EBA European Blood Alliance

CREATING A PRODUCTIVE SCREENING LABORATORY

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Abstract:
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The Sanquin Blood Supply Foundation was founded in 1998 through a merger between the 22 Dutch Blood Banks (BB) and the Central Laboratory of The Netherlands Red Cross Blood Transfusion Services. In 1999, the 22 Sanquin BB merged into 9 BB. These 9 BB had laboratories for blood donation screening but only 4 had facilities for Nucleic Acid Testing (NAT). Routine NAT minipool screening (48 donations) of all blood donations was implemented in July 1999 for HCV-RNA and was combined with HIV NAT in November 2000. In 2001, it was decided to reorganize from 9 to 4 BB, each with their own testing facilities. This reorganization was completed in 2004. In 2006, a study started to determine the feasibility of the implementation of centralized screening. Major motives for this were to establish uniformity in testing, to anticipate on the possibility of an open EU market for blood products and to improve the efficiency and cost effectiveness of the testing process. The actual project for the centralization of blood donation screening started in 2007. At that time, Greenfield calculations were made on 22 different models. It was demonstrated that the most efficient model for Sanquin was to establish a central testing facility in Amsterdam with two working shifts (day and night). At the end of 2008, centralized testing in the new Sanquin National Screening Laboratory (NSS) was a fact. In 2009, NSS moved into a new building.

Due to the centralization of blood donation screening, it was necessary to reorganize the collection, transportation and preanalytical processes regarding the blood samples needed for testing. Nowadays, blood samples are drawn in color coded sample tubes which are prepacked in sealed bags for the different donation types. For whole blood and platelet aphaeresis donations, three tubes with red caps are used. For plasma donations three tubes with yellow caps and for new donors and first-time donations three and four tubes with pink caps, respectively. Tubes with red caps have a higher priority within the testing process because most of the corresponding blood donations are used for platelet preparation. Inside the caps of the tubes, colored rings are present. Tubes with red rings are used for blood grouping, tubes with black rings for viral serology testing and tubes with yellow rings for NAT. From Monday through Thursday, sample tubes drawn throughout the country are packed in dedicated colored boxes that arrive between 23:00 to 3:00 at NSS. The technicians (n=3) working in the nightshift immediately start with the preanalytical processes and NAT. Between 5:00 and 6:00 they start with viral serology testing. Between 6:00 and 7:00 the first technicians from the day shift arrive. They continue with any unfinished work and start immediately with blood group serology testing.

At approximately 7:00 (prior to the availability of the first test results) a file with testing orders for each donation is send from the Blood Bank Information System e-Progesa (BIS) to the NSS Laboratory Information Management System (LIMS). After processing this file, it is possible to send the laboratory results to LIMS. The results are consecutively processed, checked, validated and sent to BIS. The order file is also used for the automated sorting of already processed sample tubes to perform any required additional testing (e.g.: anti-Parvo B19, Total protein, extended phenotyping). Before 14:00 the results of the tubes with red caps must be available for the BB to release the corresponding blood components. The results of the other tubes are available before 15:00. At the end of each dayshift, checks are performed in both BIS and LIMS, to determine whether additional testing on sample tubes is necessary. The last technicians leave NSS around 17:00. Samples tubes drawn on Fridays (approximately 6.000) are tested on Saturdays by 6 technicians and all test results are available before 14:00. NSS also facilitates priority and 24/7 Stat testing.

An investigation on the economics of centralized testing showed savings of at least 7 million euro's a year. This mainly because in daily practice only 30 FTE were needed for testing over 930.000 donations (EBA benchmark in 2011: 32000 equivalent units/FTE/year) and testing can be performed with ~50% of the original number of laboratory devices.

Looking back on the process of centralization revealed that the major challenges were the propagation of the message, to deal with the initial distress and disbelief among (laboratory) staff, to anticipate on the premature closure of some or parts of the laboratories involved, to recruit and train new employees in a very short time frame, to initially organize the workflows in a very limited space, to reorganize the logistic system for the collection, transportation and handling of sample tubes, to realize a new laboratory, to deal with the automation of the processes, to (re)validate new equipment and processes, to implement a whole new NAT system (pools of 6 including NAT for HBV) and last but not least to arrange back-up facilities.