ISBT 128 - Improving Quality and Safety Through Standardization

Submitted by: ICCBBA
ISBT 128 - Improving quality and safety through standardization

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ICCBBA

Outline

- Background to ISBT 128
- ICCBBA
- Current Status of ISBT 128
- External Relationships
- ISBT 128 and APEC Initiative
The Acronyms

- ICCBBA – International Council for Commonality in Blood Bank Automation
- ISBT 128
  - ISBT Derived from ‘International Society of Blood Transfusion’
  - Now interpreted as ‘Information Standard for Blood and Transplant’
  - 128 – ISO character set

A short history of ISBT 128

- Trigger Event – First Gulf War
  - Blood dispatched to war zone from many countries
  - No unique identification
    - Duplication of donation numbers
  - No common product descriptions
    - Different products, different specifications, different languages
    - Label layouts varied, difficult to understand
  - No common electronic coding of information
    - Barcodes could have different meanings in different countries
    - Had to rely on manual inputs
  - Led to
    - wastage
    - Risk of serious transfusion errors
A short history of ISBT 128

- Issues highlighted by Gulf War were not unique to major emergency situations
- Movement of blood on a domestic scale faced similar issues
- Duplication of numbers (recycling) was causing problems in hospital computer systems
- Lack of standard terminology could cause confusion

A new standard

- In 1989 the International Society for Blood Transfusion assigned its Working Party on Automation and Data Processing the task of devising an international coding and labeling system
- In 1994 the first version of the ISBT 128 Standard was released
Key Elements of ISBT 128

- Globally unique donation identification number supports global traceability
- Standard terminology for describing MPHO
- International product codes
- Standard bar coding of information (donation number, product code, other key information)
ICCBBA

- Recognition of the need for this new standard to be a managed standard
- ICCBBA was formed in 1995 through the actions of AABB, ARC, and ISBT
- Established as a not-for-profit, tax-exempt organization
- Governed by volunteer Board of Directors
- Created to provide a permanent maintenance organization for the ISBT 128 Standard

Board of Directors
ICCBBA Vision and Mission

- Vision: Global adoption of ISBT 128 for all medical products of human origin
- Mission: Enhancing patient safety by promoting and managing the ISBT 128 international information standard for use with medical products of human origin

Implementation and Extension

- First national implementation of ISBT 128 for blood transfusion was in Estonia in 1996
- The standard was extended to cover cell therapy and tissues in 2000
- Today ISBT 128 includes coding for organs, milk, tissue engineering/advanced therapies
ISBT 128 Current Status

- 4896 licensed facilities in 77 countries
- Distribution
  - Blood: 4344
  - Cell Therapy: 644
  - Tissue: 106
  - Ocular: 85
  - Milk: 2
- More than 50 million products ISBT 128 labelled worldwide
External Relationships

- Official Relations with World Health Organization
- Memorandum of Understanding with:
  - GS1
  - GMDNA (Global Medical Device Naming Agency)
- Formal agreement with European Commission
- FDA Approved Medical Device UDI Issuing Agency
- HL7 Member and OID identifier assigning authority
- Working relationship with WHO International Nonproprietary Naming (INN)

WHO and ICCBBA

- Initial meeting between WHO and ICCBBA in August 2007
- May 2010 the 63rd World Health Assembly adopted resolution WHA63.22 (Human Tissue and Organ Transplantation)
- WHO/ICCBBA joint work program put in place in 2010
- ICCBBA accepted as an NGO in official relations with WHO in Jan 2014
WHO/ICCBBA Joint Work Program

WHO Area of Work:
- Human Transplantation and Blood Transfusion

WHO Strategic Objective:
- SO 11: To ensure improved access, quality and use of medical products and technologies

WHO Organization-Wide Expected Result(s):
- OWER 11.2 International norms, standards and guidelines for the quality, safety, efficacy and cost-effective use of medical products and technologies developed and their national and/or regional implementation advocated and supported.
- OWER 11.3 Evidence-based policy guidance on promoting scientifically sound and cost-effective use of medical products and technologies by health workers and consumers developed and supported within the Secretariat and regional and national programmes.

Raising Awareness of Member States Health Authorities to the role of ISBT 128 in Global Governance.

To improve communication between ICCBBA and Member States Health Authorities.

Facilitate access of low and middle income countries to ISBT 128

Standardize global V&S with the adoption of consistent ISBT 128 product terminology
Supporting organizations

Global Advisory Panel (GAP) on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies

ISBT 128 and APEC

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Supporting the Road Map

- promoting harmonization and implementation of international standards for blood and blood products;
- optimizing the efficiency of the blood supply chain through capacity building for blood processing, testing and distribution systems;
- opportunities for centralization/regionalization, testing strategies, and plasma.

ISBT 128 and MPHO

- The WHO initiative for medical products of human origin aims to create a global framework on common principles for the donation and use of all medical products of human origin (EB136-32 Dec 2014);
- Member States should strengthen accountability through global systems of traceability, surveillance, vigilance and rapid alert;
- ISBT 128, managed by ICCBBA, is the sole global standard for the identification and coding of MPHO.