ISBT 128

International Coding System for Blood, Tissues and Cells

Paul Ashford
History

- Blood transfusion was one of the earliest applications in healthcare to use bar coding
- CCBBA formed in 1974 to address errors in transfusion events
- ABC Codabar Standard developed in early 80’s
- 1985 - FDA published “Guideline for the Uniform Labeling of Blood and Blood Components”
“This [1985] guideline had the stated objective of reducing the dangers of transfusion caused through human errors by presenting important information on the label in a clear and logical format; it proscribed exactly where to place the eye-readable and bar code scanner-readable label information about the collecting center, blood type, component type, collection and expiration dates, and bag manufacturer information.”

Wallas C. Transfusion 2005
History

- Bar coding was essential to ensure correct association between samples, donations and documentation
- Primarily used at Blood Centres
- Hospital blood banks typically only received blood from a single Blood Centre
Problems with Codabar

- Misreads
- Seven digit identifier – not unique between organisations
- Re-cycling of numbers
- Product code capacity inadequate
- No management system
- Breakdown in product code assignment
First Gulf War

- Blood sourced from many countries and blood centres
- Duplicate numbers
- Product code mismatches – exacerbated by multiple language
- Traceability difficulties
WPADP

- International Society of Blood Transfusion
- Working Party on Automation and Data Processing – sponsored to develop a new standard
- Established ICCBBA as not for profit body to manage the new standard
What is ISBT 128?

- ISBT 128 is an international standard for the coding and labeling of blood components, cellular therapy products, tissue and organ transplant products.
- Provides a standard coding system that:
  - supports the open movement of blood, tissues and cellular therapy products around the world in such a way that critical information is rapidly, accurately and unambiguously communicated;
  - satisfies regulatory requirements;
  - support traceability and retention of information.
International Movement

Percentage of unrelated stem cell donations provided for national and international patients

Year

Percentage

Stem Cell Donations International Provided

Stem Cell Donations National Provided

WMDA Annual Report 2005
Regulatory Requirements

  - Article 14 Traceability
  - Article 15 Notification of Serious Adverse Events and Reactions
Art. 14 - Traceability

- Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa.

- To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component.
Art. 14 - Traceability

- Data needed for full traceability in accordance with this Article shall be kept for at least 30 years.

- (30 years from time of use, some products may be stored in liquid nitrogen for 10 years or more before use)
Art. 15 - Serious Adverse Events

- Member States shall ensure that:
  - (serious adverse events are notified)
  - blood establishments have in place a procedure accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.
Key Elements of ISBT 128

- Unique donation numbering system (global)
  - G151707123456

- International product list, definitions and codes
  - E3214 - Apheresis PLATELETS|ACD-B/XX/20-24C|Irradiated|ResLeu:<5log6

- Standard structures and formats for a wide range of information – allows interoperability

- Mechanism and organisation for development and maintenance of the standard
Manufacturer

Product

Batch

Serial No

Collection Facility

Donation (Serial No)

Product

Divisions
Collection Facility

Donation (Serial No)

Product

Divisions

Welsh Blood Service

G151707123654

Red Cell in SAG-M

Pack 2
Collection Facility

Donation (Serial No)

Pooled Intermediate

Product

Welsh Blood Service

G151707123654
G151707123655
G151707123656

G151707911203

Pooled Platelets
KOosteVERI

Valmistettu valkosoluttomista
puunasolutista ja jääplasmasta.
Säilytettävä 2 °C – 6 °C

Valmistus pvm: _______ klo. _______
Käytettävä 24 h sisällä valmistuksesta.

Sisältö: 428 ml
KOOSTEVERI
Valmistettu valkosoluttomista punasolutista ja jääplasmasta.
Säilyttävä 2 °C - 6 °C

Valmistus pvm: __________ klo. __________
Käytettävä 24 h sisällä valmistuksesta.
Sisältö: 420 ml.
KOOSTEVERI

Valmistettu valkosoluttomista
punasoluista ja jääplasmasta.

Säilytetään 2 °C – 6 °C

Valmistus pvm: _________ klo. _________

Käytettävä 24 h sisällä valmistuksesta.

Sisältö: 428 ml
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<th>PRODDESCRIPCODEFORM</th>
<th>PRODDESCRIP0</th>
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**RED BLOOD CELLS**

CPD, 450ml, refg

Res Leucocytes < 1 x 10^6

Plts & Cryo reduced
Labeling

- Based on principles of good labeling
- Based on established ISBT 128 label design
- Adapted for different container sizes
- Consistent across different languages
- Balance of human and machine readable information
Principles of Good Labeling

- Clear
- Carry sufficient information
- Critical information emphasised
- Capable of being read by machines and humans
- Consistent
- Compatible with printing and reading technologies
- Compliant with regulatory requirements
ISBT 128 Labelling

Accurate Blood Center
Anywhere, Worldwide

Properly identify intended recipient. See circular of information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.

R only
VOLUNTEER DONOR

RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED

From 450 mL CPD Whole Blood

Blood Group

Donation Identification Number

Product Code

Expiration Date

W1234 02 1234565 W

5100

E0291 V00

0022062359

Expiration Date

31 JUL 2002
Use of *ISBT 128*

- Over 3,300 Licensed Facilities worldwide
- Rapid growth: over 2,000 Licensed Facilities added this year to date
- 30 million units of blood *ISBT 128* labeled each year
- 73 Licensed Vendors including bag manufacturers, software developers, lab equipment manufacturers
- *ISBT 128* compliant products
Countries with ISBT 128 Licensed Facilities
Licensed Facilities in Europe
ICCBBA

- Established in 1995 by AABB, ARC and ISBT
- Not-for-profit organization
- Head office in CA, USA
- Mission Statement:
  - ICCBBA enhances safety for patients by managing the ISBT 128 international information standard for use in transfusion and transplantation
Management

- Management by ICCBBA delivered through a small staff.
- Administrative team deals with allocation of codes and user liaison
- Technical team supports standard documentation and development, technical liaison and education.
- Wide involvement of the user community through Technical Advisory Groups (TAGs) to ensure ISBT 128 meets user needs
- Liaison with relevant Standards Bodies, Regulators and Professional Organisations
Activities

- Assign and control key identifiers, databases and reference tables
- Manage product database
  - Assign new codes
  - Develop to support new procedures
- Manage and update standard documentation
- Liaise with user and vendor communities
- Future development process
- Education
Working with GS1

- Manufacturer information for blood bags – carton vs individual unit
- Plasma derivative coding (albumin solutions, immunoglobulins)