STATUS OF ISBT 128 IMPLEMENTATION FOR CELLULAR THERAPY WORLDWIDE

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Background

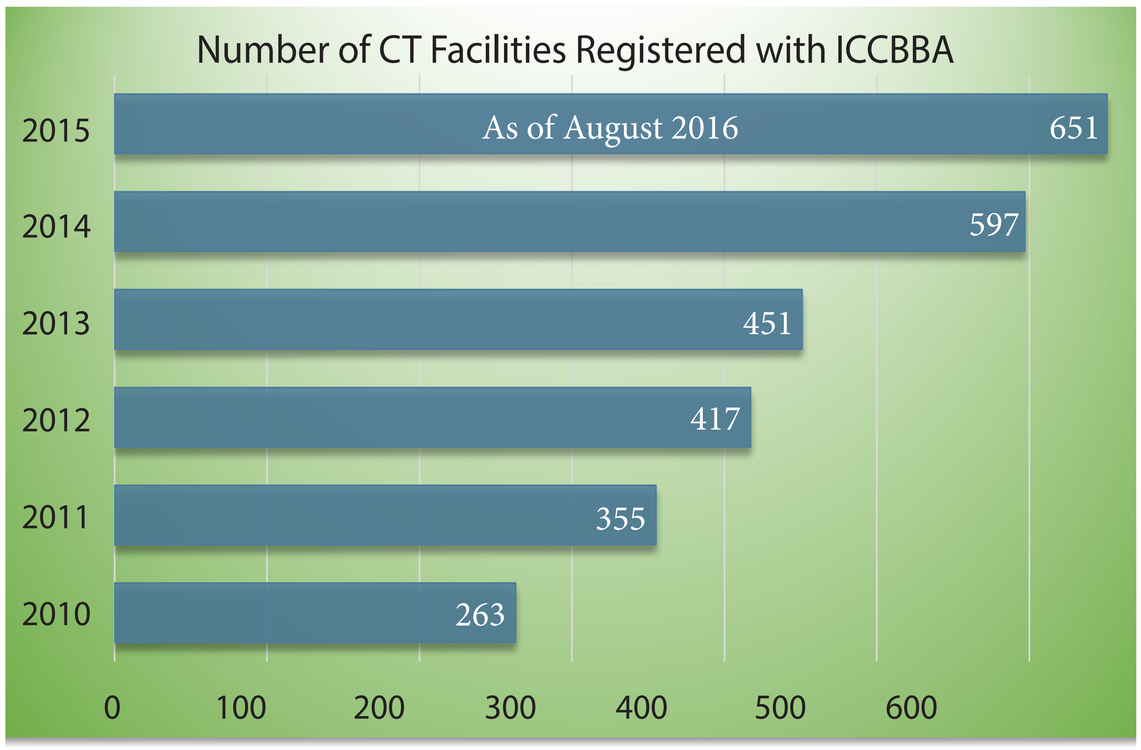
In 2010, the World Health Assembly Resolution WHA63.22 urged member states "to encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation." ISBT 128 is such as system, and, according to the WHO website, "is the sole global standard for the identification and coding of MPHO [Medical Products of Human Origin]."

Given the high frequency of international distribution of cellular therapy (CT) products, standardized coding and labeling is particularly important in CT to achieve efficient and accurate communication across language barriers.

The use of ISBT 128 terminology, coding, and labeling for CT products has been increasing steadily around the world. AABB, FACT, and JACIE require the use of ISBT 128 terminology and a plan for full implementation. Of interest in the coming year, ISBT 128 is compatible with the mandatory Single European Code.

Current Status

There has been a steady growth in CT facilities registered with ICCBBA to use ISBT 128.



110 ICCBBA-registered CT facilities in 25 countries responded to a recent survey on their status of implementation of ISBT 128. 52% indicated they have fully implemented ISBT 128 and another 28% indicated they are using ISBT terminology, but have not implemented ISBT 128 labeling. Of those who had not implemented, 66% indicated they planned to implement within a year, while 34% said they would implement within 2 years.

Conclusions

The increasing number of CT facilities committing to the use of ISBT 128 is encouraging. Implementing ISBT 128 takes time given the need to update computer systems, or in some cases, to select and implement such systems. While response to the survey was not high, it shows a commitment to implementing both the terminology and the full labeling system which includes electronically-readable key information. Such global implementation will go far towards meeting the WHO recommendation for a globally consistent coding system for human cells.

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ISBT 128
More than Identification

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