A Journey to Unity: The Expansion of Internationally Standardized Terminology for Medical Products of Human Origin

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Background

The 1990–1991 Persian Gulf War sparked the development of internationally standardized terminology for medical products of human origin (MPHO). The prevalent language and nomenclature discrepancies observed in vital international blood donations put patient safety at risk and urged the need for a unified system to ensure accurate interpretation of product information. In response, the first ISBT 128 standard terminology for blood products was introduced in 1994, providing a solid foundation for the subsequent expansion of standardized terminology into tissue, ocular, and other MPHO categories.

Hypothesis

International collaboration among technical experts, professional societies, regulatory bodies, and end-users plays a pivotal role in developing, expanding, and sustaining internationally standardized terminology for MPHO, improving the transfer, traceability, and transfusion/transplantation of blood, cells, tissues, and organs.

Methods

The International Council for Commonality in Blood Banking Automation (ICCBBA) formed Technical Advisory Groups (TAGs) with the voluntary support of international experts in blood, cellular therapy, and tissue banking to develop internationally standardized terminology based on three main ISBT 128 classification ranks: (1) Categories, (2) Classes, and (3) Attributes. TAGs employed a consensus-based approach where decisions were thoughtfully deliberated and incorporated diverse views. Group voting was utilized when appropriate. Additionally, public consultation was opened during critical developments to facilitate broad stakeholder participation and engagement.

Results

Since 1994, 12 TAGs have been formed, including the International Tissue Technical Advisory Group and Eye Bank Technical Advisory Group. As a result, ISBT 128 terminology has been issued for 12 product categories. To date, it includes 362 classes to broadly describe products (e.g., BONE) and 912 attributes to precisely define product characteristics (e.g., Cryomilled). This comprehensive terminology has facilitated the creation of 16,039 globally unique product descriptions, including 2,189 for tissue and eye banks, and 397 for convalescent plasma which healthcare professionals urgently needed during the COVID-19 pandemic. Acknowledging the regulatory disparities across countries, ISBT 128 allows users to tailor product descriptions according to their specific needs. Table 1 shows the total number of globally

unique product descriptions issued for each category to support international traceability, biovigilance, and rapid recall of MPHO.

Conclusions

In the past 30 years, international collaboration of nearly 590 volunteers made it possible to create, expand, and sustain ISBT 128 terminology, a unifying language for MPHO. As a result, ISBT 128 has been adopted by facilities in 78 countries and endorsed by 26 international professional societies as one path to improve patient safety. Remarkably, its practicality and effectiveness have been tested and demonstrated in times of global turmoil, such as the COVID-19 health crisis.

Table 1. ISBT 128 globally unique product descriptions for each MPHO category

Category	Product Descriptions
Blood	10,724
Cellular Therapy	3,032
Tissues	1,744
Ocular	445
Reproductive	30
Topical Products of Human Origin	17
Organ	15
Plasma Derivatives	13
Human Milk	8
Fecal Microbiota	4
In Vivo Diagnostic MPHO	5
Regenerated Tissues	2
Total	**16,039**