

ISBT 128

International Information Standard for
Transfusion and Transplantation

Outline

- The Objective
- The Information Environment
- *ISBT 128*
- Role of ICCBBA, Inc
- Basics of Labeling using *ISBT 128*

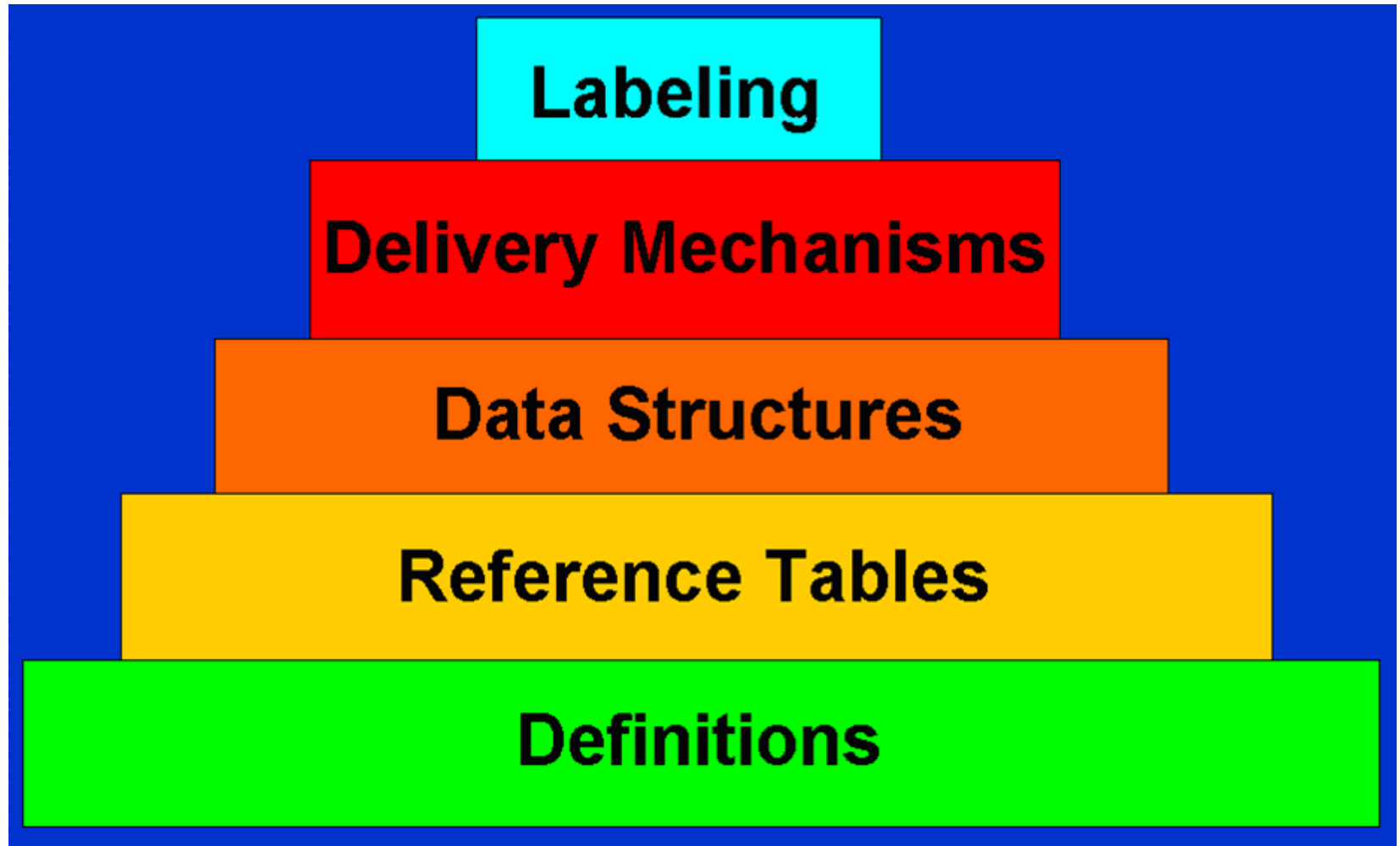
The Objective

- To provide a standard information environment that:
 - supports the open movement of 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.

The Information Environment

- Standard Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling

Information Hierarchy



The Basic Elements

- Standard Definitions
 - Ensure common understanding across the community
 - Built and managed by international consensus of experts
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling

The Basic Elements

- Standard Definitions
- Reference Tables
 - Provide means of mapping definitions to codes
 - Ensure consistent interpretation
 - Flexible but managed
- Data Structures
- Delivery Mechanisms
- Labeling

ABO and Rh(D) Blood Groups	Default: Intended Use Not Specified	Directed (Dedicated/ Designated) Collection Use Only	For Emergency Use Only	Directed (Dedicated/ Designated) Collection/ Biohazardous
O Rh(D) negative	95	91	92	93
O Rh(D) positive	51	47	48	49
A Rh(D) negative	06	02	03	04
A Rh(D) positive	62	58	59	60
B Rh(D) negative	17	13	14	15
B Rh(D) Positive	73	69	70	71
AB Rh(D) negative	28	24	25	26
AB Rh(D) positive	84	80	81	82
O	55	P2	P3	P4
A	66	A2	A3	A4
B	77	B2	B3	B4
AB	88	C2	C3	C4
para-Bombay, Rh(D) negative	D6	D2	D3	D4
para-Bombay, Rh(D) positive	E6	E2	E3	E4
Bombay, Rh(D) negative	G6	G2	G3	G4
Bombay, Rh(D) positive	H6	H2	H3	H4

The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
 - Technical definitions for data transfer
 - Allow independent systems to communicate
 - Developed and maintained to meet community needs
- Delivery Mechanisms
- Labeling

Data Structure

=%9100

Group O, Rh negative

The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
 - Means of delivering information
 - Linear bar coding, radio frequency tags (RFID), Reduced Space Symbolology (RSS) codes, 2-dimensional bar codes
 - Need the underlying elements to provide the required functionality
- Labeling

The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling
 - Defines means of providing information in the right place and format
 - Ensures consistency between electronic and eye-readable information

What is *ISBT 128* ?

- *ISBT 128* is an information standard for transfusion and transplantation
- Developed for transfusion by International Society of Blood Transfusion (ISBT) in 1994
- Being extended to further support Cellular Therapy
- Defines:
 - ❑ Reference Tables
 - ❑ Data Structures
 - ❑ Delivery Mechanism
 - ❑ Labelling Guidance

Key Elements

- 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

Role of ICCBBA, Inc

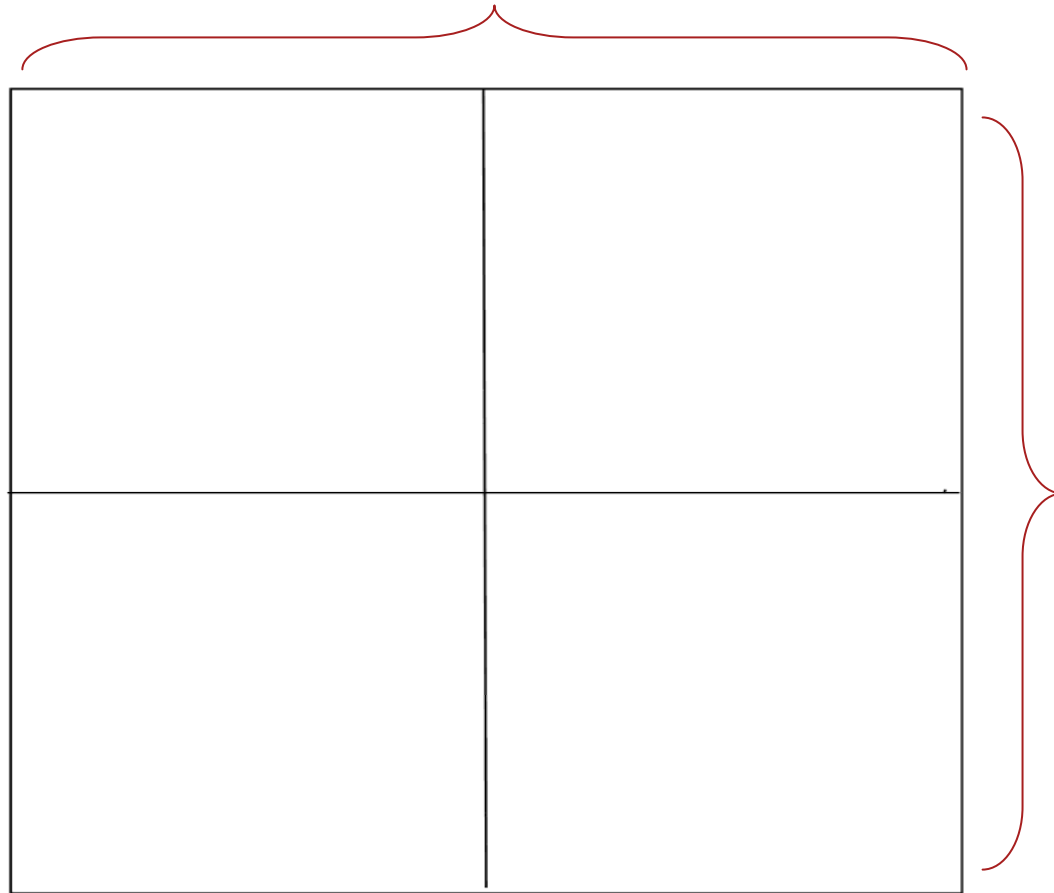
- Not-for-profit organization
- development and maintenance of the standard
- assignment of new codes
- technical support
- educational material
- promotion

ISBT 128 Labels

- Blood
- Tissue
- HPCs

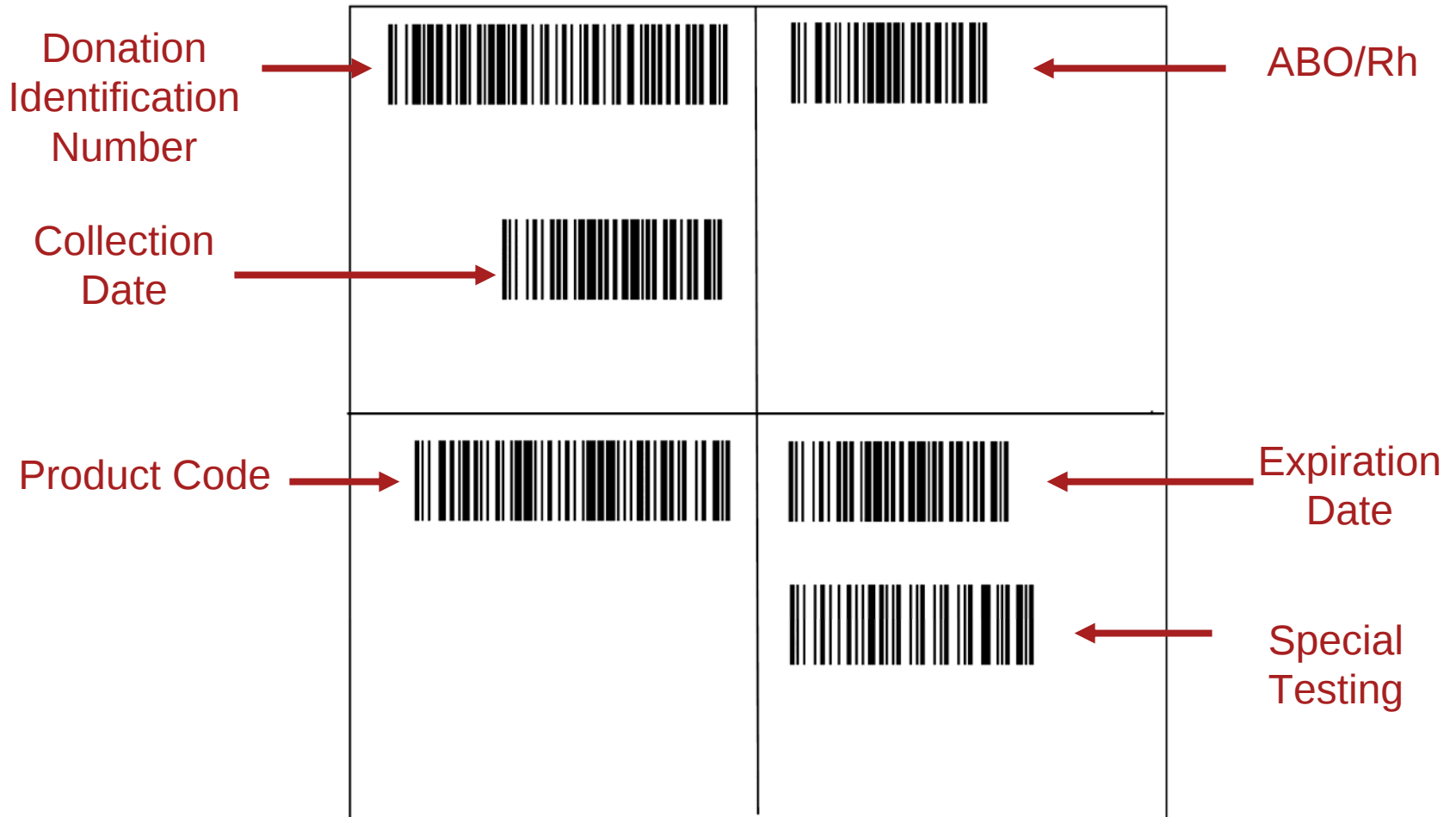
If space permits...

102 mm x 102 mm (4" x 4")



102 mm x 102 mm
(4" x 4")

Location of bar codes



Full size blood label (US)

 W1234 06 123456 8 1	 5100
Accurate Blood Center Anywhere, USA FDA Registration Number 123456	 Rh POSITIVE
Properly Identify Intended Recipient See Circular of Information for indications, contraindications, cautions and methods of infusion.	
May transmit infectious agents Rx Only	
VOLUNTEER DONOR	
 E0291V00	 0060312359
RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED	Expiration Date 31 JAN 2006
From 450 mL CPD Whole Blood Store at 1 to 6 C	 N0008
US License Number 123	Negative for antibodies to CMV



ISBT 128

More than Identification