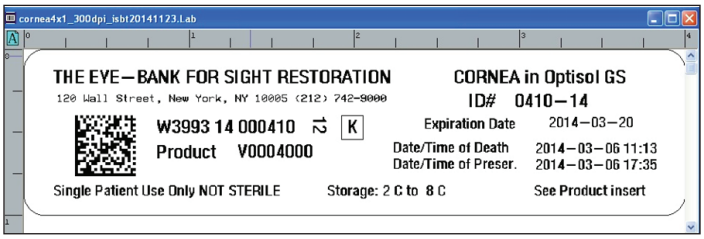
During the same time period, two changes in The Eye-Bank for Sight Restoration's laboratory procedures were initiated and later facilitated by the implementation of ISBT 128. In 2012, The Eye-Bank began to renovate and expand its office and ocular laboratory to include two laboratory spaces each equipped with a tissue bank refrigerator. The new laboratory spaces included a limited access room for receiving/shipping tissue and instrument preparation, as well as a separate International Standards Organization (ISO) 7, class 10,000 hepa-filtered room for tissue evaluation and processing. To eliminate casual access into the laboratory, a change in standard operating procedures required donning booties before accessing the instrument room as well as additional personal protective equipment (PPE), such as scrubs, gown, cap and booties before accessing the evaluation and processing room. This created a significant culture change for the laboratory staff, who were accustomed to entering the laboratory without required advance preparation. Additionally, the change in procedure requiring PPEs before entering the evaluation and processing room, created a need to be able to track tissue in-house without having to physically enter the laboratory.

Another change in standard operating procedures for The Eye-Bank occurred in 2010, when it was agreed to be a supporting member of the Cornea Preservation Time Study (CPTS). As an eye bank participant, it was required as a standard practice to bring donor corneas stored in Optisol GS to room temperature for at least two hours prior to specular microscopy evaluation in order to achieve an optimal image of endothelial cell density. Initially, a paper log was utilized to record the time when corneas were removed from and returned to a refrigerator. While the practice of letting corneas "warm up" was successfully implemented, calculating the time lapse from hand-written forms was arduous and gaps in documentation could be found during internal audits by the quality assurance department.

To simplify the tracking of ocular tissue internally, including identifying which processes were completed by specific technical staff inside the more restrictive evaluation and processing room, and to eliminate paper documentation of tissue movement in and out of refrigerators as required by the CPTS, The Eye-Bank decided to implement ISBT 128 labeling with two dimensional (2-D) symbols and data matrix bar coding.

Compliance with EBAA Medical Standards

Annually, more than 28,000 corneas are distributed internationally by U.S. EBAA accredited eye banks.[6] In response to 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,[7] the EBAA Medical Standards were revised in June 2014 to require its accredited members to implement ISBT 128 labeling. Implementation would be phased in across three years.[8] The first phase required EBAA members to register with ICCBBA and implement ISBT 128 terminology by June 30, 2015. In the second phase, eye banks are required to use ISBT 128 standardized product codes and associated identifiers by January 1, 2016. The identifiers include the Donation Identification Number (DIN), Product Code, and all dates. The DIN consists of the facility identification number (FIN), the current year (in a two digit format), followed by a six digit sequence number. Each eye bank is issued a unique FIN upon registering with ICCBBA. The six digit sequence number specifies the donor and a product code specifies the tissue, such as left or right tissue, full thickness or sectioned, and the storage media used. The January 2016 deadline also requires utilizing ISBT 128 DIN and Product Code on eye bank Tissue Report Forms and all other internal reports related to the donor tissue. The third and final phase requires eye banks to use ISBT 128 bar code labeling for tissue distributed internationally beginning January 1, 2017.



Sample ISBT 128 label

CSVC with ISBT label showing 2-D bar code

Programming a Customized Database

The Eye-Bank uses a customized Unidata database. Integrating the ISBT 128 labeling process into the database allows for analyzing the time lapses in refrigeration and for identifying when technicians perform various tissue evaluation and processing procedures, as well as tissue distribution. The programmer, who had previous experience with creating bar coded software, was given a copy of the ISBT 128 product codes from ICCBBA, as well as a list of destination stations in The Eye-Bank's laboratory, including both refigerators, the specular microscope, slit lamp biomicroscope, ocular coherent tomography system, tissue transportation box and an "in transit" status. The goal was to create an computerized tracking history of where the tissue goes once it is received at The Eye-Bank and its final destination. After nine months of intermittent work on the software, the programmer presented the software for testing and validation.

To avoid possible complications between the existing database and the newly created scanning software, a standalone scanning kiosk was created using a separate all-in-one module based on an Android operating system with restricted access. Once a label has been created, scanning the tissue is the only way the DIN and product code can be entered into the data base when moving the tissue in and out of the refrigerators. The system does not allow for any manual entries. The scanning kiosk also included a touchscreen option, which added a user friendly factor to the process, thereby encouraging its use.

Additional equipment purchases were also required, including two handheld scanners and one label printer. Of the commercially available scanner options, the Motorola Hand Held – DS6878-HC was chosen because it was wireless, could be sanitized and was listed as hospital grade, suggesting it would sustain rough handling by multiple technicians. Two scanners were purchased and located in close proximity of the two refrigerators where most scanning would be performed. A Zebra Bar Code Printer – GX430T was chosen because of previous experience with this brand and the fact that it features thermal printing (requiring no ink) on the desired label size of 1inch x 4 inches (#10010045).

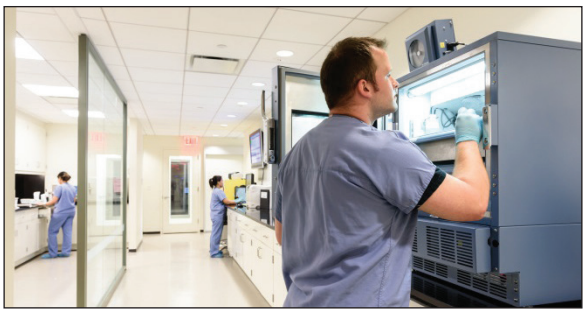
The cost of developing the customized integrated ISBT 128 labeling system was significant, totaling $35,000, with 70% attributed to programming and the rest for purchasing the necessary equipment.

Training and implementation

Updates to The Eye-Bank's SOP manual were made requiring technicians to scan tissue placed into or taken from the refrigerator and to designate the purpose for removing , e.g., evaluation, processing or distribution. Changes were also made to the SOP to reflect the new EBAA Medical Standards requirements. To verify that the new tissue label could be correctly read by an ISBT 128 scanner, a sample was sent by email to ICCBBA, who successfully confirmed the identity of the tissue type and storage.

Training the laboratory staff on how to use the new scanning equipment was accomplished with one-on-one 15-minute sessions. While not a requirement, all exisiting tissue in the laboratory (corneas and sclera) were relabeled with ISBT 128 labels and scanned to reflect the particular storage locations. Additionally, each destination station was labeled with an applicable 2-D data matrix barcode, which allowed technicians to log into the scanning kiosk and simply scan the tissue label followed by the destination station barcode. Alternatively, the destination station could be selected from a drop down menu in the scanning kiosk.

To alert surgeons and operating room staff of the new labeling system, a memo announcing the new label features was prepared and included in the transportation box with each donor tissue when tissue was sent to a transplant facilities. Additionally, an email was sent to surgeons to announce the new labeling system.



Technician conducting daily review of laboratory refrigerator

Scanning a ISBT 128 label

Quality Assurance application

On a regular basis, the quality assurance department accesses a Tissue Location History menu in The Eye-Bank's database to confirm whether tissue intended for distribution was appropriately scanned and distributed in a timely manner to meet operating room schedules and whether appropriate ISBT 128 labels were applied to reflect special processing procedures. QA also confirms that all incoming tissue was scanned before refrigeration, including recently recovered tissue, as well as tissue returned after medical director consults or from cancelled surgeries. Daily, QA makes random selections of tissue in the laboratory to confirm the length of time the tissue has been "warmed up" and whether the tissue was appropriately scanned after being removed from a refrigerator. Additionally, QA confirms the final disposition of any tissue with positive serologic results.

CONCLUSION

Whereas ISBT 128 is generally perceived as an effective method for tracking tissue for worldwide distribution, The Eye-Bank for Sight Restoration chose to integrate it with its database as a means to also establish an in-house tracking system. As a result, ISBT 128 has helped provide a computerized history, including dates, times, and technician identification involved in the processes that occur once tissue is received in the ocular laboratory. Use of ISBT 128 labels and scanners provides more accurate data and eliminates illegibility in documentation. Going forward the system will be used to trace tissue distributed nationally and internationally. It is anticipated to also be a key step toward implementing a complete electronic laboratory record.

REFERENCES

1. formerly known as the International Council for Commonality in Blood Bank Automation, is an international non-governmental organization (NGO) in official relations with the World Health Organization (WHO) that manages, develops, and licenses ISBT 128
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6. EBAA Annual Statistical Report 2014
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