



HARMONIZED CODING AND TERMINOLOGY FOR MEDICAL PRODUCTS OF HUMAN ORIGIN

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SUMMARY

Introduction: The need for internationally standardized terminology, coding, and labeling for medical products of human origin has been recognized by professional scientific societies, accreditation bodies, and the World Health Organization as a means to facilitate traceability.

Materials and methods: ICCBBA, a not for profit, non-governmental organization, is responsible for managing the ISBT 128 Standard and a network of over 300 volunteer experts from all over the world in order to harmonize terminology and coding in 13 subject areas including blood transfusion, cellular therapy, tissue banking, and regenerative medicine.

Results: The combined efforts of various international and regional volunteer expert groups, utilizing a transparent proposal process, has led to the compilation of a robust globally harmonized dictionary of product terminology. Utilizing this terminology in unique combinations of Class, Modifier (as applicable), and Attributes (as applicable), ICCBBA has developed a continuously growing database of over 13,000 Product Description Codes. When combining a Product Description Code with a donation identifier, it can be seen that ISBT 128 provides a mechanism to achieve traceability for medical products of human origin by uniquely identifying each product that is made. A globally unique donation identifier allows each donation to be linked to a donor, and, in combination with a Product Code, allows each product from that donation to be linked to a recipient. This system for traceability has since gained the support of the international community and is used in 89 countries or territories globally.

Discussion: International acceptance of harmonized coding and terminology for medical products of human origin by facilities, governments, and scientific professional societies means that potential users can expect a dependable and lasting standard.

Conclusion: Adoption and use of the ISBT 128 standard continues to increase, signifying global confidence in an internationally harmonized system for coding and terminology as a means to facilitate traceability.

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