ISBT 128

An Introduction

ISBT 128

More than Identification

ISBT 128
An Introduction

3rd Edition - 2006

Editorial Board

Editor

Paul Ashford, MSc. CEng. CSci.
Executive Director
ICCBBA, Inc

Published by:
ICCBBA, Inc
204 St Charles Way, Unit 179E, York, PA 17402, USA
www.isbt128.org

Warranty

ICCBBA, Inc provides no warranty that the use of *ISBT 128* is suitable for any particular purpose and the selection, use, efficiency and suitability of *ISBT 128* is the sole responsibility of the Licensed User.

Liability

ICCBBA, Inc's liability is limited to that specified in the ICCBBA, Inc. License Agreement which is available on the ICCBBA web site. Under no circumstances shall ICCBBA, Inc's liability exceed the current annual license fee, and ICCBBA, Inc will in no circumstances be liable for any damages whatsoever, including without limitation damages for loss of data, business or goodwill or any other consequential losses of any nature arising from the use of *ISBT 128*.

Table of Contents

1 Copyright

This document may be distributed freely provided that the copyright statement remains an integral part of the document or any quoted portion.

It may also be translated, without written permission, provided that the translation indicates that it is a translation from an ICCBBA, Inc copyrighted document and that ICCBBA, Inc is not responsible for the accuracy of the translation.

Those wishing to implement *ISBT 128* must register with ICCBBA, Inc and pay the annual license fee.

2 Preface

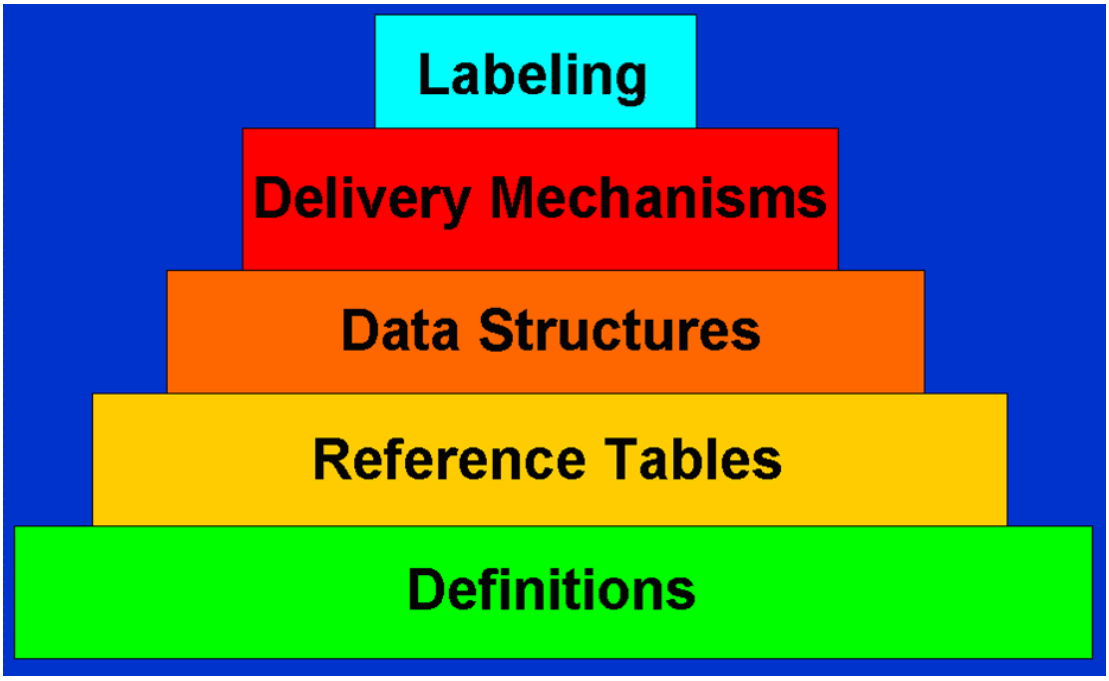
A great deal of important information is presented on the label of a blood, cellular therapy or tissue product. The information varies from country to country according to licensing regulations, language differences and local practice but, in all cases, it is essential that it is recorded accurately,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

In today's world of multinational disaster relief programs, military operations, and international databases of patients and donors, blood or tissue products collected in one country may be used in another. In such situations the criteria identified above still have to be met. In the fields of cellular therapy and tissue such international transfers occur on a routine basis.

Increasingly, collection and transfusion/transplantation 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.

3 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.



Definitions

At the base lies the dictionary of definitions that will ensure common understanding of terms. Without clarity at this level any further attempt at standardization is lost. However, obtaining agreement on definitions 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 leucocytes that are used to define leukodepleted. In order to accommodate these variations a range of definitions and associated values are required. Extreme care is needed in order to ensure that an internationally agreed dictionary is defined at the required level granularity. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The dictionary of definitions needs to be accessible to all users of the standard.

Reference Tables

Once the definitions are in place, these can be combined to give the required items of information. Reference tables are built to map each item to a suitable coding. Such tables can be large and complex and it is essential that they are managed to ensure that they can be modified to cater for changing clinical practice in a manner which 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 which cannot be anticipated.

Successful management of definitions 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 Mechanism

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. There are in fact several types of linear bar codes including the old fashioned Codabar system that was only capable of encoding numeric information, and Code 128, a bar code standard widely used in coding standards such as EAN and *ISBT 128*.

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 we are seeing the development of radio frequency ID chips which can carry encoded information.

It is important to recognize that a range of delivery systems can sit at this level of the hierarchy. The definitions, 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 re-writable 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.

4 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 definitions, 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 accepted by the ISBT Council in 1994, has gained widespread acceptance and is now endorsed by the American Association of Blood Banks, European Plasma Fractionators Association, European Blood Alliance and the US Food and Drug Administration. By the end of 2006, facilities in 49 countries across six continents were registered to use *ISBT128*, and this number continues to grow.

5 Data Structures

The data structures specified in *ISBT 128* are simply the formal definitions of how information is to be identified and electronically presented. These definitions identify each piece of information being transmitted and allow software developers to provide the interfaces necessary to output and input messages containing *ISBT 128* data structures. The use of *ISBT 128* data structures ensures that completely independent systems from different suppliers are able to communicate information in a clear and unambiguous manner thus improving safety.

The data structures also provide a standard reference that allows transfusion and transplantation information to be encoded within electronic messages such as HL7. The next three sections discuss some of these data structures.

6 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:

where:

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

07 identifies the collection year as 2007;

600001 is the sequence number of the donation assigned by the collection facility.

The two digits printed vertically allow individual bar codes in a number set to be discreetly identified hence providing an option to add process control into the collection process.

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.

Collection facility codes are assigned by ICCBBA, Inc, who maintains a database of all registered facilities on their website (www.iccbba.org).

7 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 dictionary of definitions which is constructed by international consensus to ensure global consistency in use and understanding.

New products are defined by combining pieces of information from the dictionary in a way that unambiguously describes the product. This process is made easier by the use of the concepts of component class, modifier, and attributes. Blood Components and Cellular Therapy products include core conditions among their attributes.

This unique product description is assigned a product code number that becomes incorporated into the *ISBT 128* product description 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 dictionary 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.

Examples taken from the database tables follow:

Component Class:	Red Blood Cells
Modifier:	None
Core Conditions:	anticoagulant CPDA-1; original volume 450 mL; storage conditions refrigerated
Attribute:	Irradiated

has product code E0206.

Component Class:	HPC, Cord
Modifier:	Cryopreserved
Core Conditions:	DMSO; volume not specified; storage conditions <-120 C
Attributes:	Open 10% DMSO

has product code S0017.

Component Class:	Cancellous Bone Peg
Modifier:	Freeze Dried
Attributes:	Single Irradiated

has product code T0055.
Note: Core Conditions are not used in coding tissues.

8 Other Data Structures

In addition to the donation identifier and product codes, many other pieces of important information need to be provided with a donation. *ISBT128* provides a wide range of other data structures including:

- ABO and Rh(D) Blood Groups;
- Product Description (see next section);
- 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 and identification number.

9 Delivery Mechanisms

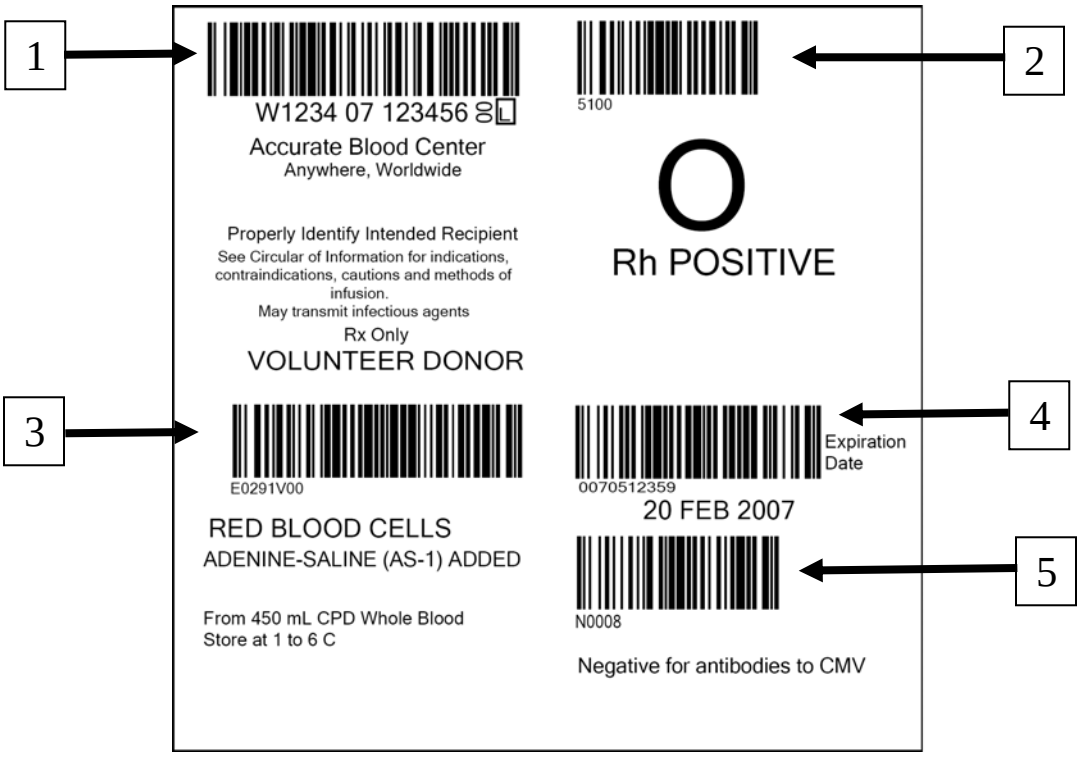
The delivery mechanism is the means by which the information is represented in a machine readable manner. The most common such mechanism is the linear bar code. *ISBT 128* has traditionally been based on the linear bar code using the Code 128 symbology and this is still used where space permits. With very small containers label size is severely restricted and in these situations a more efficient two-dimensional Data Matrix code can be used. By using the *ISBT 128* Compound Message, many pieces of information can be combined into a single code that occupies a very small area.

There is much interest in the use of radio-frequency identification (RFID) tags. This technology is still developing, but may provide significant benefits in some situations. *ISBT 128* Compound Messages are compatible with RFID.

10 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 product labels with the bar codes, and critical eye readable information such as blood groups, product description, and expiration date appearing in fixed positions on the label. This reduces the risk of confusion when products from multiple sources are being used.

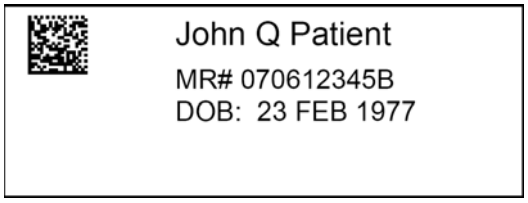
The *ISBT 128*-specified label is illustrated below.



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

11 Improving Safety at the Bedside

The risk of error due to misidentification at the bedside is recognized as one of the prime causes of incorrect transfusion. In order to support improved safety at this critical point, *ISBT 128* data structures have been developed to hold patient critical information including date of birth and hospital number. An important characteristic of these data structures is the use of a 'location code' which allows the reading system to identify the item from which a code was read; hence it is possible to electronically distinguish between a patient identifier scanned from a wrist band or from a cross match label. This permits a high degree of control over the verification process.



12 The Role of ICCBBA, Inc

ICCBBA, Inc is a not-for-profit standards body responsible for the management, development and distribution of the *ISBT 128* specification and databases. 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 made up of experts from both the transfusion/transplantation community and relevant manufacturers.

Blood, Cellular Therapy and Tissue collection facilities, and manufacturers of equipment or software that uses *ISBT 128*, are required to register with ICCBBA, Inc and pay a registration and an annual license fee. Registered organizations obtain access to all ICCBBA, Inc documents and databases.

For further information on *ISBT 128*, visit the ICCBBA, Inc Website at www.iccbba.org.

