

Case Study: Implementation of ISBT 128 in Scandinavia

There are several similarities among the Scandinavian countries, including healthcare. In regards to blood banking, Sweden, Norway, and Denmark have all implemented the ISBT 128 international standard for coding and labeling throughout their countries.

This case study looks at the collaborations that were utilized when adopting the ISBT 128 international standard for blood transfusion.

BACKGROUND

Prior to the development of the ISBT standard in 1995, there were no internationally standardized coding and labeling systems in the field of transfusion medicine. As a result, blood collection facilities had no choice but to develop their own labeling methods, or follow the prescribed local, regional, national, or professional society-based specifications, such as ABC Codabar. ABC Codabar was published in 1985 by the US Food and Drug Administration and ABC (American Blood Commission) as a guideline for uniform labeling of blood and blood components. As is the case with many localized coding and labeling paradigms, there was no continuous upkeep, which is necessary for a field as dynamic as transfusion medicine. In the case of ABC Codabar, this led to security and capacity flaws in addition to the inability for expansion of bar coded information.

Another issue with utilizing localized systems was that the variability in identification schemes between individual blood centers opened the possibility of blood components having duplicate identifiers as they moved throughout the supply chain. When used correctly, ISBT 128 reduces this risk by ensuring that Donation Identification Numbers remain globally unique for a period of 100 years.

A national labeling system was first introduced in Sweden in 1965, and was revised in 1983 to be better adapted to the production and use of blood components. During the 1990s, the importance of an international identification and labeling system was more widely recognized. The first Swedish blood center registered with ICCBBA in 1996, with most others registering in 2001.

Similarly, the first Norwegian blood center registered with ICCBBA in 1996 with most others registering between 2001 and 2005. In Denmark, about 25% of facilities registered between 1996 and 1997, with most others registering between 1999 and 2006.

NATIONAL BLOOD SYSTEMS

The responsibility for healthcare is divided between the state and municipalities in Norway, and is decentralized to the regional and country level in Denmark and Sweden, respectively (Jon Magnussen, 2009). In Sweden, it was professionals in the field that pushed for the change from an antiquated system for coding and labeling, to the ISBT 128 international standard. Working with professionals in Denmark, representatives from both countries were able to collaborate on what the final label would look like. Although Sweden's key supervisory authority, the National Board of Health and Welfare, was not involved, they accepted the use of ISBT 128 without any comment. Soon thereafter, a national organization was created for the follow up of ISBT 128 implementation. Likewise, Norwegian Health Authorities accepted and advised all blood banks to implement ISBT 128 after a successful implementation at blood banks in Norway.

The Swedish Blood Alliance was formed in 2004 as a non-profit organization that would generate and maintain national developments related to the quality and safety of blood. Today, the Swedish Blood Alliance administers the translation, incorporation, and availability of ISBT 128 codes through a web-based database. In addition, the Swedish Society for Transfusion Medicine recommends practice and policy, generates manuals of procedures, guidelines and annual reports, conducts training programs, operates the national hemovigilance program, and monitors blood production and use. The Handbook for

Blood Centers was developed in the 1990s and constitutes standards for the blood activities in Sweden. The standards have been continuously developed, including the addition of a chapter specific for the identification and registration of blood, cells, and tissues according to ISBT 128 (Medicine, 2019).

Regulations for blood transfusion and reporting in Norway are published by the Ministry of Health and Care Services.

In Denmark, since 2001, the Organisation of Transfusion Centres coordinates countrywide responsibility for blood transfusion services. By law, health care in Denmark is the responsibility of the five regions (Stenholm, 2015).

HEMOVIGILANCE SYSTEMS

Hemovigilance in Sweden and Denmark is monitored utilizing SCANDAT, the Scandinavian Donations and Transfusion database. This database utilizes data from ISBT 128, as well as other sources, to perform studies of blood donations and transfusions for research topics, such as clinical nuances of blood transfusion, the health effects of long-term storage of red-cell concentrates, and the influence of plasma from female donors (Karolinska Institutet, 2019).

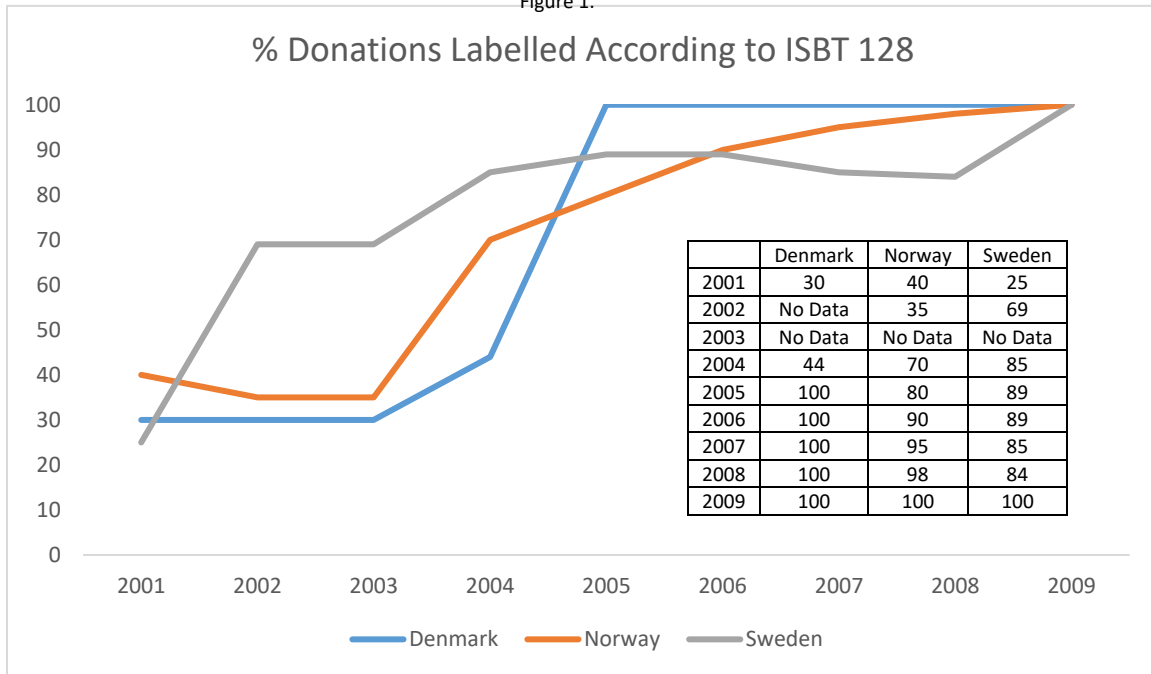
The Directorate of Health in Norway has had responsibility for the country's hemovigilance system, TROLL, since 2007. Each year an annual hemovigilance report is published that is intended as a documentation basis for the continual improvement in transfusion service, including recommendations relating to ISBT 128 (Steinsvåg, Espinosa, & Flesland, 2011).

CONCLUSION

Unlike other nationwide ISBT 128 implementations that were driven by regulations and/or accreditation requirements, Swedish and Danish professionals in transfusion medicine were quick to recognize the benefits of an internationally standardized coding and labeling system. This happened shortly after ISBT 128's initial release and implementation. As most centers began implementing a new coding system in 2001, reports indicate that between the years 2001 and 2002, Sweden saw a nearly 45% increase in the number of donations that were labeled with ISBT 128, bringing the total percentage to nearly 70%. It took Norway five years to yield a 50% increase, and four years for Denmark to yield a 70% increase in blood donations labelled with ISBT 128 (fig.1).

The efficiency with which Scandinavian countries were able to implement an all new coding system shows that a country with a population of up to 10 million can successfully implement a new coding system given enough input from the stakeholder community, and adequate planning. Resources for such are plan are made available on the ICCBBA website at www.iccbba.org.

Figure 1.



Data taken from The Collection, Testing and Use of Blood and Blood Products in Europe 2004-2009 Reports

<https://www.edqm.eu/en/blood-transfusion-reports-70.html>

References

- Jon Magnussen, P. (2009, May). The Scandinavian Healthcare System. *Medical Solutions*, 63-68. Retrieved from Semantic Scholar.
- Karolinska Institutet, S. S. (2019, 03 14). *SCANDAT Background*. Retrieved from SCANDAT: <http://www.scandat.se/background/>
- Medicine, S. A. (2019, 03 14). *Manual for Blood Centers*. Retrieved from Svensk forening for klinisk immunologi och transfusionsmedicin: <http://www.kitm.se/sv/handbokskapitel/>
- Steinsvåg, T. T., Espinosa, A., & Flesland, Ø. (2011, November). *Monitoring of Blood in Norway 2010*. Retrieved from Norwegian Institute of Public Health: https://www.fhi.no/globalassets/dokumenterfiler/rapporter/2011/hemovigilans2010_delrapport2_a_nbefalinger.pdf
- Stenholm, E. (2015, October). *Monitoring of blood transfusion operations in EU-countries*. Retrieved from European Commission: https://ec.europa.eu/environment/life/project/Projects/index.cfm?fuseaction=home.showFile&rep=file&fil=PVC_DEHP_BLOOD_BAGS_transfusion-in-EU-countries.pdf