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## Initial Stage

## Presentation type \*

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## Title of your abstract ?

## Abstract content (max: 250 words) \*

## Background and Aim

Biobanks support their clinical collaboration partners by providing sample processing and storage under controlled conditions. In that, biobanks help to avoid irreproducible research that is known to produce tremendous economic and ethical burden. However, the choice of the best possible sample handling approaches is a challenge even to professional biobanks, since little evidence is available regarding the influence of biobank-specific storage environments on the quality of analytes. Especially in single freezer-based biobanks, repeated opening and closing of freezer doors leads to multiple rises in temperature which might impact the biospecimens. We thus aimed to investigate, whether and to what extent subsequently measured blood levels are altered by freezer-based storage with recurrent opening/closing of the freezer doors when compared to a constant storage temperature.

## Methods

Samples, all of them pre-analyzed for several biochemical analytes, were put either on  $<-75^{\circ}\text{C}$ , and freezer doors were opened 30 times, allowing a temperature rise to  $-65^{\circ}\text{C}$  and a freezer-specific re-cooling period ( $\sim 2$  h lasting) to the initial temperature, or stored constantly at  $<-75^{\circ}\text{C}$ . After 10, 20 and 30 temperature fluctuations, samples from both groups were re-analyzed.

## Results

Although storage per se caused changes of some biomarkers over time, which sometimes exceeded the analytical variability of the respective parameter, this developments did not markedly differ between samples experiencing temperature fluctuations and control samples.

## Conclusion

Temperature fluctuations, as they occur in freezer-based biobanks due to recurrent opening/closing of the freezer doors, might not produce considerable pre-analytic variability for a broad set of blood markers.

## Keyword 1

## Keyword 2

## Keyword 3

Link of interest : regarding the abstract you have just submitted, do you have any links of interest ? \*

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## **Manual storage or fully-automated innovative storage system? What and how?**

K. Sargsyan, G. Hartl, K. Plattner, M. Bayer, B. Huppertz

### Background

Nowadays most biobanks still keep their fluid samples in manual freezers and only a very small percentage of biobanks uses automated systems. As with manual freezers tube handling takes place at room temperature quality of samples could not be ensured.

### Methods

Biobank Graz has 5 generations of storage systems starting from historically inherited, decades old freezers, than to water cooled freezer, than fully automated storage system with -20°C tube peaking to fully automated system with -80°C tube peaking and also a walk-in manual store is in place. As all systems are in use Biobank Graz has exact overview on all features of the systems: advantages as well as disadvantages. This topic has been systematically reviewed and evaluated.

### Results

Each of these storage systems is specifically suitable for storage of different kind of fluid samples at -80°C, depending on vial type and volume, identification type (e.g. 2D barcoded or written), amount of daily incoming aliquots, sample distribution frequency etc.

### Conclusio

The new fully automated storage systems at -80°C with high storage capacity can be functional and suitable as well as manual walk-in stores and water cooled freezers, depending on local technical requirements and sample turnover capability.

## **Major project management pitfalls of clinical projects and how to avoid them**

F. Vogl, T. Macheiner, B. Huppertz, K. Sargsyan

### Background:

Modern biobanks are no longer seen as storage facilities only, but rather as central hubs for biomedical research. In addition to biospecimen collection, processing and archiving, they are also involved in management of clinical projects. Project management in a biobank includes diverse tasks: donor selection, clinical data acquisition or cost calculation for biobank services.

### Methods:

Biobank Graz successfully processes inquiries from academic and industrial research for more than 10 years and provides samples to researchers all over the world. The project database of Biobank Graz comprises all inquiries since its foundation until today. Systematic evaluation of these requests allowed us to identify the major pitfalls during project planning and implementation, as well as the most frequent causes for project delays and cancellations.

### Results:

The lessons learned during 10 years of experience in management of clinical projects were collected, summarized and divided into different categories. By this means, we were able to identify the 7 major project management pitfalls of clinical projects. These pitfalls include different scenarios from simple communication problems and planning mistakes (e.g. appropriate control cohort) to more complex bottle necks (e.g. availability of clinical data). We provide tips and helpful hints for the daily work of project managers in biobanks in order to avoid common pitfalls.

### Conclusion:

Biological materials are retrospectively not customizable, thus not everything is predictable in biobank project management. However, awareness of the 7 major project management pitfalls contributes to effective and successful project development and management in the highly interdisciplinary environment of biobanks.

## **CEN standards: from paper to action**

V. Perz, J. Woger, K. Sargsyan, B. Huppertz

### Background:

Recently, the European Committee for Standardization published several European Technical Specifications (CEN/TS) with high relevance for biobanks. In detail, technical specifications for the pre-examination processes of urine, venous whole blood, serum, plasma, snap frozen tissue and FFPE tissue are waiting for their realization in biobanking. Here we present a guideline for the successful application of CEN/TS in biobanks.

### Methods:

To identify the relevant parameters and responsible stakeholders, the described workflow of all relevant CEN/TS was divided into the phases: patient data assessment; lab work – sample preparation; transportation and storage. Standard operating procedures (SOPs) affected by CEN/TS were defined and adapted accordingly. Moreover, we collected all points with relevance for documentation. Databases should be modified to comply with CEN/TS requirements and data input devices must be adapted. Finally, responsible staff was/will be instructed concerning the new procedures.

### Results:

Existing cohorts were evaluated regarding their CEN/TS status quo. Thereafter, the fitting in CEN/TS of SOPs and databases was the major focus. For fast and sound data assessment, data collection and future data query it is of great importance to avoid description fields wherever possible and use tick boxes, drop down lists or automatically generated data (time points, temperatures, volumes, barcode numbers etc.) instead.

### Conclusion:

CEN/TS were predominantly not elaborated for biobanking which challenges biobanks. Likewise, we need to evaluate the applicability of CEN/TS in the daily routine. Nevertheless, strategic approaches could enable biobanks to accomplish CEN/TS, to assure highest quality and provide biological material with reliable value in the long run.

## **Bio-value in bio-banking. Citizens' understandings of value, trust, and engagement in the Austrian context**

Melanie Goisauß

Biobanks have become essential infrastructures in biomedical research. In collecting, storing, and providing biological samples and health related data, they could also be considered as a site of 'biovalue' production. In this regard, biobanking practice is entangled with questions of ownership, (commercial) access and benefit-making as well as sharing. Associated with these questions are debates about privacy, trust, and ownership in biobanking. Against this background, the paper examines the specific ways in which citizens discuss the processing of donated data and biological material in the context of the Austrian biobanking infrastructure BBMRI.at. It builds on the in-depth analysis of nine group-discussions where citizens and patient representatives, together with professionals from the field debated about biobanking. The paper explores how citizens produce value in participatory settings, their practices in creating 'biovalue', and their concept of donated samples as carriers of valuable 'bio-information'. The analysis focusses on how this entanglement is enacted in participatory group-settings where biobanks are addressed as sites of 'biovalue' production. It further allows insights in perceptions of and trust towards research institutions in which biobanking practices take place. In connecting these findings to understandings of consent and ownership of samples and data, the paper concludes with a discussion of new models for engaging individuals and publics in biobanking where donors are considered as partners of research.

## **Data in Question. ELSI Challenges in biobank-based research**

Melanie Goisaufl, Gillian Martin

Researchers and stakeholders in the field of biobanking are facing different social, ethical and legal challenges that impact established practices related to biological samples and health-related data handling and sharing. Against this background, BBMRI ERIC CS ELSI , in collaboration with COST action CHIP ME, RD connect , IMI DO-IT, Biobank Norway conducted a survey that aims to identify challenges arising from legal, ethical or social developments from the perspective of European biobankers and biomedical science researchers. This presentation will outline preliminary results of this work in progress, highlighting data collected via an online questionnaire fielded through the BBMRI ERIC network of biobankers, and analyzed using SPSS.

The key focus of enquiry is the effect of the growing demand for engaging with third parties from industry, patients or citizens. The major topics covered by the survey are: (1) secondary use of data (2) informing and/or re-contacting participants (3) sharing of data with third parties from industry, (4) participant engagement, and 5) collaboration with industrial partners. In our paper, we are going to present key results of the survey and discuss them in the context of new legislation such as the EU General Data Protection Regulation, and the growing demand for engaging with third parties from industry, patients or citizens.