ISBT128 Standards for Blood and Blood Components: How it Translates to Patient Safety

Diana Teo
Blood Services Group
Health Sciences Authority
Singapore
Declaration of Conflict of Interest

- Member of the ICCBA Board of Directors
- ICCBBA is a non-profit organisation that manages, develops and licenses ISBT 128
- ICCBBA is organised and operated exclusively for charitable, scientific and educational purposes
- ICCBBA Board of Directors are volunteers and do not receive any compensation
The Blood Transfusion Chain
Blood Transfusion Chain

Donor Recruitment  Blood Collection  Processing / Testing / Storage  Pre-Transfusion Testing  Issue / Transfusion

Vein to Vein
VEIN TO VEIN ORGANISATION

Quality Manager

DONOR RECRUITMENT

DONOR SELECTION

BLOOD COLLECTION - whole blood - apheresis - autologous blood

BLOOD DONOR TESTING - blood group testing - HBsAg, anti-HCV, anti-HIV, TPHA testing - HIV/HCV/HBV NAT

IN-PROCESS CONTROL

COMPONENT PREPARATION

COMPONENT PROCESSING & INVENTORY

INVENTORY, STORAGE & DISTRIBUTION

LABEL & RELEASE

INVENTORY, STORAGE & DISTRIBUTION

QUARANTINE & DISPOSAL

Clinical Service

THERAPEUTIC APHERESIS

HAEMOVIGILANCE

CLINICAL CONSULTATION

TRANSFUSION TO PATIENT

Hospital Service

CROSSTMATCH LABORATORY

IMMUNOHAEMATOLOGY - red cell reference lab - platelet serology lab

TRANSPLANT SUPPORT - tissue typing lab - cell processing lab

Blood Programme Support

Blood Resources

Quality Control
Separation of Blood into Components
Leucocyte-Reduced Red Cells
Irradiated Blood
Washed Red Cells
Frozen Cellular Components

Further Modification

Cryoprecipitated AHF
Fresh Frozen Plasma
Fibrinogen Concentrate
Liquid Plasma

Derivative Production

5% Albumin
20% Albumin
Intravenous Immune Globulin
Factor VIII Concentrate
Factor IX Concentrate

Production of Modified Components
Apheresis Technology

Using apheresis machines, individual blood components can be collected from the donor.
Patient Transfusion Safety
Haemovigilance

Defined as:

A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow up of its recipients), intended to collect and assess information on unexpected or undesirable events resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence.
How Haemovigilance Contributes to Patient Transfusion Safety

• Provides medical community with reliable source of information about untoward effects of blood transfusion

• Indicates corrective measures required to prevent recurrence of some accidents/dysfunctions in transfusion process

• Alerts hospitals and blood services about adverse events that could involve more than a single recipient, including those related to:
  – Transmission of infectious diseases
  – Blood bags, solutions or blood processing
Recipient Haemovigilance

• Adverse transfusion reactions:
  – Immediate reactions during transfusion, e.g. haemolysis, febrile non-haemolytic reactions, rash, bacterial contamination, etc
  – Delayed untoward effects after transfusion - haemolysis, acute GVHD, etc
  – Occurrence of allo-immunisation against red cell, HLA or platelet antigen

• Identification of transfusion transmitted infections through trace-back and lookback activities
Process Haemovigilance

• Surveillance of errors in the process of both production and transfusion of blood components
  – Systematic surveillance of errors and near misses
  – Monitoring traceability of blood products
  – Surveillance of blood utilisation

• Near miss - any error, which if undetected, could result in the determination of wrong blood group, or issue, collection, or administration of an incorrect or unsuitable component but which was recognised before the transfusion took place
Donor Haemovigilance

- Untoward events observed during blood donation
- Data related to donor selection, such as frequency and causes of blood donation exclusion
- Epidemiologic data on the donors found positive in marker screening
Schematic of Haemovigilance

Donor

Blood Centre

Haemovigilance body
Centralised info

Patient

Hospital

Data analysis
Diffuse info
Research

Corrective action
New strategy

Essential elements:
• Traceability
• Cooperation
• Homogeneous reporting
• Data analysis
Traceability

• Ability to trace each individual unit of blood or blood components derived thereof from the donor to its final destination, whether this is a patient, a manufacturer of medicinal products or disposal, and vice versa

• Final destination may be:
  - Patient
  - Manufacturing of medicinal products
  - For research and investigational purposes
  - Disposed of

• Essential element is a unique identification numeric or alphanumeric code for each donation, with subsidiary code for each component prepared for that donation - linked with data identifying both the donor and recipient
International Movement of Blood, Cell, Tissue Products

- Risk of duplication of identifiers
- Misidentification of products resulting in wrong blood, cells or tissue graft being transfused or implanted
- Weak traceability path
- Need to renumber units when products are received from outside a local area
- Slow or non-existent alert in situations of adverse events requiring product recall
Need for Standardisation

- Bar codes have same meaning globally, thus eliminating language barriers
- Eliminates need to renumber units because identifiers are globally unique
- Improved safety because receiving facility can understand detailed product characteristics
- Reduces software costs
- Facilitates movement into newer technology data transfer mechanisms
ISBT 128

- Initially developed by working party of the International Society of Blood Transfusion (ISBT)
- First used in blood bank in Estonia in 1997
ISBT 128

- Global standard for identification, labelling, and information transfer of human blood, cell, tissue, and organ products
- Provides:
  - Globally unique donation numbering system
  - Internationally standardised product codes
  - Standard data structures for bar coding and electronic data interchange
  - Standardised labelling
- Intended for use across international borders and disparate health care systems
- Managed by ICCBBA
ISBT 128

• Specifies:
  - Donation numbering system that ensures globally unique identification
  - Information to be transferred, using internationally agreed reference tables
  - International product reference database
  - Data structures in which this information is placed
  - Bar coding system (linear or 2-dimensional) for transfer of the information on the product label
  - Standard layout for the product label
  - Standard reference for use in electronic messaging
Unique Donation Identification Number (DIN)

Donation Identification Number (DIN)  Process Control Characters
Unique Donation Identification Number (DIN)

Collected by - Blood Services Group
HSA, Singapore
# Product Codes

<table>
<thead>
<tr>
<th>Product Description Code</th>
<th>Type of Donation or Collection</th>
<th>Division Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>RED BLOOD CELLS</td>
<td>ADENINE-SALINE (AS-5) ADDED</td>
<td></td>
</tr>
<tr>
<td>E0385V00</td>
<td>RBC5</td>
<td>BSG#0001</td>
</tr>
</tbody>
</table>

3-character division code for tissues
Product Codes

RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED
LEUCO-REDUCED, IRRAD
E0307V00 RBC1ILR BSG#0023

PLATELETS
E2807V00 PLC5 BSG#0101

APHR PLATELETS
LEUCO-REDUCED, ACD-A
E3077V00 APLR BSG#0603

FRESH FROZEN PLASMA
E4052V00 FFP BSG#0201

APHR PLATELETS
Leuco-Reduced IRRAD ACD-A
E3046V00 APLRI BSG#0806
Blood Product Label

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)
Cell Product Label

1 Donation Identification Number
2 ABO/RhD
3 Product Code
4 Expiration Date and Time
# Delivery Mechanisms

Comparative size of Code 128 and Data Matrix Symbols

<table>
<thead>
<tr>
<th>Data Matrix</th>
<th>Code 128</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="" /></td>
<td><img src="image2.png" alt="" /></td>
</tr>
</tbody>
</table>

- **Donation ID number**
- **ABO/Rh**
- **Product Code**
- **Expiration Date/Time**
- **Special Testing results**
Radiofrequency Identification

Tracking blood products in blood centres using radio frequency identification: a comprehensive assessment

Rodeina Davis,1 Bradley Geiger,2 Alfonso Gutierrez,2 Julie Heaser2 & Dharmaraj Veeramani2

1BloodCenter of Wisconsin, Milwaukee, WI, USA
2UW RFID Lab, University of Wisconsin

Radiofrequency identification technology can standardize and document blood collections and transfusions

S. Gerald Sandler, Al Langeberg, Leo DeBandi, Joan Gibble, Charles Wilson, and Charles L. Feldman

Radio frequency identification for prevention of bedside errors

Sunny Dzik

"TO ERR IS HUMAN . . ."

In the landmark publication "To err is human," the Institute of Medicine brought attention to the consequences of medical errors in U.S. health care. The

BAR CODE OR RADIO FREQUENCY IDENTIFICATION (RFID) OR BOTH?

Bar code technology is an established technology within healthcare laboratories. Indeed, laboratories are familiar
Using ISBT 128 in the Blood Service
Successful Implementation from Codabar to ISBT128 standard in 2006
Why Change?

- Limitations of ABC Codabar standard
- Old component code system unable to systematically name modified products with multiple attributes, e.g. autologous deglycerolized leuco-reduced RBC irradiated divided unit
- Improved donation look back system with international DIN system
- ISBT 128 global standard for blood services in future
## Product Code Mapping – from old to new

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Label Name (ISBT)</th>
<th>ISBT 128 code</th>
<th>ISBT 128 Divided unit 1</th>
<th>ISBT 128 Divided unit 2</th>
<th>ISBT 128 Divided unit 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>04050 RC1</td>
<td>RED BLOOD CELLS CPD</td>
<td>E0240V00</td>
<td>E0240VA0</td>
<td>E0240VB0</td>
<td></td>
</tr>
<tr>
<td>NEW</td>
<td>RED BLOOD CELLS CPDA-1</td>
<td>E0291V00</td>
<td>E0291VA0</td>
<td>E0291VB0</td>
<td>E0291VBa</td>
</tr>
<tr>
<td>04210 RC3</td>
<td>RED BLOOD CELLS AS1</td>
<td>E0463V00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEW</td>
<td>RED BLOOD CELLS AS1 LOW VOL</td>
<td>E0385V00</td>
<td>E0385VA0</td>
<td>E0385VB0</td>
<td>E0385VBa</td>
</tr>
</tbody>
</table>
Blood Product Labelling
Ability to Incorporate Standard Label for New Blood Products
Blood Collection
Blood Donation Testing
Labeling of Blood - Final Confirmation of Suitability for Clinical Use
Issuing Blood for Patient
Thank You