National guidelines for preanalytical processing of bioliquids – The Swedish strategy

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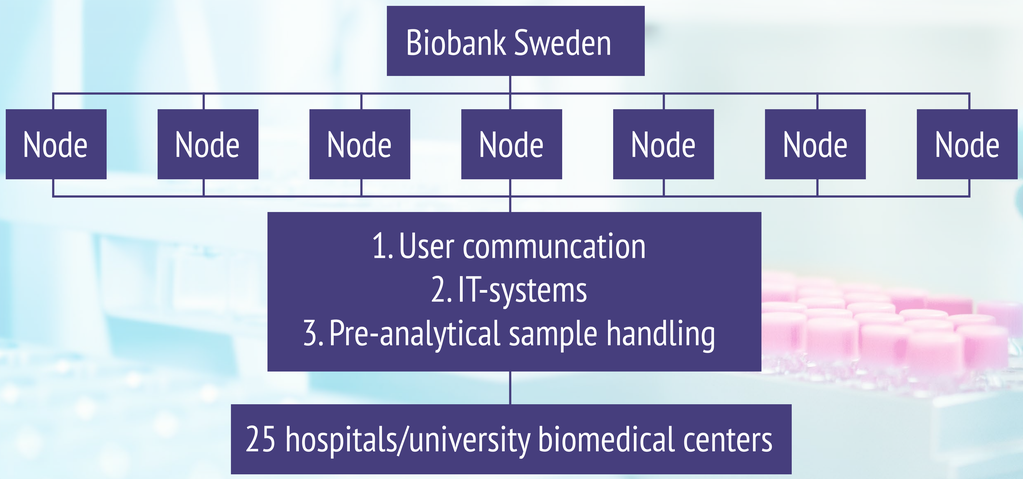
Abstract

Biobank Sweden is a national biobank infrastructure, and the Swedish node of BBMRI-ERIC. With the aim to strengthen the conditions for biobank-based medical research, it is a collaboration between healthcare, academia, industry, and patient organisations. A national program for healthcare-integrated biobanking has been created, whereby similar biobank services were established at 25 participating hospitals and university medical centres across Sweden. The goal of the program is to provide professional biobank services to research projects within a variety of disease areas, as well as for population and epidemiological studies. The focus is on enabling and harmonizing the processing of blood samples, supporting automation of the pre-analytical handling, and linking data to LIMS systems.

Here, we summarize the current strategy for Biobank Sweden towards national guidelines for preanalytical handling of bioliquids, with focus on blood samples collected and processed in healthcare-integrated biobanking. These guidelines describe several factors that affect sample quality, including a) early interaction between the principal investigators and the profession at the local/regional biobank service facilities to ensure that all aspects for collecting and processing samples are included in the research plan, b) harmonization of preanalytical sample processing to reduce the variability of preanalytical factors within a cohort as well as the inter biobank variability, and c) careful documentation of the sample history to LIMS systems to enable assessment of sample value for specific research questions and analyses and for future use of samples stored in biobanks.

Introduction

During 2020, meetings were held with all seven regional nodes within the Biobank Sweden infrastructure, with the purpose of investigating the implementation of the Swedish strategy guidelines for pre-analytical handling of bioliquids, and to find out if there are any unmet user needs. During the meetings, it was clear that all nodes were following the national guidelines as well as they could and the knowledge among the participants about pre-analytical sample handling issues was good. The experiences and difficulties were very similar across the nodes and could be divided into three major areas; 1) user communication, 2) IT-systems, and 3) pre-analytical sample handling.



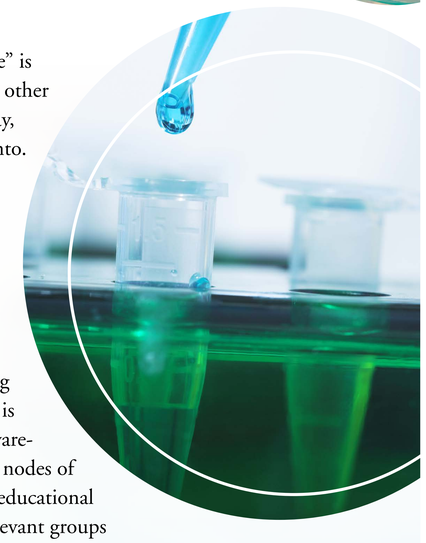
Results user communication

One of the major issues that affects pre-analytical sample handling was a lack of knowledge among the users. This can be solved in part by early communication between user and biobank service facilities, where the user will get help to set up their research study. We all agreed that the national guidelines on pre-analytical sample handling should be used as much as possible in the communication with users, to educate users and to clarify the impact of pre-analytical sample handling on results of a study. Increasing awareness about the term "fit for purpose" was another thing that was discussed, as well as having a check list about pre-analytical sample handling for users who want to start a study.

Results IT-systems

Due to regional differences, there are large variations in IT-systems among hospitals and university biomedical centers. In addition, regional differences also apply to sample data; in some regions, the biobank user is the one responsible for getting and storing the data for a sample collection and in other regions of Sweden this task is performed by the regional biobank service facilities. In the best of cases, all relevant sample data is gathered and stored in a LIMS system at a regional biobank service facility. However, in some regions, IT-systems at hospitals/university biomedical centers cannot communicate with the LIMS system of the coordinating biobank service facility. This issue with two non-communicating systems means difficulties in getting sample data, and might lead to loss of sample data altogether.

Another issue brought up by a majority of the nodes was the difficulty of getting a time stamp for the time to sample centrifugation. Since the time to centrifugation has a major impact on sample quality, it is of great importance that this time stamp is gathered and stored. If not, there is a risk that samples with a large variation in the time to centrifugation variable are used for down-stream analyses, which might be devastating to the results from the more sensitive analytic methods. Again, the importance of "fit for purpose" is brought to light. No solution other than manual notes exists today, but the issue will be looked into.



Results pre-analytical sample handling

Apart from the issues for pre-analytical sample handling stated above, the largest issue is the lack of knowledge and awareness of the biobank users. All nodes of Biobank Sweden agreed that educational efforts are needed to teach relevant groups about important pre-analytical sample handling factors like phlebotomy, transportation, storage temperature until centrifugation, and time until centrifugation, as well as awareness of "fit for purpose" sample handling.

Summary

Biobank Sweden has a solid strategy in place, for the harmonization and enabling of pre-analytical sample handling across 25 hospitals and university biomedical centers. There are national guidelines for pre-analytical sample handling of bio-liquids and a large part of these are implemented in the work-flow of the hospitals/biomedical centers, together with the regional biobank service facilities. However, as described here, some issues remain to be solved in the future.

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