ISBT 128

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ISBT 128
For Human Milk

An Introduction

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Table of Contents

1 Preface

A great deal of important information is presented on the label of a banked human milk 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 expiration date and product description are clearly understood by the person administering the product. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

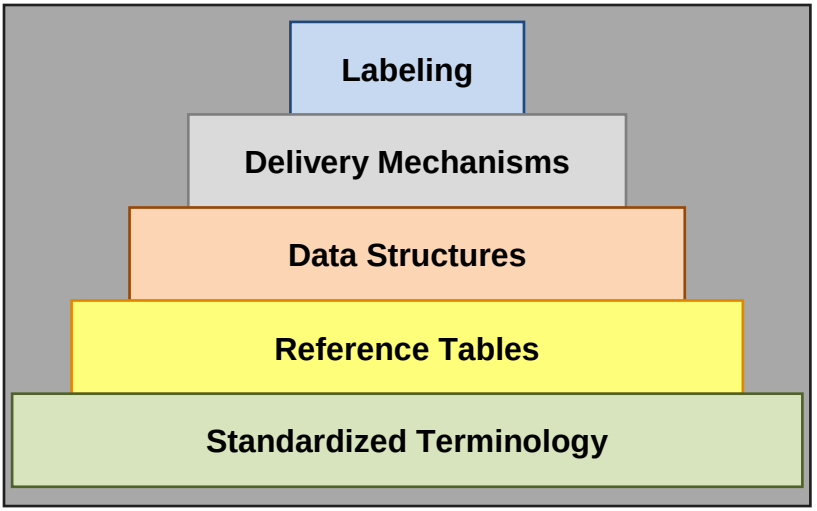
Individuals dealing with the collection and administration of banked human milk must ensure the safety of the recipient by making certain the right product gets to the right recipient and that traceability records are accurately maintained. Transfer of information by electronic means enhances accuracy as well as adding efficiency to the process.

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 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.

The development of ISBT 128 for milk banking is being overseen by an international advisory group supported by the European Milk Banking Association and the Human Milk Banking Association of North America. These organizations have issued a consensus statement on the adoption of ISBT 128 (see page 18).

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 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. While the term 'pasteurized' is defined as heating a liquid to a specific temperature, different national guidelines may exist to achieve this process. 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 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 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 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.

3 The ISBT 128 Standard

The ISBT 128 Standard provides the specification for many of the elements of the information environment required in product administration. 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, 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;
- standardized product label layouts for some subject areas;
- a standard reference for use in electronic messaging.

The standard, originally accepted by the ISBT Council in 1994, has gained widespread acceptance. It has been extended beyond blood transfusion to include cellular therapy, tissues, organ, and banked human milk products. There are over 5,500 facilities in 89 countries registered to use ISBT 128, and this number continues to grow. There are currently milk banks in Canada, Spain, the United Kingdom, and the United States registered with ICCBBA.

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 from three elements, the first identifying the collection facility, the second the year, and the third a sequence number for the collection. For example:

G222018600002 00 **L**

where:

G2220 identifies the collection facility (in this case Greater Glasgow and Clyde Milk Bank, Scotland);

18 identifies the year in which the DIN was assigned (i.e., 2018);

600002 is the sequence number of the collection assigned by the collection facility.

The two digits printed vertically allow individual bar codes in a number set to be discretely identified hence 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 on their website (www.iccbba.org). A lookup program allows lookup 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. Human milk terminology and coding is managed by ICCBBA and the international Milk Banking Technical Advisory Group (MBTAG), supported by the European Milk Banking Association and the Human Milk Banking Association of North America.

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 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 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:	HUMAN MILK
Attributes:	<=-30C
	Pasteurized
	For nutritional use

has product code M0001.

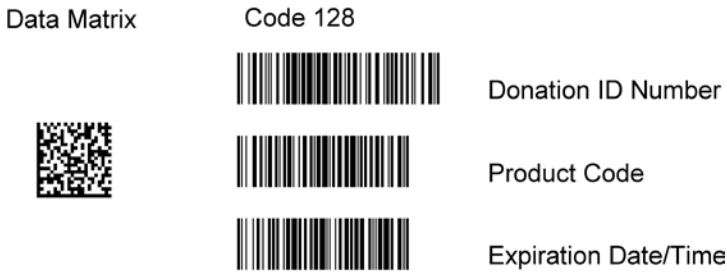
While the description of a product in the product code database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

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 the Code 128 symbology. However, a two dimensional Data Matrix symbol can be used on banked human milk labels and is preferable to maximize space on the label.

A single Data Matrix symbol can carry the same information as encoded in multiple linear bar codes. This allows much more rapid scanning of units at the point of milk bank issue and administration. Banked human milk often is stored in small containers which means that label size is severely restricted and in these situations the use of Data Matrix symbol is strongly recommended.

Comparative Size of Code 128 and Data Matrix Symbols



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

There is much 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.

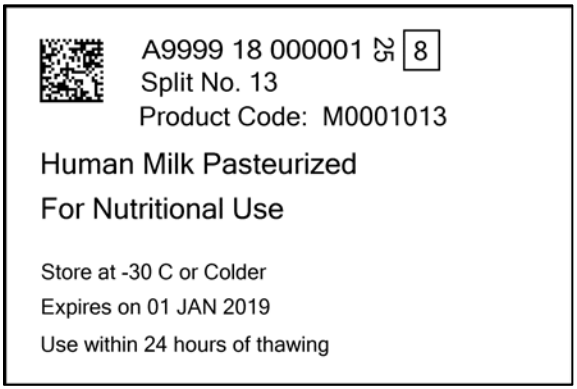
7 Product Labeling

In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides requirements for information that shall appear on the final label for human milk products. Eye readable information such as the Donation Identification Number and text of the Product Code are among the minimum elements required.

Since there is not a standard size container used for milk products, the ISBT 128 Standard does not specify a particular size of label. Additional nationally defined requirements for information on the label may influence the label size.

Example Label 4.5cm x 4.5cm

Example Label 5cm x 7.5cm



Below are images of banked human milk labels generously provided by the Greater Glasgow and Clyde Milk Bank in Scotland. These pictures serve as an example of how ISBT 128 has been implemented for use in labeling banked human milk.

8 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.

In order to ensure a common approach to the identification, a Milk Banking Technical Advisory Group (MBTAG) was established in 2013. The advisory group is supported by the European Milk Banking Association and the Human Milk Banking Association of North America.

9 The Role of ICCBBA

ICCBBA is the not-for-profit, nongovernmental standards body responsible for the management, development, and distribution of the ISBT 128 Standard. It maintains a permanent office to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports the Technical Advisory Groups comprising 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 milk 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 these 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, banked human milk collection facilities, and manufacturers of equipment or software that uses ISBT 128, are required to register with ICCBBA and pay an annual license 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.

Appendix

Milk Banking Consensus Statement

International Consensus Statement on the Terminology, Coding and Labeling of Human Milk Donations

The Boards of the European Milk Bank Association, Human Milk Banking Association of North America and ICCBBA, recognizing:

- the rapidly increasing demand for donated human milk as the nutrition of choice where mother's milk is not available;
- the global growth in the numbers of milk banks and the need for common standards of practice;
- the need for globally unique identification of milk donations to support international traceability and biovigilance;
- the benefit of international standardization of terminology, coding and labeling in clinical practice;
- the benefit of bar coding and other electronic messaging systems to ensure accurate and rapid transfer of critical information and to help eliminate manual transcription errors;
- the existing widespread use of the international information standard ISBT 128 in the fields of transfusion and transplantation;
- the successful implementation of an ISBT 128 bar coding and labeling system for human milk by the 'the NHS Greater Glasgow and Clyde (GGC) Milk Bank, Glasgow, UK;
- the need for international management and technical co-operation for the successful maintenance and development of such standards;

support the use of the ISBT 128 international coding standard for the bar coding and labeling of human milk donations.

To achieve this objective the above associations will form an international advisory group to:

a) develop a standard terminology to describe milk donations;
b) provide guidance on standard labeling of milk donations;
c) provide advice and support to milk banks introducing the standard;
d) advise on the ongoing development of the ISBT 128 standard to support new developments in milk banking.

Milk banks should take note of this initiative and plan for adoption of ISBT 128 coding and labeling of their products once the standard has been published.

For further information on this initiative see http://www.iccbba.org/subject-area/milk-bank

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