US Implementation of ISBT 128 Case Study

The United States is one of the countries that has adopted the use of ISBT 128 nationwide for blood products. With a blood donation rate of ≥30 per 1,000 population (World Health Organization 2011), the US collects over 15 million blood donations and transfuses a total of 30 million blood components annually. (American Red Cross n.d.)

This case study looks at the methods and organizations involved in adopting the ISBT 128 international standard for blood transfusion in the United States.

BACKGROUND

In the late '70s, issues stemming from the usage of ABC-Codabar for blood products sparked the implementation of a new standard for coding and labeling. In an editorial written by Charles H. Wallas, MD, Wallas states that "…the systems for tracking, tracing, and proper identification of units of blood and components is in a state of disrepair, leading to safety issues as long as ABC Codabar remains in use." He then goes on to state issues with ABC Codabar including data security issues, a non-sufficient unit identification number, a non-sufficiently flexible product code structure, and the lack of an established clearinghouse to standardize any changes made to the labeling standard. (Charles H. Wallas 2005). ISBT 128 was the solution to these issues as it featured globally unique identifiers and allowed for growth in product coding, among other advantages.

NATIONAL BLOOD POLICY

According to the World Health Organization (WHO), "Ensuring the safety and availability of blood and blood products is an essential public health responsibility." Additionally, WHO states that "Consistent quality and safety in the provision and administration of blood and blood products cannot be achieved without a coordinated service with an appropriate national blood policy." (World Health Organization n.d.)

In 1974, the United States implemented a national blood policy designed to improve the supply, quality, accessibility, and efficiency of the country's blood program. Key improvements focused on the regionalization of blood collection and distribution, an all voluntary blood donation system, and harmonization of charges associated with blood services. (U.S. General Accounting Office 1978) Although not without hurdles to implementation, the national blood policy laid the foundation for the future of blood transfusion in the United States.

A part of this national blood policy included blood inventory control. The functions for blood inventory control were bestowed upon the Committee for Commonality in Blood Banking Automation (Commonality Committee) – an early version of the current ICCBBA organization. At the time, the Commonality Committee comprised representatives from the American Red Cross, the International Society for Blood Transfusion, and the American Association of Blood Banks (AABB). (U.S. General Accounting Office 1978)

AUTOMATING BLOOD BANKING

Automation in blood banking could have been accomplished in several ways. However, different equipment and software companies existed that may not have allowed for interoperability between blood centers and hospital transfusion centers. To address this, the early Commonality Committee

developed a blood bag label that could be used by blood banks that were not automated, and by those that were. This label would be both machine readable and eye readable allowing for the transfer of products without data loss. (U.S. General Accounting Office 1978) The. label, then called ABC-Codabar, was implemented in 1977. By 1997, talk about an all new uniform labeling system had already begun. The new labeling system would later be known as ISBT 128.

BLOOD BANKING STANDARDS

As a leader in standards for blood banking, AABB recognized the importance of ISBT 128 for traceability and created the AABB ISBT 128 Task Force to develop an implementation guide for the use of ISBT 128 that was completed in 1998. Although revisions were made throughout the document, it provided a means to inform users of what to expect before, during, and after the transition. Within it was a sample implementation plan, reference documents, and resources for additional information. This approach was beneficial to organizations in that it allowed them to customize ISBT 128 implementation to fit the needs of each hospital or blood center and any of its affiliates. Eventually, recommendations from users who had already implemented became available as well.

COLLABORATION BETWEEN BLOOD CENTERS AND HOSPITALS

Although the primary responsibility of blood labeling fell upon the collection centers, the role played by the end user was just as important. To ensure the full forward and backward traceability or products, hospital software systems had to be changed or updated to include the capability to scan and interpret ISBT 128 bar codes. During the transition period, many hospital's software had to accommodate for both ABC-Codabar and ISBT 128 labels simultaneously since blood centers introduced the new labels at different times. In an article published on www.mastercontrol.com, David Linnemeyer stated, "…I thought the ISBT capabilities of our computer system might be sufficient for the department's ISBT needs. I discovered that just because a system had ISBT capabilities does not necessarily mean these capabilities will be sufficient for the department's needs." He continued," I did not realize that it would be important to minimize the time frame when both Codabar and ISBT components would be used concurrently in the blood bank. I attempted to coordinate ISBT implementations of with my own transfusion service and donor room. Ultimately this was thwarted by "floating" implementation dates of outside blood sources and unexpected computer software limitations of our in-house donor computer. As a result, the blood bank has had to handle both Codabar and ISBT labeling for an extended period of time." (David Linnemeyer 2009) Eventually, a date for implementation was proposed by AABB that gave centers and end users ample time to prepare. Final implementation was included in AABB's 25th edition of *Standards for Blood Banks and Transfusion Services* and required an implementation of ISBT 128 by May 1, 2008.

CONCLUSION

Although the US national blood policy was vital in improving blood safety, it acted only as a segue to the promotion of higher standards for the labeling of blood and blood components. Support from an accrediting organization, coupled with bar code requirements from the US Food and Drug Administration, proved to be a crucial driving force for US implementation of ISBT 128. Recently, this model has been adopted by the Eye Bank Association of America with the same positive results for ocular tissue. Currently, professional societies such as AABB, FACT, and JACIE are utilizing a step-wise approach for use of ISBT 128 with cell therapy products. These steps involve an implementation plan,

active implementation, and full implementation. Other countries who have successfully implemented ISBT 128 nationally for blood are Poland, Austria, and Estonia.

KEY POINTS:

- The appointment of an influential champion that coordinated and collaborated efforts with other influential organizations in industry.
- Creation of a core team comprised of experts in IT, standards and accreditation, software development, regulations, industry leaders, and end users.
- Strong industrial commitment from organizations such as AABB, FDA, the US Department of Defense.
- Support from regulatory body (US FDA) by recognizing as acceptable for use the document *The United States Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128* although they did not require use of ISBT 128.
- Support from the user community.

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