Introduction to *ISBT 128*

Paul Ashford  
Executive Director  
ICCBBA
ICCBBA enhances safety for patients by managing the *ISBT 128* international information standard for use in transfusion and transplantation.
Role of ICCBBA

- Not-for-profit organization, funded from license fees
- development and maintenance of the standard
- assignment of new codes
- technical support
- educational material
- promotion
The Objective

To provide a standard information environment 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 for traceability and retention of information.
What is ISBT 128?

- **ISBT 128** is an international standard for the coding and labeling of blood components, cellular therapy products and tissue transplant products.
- Developed for transfusion by ISBT in 1994
- Extended to support Tissue Banking and Cellular Therapy in 2000
- Extended to support Solvent Detergent Plasma in 2006
ISBT 128 for Blood Transfusion

- 3,500 Licensed Facilities worldwide
- 30 million units of blood *ISBT 128* labeled each year
- Extensive use in Europe and Middle East
- Rapid rollout in N. America to 2008 deadline
- Australian NBA decision to implement by July 2011
**ISBT 128 in Cellular Therapy**

- New *ISBT 128* Terminology and Labeling Standards published by the International Cellular Therapy Coding and Labeling Advisory Group
  - Transfusion 2007:47 1312-1327,
  - Bone Marrow Transplantation (2007) 40, 1075-1090

- Terminology being widely accepted
- Implementation in facilities across the world
- Over 180 CT Facilities registered in 28 countries
ISBT 128 for Tissues

- ISBT 128 Standard extended to support Tissue Products in UK in 2000
- Adopted for coding and labelling of all tissues provided by the UK NHSBT
- CEN (European) Workshop Agreement recommends *ISBT 128* standard with addition of “key code”
- AATB/ICCBBA North American Tissue Technical Advisory Group developing terminology
Key Elements of **ISBT 128**

- Unique donation numbering system (global)
- Standard structures and formats for information
- International product list, definitions and codes
- Standard data structures for other key information (status information, expiry, HLA profiles etc.)
- Mechanism for development and maintenance of the standard
ISBT 128 Labeling

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.

O
Rh(D) Positive

Product Code
E0291V00

Expiration Date
31 JUL 2002

From 450 mL CPD Whole Blood

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Donation Identification Number

G1517 02 123456

- Comprises 4 elements:
  - Facility identification code
  - Year indicator
  - Sequential number
  - Flag characters

- Manual entry check character
Facility Identification Code

- Assigned by ICCBBA to ensure global uniqueness
- Assigned to Collection Facilities at the time of Registration and Licensing
- Reference Lookup Table available to Registered Facilities and Vendors
- Provides a key to donation tracing
## Facility Code Lookup

### G1517 02 12345600 M

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<tr>
<th>Code</th>
<th>Facility Name</th>
<th>City</th>
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<td>Edinburgh</td>
<td>Scotland</td>
<td>EM17 7QT</td>
<td><a href="http://www.scotblood.co.uk">www.scotblood.co.uk</a></td>
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Product Code

- Provides an international reference table of products
- Clear unambiguous definitions
- Structured presentation of information using concepts of class, modifier and attributes
- Simple process for requesting new codes
- Regular updates are published by ICCBBA
Product Code Hierarchy

- **CLASS** – a description of the product type
  - A product belongs to only one class

- **MODIFIER** – describes the physical state of the product
  - A product may have up to one modifier

- **ATTRIBUTES**
  - A product may have many attributes
  - Each attribute group has a range of possible values
  - A combination of attribute values describes the product to the level of detail **required by the user.**
Example

- CLASS
  - Ground Bone
- MODIFIER
  - Freeze Dried
- ATTRIBUTES
  - Irradiated
  - Medium Granule
Benefits of the structure

- Flexible system supports future developments in tissue banking and CT
- Structured
- Supports analysis of information at various levels
- Allows the user to specify the degree of detail in the definition
Other ISBT 128 Data Structures

- ABO/Rh D Blood Group
- Expiration Date (and Time)
- Collection Date (and Time)
- Special Testing (General)
- Red cell Phenotypes
- Platelet Specific Antigens and HLA Phenotypes
- HLA Genotypes
- Manufacturers Code and Catalogue Number
- Manufacturers Lot No
- Donor Identification Number
- Staff Identification Number
- Potential to add new structures as required
ISBT 128 Identification of Derivatives

- Donation Identification Number provides unique identification. FIN assigned to the fractionator
  - X0001 08 123456
- Product Code identifies the specific derivative product
  - X0004000 - SOLVENT DETERGENT POOLED PLASMA Group AB
- Lot Number and Expiry Date data structures
Identification of Blood Derivatives
Background

- Initial approach from blood transfusion institutions and derivative manufacturers
- Discussion over labeling of solvent detergent plasma
  - Product is processed by plasma fractionator but distributed as frozen plasma product
  - Unique identification essential to manage post-thaw control of product
Background

- Australian NBA decision to label plasma derivatives with GS1
- Québec request for ISBT 128 labelling of plasma derivatives
  - Customer complaint from APCSTQ (Association professionnelle des chargés de sécurité transfusionnelle du Québec) to Government of Québec
- Introduction of ISBT 128 for solvent detergent plasma in Finland
ICCBBA/GS1 Memorandum of Understanding

Desire to achieve global standardization

Need to explore the needs of relevant stakeholders
- Users (hospital and blood center)
- Manufacturers
- Regulators
Key Issues

- Requirement for unique identification
- Dual path for derivative management
- Blood product or drug?
Unique Identification

- Current situation
  - Derivatives identified by
    - Product name
    - Lot number
    - Expiry date
Why unique ID?

- Individual containers in a lot are identical at the point of release from manufacturer
- Following release, their history changes:
  - Different recipient organizations
  - Different storage conditions
  - Different time of use
- In order to follow product history unique identification is essential
Dual path

- Hospital level management of derivative products follows two paths
  - Management through Blood Bank
  - Management through Pharmacy
- The former approach is based on treating derivatives as blood products
- The latter approach is based on treating derivatives as drugs
Blood Product or Drug?

- Product is batch produced, and in most cases has a long shelf life
- Source for blood derivatives is human blood donations
- Different regulatory framework
- Haemovigilance and traceability requirements mean there is a need to maintain the donor–recipient pathway for a period of at least 30 years

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