

# **Traceability and the Use of Unique Identifiers**

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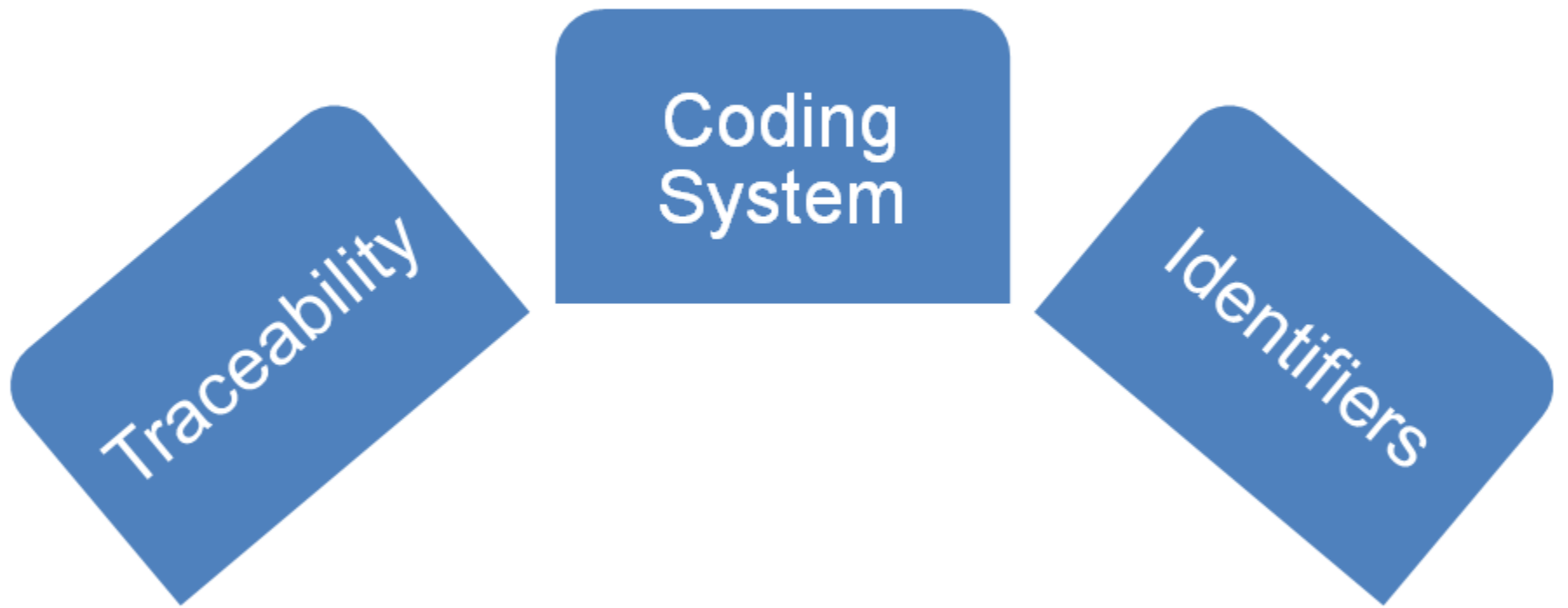
# TRACEABILITY FOR MEDICAL PRODUCTS OF HUMAN ORIGIN



Capability of tracing a medical product of human origin (MPHO) from donor to recipient and vice versa

# Traceability

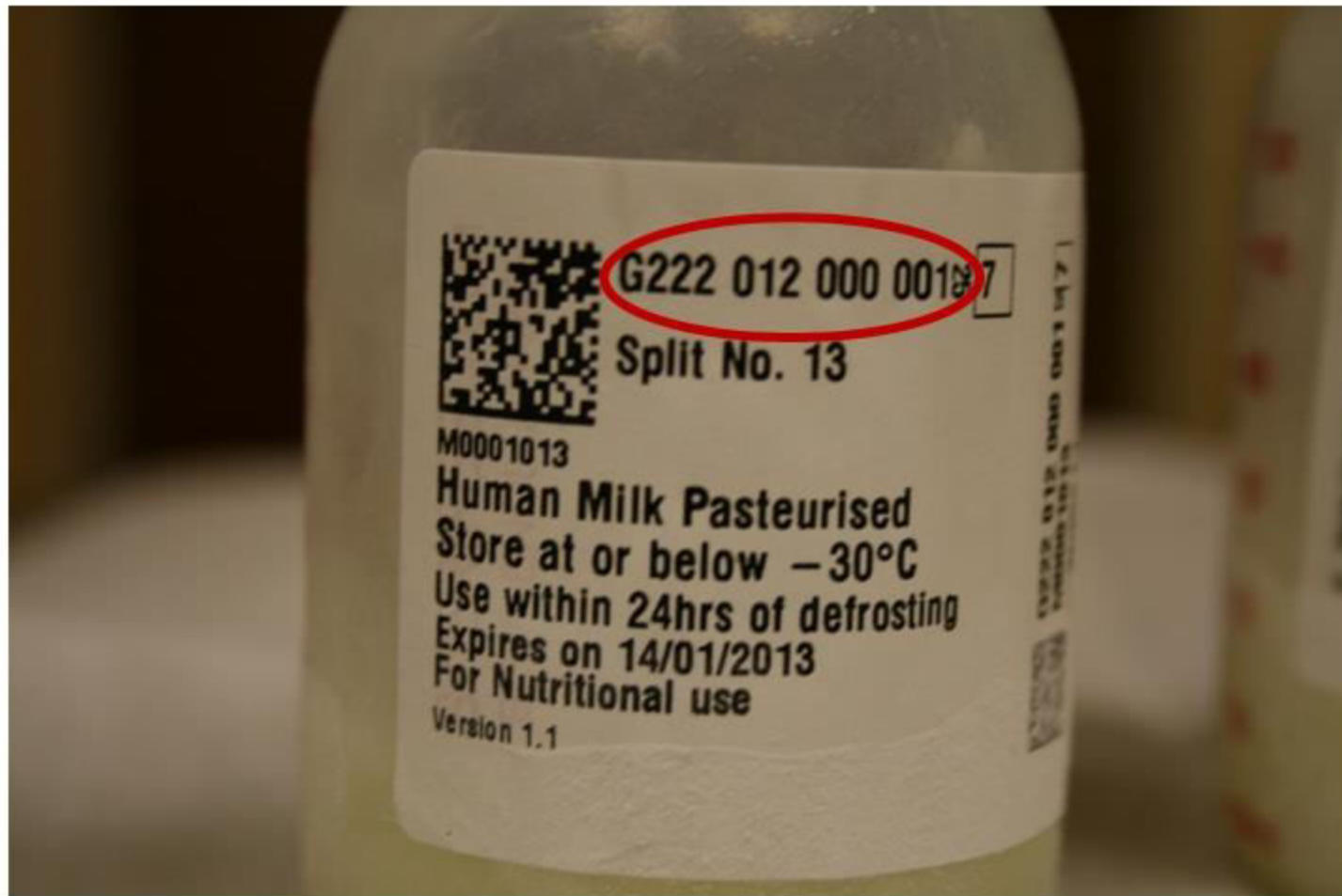
- Requires that each product be uniquely identified in order to provide a clear, unambiguous path
- Requires globally unique identifiers be assigned to each product



# Coding systems provide

- A mechanism to allow distinct items to be uniquely identified and consistently characterized to all participants within the system
- The means to **allocate identifiers** in a manner that avoids duplication
- The information infrastructure on which effective traceability can be built (if an automated system)

# Unique Identifier



# Coding systems support interoperability between computer systems

- Create codes and establish the meaning of the codes
- Provide the rules for how the codes are used
  - How the coding system is identified (e.g., first character is = or & with ISBT 128)
  - The length and format of all codes
  - What information may be encoded
  - What type of bar codes (symbology) may be used

# Establishing the meaning of the codes





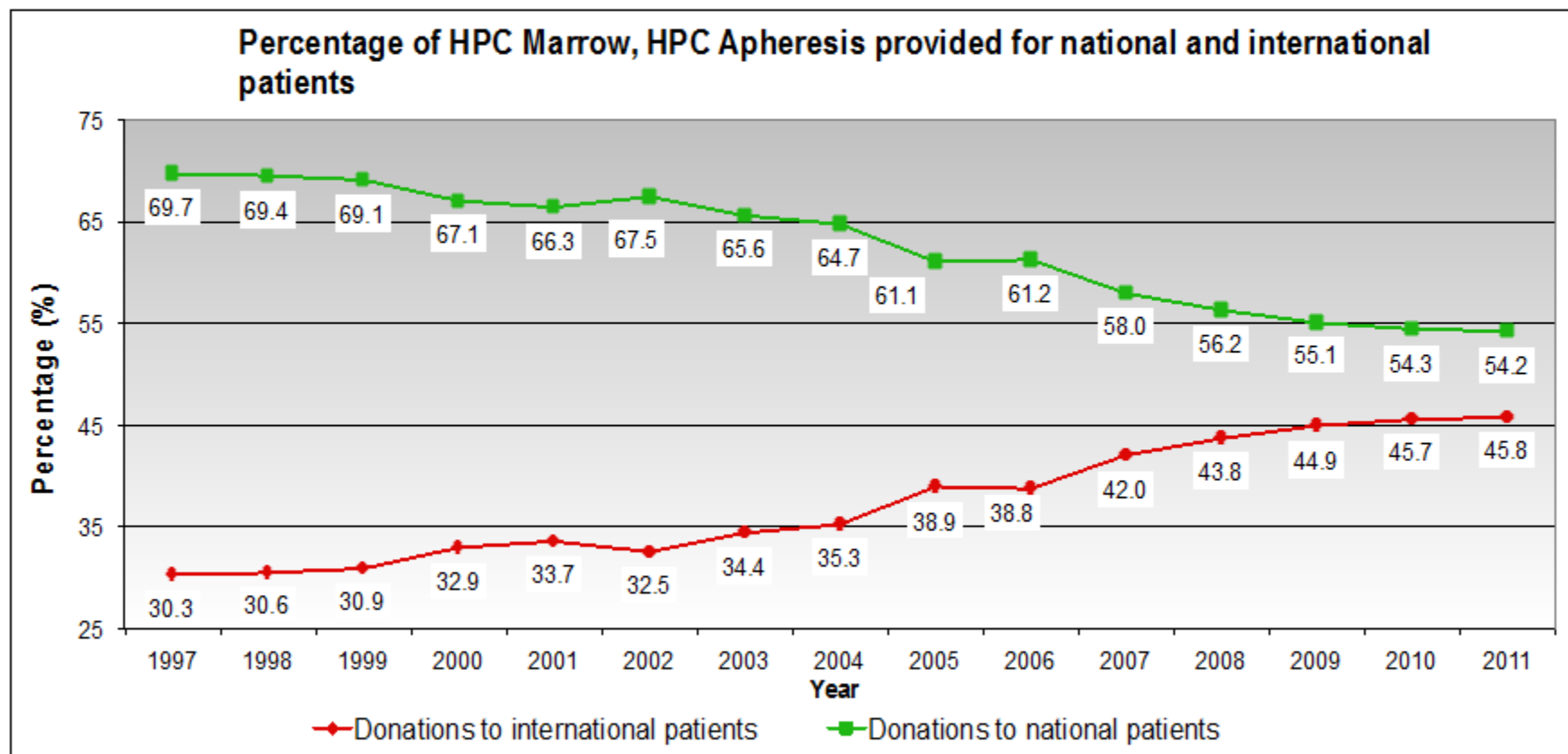
# WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation - 2008

Commentary for Guiding Principle 10:  
Internationally agreed **means of coding**  
to identify tissues and cells used in  
transplantation are essential for **full  
traceability**.

# World Health Assembly of WHO (Resolution WHA63.22, 2010)

“Conscious of the extensive cross-boundary circulation of cells and tissues for transplantation...Urges Member States...to encourage the implementation of **globally consistent coding systems** for human cells, tissues and organs...**to facilitate** national and international **traceability** of materials of human origin for transplantation.”

# Cell Therapy International Distribution



World Marrow Donor Association  
statistics

# WHO Organization-wide Initiative for Medical Products of Human Origin

- Three strategies for global governance
  - Global consensus on a series of principles inherent to the human origin of MPHO – in particular, prohibition on making the human body and its parts as such a source of financial gain
  - Global **use of ISBT 128** for all MPHO to ensure unique identification, optimal traceability and interoperability between countries and across all MPHO for both routine and emergency use
  - Global collaboration on vigilance and surveillance of MPHO to support operation and oversight and to establish transparency for trust

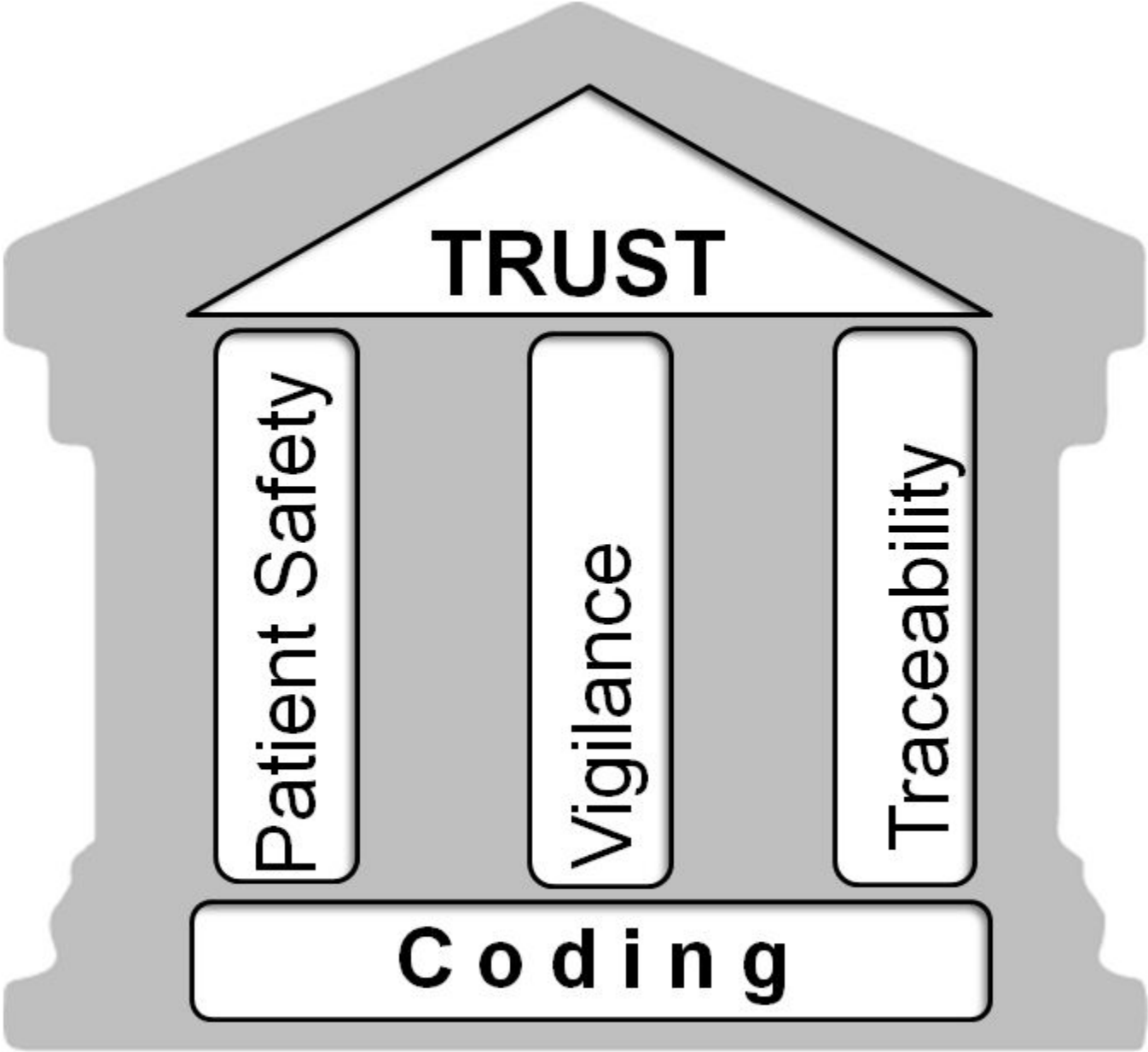
TRACEABILITY

CODING

PATIENT  
SAFETY

VIGILANCE

TRUST



# ISBT 128 Coding System

- Global coding system designed to support traceability
  - Allows assignment of globally unique identifiers
  - Provides standardized terminology, coding, and labeling format
  - Created by the Working Party on Information Technology of the ISBT in 1990's

# 75 Countries with Facilities Registered to Use ISBT 128





# Blood - China



90003 05 217134 8 **H**

上海市血液中心

血站执业许可证：  
沪卫血站字(2001)第001号

临床适应症：适用于贫血且需要补充血容量的患者。

注意事项：输注前请检查包装是否完好无损，外观是否正常；除0.9%的生理盐水外不得与任何药剂在同一输液器内输注。



8400

**AB**

Rh 阳性



Z0203000

病毒灭活冷沉淀凝血因子

原料浆预制品

容量：100mL ± 10%

保养液：ACD-B

储存条件：2-6℃

制备者：1234



200511221200

失效期：

2005-11-22 12:00

保存期：21天

制备时间：

2005-11-02 12:00

# Stem Cell - Denmark



# Milk Bank- Scotland



## Tissue - Poland

  
Z4200 12 0000688J  
KRAJOWE CENTRUM BANKOWANIA  
TKANEK I KOMÓREK  
Ul. Chałubińskiego 5 02-004 Warszawa  
Telefon fax: (22) 621 75 43  
E-mail: banktk@kcbtk.pl

  
D0280001  
mrożony  
TALERZ BIOCROWY LEWY GRUZ  
sterylizacja radiacyjna  
1,00 szt.  
Opakowanie Nr. 1  
GRUZ KOSCI KOROWO-GABCZASTEJ 30cm3

  
T300  
DO UŻYTKU  
KLINICZNEGO

Wskaźnik czerwony  
wysterylizowane  
radiacyjnie

  
0172471017  
Data ważności  
4 wrz 2017 10:17  
Ważność (-70C 5lat, -20C 3m-ce)

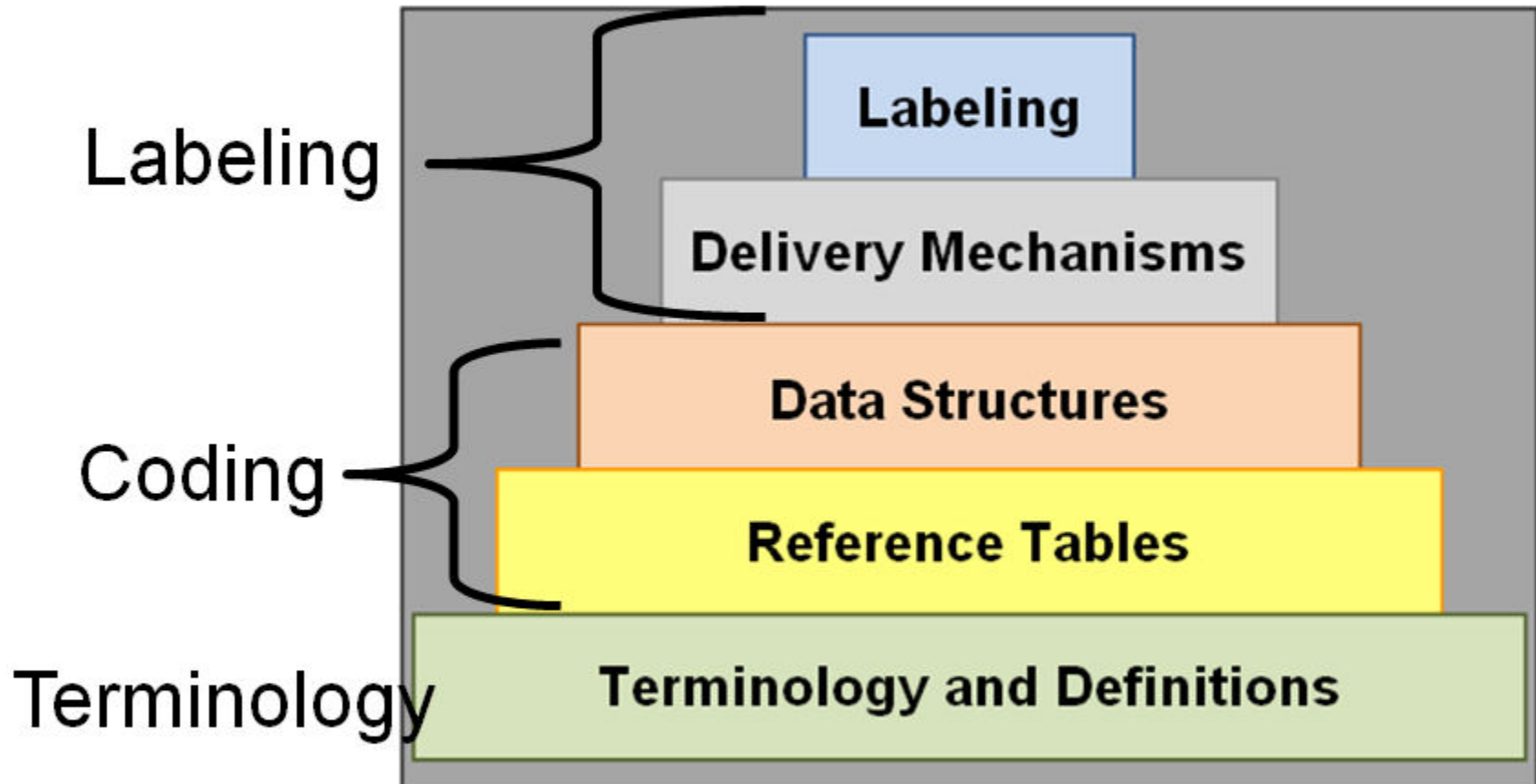
## Ocular - Canada



# Support from scientific and professional societies

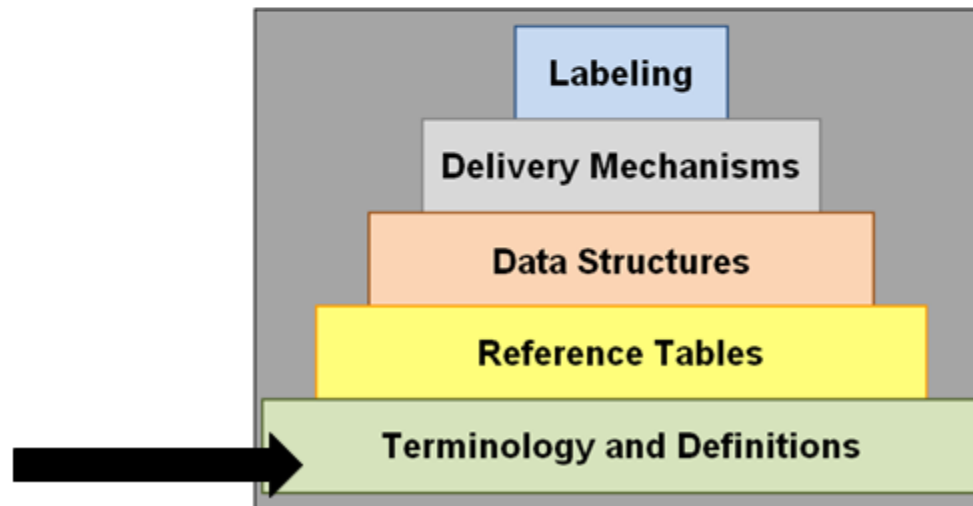


# ISBT 128 Coding System Pyramid



# ISBT 128 – Standardized Product Codes

- Terminology is the first step in standardization
- Defined by expert groups (Technical Advisory Groups or TAGs)
- Terminology is available for all to use

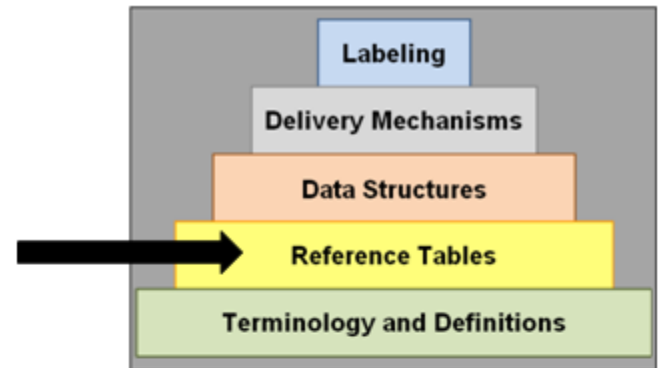


# ISBT 128 Terminology



- Products are described in terms of Classes, Modifiers, and Attributes
  - “Classes” are broad categories of products (e.g., Red Blood Cells)
  - “Modifiers” provide the next level of detail (e.g., Apheresis)
  - “Attributes” are details about the product (e.g., Irradiated)
- Example: **Washed POOLED PLATELETS |No anticoagulant/20-24C|Open System|Buffy coat platelet preparation|2 units**

Descriptions entered into a reference table and codes assigned



**CODE**

**PRODUCT DESCRIPTION**

- |              |  |
|--------------|--|
| <b>E7221</b> | <b>PLATELETS CPD/500mL/20-24C Bacterial test</b>                                     |
| <b>E7222</b> | <b>Apheresis FRESH FROZEN PLASMA NaCitate/XX/<br/>&lt;-25C</b>                       |
| <b>E7223</b> | <b>Apheresis FRESH FROZEN PLASMA ACD-A/XX/<br/>&lt;-25C For mnf:noninjectable</b>    |
| <b>E7224</b> | <b>Washed POOLED PLATELETS None/XX/<br/>20-24C Open Buffy coat plts prep 2 units</b> |

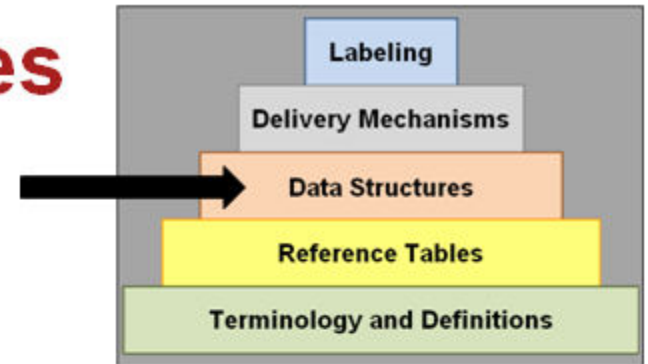


# Codes into Data Structures

= < S 1 2 3 4 X 0 0

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Data Identifier      Data Content



## ■ Data Identifier

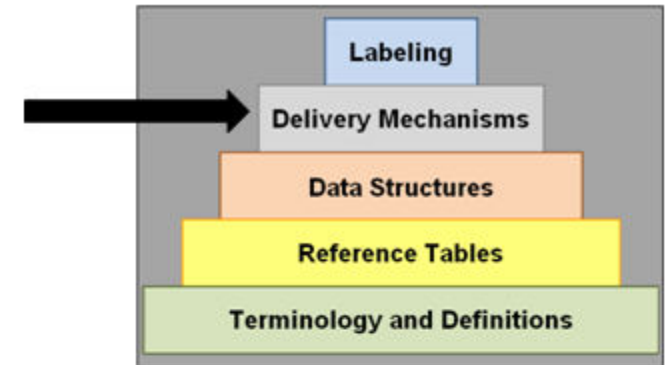
- ❑ Indicates an ISBT 128 data structure
- ❑ Indicates the type of data (e.g., product code)
- ❑ Allows data to go into the right field

## ■ Data Content

- ❑ Provides control by defining the type and number of characters (“rules”)



# Data Structures into Bar Codes



=<T1295003



=<T1295003

Linear bar code



=<T1295003

2-D Symbol

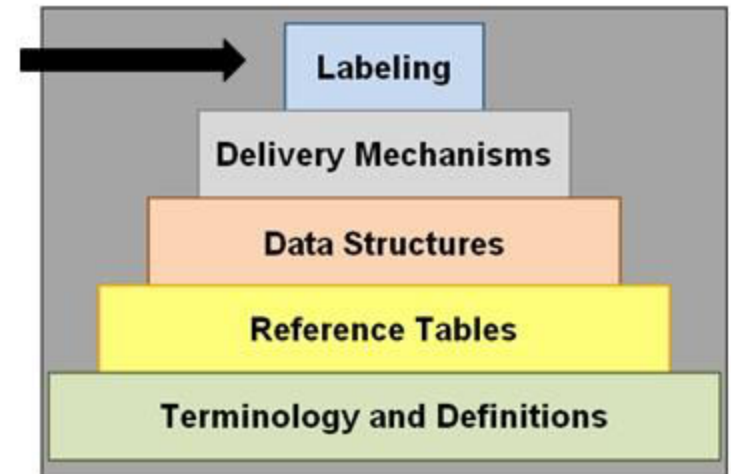


RFID



Computer to Computer Communication

# Bar Codes onto Labels or Other Documents



Donation Identification Number



A9999 14 123458 ☞ ☐

Accurate Blood Center  
Anywhere, World

Collection Date

Collection Date



014005

05 JAN 2014

VOLUNTEER DONOR

Product Code



E029 1V00

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

From 450 mL C PD Whole Blood  
Store at 1 to 6 C



5100



Rh POSITIVE

ABO and Rh

Expiration Date/Time



0140472359

16 FEB 2014 23:59

Expiry Date



N0008

Negative for antibodies to CMV

Special Testing





S0020 08 015114 = 3 H



0 RhD  
pos

Tapp-  
datum



0080460738

15 FEB 2008 07:38

Donator

R50321 -

Name

Avslutad

12:36



S0154200

HSC, aferes

Riktad



0080481314

17 FEB 2008

Använd  
venst.

13:14

Öppet system  
delenhet 1

Volym 100ml  
Lösning ACD - A  
Lagringstemp 2 - 6C

Donator

Recipient

19 861222 -

Name

iA

Recipient

Tapp datum 15 FEB 2008

S0020 08 015114 = 3

S0154200

HSC, aferes

Öppet system delenhet 1

# Unique Identifiers in ISBT 128

- Donation Identification Number (DIN) creates uniqueness for each donation



- Product Code creates uniqueness for each product made from a donation



# Donation Identification Number

A9999 12 123456



Facility Identifier



Year

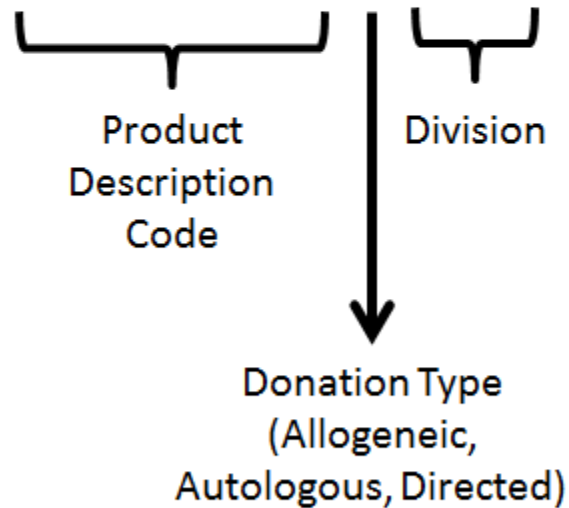


Sequence  
Number

- Facility Identification Number: Assigned by ISBT 128 to ensure each number is globally unique
  - ❑ 5-Character alphanumeric code
  - ❑ ICCBBA maintains a database of all FINs available to registered users
  - ❑ “Look-up” program available to all on the ICCBBA website
- Year Code: Ensures uniqueness for 100 years
- Sequence Number: Facility ensures uniqueness of the sequence number

# ISBT 128 Product Code – Blood and Cells

**S12410A0**



# Product Descriptions assigned computer codes

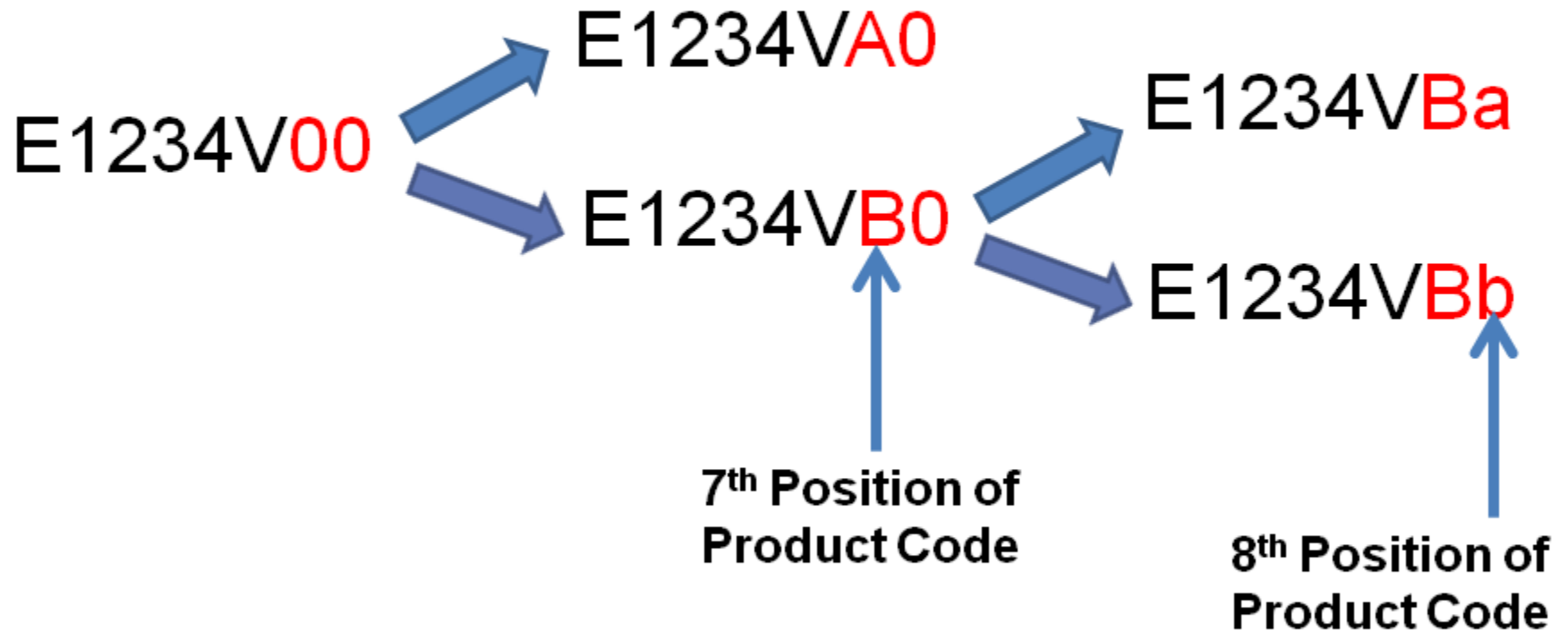
Product Description Code	PRODUCT DESCRIPTION
S1851	HPC, CORD BLOOD None/XX/refg Thawed Washed
S1852	MNC, APHERESIS None/XX/refg Thawed Washed Non-mobilized
S1853	HPC, MARROW None/XX/refg Thawed Washed



# Donation Type Codes

<b>Character</b>	<b>Type of Donation</b>
<b>0 (zero)</b>	<b>Not specified (null value)</b>
<b>V</b>	<b>Volunteer homologous (allogeneic) donor (default)</b>
<b>A</b>	<b>Autologous collection, eligible for crossover</b>
<b>1 (one)</b>	<b>For autologous use only</b>
<b>X</b>	<b>For autologous use only, biohazard</b>
<b>D</b>	<b>Volunteer directed collection, eligible for crossover</b>

# Divisions – Blood and Cells



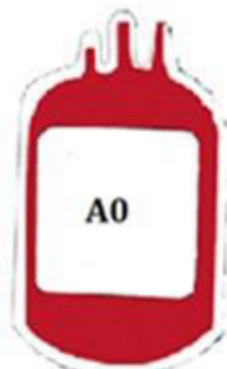
Collection

First Level Division

Second Level Division



E0164V00



E0164VA0



E0164VB0

(now in an open system)



E0158VBa



E0158VBb



E0158VBc

# Traceability & Coding Systems

- Global
- Across all Medical Products of Human Origin (MPHO)
- Create uniqueness for a minimum of 30 years

# The World Health Organization Global Forum on Blood Safety (2013)

Adoption of ISBT 128 has been identified by WHO as an important element in a global strategy for governance of MPHO

# ISBT 128

- Well-established system that is unique in being designed specifically to provide traceability between donor and recipient for medical products of human origin
- Provides a global approach to identifiers, terminology, coding, and labeling for medical products of human origin

