

IBTS ISBT128 Implementation

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Agenda

1. ISBT128 background
2. IBTS proposed ISBT128 label, unit id, flags, special testing, product code structure
3. IBTS Product Codes, Octaplas/Uniplas
Lunch
4. Impact for Hospitals, LIMS, Bloodtrack etc
5. Timelines/Transition
6. Discussion

ISBT128 Overview

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ISBT128 is an international standard for identification, labelling, and information transfer of human blood, cell, tissue, and organ products across international borders and disparate health care systems.

ISBT128 Benefits

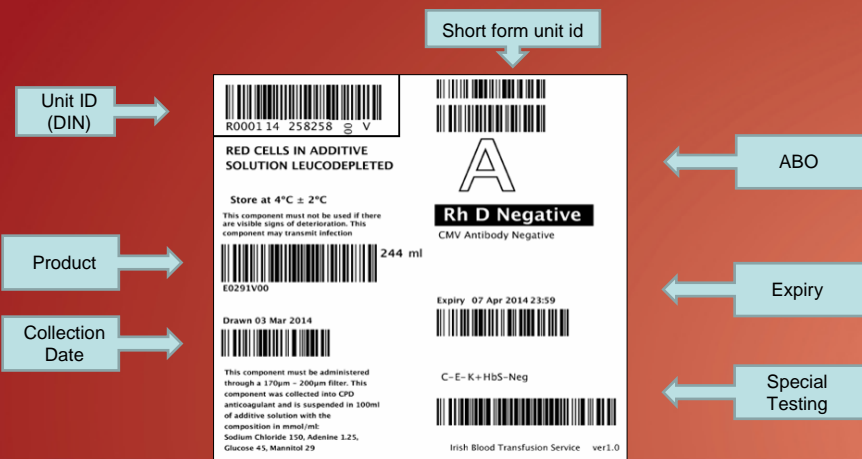
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- A globally unique donation numbering system
- International standardised product definitions
- More product codes and the product codes more specifically define the product
- Standard data structures for bar coding and electronic data interchange
- More information available in barcode and eye readable format. This facilitates the electronic exchange of information between information systems.
- Data identifiers included in the bar code structure provide added controls to reduce errors and improve safety

Drivers for Implementation

- Current codabar unit id numbering repeats - this is an issue for the hospital LIMS, current dual label work around in place
- Hospitals transitioning to ISBT128
- Upgrade of IBTS blood banking application which will facilitate the introduction of full ISBT128
- Compatible with 2D barcoding
- Supports international exchange of blood

IBTS Proposed ISBT128 Label



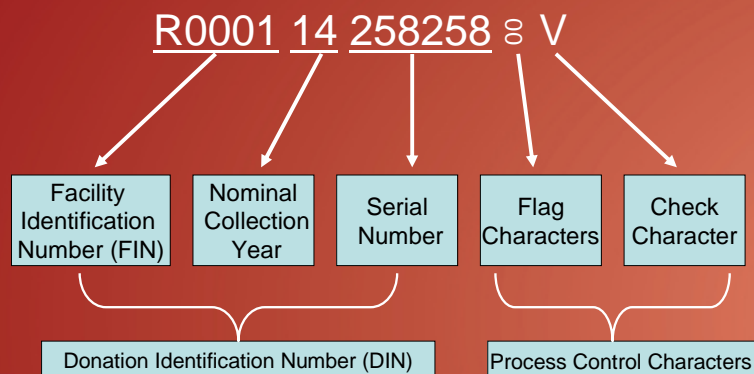
Donation Identification Number (DIN)

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- ISBT 128 provides for unique identification of any donation worldwide.
- It uses a 13 character identifier built up from three elements
 - the collection facility,
 - the year
 - a sequence number for the donation
- unique to 100 years!

Donation Identification Number (DIN)

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Flag Characters

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- 2 character code that can be used by the blood establishment for process control
- Appears in the eye readable, rotated 90⁰ clockwise
- Not part of the unique DIN
- Replaces the barcode check digit on the DIN in the barcode read
- When not in use default flag value is 00

Product Information

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- ISBT 128 provides a Standard Terminology for describing products.
- It is designed to allow distinction between products based on safety, clinical practice, or inventory management grounds.
- The underlying structure of the terminology is based on the concepts of Classes, Modifiers, and Attributes

Classes, Modifiers, Attributes

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- **Classes** are broad descriptions of products, e.g. red blood cells; apheresis; solvent detergent pooled plasma.
- **Modifiers** are applied to Classes in order to provide the next step in the categorization of the product, e.g. Washed, Thawed, and Deglycerolized.
- **Attributes** provide the means to uniquely define the product.
- For Blood, Cellular Therapy, and Derivative products, there is a mandatory attribute group of **Core Conditions**

Groups and Variables

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- Any additional manipulation or change to the product from its “core” state is reflected by the addition of one or more attributes from a predefined list of groups and variables
- Examples - **Irradiated**, **Dosage**, **Intended Use**.
- Such additional manipulations or changes are
- indicated by a different Product Description Code

Special Testing Information

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- Various Special testing data structures available in ICCBBA standard, IBTS will use
- Data Structure 012 – Special Testing Red Blood Cell Antigens: General
 - Will provide information regarding red blood cell phenotypes, CMV antibody, IgA and Haemoglobin S status of the product.
- Data Structure 010 – Special Testing General
 - IBTS is currently looking at this data structure with a view to managing our neo natal products

Data Structures

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=<E0151V00

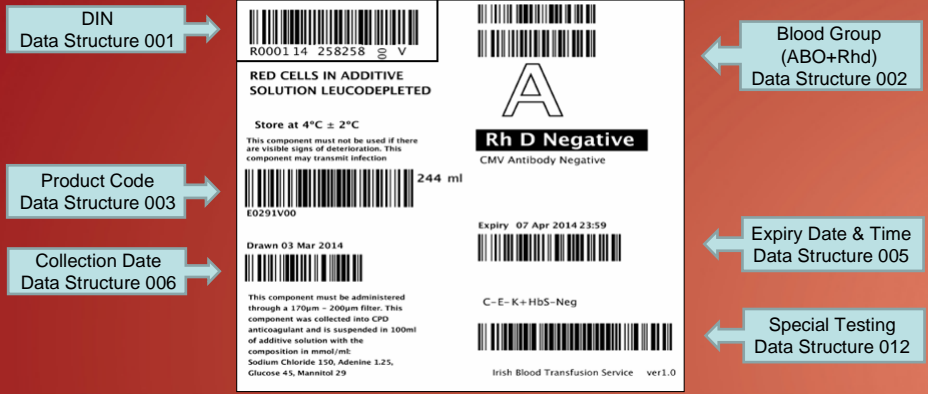
Data Structure

Data Identifier

Data Content

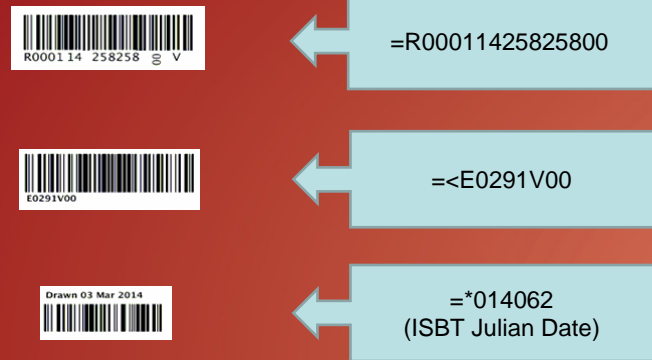
Data Structures on IBTS Label

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Barcoded Information

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Barcoded Information

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&a258258



=%06Z0



&>0140972359
(ISBT Julian
Date and Time)

Barcoded Information

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=\96999999999911196

Position 2 value of 6 denotes K+
Position 14 value of 1 denotes C-
Position 15 value of 1 denotes E-
Position 16 value of 1 denotes CMV-
Position 17 & 18 value 96 denotes HBs Neg

- For Data Structure 010 refer to the Special Testing Database on the ICCBBA site
- Code structure is of the form ZZZZZ (5 character alpha numeric code)
- E.g. N0119 – 'CMV seronegative and product meets additional nationally specified requirements for pediatric use'

Management of DIN for LIMS

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- Currently ISBT128 unit id being read by the LIMS systems has no flags
- This means that the machine/barcode check digit is part of the barcode
- With the introduction of the flag characters, this check digit will need to be calculated
- Calculating the machine/barcode check character and eye readable check character [\[example\]](#)
- Appendix A of the technical standard provides detailed calculation of the eye readable check character

Supporting Documentation

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- Significant range of resources at www.iccbba.org including Product and Special Testing databases, presentations, guidance documents.

In particular –

- ISBT128 Standard Technical Specification version 4.5.0
<http://iccbba.org/uploads/31/84/318434fae0bcbbad53be07fbba6a2a3c/ST-001-ISBT-128-Standard-Technical-Specification-v4.5.0.pdf>
- Product – Attributes, Classes and Modifiers
<http://www.iccbba.org/uploads/62/09/6209c89bef31964d045760bc62a6e865/Standard-Terminology-for-Blood-Cellular-Therapy-and-Tissue-Product-Descriptions-v4.32.pdf>

Changes to Product Codes in ISBT 128 format

Impact of ISBT 128 on Product codes

- Unit Number will be different- will include flag characters
- Product codes will change- aim is to have the same code that reflects what the product contains
- Note different codes if product has been altered e.g. irradiated or reflects donor criteria e.g. Paediatric
- Review all IBTS product codes against ICCBBA standard

ISBT Product Codes

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ISBT Products determined by

- Class e.g. Red Blood Cells, Whole Blood
- Modifier e.g. Washed, Thawed
- Attribute(s) e.g. Core Conditions, Irradiated

Details can be found in Chapter 2 of the ICCBBA Standards document.

[Standard-Terminology-for-Blood-Cellular-Therapy-and-Tissue-Product-Descriptions-v4.32.pdf](#)

ISBT Product Codes

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Using ICCBBA Product Look Up Facilities

04333 Red cells in A.S. leucodepleted CPD SAGM irradiated



Is interpreted as follows :

- **ISBT Code E7442V00**
 - E7442 – stores the class, modifier, core conditions, attributes.
 - V volunteer
 - 00 divisions
- Progressing with ICCBBA - when finalised IBTS will issue full Product List

UK Workshop

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- Workshops UK on label design
- Clinicians, blood bank, blood establishments
- Plans for ISBT128
- 2D Barcode Update
- Variations of ISBT128

R000 114 123 456 W		EXPIRY DATE (do not use after)	
		21 March 2014	
		TIME: 23:59	
Rh D Positive			
Red Cells for Intrauterine Transfusion (IUT), LD, Irradiated		160 mL	
<p>Store at 2°C to 6°C. This component must not be used if there are visible signs of deterioration. Always check patient/component compatibility/identity.</p> <p>Risk of infection including vCJD. Do not vent. This component must be administered through a transfusion set incorporating a 170 to 200µm filter. Contains phthalate (DEHP). Latex free.</p> <p>This component was collected into 83ml of CPD anticoagulant with the composition in mmol/l: Anhydrous Glucose 120, Sodium Citrate 80.4, Citric Acid Monohydrate 15.6, Sodium Dihydrogen Phosphate Dihydrate 18.1</p>		<p>Suitable for IUT Negative for: c, E, K, Fy (a), Jk(b), S, s, M, N, U, Kp(a), Lu(a), Le(a), Le (b), P1, Vw(a), Js(b), Js(b), Di(a), Yt(a), Co(a), CMV, HbS, H.T.</p> <p>Date bled: 20 Feb 2014</p>	
REF	2FRP031460	LOT	43FA28000

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ISBT128

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Octaplas & Uniplas

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- Transition label
- Move to full label ICCBBA group (Solvent Detergent Plasma subcommittee)
- Recent labelling issue
- Smart cards

			
x00021 3280334		6610	
			
x0002000		0171972359	
<p>LG-octaplasSM Solution for infusion. One bag contains 200 ml.</p> <p>LG-octaplasSM 45 - 70 mg/ml solution for infusion 200 ml contain 9 - 14 g human plasma proteins, Sodium citrate dihydrate, sodium dihydrogen phosphate dihydrate, glycine. Read the package leaflet before use. Intravenous route. Keep out of reach and sight of children. Do not use solutions which are cloudy or have deposits. After thawing LG-octaplasSM can be stored for up to 24 hours at +2-8°C, or 8 hours at room temperature (+20-25°C), before use. Store in freezer in the dark at -18° C. Unused product must be discarded. Medicinal product subject to medical prescription. Follow instructions for use carefully.</p> <p>Batch: E. 952. 005. IRL</p>		<p>PA 331462</p> <p>A</p>	
		C 329A9521 16/07/2017	
C 329A9521			
<p>Octapharma Limited The Zenith Building 20, Garsington Road, Mansfield MK12 1SD United Kingdom</p> <p>Manufacturer: OCTAPHARMA</p>		<p>Product: Blood Group A, 200 ml Batch: EXP</p> <p>Product: Blood Group A, 200 ml Batch: EXP</p> <p>C 329A9521 16/07/2017</p> <p>C 329A9521 16/07/2017</p>	

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Timeline for Implementation

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- Project Manager Paul Hendrick
- eTraceline 15th March
- ISBT 128 Docket
- eProgesa Quarter 4 2014
- ISBT Label
- Regular updates

Impact on Hospital Systems

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- Minimum requirement to read unit id, product code, expiry, ABO
- Current ISBT128 configuration for unit will need to change to incorporate flag characters
- Configuration required to parameterise IBTS Product master list
- Decide how to handle special testing barcodes
- Consider also impact on other Hospital systems e.g. Reporting, Billing, Printing, Scanning, Instruments etc.
- Minimal impact on Blood Track – some configuration required

To Consider

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- Standardise Product Names
- Full face ISBT 128 label
- Validation of systems
- Procedural changes
- Training of Blood bank staff, Clinical staff, Haemovigilance staff
- Managing stock during transition
- Codabar/ current ISBT128 version unit ID (how will your LIMS/Blood Track manage different configurations)

Date for your diary

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- Biomedica April -29th -30th
- TTSAB Biomedica presentations-30th April
- “Blood grouping by molecular genetics: present and future” Mr. Geoff Daniels
- “The minor keys of red blood cells – sex, seasons, vasodilation and enucleation”
Dr. William Murphy