Further development of biobanking processes through the introduction of a uniform standard for the harmonization of national biobanks

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Background

In order to harmonize biobank quality standards, the BMBF-funded project “German Biobank Alliance” aims at developing a biobanking accreditation norm within a group of 11 national biobanks. This includes, among others, quality indicators which provide information about working methods and management of a biobank. During “friendly audits”, the successful implementation of the accreditation norm will be reviewed.

Materials and methods

During the preparation of the first performed friendly audit at the site of Aachen, quality markers such as fill levels and transport conditions of the blood monovettes as well as the transport conditions of tissue samples were integrated into the biomaterial entry process. In order to determine the fill level of a monovette, the monovette is manually held to a modified measuring scale, which indicates the percentage fill level. The quality markers are recorded in the sample management system. To limit the documentation effort, only non-SOP-compliant findings are documented.

Results

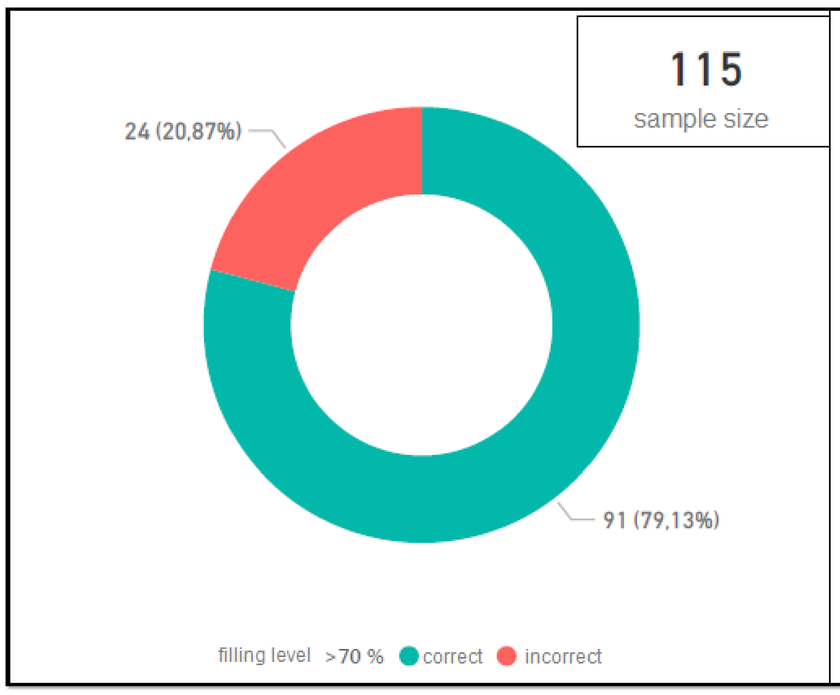

Figure 1. SOP conformity of the submitted liquid samples with regard to their filling level
This diagram shows the correctness of the filling quantity of the received monovettes. The aim is to fill a monovette at least 70% with regard to the calibration mark. For later analyses, which have not yet been determined, it is important for the researcher to know how the samples were previously treated and processed. The coagulants react more strongly to a lower blood volume, so that a falsification of the analysis results is highly possible.

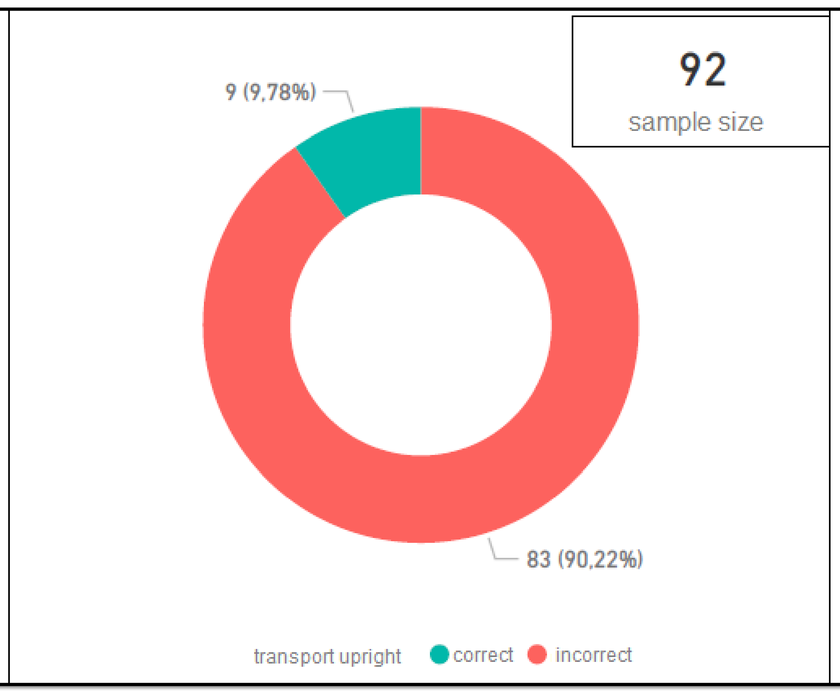

Figure 2. SOP conformity of the submitted serum samples with regard to their transport
This diagram shows the correctness of the transport of serum monovettes. Serum monovettes should be transported upright to avoid blood clumping.

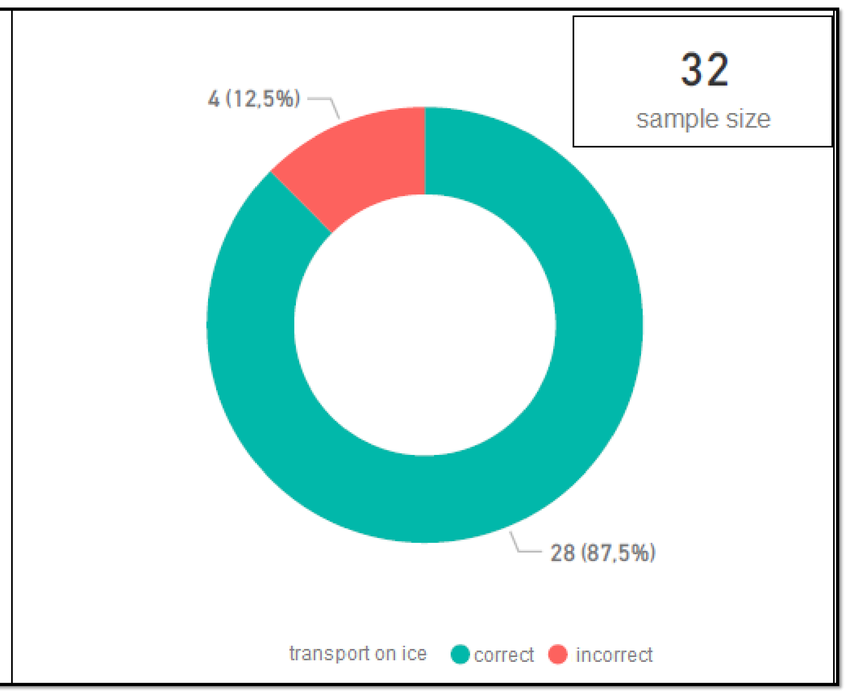

Figure 3. SOP conformity of the submitted tissue samples with regard to their transport on ice
In order to maintain the cold chain (cold ischemia), the tissue samples from the operating theatre must be transported directly on ice to the pathology premises.

Future perspective

In the future, quality indicators will be recorded automatically by using an app. The monovette filling level will be detected via image recognition. In addition, each incoming sample at the RWTH cBMB will be equipped with a time stamp via scan to enable the biomaterial delivering researcher to track his sending.

The reporting system will comply with the currently valid data protection regulations, so that different user roles of the app will have different views within the app.

Quality markers like blood clotting, especially in serum monovettes, are to be recorded in the sample management system. In this context, it is important to be able to estimate the effects of the non-compliant transport of serum monovettes. This will allow a better communication between the biomaterial delivering clinics and institutes. To prevent deviations in the future, the clinics and institutes will be trained to carry out the biomaterial collection in a SOP-compliant manner.

Summary

In summary, it can be stated that most processes are SOP-compliant. However, there is a strong need for training in the transport of serum monovettes. Despite the small sample size, there is a noticeable bias.

Biobanks see themselves as service providers. Not only the biobank processes but also external processes that can influence the biobank should be planned, controlled and monitored. Quality controlling and awareness still need to be expanded, but the RWTH cBMB has already pioneered this at the site of Aachen.

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