ISBT 128

ICCBBA is a nongovernmental organization in official relations with the World Health Organization

ISBT 128
For Human Organs

An Introduction

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Table of Contents

1 Preface

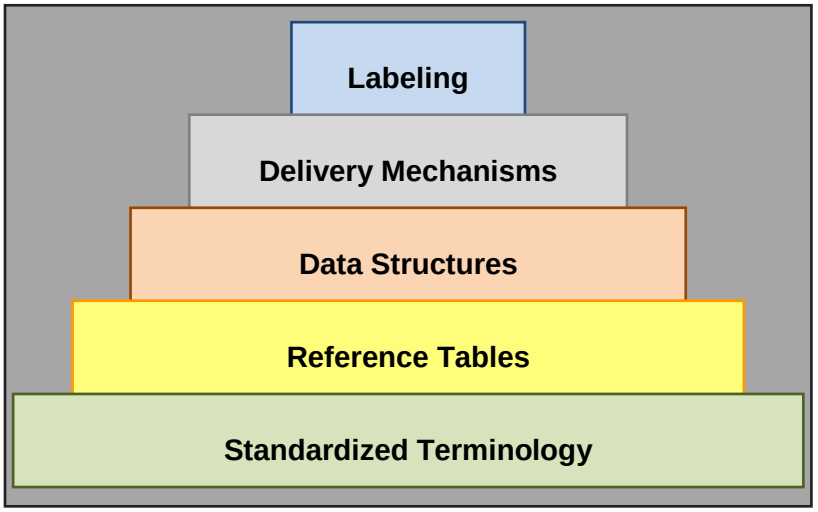
A great deal of important information is presented on the label of an organ product. The information varies from country to country according to licensing regulations, language differences, and local practice but, in all cases, it is essential that it is recorded accurately, transferred correctly, and that critical items such as the organ description, ABO type, and donor identifier are clearly understood by medical personnel transplanting the organ. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

There is a clearly identified need for international agreement on product descriptions and a means of ensuring the unique identification of each donation throughout the world. These fundamental requirements are essential for effective traceability on a global scale. An editorial in the Bulletin of the World Health Organization (WHO) (http://www.who.int/bulletin/volumes/91/5/12-116988/en/) recognized the need for effective traceability of all medical products of human origin (MPHO), including blood, organs, bone marrow, cord blood, corneas, tissues, reproductive cells, and milk, to ensure donor and recipient safety. In addition, the bulletin called for the global adoption of ISBT 128 as the coding system for all MPHO. WHO and ICCBBA worked together to develop the WHO Standard Organ Transplant Nomenclature (available at http://www.who.int/entity/patientsafety/WHO-Standard-Organ-Transplant-Nomenclature-1-0.pdf) and have an ongoing joint work program to take forward the adoption of ISBT 128. ICCBBA has been recognized as a nongovernmental organization in official relations with the WHO since 2014.

To enhance safety and efficiency, facilities may operate sophisticated computer systems. Transfer of information between facilities by electronic means ensures accuracy, but can only be effectively achieved in a global context by use of internationally agreed standards to define the information environment.

2 What is the Information Environment?

The information environment comprises a number of layers each of which needs to be in place to ensure that standardization can be achieved.



Standardized Terminology

At the base lies the standardized terminology (ISBT 128 Standard Terminology for Medical Products of Human Origin) that will ensure the common understanding of terms. Without clarity at this level, any further attempt at standardization is lost. However, obtaining agreement on standardized terminology at the necessary level of detail involves careful analysis and robust consensus. Terminology must be defined to ensure terms have the same meaning to all. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The standardized terminology needs to be accessible to all users of the standard. For organ transplantation the WHO Standard Organ Transplant Nomenclature has been developed by a WHO consultative process and is used as the basis for the standardized terminology.

Reference Tables

Once the standardized terminology is in place, the definitions can be combined to form tables. Reference tables are built to map each term to a suitable code, and such tables can be large and complex. It is essential that reference tables are managed to ensure that they can be modified to meet the changing needs of clinical practice in a manner that maintains their integrity and avoids ambiguity or redundancy.

Product reference tables in particular need to combine a tightly defined structure with the flexibility to accommodate expansion and change in ways that cannot be anticipated.

Successful management of the standardized terminology and reference tables requires input from both clinical experts in the field and information specialists. The tables themselves need to be published in a manner that allows all users of the standard to access the most up-to-date versions in a timely manner.

Data Structures

Having built reference tables which convert the clearly defined information into codes suitable for electronic transmission, it is necessary to define data structures in which to embed the data. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure and provide the links to the appropriate reference tables for conversion of codes to meaningful information.

Data structures must be clear, unambiguous, and suited to the anticipated delivery mechanisms.

Delivery Mechanisms

The delivery mechanism is the means of delivering the electronic information. Probably the most well-known delivery mechanism is the linear bar code that has been used for many years. There are several types of linear bar codes.

Higher capacity delivery systems are available using two-dimensional bar codes. These codes can carry much more information in each symbol.

ISBT 128 uses Code 128 linear barcodes and Data Matrix two-dimensional codes.

It is important to recognize that a range of delivery systems can sit at this level of the hierarchy. The standardized terminology, reference tables, and data structures of the information standard can be delivered as easily in a linear bar code as they can in an RFID tag. The standards themselves need to be adaptable in order to make the best use of new delivery mechanisms as they are developed.

Labeling

The final element in the coding system is the associated labeling. Although there will be other labeling requirements that fall outside the coding system, an effective coding system needs to consider the physical association between the information and the product. Whether incorporated into a bar code or an electronic tag, there needs to be a mechanism that will ensure correct physical assignment of information to the product, and confidence in the association between electronically stored information and eye-readable printed information.

The Information Environment

Together these elements form the Information Environment. For such a system to be, and to remain effective, it must be carefully designed and managed. There must be an ongoing dialogue between clinical users, scientists, information specialists, and equipment and software vendors to ensure that the standard continues to support rapidly developing clinical practice.

3 The ISBT 128 Standard

The ISBT 128 Standard provides the specification for many of the elements of the information environment required in transfusion and transplantation. It defines the lower three levels of the model: the standardized terminology, reference tables, and data structures. Minimum requirements are also defined for delivery mechanisms and labeling. By complying with ISBT 128, procurement and transplant facilities can provide electronically readable information that can be read by any other compliant system.

ISBT 128 specifies:

- a donation numbering system that ensures globally unique identification;
- the information to be transferred, using internationally agreed reference tables;
- an international product reference database;
- the data structures in which this information is placed;
- a bar coding system for transfer of the information on the product label;
- a standard layout for the product labels of some MPHO;
- a standard reference for use in electronic messaging.

The standard, originally designed for use in blood transfusion, has gained international acceptance and is now in widespread use. It has been extended beyond blood transfusion to include cellular therapy, tissues, organs, regenerative medicine, and banked human milk products. More than 80 countries across six continents are registered to use ISBT 128, and this number continues to grow. More than 40 million blood, cell, and tissue products are labeled with ISBT 128 each year.

The most current version of the standard terminology is maintained on the ICCBBA website at www.iccbba.org.

4 Unique Donation Identification Number (DIN)

ISBT 128 provides for unique identification of any donation worldwide. It does this by using a 13-character DIN built up from three elements: the first identifying the procurement facility, the second the year, and the third a sequence number for the donation. For example:

S0020 17 001022 10 **G**

where:

S0020 identifies the procurement facility (in this case Karolinska University Hospital, Stockholm, Sweden);

17 identifies the procurement year as 2017;

001022 is the sequence number of the donation assigned by the procurement facility.

The two digits printed vertically are flag characters that allow individual bar codes in a number set to be discretely identified providing an option to add process control.

An additional character is enclosed in a box at the end of the identifier. This is a checksum character used when a number is entered into a computer system through the keyboard to verify the accuracy of the keyboard entry.

Facility codes are assigned by ICCBBA, who maintain a database of all registered facilities that can be found on their website (www.iccbba.org). A lookup program allows the look up of individual facility codes. ICCBBA licensed facilities and vendors are able to download a full listing of all registered facilities.

5 Product Descriptions

ISBT 128 provides a comprehensive and highly flexible system for describing products and assigning product codes. The foundation of this system is a standard terminology which is constructed by international consensus to ensure global consistency in use and understanding. The ISBT 128 terminology for organs is based on the WHO Standard Organ Transplant Nomenclature v1.0 (see section 8 below). The standard terminology is maintained on the ICCBBA website and is publicly available.

New products are defined by combining pieces of information from the standardized terminology in a way that unambiguously describes the product. This process is made easier by the use of the concepts of component class and attributes.

This unique product description is assigned a Product Code that becomes incorporated into the ISBT 128 Product Description Code Database, ensuring that the product will be accurately identified in any country in the world that is using ISBT 128.

New entries into the Product Description Code Database can be readily accommodated allowing the system to expand to meet a growing range of products without losing the overall structure of the coding system.

The following example is taken from the database:

Component Class:	KIDNEY, SINGLE
Attribute:	Left

Product Description Code: N0002

While the description of a product in the Product Description Code Database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

6 Delivery Mechanisms

The delivery mechanism is the means by which the information is represented in a machine-readable manner. The most common such mechanism is the linear bar code. ISBT 128 has traditionally been based on the linear bar code using Code 128 symbology. To achieve greater efficiency, or to label very small containers, a two-dimensional Data Matrix symbol can be used. By using an ISBT 128 Compound Message, multiple pieces of information can be encoded into a single symbol that occupies a very small area.

Comparative Size of Code 128 and Data Matrix Symbols

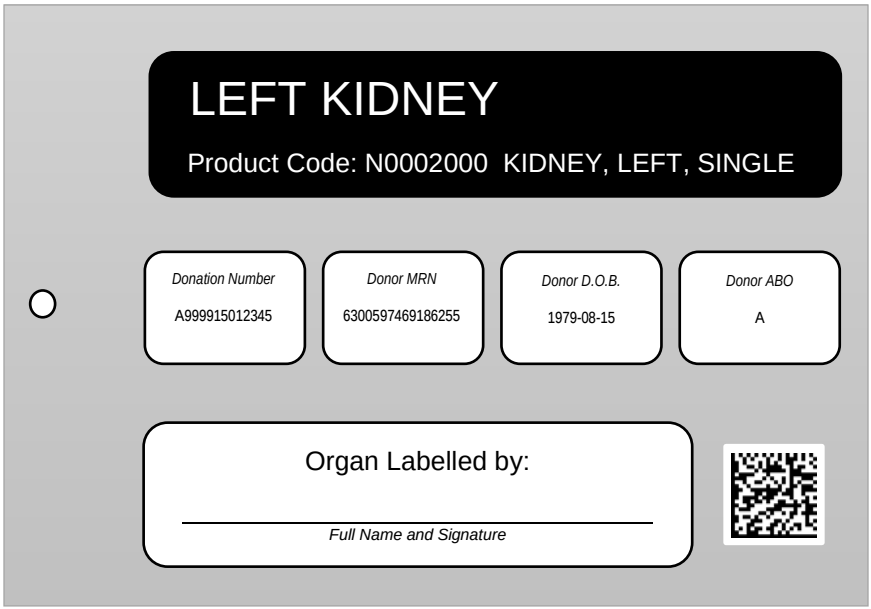
The Data Matrix symbol on the left contains all of the information held in the five Code 128 symbols on the right.

There is some interest in the use of RFID tags. This technology is still developing, but may provide significant benefits in some situations. ISBT 128 Compound Messages are compatible with RFID.

7 Product Labeling

In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides information on general labeling principles and minimum information that should appear on product labels. Critical eye-readable information such as product description, ABO group, and donor identifier also appear on the label. This reduces the risk of confusion when products from multiple sources are being used.

An example label using ISBT 128 data identifiers is illustrated below.



8 Standardized Terminology for Organs

In 2013, ICCBBA introduced terminology for organs as a result of the Standardization of Organ Nomenclature Globally (SONG) Project established by the World Health Organization in collaboration with ICCBBA.

The SONG project was undertaken in response to the World Health Assembly resolution WHA 63.22 on Human Organ and Tissue Transplantation that urges Member States to collaborate in collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology, and ethics of donation and transplantation; and encourages 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. More information can be found at http://www.who.int/transplantation/tra_song/en/

9 The Role of ICCBBA

ICCBBA is the not-for-profit standards body responsible for the management, development, and distribution of the ISBT 128 Standard and is a nongovernmental organization in official relations with the World Health Organization. It maintains a permanent office to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports volunteer Technical Advisory Groups that include experts from both the transfusion/transplantation community and relevant manufacturers. Fees collected by ICCBBA from registered facilities are used to support these functions.

Through its activities ICCBBA provides the management support essential to sustain standard coding in the complex and rapidly changing fields of transfusion and transplantation. In particular it delivers:

1) stability – users can be confident in the stability of the standard to satisfy the long time periods over which information has to be retained (e.g., European Commission requirements for data to be stored and traceable for 30 years);
2) user focus – the user community are the experts in their field and ICCBBA, through its volunteer Technical Advisory Groups, ensures that the information standard meets, rather than dictates, user needs;
3) flexibility – as clinical and scientific knowledge grows there is rapid development with changing information needs. ICCBBA ensures that the standard is flexible enough to accommodate those needs;
4) responsiveness – in these rapidly developing medical fields ICCBBA ensures that the standard is able to respond to user needs in a timely manner;
5) globalization – ISBT 128 is a truly international standard with endorsement worldwide;
6) compatibility – standards do not work in isolation but need to interface with equipment, software, and other standards. ICCBBA works with industry and other standards bodies to maximize compatibility.

Blood, cellular therapy, tissue, organ, regenerative medicine, and human milk collection and processing facilities, and manufacturers of equipment or software that uses ISBT 128, are required to register with ICCBBA and pay a registration and an annual licensing fee. Registered organizations obtain access to all ICCBBA documents and databases.

For further information on ISBT 128, visit the ICCBBA website at www.iccbba.org or call us at +1 909 793 6516.

