Globally consistent coding systems for medical products of human origin

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Medical products of human origin (MPHO) include blood, organs, bone marrow, cord blood, corneas, tissues, reproductive cells and milk derived from humans for therapeutic use. These materials, obtained from people whose safety, privacy and human rights need to be protected, provide important and often irreplaceable therapies.

Obtaining MPHOs from living and deceased donors entails practical, scientific and ethical considerations. Transplantation of vascularized organs and viable tissues carries the same types of risk of disease transmission and incompatibility as blood transfusion, with additional risks and benefits. Donors must be carefully screened through medical history and laboratory tests, yet a thorough history is seldom available for deceased donors. Furthermore, the time from donation to transplantation is often short. Recipients, on the other hand, can die without a transplant. Thus, an MPHO, especially an organ, must be directed to a specific recipient, once the risk of disease transmission and the viability of the MPHO have been weighed against the poor prognosis without transplantation. This individual tailoring, which is critically important in the case of MPHOs, must be conducted reliably and verifiably.

For MPHOs to be managed safely, organizational governance must guarantee transparency and traceability. Traceability – the ability to identify the unique origin of an MPHO by tracking the path from donor to recipient – is essential for vigilance, surveillance and activity reporting and to support recall of an MPHO. Because MPHOs can transmit disease,[1] the risk of harm can be reduced by rapid notification or recall after disease transmission is identified in one recipient. The medical uses of MPHOs continue to expand. Many MPHOs are transported across national boundaries, but without uniform global standards for identifying their origins, their safety is compromised. Several countries have traceability requirements. However, these often vary for different types of MPHO because there is no global governance framework to ensure international consistency.

These important problems have been recognized in global consultations on human cells and tissues for transplantation led by the World Health Organization (WHO). World Health Assembly Resolution WHA63.22 urges Member States "to encourage the implementation of globally consistent coding systems to facilitate national and international traceability".[2] A standard coding system based on globally standardized nomenclature would allow critical information on each MPHO and its origin to be presented in a format conducive to consistent interpretation globally and would overcome language barriers and facilitate electronic data capture and information transfer.

An international initiative to ensure the global traceability of MPHOs is already well established. The Information Standard for Blood and Transplant (ISBT 128)[3,4] was developed in response to problems in identifying the blood provided by different nations during the First Gulf War. The International Council for Commonality in Blood Bank Automation (ICCBBA) was established in 1995 as a not-for-profit organization to manage ISBT 128, which was introduced in 1996 for blood and extended to cell therapy and tissues in 2000. Today, ISBT 128 is used by more than 4500 facilities in over 60 countries and its use for organ transplantation is being piloted. It is endorsed and strongly supported by many international professional bodies and accreditation organizations and is being expanded to harmonize the nomenclature and coding of all MPHOs to ensure global traceability and biovigilance. To manage ISBT 128, the ICCBBA works closely with professional associations, transfusion and transplantation facilities and individual experts to develop strong expert consensus internationally. Health authorities in many countries accept ISBT 128 as an effective solution for blood and blood products and some mandate its use. A 2012 international transplantation workshop[5] convened by WHO considered global traceability and recommended close collaboration between national health authorities and agencies and scientific and professional societies, with the ICCBBA and WHO managing a global governance service for the coding and labelling of MPHOs.

ISBT 128 has been highly successful where it has been adopted but global standardization, not yet realized, will depend on international confidence in the long-term sustainability of ISBT 128 and protection of the standard from commercial exploitation, potentially through agreement between the ICCBBA and WHO.

The development of an international coding system for MPHOs requires either creating a new system or ensuring a role for the ICCBBA as provider of the global service for nomenclature and coding. Attaining the WHA63.22 objective of globally consistent coding systems will involve the gradual adoption of ISBT 128 by organizations as an element of their development programmes. Implementation of such an international coding system will also require an understanding of the importance of consistent coding and of international traceability and transparency. ■

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