ISBT 128

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

ISBT 128
For Blood Components

An Introduction

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1 Preface

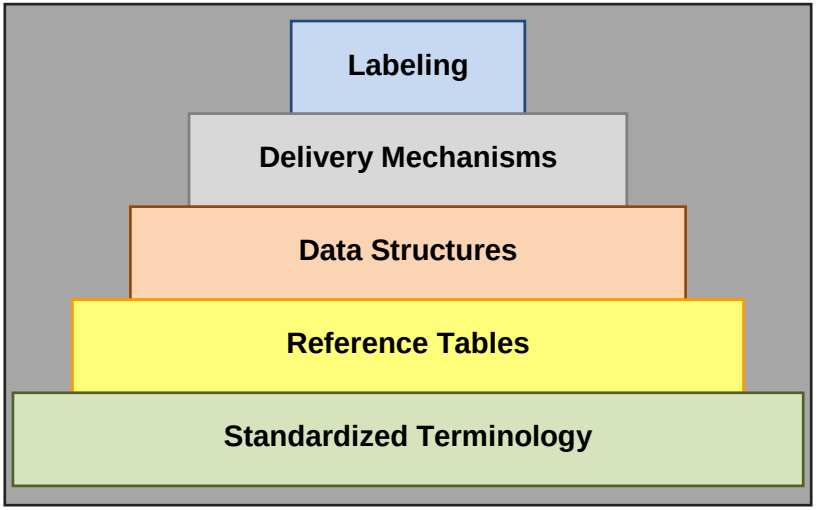
A great deal of important information is presented on the label of a blood product. The information varies from country to country according to licensing regulations, language differences and local practice but, in all cases, it is essential that it is recorded accurately, transferred correctly, and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

In today's world of multinational relief programs and military operations, blood products collected in one country may be used in another. There is a clearly identified need for ensuring the unique identification of the donation throughout the world and for international agreement on product descriptions. 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 human milk, to ensure recipient safety and called for the global adoption of ISBT 128 as the coding system for all MPHO. WHO and ICCBBA have a joint work program to take forward this initiative, and ICCBBA has been recognized as a nongovernmental organization in official relations with WHO.

Increasingly, collection and transfusion facilities operate sophisticated computer systems to enhance safety and efficiency. Transfer of information between such 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 (ST-002 *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. A simple example serves to illustrate this. The term 'leukodepleted' is widely understood as meaning the removal of leukocytes from a blood component; however there are different ways of carrying out such a removal, and differing amounts of residual leukocytes that are used to define *leukodepleted*. In order to accommodate these variations a range of standardized terminology and associated values are required. Extreme care is needed in order to ensure that an internationally agreed standardized terminology is defined at the required level of granularity. 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.

Reference Tables

Once the standardized terminology is in place, these can be combined to give the required items of information. Reference tables are built to map each item to a suitable code. Such tables can be large and complex and it is essential that they 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 need to be clear and unambiguous and must take into account any constraints imposed by the anticipated delivery mechanisms. For example, data structures that will be used in linear bar codes are limited in the number of characters they can contain.

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 in blood transfusion practice for many years.

Higher capacity delivery systems are available using 2-dimensional or reduced space symbology bar codes. These codes can carry much more information in each symbol. More recently the use of radio frequency identification (RFID) chips that can carry encoded information is being developed for medical products of human origin.

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 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. This latter requirement must not be overlooked in the enthusiasm to embrace remotely rewritable tags.

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, 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, collection and processing 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 label;
- 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, 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

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

G1517 16 600001 01 G

where:

G1517 identifies the collection facility (in this case Welsh Blood Service, Wales, United Kingdom);

16 identifies the year in which the Donation Identification Number was assigned (in this case 2016);

600001 is the serial number of the donation assigned by the collection 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 standard terminology is maintained on the ICCBBA website and is publically available. Blood component terminology is managed by the blood transfusion Technical Advisory Groups of ICCBBA.

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, modifiers, core conditions, and attributes.

This unique product description is assigned a Product Code that becomes incorporated into the ISBT 128 Product Description Code Database table, 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 table:

Component Class:	Red Blood Cells
Modifier:	None
Core Conditions:	CPDA-1 (anticoagulant)
	450 mL (nominal collection volume)
	Refrigerated (storage condition)
Attribute:	Irradiated

has a Product Description Code of E0206.

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 Other Data Structures

In addition to the donation identifier and product codes, many other pieces of important information need to be provided with a blood donation. Through its wide range of data structures, ISBT 128 provides significant information including, but not limited to:

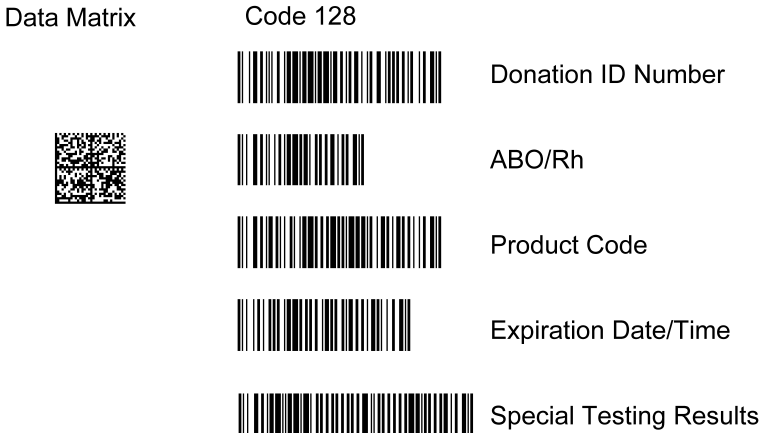
- ABO and Rh(D) Blood Groups;
- Type of Donation (Volunteer, Directed, Autologous, *etc*);
- Expiration Date and Time;
- Collection Date and Time;
- Red Cell Phenotyping Information;
- HLA Typing Information;
- CMV and other test results;
- Collection Container Catalog and Lot Number;
- Patient Date of Birth;
- Patient Identification Number.

7 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 and this is still required on blood donations. However, an additional two dimensional Data Matrix code may be added to a blood component label.

A single Data Matrix code can carry the same information as encoded in multiple linear codes. This allows much more rapid scanning of units at the point of blood center issue and receipt into the transfusion laboratory. In the cellular therapy and tissue banking fields, the need to use very small containers means that label size is severely restricted and in these situations a use of Data Matrix code may replace linear codes.

Comparative size of Code 128 and Data Matrix Symbols



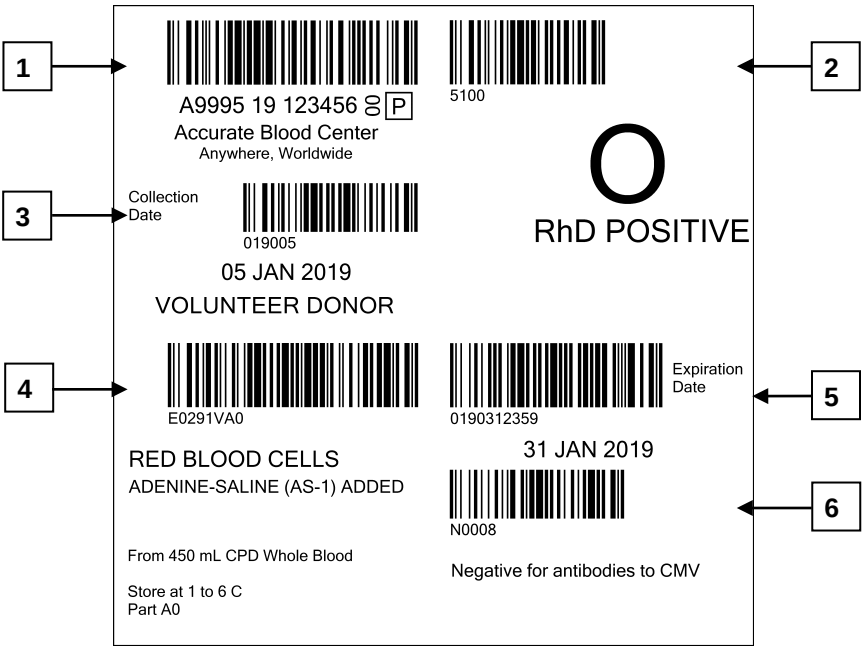
The Data Matrix symbol on the left contains all of the information held in the five Code 128 symbols on the right.

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

8 Product Labeling

In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides a standard labeling format that ensures a consistent layout of the bar codes on product labels. Critical eye-readable information such as blood groups, product description, and expiration date also appear in fixed positions on the label. This reduces the risk of confusion when products from multiple sources are being used.

The ISBT 128-specified label is illustrated below.



1	Donation Identification Number
2	ABO/Rh Blood Groups
3	Collection Date (optional)
4	Product Code
5	Expiration Date (and Time)
6	Special Testing (optional)

In addition to linear bar codes, a 2-D bar code, comprising all the information in the linear bar codes, may be placed on the label. Scanning a single code improves efficiency, but requires an imaging scanner.

9 The Role of Technical Advisory Groups

ICCBBA involves international volunteer experts in blood, cellular therapy, tissue, and milk banking in the development and maintenance of the standard. These experts are organized into Technical Advisory Groups (TAGs) that meet regularly (both face-to-face and through conference calls) to further develop and expand the standard ensuring it continues to meet the needs of its users. The vital role of these groups cannot be overemphasized. It is only through the involvement of such expert panels that ICCBBA can be assured it has the knowledge base to anticipate the needs of its users in fields where change is constant. More than 300 experts participate in the ICCBBA TAGs.

For Blood Banking, the advisory groups are the Asia Pacific Technical Advisory Group (APTAG), the Europe, Middle East, and Africa Technical Advisory Group (EMATAG), and the Americas Technical Advisory Group (ATAG). The groups comprise participants from blood collection facilities, testing laboratories, transfusion services, professional organizations, regulatory agencies, and vendors from around the world.

10 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 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 blood banking environment. 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;
2) user focus – the user community are the experts in their field and ICCBBA, through its 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, and banked human milk collection 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.

