Implementation of an international barcode labeling standard, International Society of Blood Transfusion 128, and its integration with local regulations at a blood center in India: Step-by-step journey

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Abstract:
The International Society of Blood Transfusion (ISBT) 128 is an internationally endorsed, electronically readable labeling standard that provides a convenient and accurate means of identification, traceability, publication, and storage of information for blood and blood products. The authors' center recently registered with the International Council for Commonality in Blood Banking Automation (ICCBBA) and progressed to ISBT 128 labeling standard. This manuscript was written with the objective of sharing the authors' experience with respect to the implementation of ISBT 128 standards for whole blood donations and integration of ISBT 128 standards with Indian licensing regulations. The authors explore the process of implementation of ISBT 128 standards through a step-by-step journey that included facility registration with International Council for Commonality in Blood Banking Automation (ICCBBA), allotment of facility identification number, development of four-quadrant label for blood components, and integration of local regulatory requirements in the final "composite" label. Acknowledging the lack of any published report from India on ISBT 128 standards implementation, the authors wish to attempt help their peers in understanding and implementation of this global standard at their respective facilities.

Keywords:
International Society of Blood Transfusion 128, labeling standard, software

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Introduction

"Automation" is performing a process or procedure with minimal human involvement. Automation is used to enable, expedite, and increase the efficiency and effectiveness of routine laboratory work, *in-vitro* diagnosis, and scientific research.[1] In the field of blood transfusion services (BTS) automation comprises robotic equipment (the most common

being autosamplers), software including enterprise resource planning, and labeling methodology (like barcode label).

In BTS, labeling of blood and blood products is extremely important for the identification, traceability, and storage of information. An electronically readable coding system like barcode symbols provides a convenient and accurate means of publishing, storage, and retrieval of information. The International Society of Blood Transfusion (ISBT) 128 is an internationally endorsed standard for the

identification and labeling of blood and blood products.[2] It has been adopted and implemented by organizations including hospitals, blood centers, tissue banks, cellular therapy facilities, and plasma fractionators. In 1994, ISBT designated and empowered the International Council for Commonality in Blood Banking Automation (ICCBBA) for the promotion and management of the ISBT 128 standard.[3]

According to a report published in 2019, there were facilities in 89 countries on six continents registered to use the ISBT 128 standard.[4] However, in large countries like India with more than 3840 licensed blood centers,[5] only five blood center facilities (overall 17 facilities; five blood centers, and 12 cellular facilities) are registered with ICCBBA. The authors' center recently registered with ICCBBA and progressed to ISBT 128 labeling standard. Unlike few references from Western countries, there is a lack of any published report from India on ISBT 128 standards implementation. The authors would like to share the step-by-step journey of implementation of ISBT 128 at their blood center and its integration with local regulatory guidelines. Authors wish to attempt to help their peers in the implementation of this global standard at their respective facilities.

Objectives of the journey
This manuscript was written with the objective of sharing our experience with respect to the implementation of ISBT128 standards for whole blood donations and integration of ISBT128 standards with local licensing regulations.

ISBT 128 specifies two types of general labels: Base label (the label applied by the manufacturer of the container) and final label (the label placed on a product container by the processing facility). The manufacturer places the base label on the blood bag or container. It carries the manufacturer's identity, the catalog number, and the lot number of the container (or container set) encoded as ISBT 128 data structures.

The specification of the final label for the use of ISBT 128 for the labeling of blood products was developed by the ISBT Working Party on Automation and Data Processing (now called the Working Party on Information Technology) and published by ICCBBA in 1995. International standardization of labeling is a key element of ISBT 128. Standardized bar codes allow blood products to be shipped internationally with clear and unambiguous labeling that overcomes language barriers.

The default size of the final label is 100 mm (±2) by 100 mm (±2). The final label may be a single label or built with smaller labels. The label is divided into four equal quadrants. Regardless of the site of

collection worldwide, the information in form of either eye-readable data (maximum-10 data parameters) or machine-readable barcodes [maximum-six barcodes; Table 1], should be placed in the same relative positions in the four quadrants [Figure 1].

Prerequisites Before Undertaking the Journey

Facility registration and fee
Each blood center/facility is required to register with ICCBBA to obtain a unique facility identification number (FIN) and corresponding donation identification number (DIN). Individual facility has to complete and submit a facility registration form (available on ICCBBA website; https://www.isbt128.org/how-to-register) along with appropriate fee. To support its activities, ICCBBA charges a one-time registration fee and an annual licensing fee for the use of the ISBT 128 standard. Fee is calculated according to the type of facility (such as blood collection facility [BCF], cellular therapy facility, and tissue facility) and number of collections per year. Authors' center registered as (BCF; fee \$200) with annual volume of >20,000 products (authors were charged an annual license fee US \$407 plus \$0.0172 for each unit over 20,000). The total fee calculated for the authors' center was US \$611.1 (\$200+\$407+\$4.1). Registration of additional facility under the mother facility is charged a fixed additional registration fee (US \$182) and is allotted a new FIN.

Allotment of facility identification number
ICCBBA acknowledges the application for registration and assigns a unique FIN to individual facility. ICCBBA also provides "single" user login and password for each FIN for access to technical publications by ICCBBA, which includes documents such as the ISBT 128 standard technical specification as well as the standard terminology
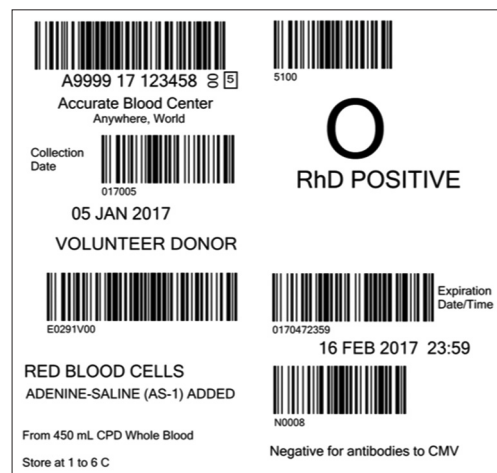

Figure 1: Relative positions of various data structures on the final label (reproduced from ISBT-128-Standard-Technical-Specification-v5.10.0.pdf). ISBT = International Society of Blood Transfusion

Table 1: The information contained in the final label in accordance with International Council for Commonality in Blood Banking Automation standards

Location	Information	Data structure type	
		Eye-readable	Machine-readable (barcode)
Left upper quadrant	DIN	✔	✔
	Collection date or collection date and time	✔	✔
	Type of donation or collection	✔	
	Details of collection centre with license number	✔	
Left lower quadrant	Product code	✔	✔
	Instructions for use	✔	
Right upper quadrant	ABO/Rh blood groups	✔	✔
Right lower quadrant	Expiration date and time	✔	✔
	Special testing	✔	✔
	Extended phenotypes	✔	

DIN=Donation identification number

for blood, cellular therapy, and tissue product descriptions. FIN assigned to authors' center was Q0018. Before FIN allocation to our center, seventeen FINs were allocated to various facilities from India. Access to technical publications allows centers to understand, prepare, implement, and maintain standards in accordance with ICCBBA.

Step-by-step Journey

Donation identification number

Unique DIN was generated each time a blood donation was recorded in the donation area. On-demand DIN barcodes were printed and pasted on blood bags and pilot tubes to identify each donation as separate and unique [Figure 2].

Donation identification number with product label

During the quarantine period (i.e. after preparation of blood component till results of screening tests are available), the blood component is additionally labeled with a preprinted "product label." The product label identifies the type of blood component and provides instructions for storage and use. Once the screening test results are available, both DIN label and product label are superseded by the four-quadrant final label.

Four-quadrant final-label

The four quadrants of the label were approached in the following order; left upper, left lower, right upper, and right lower.

Left upper quadrant
Donation identification number

The ISBT 128 standards have been designed in such a manner that each donation is uniquely identified and no two collections from a given facility would have the same identifier for 100 years. Each DIN can be divided into three sections for understanding: First is a five-character FIN, second is a two-character year code, and third is a

Figure 2: DIN barcodes on blood bag and pilot tubes. DIN = Donation identification number

six-character serial number. An example of DIN from authors' center is Q001820123456 [Figure 3], where: Q0018 identifies the collection facility (in this case FIN for author collection facility); 20 identifies the year in which the DIN was assigned (in this case year 2020), and 123456 identifies the serial number of the donation assigned by the collection facility.

Individual center may include two special characteristics at the end of DIN for enhanced safety; a two-digit flag character printed vertically and a box-enclosed check character. The flag character is two-character code that is an element of the DIN data structure but not part of the unique 13-character product DIN. Flag character can be used to identify the specific instance of a DIN label (e.g. identify a primary collection bag, a sample tube, or a donation record) and allow individual bar codes in a number set to be discretely identified. The check character is used to ensure the accuracy of the data in a data structure when such data is entered manually via a keyboard (instead of a barcode scanner). The value is calculated by applying an algorithm to the appropriate

data. This, again, is not part of the unique 13-character product DIN.

Collection date or collection date and time

Blood collection facilities may choose to have either only collection date or collection date and time. This data structure is present in both eye-readable and machine-readable forms. The template for eye-readable structure may be facility specific. The machine-readable structure may be indicated as a six or ten-character data content string, cyyjjj/cyyjjjhhmm (Example of cyyjjj is 021005 and cyyjjjhhmm is 0210221305) that is interpreted as follows:

- c (0) shall specify the century of the year in which the product was collected or recovered
- yy (21) shall specify the year within the century in which the product was collected or recovered
- jjj (005 or 022) shall specify the ordinal number within the calendar year (Julian date) on which the product was collected or recovered
- hh (13) shall specify the hour at which the product was collected or recovered (00–23); and
- mm (5) shall specify the minute at which the product was collected or recovered (00–59)

Type of donation or collection

BCF may choose to include the type of donation (voluntary/replacement/autologous) in the final label

Details of collection center with license number

The text information about the facility that collected (or pooled) the unit shall be printed below the DIN. This should include the full legal name of the facility and its location. The name printed in this location shall correspond to the FIN in the DIN above it.

Label at authors' center

Left Upper Quadrant contained all the information as suggested by ISBT including DIN, name of collection center, type of collection, and collection date and time. Additionally in compliance with local regulatory requirements, the license number provided by the Drugs Controller General of India, and particulars (anti-coagulant, volume of whole blood collected) of the whole blood
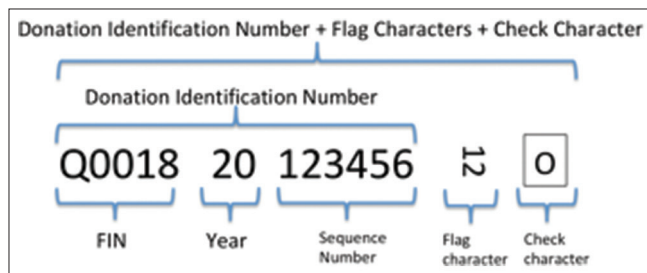
from which product was prepared, were printed in this quadrant along with other details.

Left lower quadrant
Product codes

ISBT 128 standards assign product codes using a very comprehensive and highly flexible system. Products are defined by combining pieces of information from the standard terminology in a way that each product code is unique and has a single common meaning, globally. A product code, for better understanding like DIN, can be divided into three sections. The first is a five-character product description code (PDC); the second is a one-character collection type (v/r/c) code, and the third is a two-character division code (aliquot/container). An example of product code from authors' center is E6514V00 [Figure 4], where E6514 stands for RED BLOOD CELLS | CPD > SAGM/450 mL/refg | ResLeu: <5E6; V stands for voluntary donation, and 00 identifies primary collection bag.

Product description code

The ISBT 128 PDC database table contains product codes that are specific to a product along with their description that unambiguously corresponds to that product. Alternatively, the PDC can be looked-up in *ISBT 128 Product Lookup Web Application.* The access to this database table or web application is limited to registered facilities only and use of the PDC databases requires paying an annual license fee to ICCBBA. Though unlikely, if a specific product description is not there in the database, then a new request needs to be made by submitting an E-mail to ICCBBA describing the new value required and providing a clear and concise definition

The underlying structure of the PDC terminology is based on the concepts of class, modifiers, and attributes
1. Classes are broad, general descriptions of cellular and/or non-cellular products (such as whole blood,

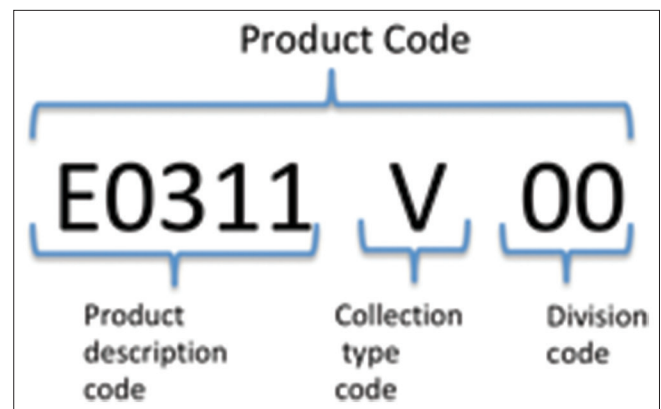

Figure 3: ISBT 128 DIN with flag character and check character. ISBT = International Society of Blood Transfusion, DIN = Donation identification number

Figure 4: ISBT 128 Product code. ISBT = International Society of Blood Transfusion

red blood cells (RBCs), fresh-frozen plasma, and hematopoietic progenitor cell)

2. Modifiers are applied to a "Class" to provide the next step in the categorization of the product. Examples are washed, thawed, and deglycerolized. Modifiers do not apply to all product types

3. Attributes provide the means to uniquely define the product. For the class of blood, cellular therapy, and derivative products, there is also a mandatory attribute group called core conditions, which must be explicitly selected, for example, irradiation. Core conditions include and convey three types of information, firstly anticoagulant and/or additive solution, secondly nominal collection volume, and thirdly storage temperature.

PDC is based on the permutation and combination of the product class, the core conditions, and attributes. These codes are maintained in a table in the database named product description. Let us illustrate this with an example of a PDC taken from the database table:
The PDC of E6319 corresponds to
1. *Component Class*: RBC
2. *Modifier*: Washed
3. *Core Conditions*: CPDA-1 (anticoagulant); 450 mL (nominal collection volume); Refrigerated (storage condition)
4. *Attribute*: Irradiated

Product lookup web application provides two ways of search – using known PDC or using step-wise search parameters. The search provides a list of all the inclusive matches within the search parameters. Multiple "attributable values" can be selected for single search.

Collection type code
The type of donation or collection/intended use can be encoded in the sixth data character of the product code bar code. A few examples of possible collection type codes and the wording of label text are V-volunteer homologous (allogeneic) (default), C-replacement, F-family reserved, etc.

Division code
These characters represent aliquots, or one or more individual collections from the donor within the same donation event. The division code may represent:
1. One of the subunits from a single container that has been divided. This can also be referred to as an aliquot or a split
2. One of the containers from a collection where the volume of product collected required the use of more than one container
3. A single collection into one container.

Label at authors' center
The left lower quadrant contained all the information as suggested by ISBT including product code, product name, volume of product, and storage requirements. Additionally in compliance with local regulatory requirements, brief instructions for use were printed in this quadrant along with other details.

Right upper quadrant
ABO/Rh blood group
The ABO/Rh must be eye readable (in form of printed text) and machine readable (in form of barcode). The specifications for the Rh-positive blood group are – ABO text is written in solid black and Rh-group text is written in black on white background, and for the Rh-negative group – ABO text is as outlined in black and Rh-group is written in white on black background.

The machine-readable data structure, along with ABO/Rh (D) group provides information about the type of donation or collection/intended use. This data structure has four characters: "ggre"

where:
• gg designates the ABO and Rh blood groups and other information;
• r specifies Rh and Kell or GP-Mur (Miltenberger III) phenotype information;
• e is reserved for future use.

For the same blood group, the value for "gg," would differ according to the type of donation or collection/intended use. For example, the value for AB positive is 84 (intended use not specified), 80 (directed collection use only), or 86 (for autologous use only). The value of data characters "r" and "e" are not used in the United States and are used as "00." However, values of "r" (0–9, A–T, and X–Z) may be used to encode the results of testing for K, C, c, E, and e, and values U and V encode Mia/Mur antigen test results.

Label at authors' center
Right upper quadrant contained all the information as suggested by ISBT including ABO and RhD blood group. In compliance with local regulatory requirements, blood center pasted an additional color-coded ABO blood group label on the blood unit. The preprinted label was pasted adjacent to this quadrant. The results of mandatory testing (hepatitis B surface antigen, hepatitis C virus antibody, syphilis, HIV I and HIV II antibodies, and malarial parasite) were printed in this quadrant.

Right lower quadrant
Expiration date and time
This is similar to the collection date and time. Blood collection facilities may choose to have either only

expiry date or expiry date and time. This data structure is present in both eye-readable and machine-readable forms. The template for eye-readable structure may be facility specific. The machine-readable structure may be indicated as a 6 or 10 character data content string, cyyjjj/cyyjjjhhmm.

Special testing

Special testing is an optional ISBT 128-specified data structure has been defined to contain the results of special or additional testing (e.g., Cytomegalovirus (CMV), hemoglobin S, and extended RBC phenotyping)

Special testing may include:
1. Data structure 010 – General (indicate special characteristics of a product such as whether it has been phenotyped, the presence of antibodies, CMV antibody status, hemoglobin S status)
2. Data structure 012 – RBC antigens – General (information regarding RBC phenotypes (see glossary), CMV antibody, IgA, parvovirus B19, hemoglobin S, and/or a nationally-specified characteristic of the product)
3. Data structure 014 – Platelet HLA and platelet-specific antigens (information regarding HLA and HPA phenotypes, CMV antibody, IgA status, and anti-A and-B for platelet products)
4. Data structure 027 – Transfusion transmitted infection marker (information on the infectious disease screening status of a product).

Label at authors' center

Right lower quadrant contained all the information as suggested by ISBT including the expiry date and time. At the time of writing this manuscript, no special testing was being done at authors' center.

Integration with Local Guidelines

ISBT 128 label is internationally consistent with high flexibility. This coding system allows blood centers to integrate the labels with local regulatory requirements and guidelines. In India, such labeling guidelines are issued by the Ministry of Health and Family Welfare, Government of INDIA, in form of the Drugs and Cosmetics Act (1940) and Rules (1945); and its amendments thereafter. A standard ISBT 128 label encompasses the majority of guidelines required in India. However, in accordance with local regulatory requirements, certain additional parameters were added to the label and the authors ensured this compliance while designing the product label. These parameters included the license number of blood center (upper left quadrant), instructions for use (upper lower quadrant), color-coded ABO group label (adjacent to right upper quadrant), and results of mandatory testing (right
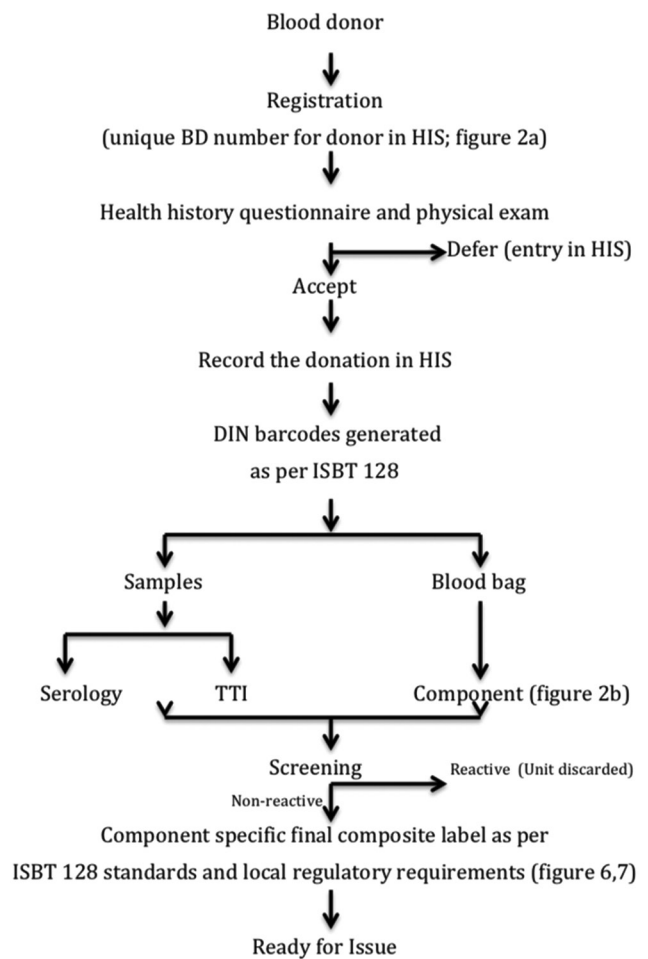

Figure 5: Flow diagram of blood donation process as aligned with ISBT 128 and HIS process flow. ISBT = International Society of Blood Transfusion, HIS = Hospital information system

upper quadrant). The final product label was also aligned with the hospital information system (HIS) to print donation and component-specific final-composite labels [Figures 5-7].

Role of Department of Information Technology

The requirements for implementing the ISBT 128 bar code symbology are documented in the "ISBT 128 Standard Technical Specification." The authors' center was already using an ISBT 128-compliant blood center software – Enterprise Management (Dedalus, Chennai, India) for registration of donors, preparation, and issue of blood components. Appropriate PDCs were selected from the database and IT software was updated. Barcode label printers were already in place. Since hospital-wide barcode printers and readers were based on code 128, no hurdles were expected. However, all bar code label printers and readers were evaluated, and tested according to the prospective product label and expanded donor identification number.

Figure 6: RBC bag with DIN barcode and pre-printed product label. RBC = Red blood cell, DIN = Donation identification number
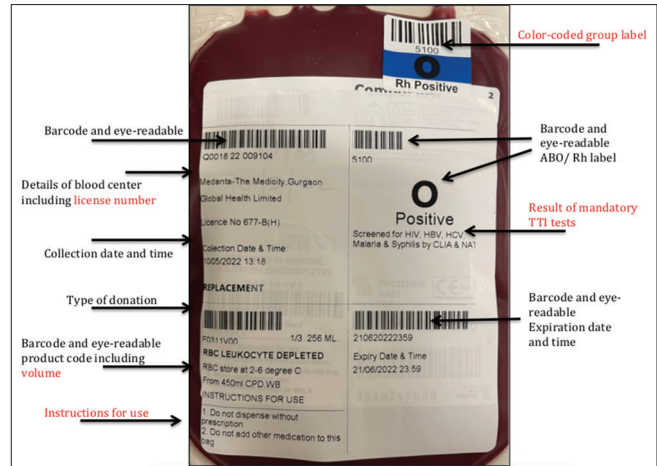

Figure 7: Composite label at authors' centre (marking in red-color denotes additional local regulatory requirements)

Stories from International Centers

ISBT 128 is a highly unique, flexible, and comprehensive database for every type of blood component prepared. This labeling system provides international consistency to support the transfer, transfusion, or transplantation of medical products of human origin (MPHO). Identification, or labeling, of biological products, is only one aspect, ISBT 128 allows unambiguous and accurate transfer of encoded information about biological products from one computer system to another

This assumes great importance on the occasions of military operations, terrorist attacks, earthquakes, etc., allowing bulk transfer of blood components from multiple sources without the need to relabel it in accordance with the requirements of its own computer system (minimal manual intervention) and complete ease using barcode-system. ISBT 128 has been recognized as a well-established initiative to ensure global traceability of MPHO and recommendation by the World Health Organization for a globally consistent coding system.[6]

By 2005, blood collection agencies of Zhejiang and Shanghai provinces in China shifted to uniform information systems based on ISBT 128.[7] This upgradation was triggered by SARS outbreak in 2003 that highlighted the problem in the transfer and exchange of blood units between agencies. The 2008 earthquake and Beijing Olympics further highlighted this problem for China as a country. Although the authors were able to successfully implement ISBT 128 in Zhejiang province, they listed the language barrier, high licensing fees, and complexity of product code database as reasons why ISBT 128 was not used throughout the country.

Hospital-based blood banks in Norway implemented ISBT-128 in 2006.[3] This enabled them to import blood products between blood banks, even with different computer systems, by scanning the data from the ISBT 128 label on the blood product directly into their own inventory. Manual relabeling was not required. Norway started the process of ISBT 128 implementation in 2000–2001 as buying and selling of the products between hospitals was extensive and since different hospitals used different labeling methods, addition of blood components was difficult and error prone. According to the authors, Norway had reported 13 incidences of transfusion-related adverse events due to incorrect administration of a blood component at the bedside.

In 2002, Kuwait became one of the leading countries to implement ISBT 128 labeling system.[8] Since the national BTS in Kuwait is centralized, they had to overcome limited administrative hurdles in the implementation. They used ICCBBA publications and bulletins to conduct educational lectures about ISBT 128. BTS had to update and revalidate the already in-use barcode system to ISBT 128.

Discussion

The acronym "ISBT 128" can be divided into two parts. ISBT stands for International Standard for Blood and Transplant and the number 128 reflects the 128 characters of the ASCII 7-bit character set that the standard uses. ASCII, American Standard Code for Information Interchange, is a character-encoding standard for electronic communication used by computers. In 1989, a working party convened by ISBT developed ISBT 128 standards in collaboration with the American Association of Blood Banks, American Red Cross, and Department of Defense, USA. In 1994, the ISBT Council approved application specifications for ISBT 128 and empowered the ICCBBA to promote the standard and maintain the new product code database. ISBT 128 was

intended to replace the ABC Codabar and other similar CODABAR-based standards in use in transfusion medicine at that time with a more secure barcode symbology, which contains more information.

A great deal of important information is presented on a blood product label. According to regulations, language differences, and local transfusion practice, this information varies from country to country and even different transfusion services and blood centers within a country. In today's world of multinational disaster relief programs and multinational military operations, blood collected and processed in one country may be used in another. In India, NACO-NBTC guidelines, now allow bulk transfer of blood components between licensed blood centers to avoid wastage of surplus blood.

It is essential that critical information such as ABO and Rh, expiration date, and product description be clearly understood by medical personnel transfusing the blood product. Given the concerns about safety and traceability, it is also important that these data be easily captured by a computer system and that each product is uniquely identified on a global basis. These goals are easier to achieve if there is standardization in blood product labeling. However, ISBT 128 is more than a labeling system; it is information standard. This means it is designed to transfer information about blood and other products of human origin electronically and is independent of the mechanism of transfer. ISBT 128 supports information transfer by a variety of mechanisms such as linear bar codes, two-dimensional symbols, radio frequency identification tags, and electronic messaging.

In their recent article, Distler and Ashford[4] concluded that ISBT 128 standard is a reliable system that has the capability to evolve with the needs of worldwide users and support the traceability and vigilance of MPHO.

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Conflicts of interest
There are no conflicts of interest.

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