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ABSTRACT **BOOK**

Presented by:

UHN Biospecimen Services

Isber

POSTER ABSTRACTS

1. Beyond Sustainability: Keeping Paediatric Biobanking Relevant

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Paediatric biobanks are key resources for translational research of childhood diseases which are crucial for future healthcare improvement for children. Development of personalized medicine for children relies on translational research using their biospecimens. Due to the rarity of childhood diseases, small specimen volumes, limited population of children, and relative smaller scale of paediatric research, the sustained activity for many paediatric biobanks is vital for their effectiveness. When considering how paediatric biobanks can maintain effective activity over an extended time, a key but unrecognised element for sustainable biobanking is maintaining the biobanks relevance, a quality that is linked to the benefit brought by the biobanking practice. Specifically this requires a balance of consistency in operations with a flexibility to adjust to the changing needs of the research ecosystem as it develops. The primary goal of this presentation is to offer perspectives from a single institutional paediatric biobank embedded within a hospital and the advantage in providing biobank activities as part of clinical care, leading to the continued relevance of a bio-resource for paediatric cancer research. In light of this, we review the activity of The Tumour Bank at The Children's Hospital at Westmead which, over 20 years, has demonstrated a consistently successful and sustainable paediatric biobanking model. Relevance of this paediatric biobank was demonstrated through its model of embedded operations, consistent research productivity, currency of tissue handling expertise, defined and accepted practices as well as it ongoing engagement of patients.

2. Approaching Our Donors to Offer Better Solutions

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Background: Advances in molecular biology and the development of new technologies have made it possible to access genetic information from the biological sample. The entry into force of Law 14/2007 on Biomedical Research in Spain supports the creation of units called Biobanks that guarantee the rights of donors as well as the traceability and physical integrity of this information medium. The objective of this study is to provide a useful computer tool for donors of biological samples for research.

Methods: Based on a previous work to collect and analyze the expectations of our donors, we have worked based on the SCRUM methodology, taking into account the objectives of the innovation project financed in a competitive public way (exp. PIN-0191-2017). The functional assessment of the tool has been carried out following the required standards, through usability tests and a validation checklist will be followed following the criteria established by the WHO mHealth Technical Evidence Review Group (2016). The problems detected during the tests have been corrected prior to the launch of the tool.

Results and Conclusions: We present a multiplatform tool that allows donors of samples and / or data of a Biobank to participate in the development of biomedical research in an accessible environment. Specifically, it allows donors to manage their informed consents for research, have information regarding donated samples and their assignment to research projects. It allows modifying contact and health data, holding conversations with the biobank, checking if there are remaining samples to decide on other uses for them. All this in a comfortable and accessible way from any device, either through a digital certificate or by access by username and password. The tool has the pertinent evaluation and complies with the legal requirements regarding data protection. We have always worked in accordance with corporate regulations. This is a pilot project. The tool can be used by any Biobank if the result is favorable after its evaluation.

3. Creation of a Collection of Blood and Components in the Biobank of the Bashkir State Medical University from Patients with COVID-19 for Translational Research, Ufa, Russia.

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During the COVID-19 crisis, there was an urgent need to create biological collections with clinical annotations for the immediate development of clinical and translational research projects addressing the biological aspects of COVID-19.

We announce the creation of a high-quality collection of samples positive for COVID-19 with accurate clinical annotations in patients with COVID-19 hospitalized at the Covid Hospital of the Clinic of the FSBEI HE BSMU of the Ministry of Health of Russia.

In these rooms, only the collection and storage of blood samples from patients who tested positive for COVID-19 were carried out.

A team of 3 specialist researchers was specifically dedicated to this activity in collaboration with the doctors of the Covid Hospital, one pathologist, two research laboratory assistants. The samples were delivered by a Biobank employee from the hospital's red zone. The time between venipuncture and centrifugation of the sample in the biobank was no more than 1 hour. Quality control parameters and benchmarking were established and determined in accordance with standard operating procedures developed at BSMU.

An electronic database based on the Freezer Pro system was created to record clinical parameters, including various prescribed courses of treatment and patient monitoring. All this data has been protected in compliance with basic health and safety requirements.

The first patient samples were registered with the COVID-19 biobank on March 15, 2020, and by July 30, 2021, samples from 10,220 patients were registered. We have taken serious precautions when handling clinical samples, knowing that the risk of infection when handling blood samples from patients with COVID-19 appears to be very low.

An informed consent form, signed by patients prior to any collection, included explanations disclosing that the intended use of biological samples was for joint projects with national and foreign scientific organizations.

Access to biological collections from certified biobanks guarantees the quality of the material used for research purposes and contributes to the reliability and reproducibility of the results of a research project. In our case, we created a biobank that prospectively collects blood from patients with COVID-19. This collection is now available to academia and private companies to develop translational research projects on SARS-CoV-2 infections.

4. Tissue Bank Oversight of Supply of Clinical Material from Pathology Departments for Research

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Statement of problem: Pathology departments have a large archive of clinical material in the form of formalin-fixed paraffin-embedded (FFPE) tissue. These form a rich and well-annotated resource for human biological research.

The Human Biomedical Research Act (HBRA)[1] came into effect in Singapore on 1 Nov 2015 and serves to regulate the conduct of human biomedical research (HBR) and the use of human tissue in research. With the implementation of the Human Tissue Framework[2] of HBRA on 1 Nov 2019, the supply of such clinical material to a researcher is considered tissue banking activity. Tissue banking activity is defined as a structured and organised activity involving human tissue for the purposes of facilitating current or future research and includes the collection, storage, procurement, importation, supply, provision or export of human tissue.

As such, pathology departments no longer can supply pathology archival FFPE material directly to researchers, and to do so, will need to either become a tissue bank or come under the supervision of an existing tissue bank for the purposes of such activities. The access of pathology archival FFPE material is critical and time-sensitive for clinical trials in which the results of biomarker testing may be critical for research trial enrolment or for research therapeutics.

Proposed solution: The pathology departments in our healthcare centre have decided not to become tissue banks. There is therefore a requirement for a tissue bank oversight process to ensure that patients who are candidates for enrolment into clinical trials continue to benefit from biomarker or other research testing performed on their clinical FFPE material. We therefore worked closely with our pathology departments to set up a workflow to comply with regulatory requirements, but yet expeditiously meet the requirements for material supply for biomarker and other research testing.

The tissue bank oversight process includes the assessment of ethical approval of the research study by Institutional Research Boards (IRB), consent of patients, and case recruitment numbers as approved by IRB. Where there is no patient consent, local regulations permit the use of clinical FFPE material in de-identified form.

Conclusions: With the implementation of the new workflows, research studies can continue to be conducted seamlessly without interruption, ensuring compliance to the regulatory requirements. There are minimal modifications to current workflows. The workflows have been established since May 2021 and have supported 7 studies so far. The change in workflow is necessary to ensure that human biomedical research and tissue banking activities carried out in Singapore follow the law and regulations and fundamentals of good clinical practice relating to ethics and science to protect the rights, safety and wellbeing of research subjects.

References

Human Biomedical Research Act 2015
Human Tissue Framework

5. Survey of Adolescents Regarding Their Opinion of Research and Vaccination During the COVID-19 Pandemic

Iryna Kayda[1] and Qudrat Aujla[1] (shared first), David Goldfarb[2,3,4], Julie Bettinger[3,4], Louise Mâsse[3,4], Jonathan Bush[1,2,3,4], Suzanne Vercauteren[1,2,3,4]

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Background: The COVID-19 pandemic has rapidly altered the daily lives of adolescents, yet there remains a limited understanding of adolescent perspectives on COVID-19 and participation in medical research. The BC Children's Hospital BioBank (BCCHB) aimed to survey secondary school students in British Columbia to investigate their perception of medical research participation and vaccination after the experience of living through the COVID-19 pandemic. This will inform ongoing research, pediatric biobanking, vaccination efforts, and public health policies related to adolescents.

Methods: A voluntary, anonymous, online REDCap survey was administered and consisted of 15 close-ended questions, including Likert scales. School district approval was obtained, and the survey was distributed to Grade 8-12 students across British Columbia via student emails and school online portals. Students received a certificate for 1 hour of volunteer time.

Results: 473 survey responses (412 fully completed) were obtained from participants aged 12-19 years old from 7 BC school districts. Most participants (90.5%) agreed that COVID-19 is a serious disease, and 84.3% stated that the pandemic had shown them the importance of medical research. The majority of participants (86.2%) agreed on the importance of research in diagnosing and treating disease before the COVID-19 pandemic, and this increased to 94% of participants after pandemic onset. Participants showed willingness to participate in research with 64.3% willing to donate additional blood at the time of a medical draw to the BCCHB for future research purposes. While reasons for research participation varied, 91.2% stated the possibility of helping others as being important to their decision. Most participants (76.7%) were in favor of deciding with parents about their own research participation, although more than half stated they were able to make that decision on their own. Most participants were planning to receive a COVID-19 vaccine (89.6%) for reasons including people they know being vaccinated, beliefs that the vaccine is safe, effective, and resumption of social activities and travel.

Conclusion: BC adolescents viewed medical research and COVID-19 vaccination favorably, were willing to participate in research, and agreed that the COVID-19 pandemic had shown them the importance of medical research in managing disease.

6. Tools and Methods in the Process of Quality Improvement in Biobanks Developed by BBMRI.pl

Joanna Gleńska-Olender[1,2], Małgorzata Witoń[1,2], Karolina Zagórska[1,2], Michał Laskowski[1,2], Patrycja Sitek[1,2], Agnieszka Matera-Witkiewicz[1,2]

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Background: As part of the BBMRI.pl project, the Wroclaw Medical University carries out the task focused on preparation of uniform QMS standards in Polish Biobanking Network (PBN) for biological material biobanking for scientific purposes. The main scope is the implementation, development and improvement of QMS in Polish Biobanking Network units by set of supporting actions. Nowadays, biobanking units are required to have access to material and associated data on which reproducible research results can be performed. Therefore, the role and tasks of QA processes in biobanking units have evolved and continue to evolve. Biobanks are responsible for building a quality model, creating a competitive, intuitive system that meets the requirements of a wide range of stakeholders.

Methods: Based on many years of experience of QMS experts, their knowledge and continuous improvement, innovative tools and methods of cooperation with entities in the Polish Biobanking Network were developed. They are intended to help to improve quality systems to fulfill the requirements of high quality samples and associated data for scientific use.

Results: The tools supporting and improving biobanks includes QMS audit system (a three-stage audit process ending with an audit of compliance with Quality Standards for Polish Biobanks); QMS consulting (dedicated tutor for a given each Biobank); development of QMS document templates; workshops and trainings (theoretical and practical workshops and QMS Caffè). Moreover QMS team performed several Handbooks: Quality Standards for Polish Biobanks, Auditor's Manual Handbook (complementary to QSBP) and Biobank's Internal auditor - a practical guide (Internal auditors of biobanking units or Biobank employees can use it to prepare for conducting internal audits).

Conclusions: The developed tools are dedicated for biobanking employees and other stakeholders related to biobanking biological material for scientific purposes, regardless of the presented level of experience. The goal of the QMS team is to support units that biobank biological material and data in the implementation and maintenance of quality standards. Complementary activities within BBMRI.pl determine the unification and harmonization of common solutions that are convergent with the international bio-

banking guidelines. Biobanks have been oriented towards the implementation of unified solutions and the improvement of the QMS which is noticeable after 5 years of the BBMRI.pl project.

7. Value of Qualification Assays in Assessing Conditions of Processing and Storage of Clinically Relevant Biospecimens

Olga Kofanova[1], Sangita Paul[2], Mohamad Baker Berjaoui[2], Yazan Qaoud[2], Camille Bellora[1], Achilleas Pexaras[1], Ala Petersons[1,3], Ana Bolanos[2], Miran Kenk[2], Heidi Wagner[2], Neil Fleshner[2], Fay Betsou[1,3]

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Background: Clinical biomedical research utilises a wide range of biospecimens for biomarker discovery, which are sensitive to initial sample quality and various uncontrolled pre-analytical variables. The application of appropriate assays for a given sample type is needed.

At Integrated BioBank of Luxembourg (IBBL) we have established a workflow to monitor the quality of different biospecimens (www.findmyassay.com). In this study we present the results of such quality evaluation for fluid samples received from McCain GU BioBank (MGB).

Methods: Plasma, serum and urine samples, with different age of storage (<1, 4-5, and 9-10 years), from the genitourinary cohort with clinical endpoints were examined. The quality stratification thresholds established for serum and plasma samples in this study included the measurements of sCD40L, IL8, IL16, VCAM1, ICAM1, and Complement C levels. Alkaline phosphatase activity (ALP) and prostate specific antigen (PSA) ELISA methods were used to classify the urine samples. Several parameters were used as quality control (QC) metrics to assess pre- and centrifugation conditions (IL8 and IL16), long exposure to room temperature (sCD40L), storage conditions (ALP) and fitness for purpose (VCAM1, ICAM1, Complement C) of the samples. Assessment of isolated cfDNA concentration, size and quality in plasma samples was also performed.

Results: Urinary ALP was detected in all samples while PSA was detected in 70% of examined samples, correlating well with the clinically relevant outcomes. ALP and PSA average concentrations did not differ based on storage duration.

Duration of storage in vapor phase liquid nitrogen, (-180C) for up to 10 years also did not impact the measured sCD40L, IL8, IL16, VCAM1, ICAM1, Complement C concentrations of serum and plasma samples.

The measured IL8 concentrations in serum and IL16 in plasma samples were congruent with the documented pre-analytical conditions [1]. The average detected percentage of cfDNA subcomponents was approximately 72% for all plasma samples regardless of the storage time.

Conclusions: We detected no declines in the PSA and ALP in urine, sCD40L, IL8, IL16, VCAM1, ICAM1, Complement C in plasma and serum samples exposed to different storage times, proving the sample's suitability for the inflammation and cancer research. The examined fluid biospecimens, stored in MGB, were found to be of high quality and appropriate for clinical biomedical studies.

References:

[1] Kofanova O, et al. IL8 and IL16 levels indicate serum and plasma quality. Clin Chem Lab Med. 2018;56(7):1054-1062.

8. Quality Control for Sample Collection, Processing, and Biobanking in the Multi-Centre Environmental Determinant of Islet Autoimmunity (ENDIA) Study.

Dao Huynh[1], Christopher M Hope[1,7], Ying Ying Wong[1], Helena Oakey[1], Griffith Boord Perkins[1], Trung Nguyen[1], Sabrina Binkowski[2], Minh Bui[3], Dexing Huang[5], Ki Wook Kim[4,6], Katrina Ngui[5], William D Rawlinson[4,6], Timothy Sadlon[1], Simon C Barry[1,7], Jennifer J Couper[1,7], Megan AS Penno [1] and ENDIA Study Group[1]

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Background: ENDIA study has collected biospecimens from pregnancy throughout the childhood to investigate potential environmental triggers to type 1 diabetes. The outcomes of 'omics' studies are highly contingent on the quality of collected samples. The QC Committee identified key vulnerabilities in the processing pipelines and conducted pilot studies to evaluate the current practice and improve standard operating procedures (SOPs).

Methods: The four areas of concern were: (1) transit temperature from the sites of sample collection to six processing laboratories, (2) consistency of workflow within the processing laboratories, (3) staff proficiency across the processing laboratories, and (4) interstate transport from the processing laboratories to the central biobank. Sample handling standards were assessed in accordance with the Integrated Biobank of Luxemburg (IBBL) z-score system where scores <2 were classed as "satisfactory/very satisfactory".

Results: The transit temperature was assessed by placing temperature loggers inside provided insulated bags with the samples. The mean±SD temperatures ranged from minimum 2.8±0.6°C to maximum 20.0±0.5°C.

To assess the consistency of workflow, processing times for each sample type (swabs, serum, plasma, PBMC, urine, stool, and breast milk) were extracted from ENDIA registry. The processing times (hours, h) were 6.3±2.6, 6.8±2.5, 7.9±3.0, 9.5±3.5, 13.1±2.4, 21.1±2.8 and 12.7±2.4, respectively. The processing times at which 80% of ENDIA samples were stored were 5.8h for swabs, 5.7h for serum, 6.3h for plasma, 7.8h for PBMC, 22.3h for urine, 29.6h for stool and 19.5h for breast milk.

Staff proficiency was evaluated based on PBMC quality. Each site prepared a quarterly PBMC QC sample following the ENDIA SOP and shipped annually to the central biobank for assessment. Post thaw viability (>80%) and functional assessment achieved "satisfactory/very satisfactory". The central biobank participated in IBBL PBMC Isolation Scheme of Proficiency Testing Program. The ENDIA method achieved a "very satisfactory" rating across two consecutive years.

Temperature loggers were placed in dry ice and liquid nitrogen shippers to assess temperatures during interstate transports. The average temperature and CoV of all dry ice shipment was -72.7°C±5.8 and 8% respectively whilst that of liquid nitrogen shipments were -184.4°C±4.4 and 2.4%, respectively.

Conclusions: The current practices associated with sample collection, handling, processing and transport are within acceptable parameters.

9. Implementing a Biorepository Quality Management System

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Background: Biospecimen collection is fundamental to both diagnostics and research studies. Results of analyses of biological samples can be influenced by conditions to which samples have been exposed during sampling, processing, and storage. Investigators need to ensure that samples used for research are of good quality. Biorepository accreditation by the College of American Pathologists (CAP) provides confidence that stored samples have appropriate quality and thus facilitates increasing intra- and inter-institutional use of research materials from biorepositories.

Methods: We developed and implemented a Quality Management System (QMS) into biorepository operations based on several best practices documents guiding biorepository quality: International Society of Biological and Environmental Repositories *Best Practices*; National Cancer Institute Guidelines for human tissue biorepositories; ISO 900126 The International Organization for Standardization; Federal Drug Administration Good Tissue Practices; and clinical laboratory standards listed in CAP checklists. The QMS includes standard operating procedures, staff training and competency evaluation, electronic inventory management, equipment maintenance and automated remote monitoring, verification processes for data collection, specimen location and quality, and consent status. Key performance metrics (e.g., counts of processing or storage, specimen placement, or inventory entry errors and compliance with pathologist case review and tissue specimen adequacy) are reviewed on monthly basis.

Results: We observed an increase in our Biorepository activity in 2021 as compared to 2020: 291.6 clinical pathology (CP) and 132 anatomic pathology (AP) samples per month in 2021 and 176.1 CP and 90.91 AP samples per month in 2020. Error rates remain low each month, meeting established goals (⇠1 error). Pathologist case review routinely meets goals (⇢30%) and reviewed specimens meet adequacy goals (⇢50%). The Biorepository received its CAP accreditation after successfully completing a site inspection.

Conclusion: Implementation of a QMS is necessary to provide high-quality samples to investigators performing biomedical research and enabled our accreditation by CAP. Our future plans are to expand this QMS to a new Biorepository branch at our research facility (Research Institute), to integrate inventory and clinical data, and to obtain feedback on biorepository services and sample quality.

10. Princess Margaret Cancer Biobank: Driving Innovation and Providing Solutions for Oncological Research

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Background: Princess Margaret Cancer Biobank (PMCB) is a multi-site, large-scale biorepository for human biospecimens and associated clinical data. It supports translational research that improves the understanding, detection, and patient specific

treatments of oncological diseases. Affiliated with the University Health Network (UHN), Canada's largest research hospital network, comprising four academic hospitals, an education institute and six research institutes, PMCB collaborates with researchers to provide a wide variety of services to facilitate oncology research through the collection, processing, annotation, storage, and distribution of high-quality biospecimens.

Methods: PMCB enables access to specimens and accompanying clinical annotations for academic and industry collaborators by accommodating study specific harvesting, processing, and storage protocols from consented participants across multiple disease cohorts. Working closely with UHN's Laboratory Medicine Program (LMP) and their Pathology department to collect surgical information and create fixed tissue. PMCB's participants are consented at multiple time points in the outpatient clinics and in-patient units across UHN and biospecimens are procured prior to, or at the time of the patient's surgical procedure.

Results: PMCB coordinates the distribution of fresh, frozen and formalin fixed/paraffin embedded (FFPE) biospecimens, harvested by our Pathology Assistants, who identify and collect tissue from tumors, normal and adjacent tissue. PMCB currently houses over 700,000 frozen and FFPE biospecimen samples collected from more than 30 disease cohorts. Our cryo-storage facility offers both short and long-term storage of biospecimens while ensuring preservation at the highest quality for downstream analysis. PMCB also provides access to clinical pathology annotation and cutting-edge digital pathology services including digital slide scanning, Tissue Micro-Array (TMA) and Laser Capture Microdissection (LCM).

Conclusion: PMCB has supported over 100 clinical trials ranging from single-site investigator-initiated pilot studies to large-scale sponsor-initiated clinical trials, to facilitate development of novel products and biomarkers for oncology, both locally and internationally. We plan to continue leading innovative developments, such as the launch of an e-library of pathology images and advancement of Biospecimen Information Management System (BIMS), to better support next generation biobanking.

11. Distribution of Biospecimens for Oncological Research: The Trajectory of Samples from UHN Biospecimen Services to Researchers

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UHN Biospecimen Services, University Health Network, Toronto, ON, Canada, McCain GU BioBank, University Health Network, Toronto, ON, Canada

Background: UHN Biospecimen Services hosts a large repository of biofluids and tissue available for both academic and industrial oncological research. The collection and storage protocol streamlines operations and ensures that high-quality biospecimens can be utilized in qualifying scientific research through different requests.

Methods: Biospecimen requests can be submitted through multiple intake avenues. Internal sample requests are processed through a centralized online application system that notifies UHN Biospecimen Services of potential studies. External requests are issued through various biospecimen platforms or directly to the Head of Operations.

As an initial step, a feasibility assessment is completed using the criteria provided by researchers to determine if the request can be fulfilled. The biorepository is searched using clinically integrated databases to filter for eligible biospecimens. During this time, discussions concerning the budget, payment, and delivery are used to create a service agreement. In parallel, a data abstraction process may take place, if data has been requested.

Multiple departments such as the organization's Research Ethics Board and legal department work collaboratively on the approval process and assist in the development of contracts, including material and data transfer agreements. This ensures that the biospecimens are used for ethically sound and scientifically relevant research. Once contracting is executed, samples are officially retrieved from the biobank's centralized cryostorage. Prior to sample distribution, an oversight committee comprising of an unbiased group of clinicians, researchers, and biobank experts reviews the research criteria during a final phase of approval.

Results: Following the final approval, samples are packaged and distributed using practices that ensure quality and viability. A survey is sent to clients soliciting their feedback, as part of the Quality Management program. Through this process, UHN Biospecimen Services has contributed to more than 400 clinical studies and projects worldwide.

Conclusion: UHN Biospecimen Services provides a diverse array of biospecimens globally to improve cancer treatment and

patient care. Each step of the distribution process is monitored to maintain sample quality, client satisfaction and fuel personalized medicine.

12. The Age of Digitization: Inspiring Innovation Through the Evolution of our Biobanking Information Management System

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Background: The efficiency of biobanking has changed tremendously in the past 20 years, shifting from paper documentation to a Biobank Information Management System (BIMS). Since 2013, the specimen data repository became more detailed and streamlined, allowing the program to pinpoint sample availability for precise clinical conditions requested by researchers. The transition, however, came with its challenges in data translation. Nevertheless, the program is motivated to develop an automated all-in-one BIMS.

Methods: Biobanking began with physical documentation per sample collection event but was hugely restricted by specimen types, storage precision, and data accessibility. This was later resolved with the first edition BIMS; yet limitations remained. Data migration to the current BIMS unlocked simultaneous banking, the continuous addition of collection protocols (CP), and virtual storage management. This integrative platform can also selectively filter parameters, utilize patient portals, and incorporate distribution protocols. Specimen lifecycle tracking such as freeze-thaw cycles, location transfers, and freezing techniques are a few of the many standard actions that demonstrate specimen transparency in the system. More importantly, patient consent statuses are also held within the same interface to maintain good practice of the Research Ethics Board's guidelines.

Results: A major advantage of the electronic database is the ability to uphold over 50 (and counting) CPs and de-identification of specimens using auto-generated participant protocols IDs trackable by staff and study teams while protecting confidential patient data. But retrospective digitization of archive specimens revealed improvements to be desired, such as CP customization-flexibility and a more holistic approach of the system to encompass data beyond specimen information (i.e., clinical events, research results, genomic data, etc.).

Conclusion: This technological advancement evolved our biorepository's data management system. Consolidation of sample information into one system significantly reduced the footprint of our paper documentation and enhanced our program's capability to pull data faster thus, expanding our potential for collaborations with academic and industry researchers. Nonetheless, the scope of biobanking precedes more than just specimen data, development of a BIMS capable of mapping sample collections with patients' clinical history is the direction we are heading towards.

13. Turn on Your Notifications! Impact of a Standardized Notification System for the Retrieval of Biospecimens Within a Multi-Site Hospital Network in Canada

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UHN Biospecimen Services, University Health Network, Toronto ON, Canada

Background: UHN Biospecimen Services, a centralized biospecimen and information management group, is part of a multi-hospital network constituting six research institutes and four hospitals. With collections in out- and in-patient units across all sites within the network, a notification system is intricately embedded with clinical and research procedures. The system is crucial to facilitate the retrieval of biospecimens from consented participants to the Biobank processing facility in a time sensitive manner to ensure the highest quality of sample integrity.

Methods: At UHN Biospecimen Services, retrieval of biospecimens from established pick-up sites are scheduled at regular intervals during the day. Non-established pick-up sites are visited upon notification from clinical study coordinators using a standardized email template that ensures efficient communication. Biospecimens are transported in a biohazardous temperature-controlled container, while carrying the Transportation of Dangerous Goods (TDG) certification.

Notifications received from various study coordinators are cross-referenced with the total number of processed samples, as part of the Quality Management System (QMS). A final specimen information list is stored for future reference in case of inquiries or any discrepancies, where further notification is required. Altogether, these systems work to refine and optimize the sample retrieval process and provide the biorepository with valuable metrics.

Results: The interval between the pick-ups ensures adequate time for other laboratory operations, such as the processing and storage of previously collected samples. Notifications from study coordinators serve to increase the efficiency of laboratory workflow by allowing Biobank staff to retrieve the samples shortly after collection. In addition, through external Quality Control (QC) validation by an unbiased third party, the process has been proven to

yield biospecimens with good viability that are fit for genetic and biomarker research.

Conclusion: Prior to initiating a study involving biospecimen collection, many parameters need to be considered that will affect the outcome. By implementing a notification system, UHN Biospecimen Services is able to cater to various internal and external collection sites as well as support a large network of researchers. Additionally, this system helps facilitate proper sample tracking and monitoring of sample quality as well as preanalytical variables until samples are processed and stored for further downstream analysis.

14. The Standardization of Biobanking Protocols: A Look into the Significance of Standard Operating Procedures and Guidance Documents

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Background: UHN Biospecimen Services, located at the heart of Toronto's Discovery District, is a core biorepository that primarily serves oncological research through the maintenance and distribution of high-quality biospecimens. In order to ensure consistency in methodologies and maintain operational efficiency, biobanks must follow standard operating procedures (SOPs), to yield high-quality specimens that support translational and genetic research.

Methods: UHN Biospecimens Services established an SOP committee as part of the Quality Management System (QMS), to determine the requirement of SOPs and guidance documents (GD) as well as develop, review, approve and ensure the proper implementation of such across the program.

The committee is comprised of experts in laboratory operations, compliance, regulatory processes, clinical research and biospecimen management. The committee designates authors for the development of SOPs and GDs based on their expertise in the subject matter.

Drafts are evaluated by a review committee which comprises of 2-3 reviewers. The primary reviewer is knowledgeable with the workflow of the topic on which the document is being written and thus ensures the validity and accuracy of the content. The secondary reviewer is unbiased to the workflow and thus focuses on elements such as writing style, grammar, and overall clarity. Upon review, the administrator of the committee notifies personnel involved in the workflow to sign a training log, verifying that it accurately reflects current procedures. The administrator also maintains a master log which contains up-to-date electronic and paper SOPs and GDs, tracking the lifecycle of the documents.

Results: UHN Biospecimens Services currently maintains a comprehensive library of SOPs and GDs in its database. These documents are utilized to train biobank personnel to ensure consistency across various operational workflows. Documents are reviewed on an annual basis or upon any significant operational changes. Outdated copies of SOPs and GDs are archived and stored for appropriate documentation of former methodologies.

Conclusion: Maintaining an up-to-date library of SOPs and GDs can assure adherence to institutional policies and the most up-to-date procedures, consequently allowing adaptability to changing research demands. Through the optimization of its operational workflows and creation of a SOP library, UHN Biospecimen Services continues to collaborate and share knowledge with researchers and the biobank community to fuel discovery on a global platform.

15. Tackling Challenges and Overcoming Obstacles for Tissue Harvesting in an Oncology Focused Biorepository

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Statement of the Problem: In the last few decades, the collection and storage of human tissue, through biobanks, has supported the worldwide scientific community in achieving significant breakthroughs in the field of medical research that help expand our understanding of diseases, and create patient-centered treatments. Presently, we are able to harvest, store and preserve tissues, biofluids, and other subcellular components on a long-term basis. However, we still face some challenges regarding the harvesting of human tissue. At the Princess Margaret Cancer Biobank (PMCB), in Canada, tissues are usually harvested from surgical resections immediately after they are examined by our pathologist assistants. At this critical step, some of the barriers preventing us from harvesting the tissue are concerns about the size, viability, and homogeneity of the tumor itself. Other barriers to tissue harvesting arise from late surgeries, meaning that the organs are received after work hours, the type of surgical procedure that's performed, procedure cancellations and a lack of consent obtained from potential participants. Although harvesting fresh tissue from surgical resection specimens is challenging as most it is difficult to identify most tumors upon gross inspection, the most common reasons for not harvesting at PMCB are a lack of consent, an

inadequate tumor size (less than 1cm) and tissue samples being dropped off after-hours.

Solution: To address the lack of consents, PMCB implemented a system in which the Research Ethics Board (REB) approved consent form would be incorporated into the patient's consent package, ensuring that the operating physician would present the PMCB consent to the patient, thus maximizing its reach. Furthermore, the non-consented patients will be approached by a member of the PMCB team to determine whether the program had been adequately explained to the patient. To address the after-hours drop off of tissue, PMCB is exploring having personnel available later in the day to be able to process and harvest these tissues.

Conclusion: While there are numerous obstacles preventing the harvesting of tissues for biobank storage, PMCB is taking steps to remove some of these barriers to ensure that we build a comprehensive and high-quality tissue and biospecimen bank, continue to lead innovation and better support global oncology research.

16. Challenges in Engaging Ethnically Diverse Participants in a Genito-Urinary Biobank

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Statement of problem: Biobanking is an essential factor in biomarker and genetic research globally. In order to advance personalized medicine, it is critical that biobanks provide high quality biospecimens that can represent diverse population and ethnic groups.

The McCain GU BioBank (MGB), a large genito-urinary focused biobank in Toronto, Canada, has evaluated the representation of diverse populations and their participation in the biobank. Through this analysis, it was determined that the majority 77% of consented participants in this cohort identify as White or Caucasian, 4.5% Latino or Hispanic, 3.76% as South Asian,3.01% as Middle Eastern, 2.26% as East Asian, and 1.5% each for Ashkenazi Jewish origin and Afro-Caribbean. Other ethnic groups are represented by <1% of the consented participants.

Through this analysis, it is evident that certain populations remain underrepresented. Factors such as language barriers, religious and cultural beliefs, socioeconomic factors, and education can hinder the recruitment, enrollment, and retention of underrepresented populations in Biobanks

Proposed solutions: It is important to build a relationship with diverse ethnic groups, and increase their knowledge and trust on importance of research. Implementing communication strategies to appeal to those individuals whose first language is not English by partnering with language and translational services and/or the translation of written consents to multiple languages can be beneficial. In addition, documenting and analysing the reasons for consent objection, understanding different religious views on the sharing of biospecimens, genetic research, as well as explaining concepts such as sample commercialization, may have a positive effect on the interest and trust of minority populations in research and may result in higher levels of recruitment and enrollment in biobanks.

Conclusion: The importance of the involvement and contribution of diverse race and ethnic groups for biospecimen donation to biobanks will add more value to the biobanking samples and will provide high quality research, integrity and equity for drug response and overall survival in diverse population patients, in the future healthcare system. This is particularly important in a country like Canada, where 75% of the population growth derives from immigration.

17. Implementing Strategies to Enhance Biobank Visibility and Promote Global Outreach

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Background: The growing needs of biomedical research, and the strong focus on implementing personalized medicine have been the primary drivers of the biobanking industry in the last few years. As such it is crucial to change public perception for long term sustainability of Biobanks. Unlike other research areas, where patient groups take an active role in defining needs and priorities in funding, it seems the public underestimates the relevance that biobanks have in clinical practice and biomedical research. At UHN Biospecimen Services we implemented diverse tools to engage patients as partners in the biobanking process.

Methods: UHN Biospecimen Services has developed a strategic plan to increase global visibility, promote sample utilization and drive collaborations within the research community.

Results: UHN Biospecimen Services developed a comprehensive and easy to navigate website that provides a detailed summary of services and biospecimen inventory available for researchers. Additionally, the website incorporates interactive and educational resources that are available for all visitors and biobank participants. By creating bi-weekly polls and sharing updates via the diverse social media platforms, UHN Biospecimen Services

engages directly with participants, researchers and the international biobank community.

Inclusion in multiple global biobank directories and specimen platforms has allowed the program to expand visibility, promote global outreach and connect with a broader audience of potential collaborators that otherwise would not be possible.

In addition, UHN Biospecimen Services has been hosting and participating in major international conferences, allowing the program to connect with a global audience and expand its collaborative network. As part of this initiative, UHN Biospecimen Services has also hosted webinars to showcase the biobanking services and inventory, but to also educate the research community on how to access services, as well as the steps involved in the workflow of a biobank prior to any distribution.

Conclusion: By increasing global outreach and changing the public's perception, while maintaining donor confidentiality, we can engage patients as partners in the biobanking process. Patient engagement is crucial to allow biobanks, as custodians of biospecimens and data from participating donors, to increase their visibility, educate the public, and build collaborative networks in order to advance translational research.

18. Fuelling Research through a Health Care Crisis: Establishing a Novel COVID-19 Biobank during a Global Pandemic

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Background: With the onset of the COVID-19 pandemic, the need arose for standardized sample processing and sample storage for COVID-19 research. As a response to the increasing demand for high-quality COVID-19 samples for research, UHN Biospecimen Services established the UHN COVID-19 Biobank in May 2020, prior to the availability of vaccines. In order to reduce the risk of exposure and spread of COVID-19, implementation of new biobanking safety protocols as well as adaptation of specialized workflow and emergency response procedures was crucial.

Methods: A COVID-19 task force was established to adhere to increased safety regulations and emergency response procedures, train dedicated personnel, and introduce automation to operational workflow.

Results: Increased safety regulations during the transportation, processing, and distribution of biospecimens collected from consented COVID-19 patients were implemented. The regulations include the use of level 3 masks, double gloves, face shields/goggles, and biohazardous gowns as well as using the UHN online PPE training course for all staff working on-site to ensure proper use of PPE. Biospecimens and the workspace were sanitized prior to and after biospecimen handling as well and all sample processing was completed in a biosafety cabinet. Furthermore, a dedicated, isolated lab space, separate from the non-COVID biobank lab, was utilized to reduce risk of transmission. Moreover, redeployed staff across UHN were trained to process COVID-19 specimens at the start of the COVID-19 pandemic. All on-site personnel undergo mandatory COVID-19 screening prior to entering the buildings and adhere to physical distancing protocols.

Recently, an automated Liquid Handler has been incorporated into the operational workflow to limit exposure to staff, lower human resource cost, and increase sample throughput to support the increasing number of COVID-19 related studies.

Conclusion: By implementing the necessary safety protocols, the COVID-19 biobank at UHN Biospecimen Services has been able to remain operational throughout the pandemic while providing high-quality specimens for various research studies. As of July 2021, the UHN COVID-19 biobank has banked over 68,000 specimens and supported multiple local and global COVID-19 research studies and clinical trials. The UHN COVID-19 biobank will continue to grow and improve to match the dynamic nature of COVID-19 research.

19. Linking Blood Plasma Protein Stabilities to ΔS-Cys-Albumin—a Marker of Exposure to Thawed Conditions

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Background: Biomolecular integrity can be compromised when specimens are exposed to improper storage or handling conditions. Measurement of compromised analytes can then lead directly to the generation of incorrect and potentially misleading results—without any indication that this has occurred. We recently introduced a marker of blood plasma/serum exposure to thawed conditions called ΔS-Cys-Albumin that quantitatively tracks exposure of plasma/serum to temperatures greater than their freezing point of -30 °C. We have now quantitatively linked ΔS-Cys-Albumin measurements to the stability of 22 plasma proteins of clinical interest measured by multiplexed ELISA.

Methods: ΔS-Cys-Albumin was measured at nine different time

points per exposure temperature in K2EDTA plasma samples from 24 separate donors in aliquots kept separately at 23°C, 4°C, and -20°C using dilute-and-shoot LC/MS as previously reported. Twenty two clinically relevant proteins were then measured at four different time points per sample and temperature using multiplexed ELISA on the Luminex platform. Protein stability was assessed by repeated measures ANOVA followed by Fisher's LSD posthoc test with correction for multiple comparisons. Coordinated shifts in stability between ΔS-Cys-Albumin and several of the 22 clinical proteins across all temperatures were documented by Pearson correlation.

Results: As expected,ΔS-Cys-Albumin dropped from a mean value of 19% to under 5% within 96 hrs at 23°C, 28 days at 4°C, and 65 days at -20°C. On average, 5 of the 22 proteins significantly increased or decreased in apparent concentration at each exposure temperature ($p < 7.5 \times 10^{-4}$ and relative concentration shift of > 10%). Considering the protein stability data from all temperatures together, a linear inverse relationship was found between the percentage of proteins destabilized and ΔS-Cys-Albumin ($r = 0.85$; $p = 0.002$).

Conclusions: ΔS-Cys-Albumin is useful for forensically tracking approximate times of exposure of archived plasma/serum samples to thawed conditions (> -30°C). Moreover, it appears to be useful for estimating the fraction of proteins that have been destabilized by exposure to thawed conditions, regardless of what the exposure temperature(s) may have been.

20. The ISBER/ASCP BOC Qualification in Biorepository Science (QBRS) Examination is Available for Application Online

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Background: Well-trained repository staff are essential for assuring high-quality research specimens. ISBER, the leading international biobanking society, and ASCP BOC (American Society for Clinical Pathology Board of Certification), an organization providing excellence in global medical laboratory professional certification, have developed a shared online qualification examination through which individuals may earn a biorepository qualification credential, the Qualification in Biorepository Science (QBRS).

Methods: QBRS Workgroup (WG) was established as a standing committee of the ASCP BOC. The WG's task was to develop, review and update the biorepository qualification examination itself, perform job task analyses, develop the examination content guidelines, eligibility requirements, and candidate professional experience documentation forms needed for the QBRS credential. All QBRS credentials awarded will be time-limited and be re-validated every three years with documentation of continuing education or other educational activities as defined by ASCP BOC. ISBER and ASCP BOC responsibilities have been established, and annual review will be performed.

Results: A Memorandum of Understanding was developed and signed. The QBRS document development was completed and the QBRS credential program application process was available online for applicants in January 2020. As of June 2021, 26 applicants have taken and passed the exam.

Conclusion: ISBER has joined forces with ASCP BOC to develop a QBRS credential program. ASCP BOC is an experienced, well-recognized organization for certifying professional competency among individuals worldwide, while ISBER Workgroup participants provide content knowledge and biobanking expertise. This agreement has allowed the development of a global QBRS credential program, requirements of which are essential for the future of sustainable quality biobanking. Further details including requirements for qualification and an FAQ document are available on the ISBER and ASCP BOC websites and will be elaborated on presentation.

21. Update of ISBER BAT Based on *ISBER Best Practices 4th* and *Addendum on LN_2 Based Cryogenic Storage*

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Background: The International Society for Biological and Environmental Repositories (ISBER) Biobank Assessment Tool (BAT) is a questionnaire aimed to help biobanks to evaluate how well they comply to the *ISBER Best Practices*. The BAT was deployed for end users in 2011, since then ISBER has published the 4th edition of the *Best Practices* and the Addendum on Liquid Nitrogen (LN2)-based cryogenic storage (Addendum 1). In addition, a new international standard-ISO 20387:2018 BiotechnologyBiobanking-General requirements for biobanking was published in 2018. In order to stay up to date the BAT needed an update.

Methods: The BAT was updated in accordance to the ISBER *Best Practices*, 4th edition and the Addendum 1 by removing ques-

tions that no longer corresponded to neither the latest edition of the *Best Practices* nor the *Addendum 1*, and replace these questions with new ones that did correspond. The questions added to the BAT cover many areas of biobanking, such as- governance, quality assurance, cold chain validation, and the different aspects of LN2-based cryogenic storage of biological and environmental specimens for research and clinical use. In addition to the update of questions, a new data model was developed to ease interpretation and comparison of the data over time, while ensuring security, reliability, and usability of the data.

Results: The BAT questionnaire provides the user with an overall score of compliance to the ISBER *Best Practices*. Each question has a risk-balanced assessment score attached to them. The score is based on an algorithm that attributes a different grade to each answer, depending on the severity of the risk associated with the subject of the question, the frequency of occurrence of the risk, and the ease of detection of the situation. After completion of the BAT, personalized results, including a ''risk-balanced assessment score'' will help evaluate how well the repository's current practices conform to the ISBER BP and the Addendum 1. In addition, where applicable, the results will also include references to the ISO20387.

Conclusions: The updated BAT will help biobanks to assess their compliance to the ISBER *Best Practices*, the Addendum 1, and on a higher level also the ISO20387 biobanking standard. The BAT can be used repeatedly, which allows follow up every year, giving it a natural place in any QMS where implementation and follow-up of quantitative indicators are required.

22. Evaluation of Human Tissue Quality After Rapid Nitrogen Vapor Freezing

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Background: The quality of frozen fresh tissue (FT) depends on the cryogenic temperature used, rapid freezing and the cold chain. Freezing with liquid nitrogen (LN_2) is considered a gold-standard technique. However, LN_2 requires a safe environment and skilled personnel, rarely available in clinical areas and the operating room. This could discourage users and drastically reduce access to FT. In order to overcome this problem, we have implemented nitrogen vapor phase freezing using Dry shipper. This device is dedicated to the transport of already frozen samples. The quality of frozen FT processed with this method has been found satisfactory (94.64%) by our users for diagnosis and translational research (Study exposed ISBER virtual meeting 2020). In this work, we share our experience in presenting both the scheme for checking the reliability of the cryogenic equipment and the tissues quality control used.

Methods: The fresh FT (tumor and non tumor) were collected between 2016 -2021 and archived (-80°C) at the Tumorothèque de Picardie. Rapid freezing was processed in nitrogen vapor using Dry Shipper (CRYO DIFFUSION, BS2002). This container is equipped inside with a porous material able to absorb LN_2 and releases it in nitrogen vapor form. For Each container performance (static loss, L/day) was verified. The Dry shippers were prepared so that temperature near the fresh tissue was -190°C. The volume in the inner container for freezing is 0.12 L. Tissue quality was assessed in blinded manner by scoring immunohistochemistry (Ki67, CD31 and Actin) and the morphology (Hematoxylin Phloxine Saffron) of the frozen tissues (n = 16) vs Formalin Fixed Paraffin Embedded tissue (FFPE) (n = 6) ranging from poor (1) to excellent (4). DNA (n=16) Quality tests (integrity, amplifiability) was performed by qPCR according to the recommendations of BIOMED2 (Leukemia, 2003).

Results: The static loss for each Dry shippers used (n=3) was 0.07 L/d which corresponds to the specifications of the supplier. Majority of tissue samples were related as excellent. Frozen FT were scored successively: HPS, CD31 and Actin 4 for 87% and 3 for 13% of the cases, Ki 67 was scored 4 in 69% and 3 in 31% of the cases. FFPE and DNA quality control were scored 4 in 100% of the cases.

Conclusions: The quality of the frozen fresh tissue was very satisfactory. Rapid freezing in nitrogen vapor and quality assessment of samples have been realized with tools widely used in Diagnostic Pathology routine.

23. Perspectives of Biobank Managers in The Arab Region Regarding Biobanking Ethical Issues: A Qualitative Study

Ahmed Samir Abdelhafiz[1], Mamoun Ahram[2], Maha Emad Ibrahim[3], Alya Elgamri[4], Samar Abd ElHafeez[5], Nada Taha Mostafa[6], Zeinab Mohammed[7], Fatma Abdelgawad[8], Eman Elsebaie[9], Ehsan Gamel[10], Manal Shahouri[11], Latifa Adarmouch[12], Karima El Rhazi[13], Henry Silverman[14]

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Background: Although several biobanks have been established in the Arab world, it is still a relatively new concept. Arab Biobankers are developing experience and transferring this experience to each other within the community. The aim of this study is to ascertain the views of Arab biobank managers regarding several significant ethical issues that are relevant to the operations of biobanks.

Methods: Qualitative study consisting of semi-structured interviews conducted with biobank directors. Interviews were conducted in English and the transcripts were coded and underwent thematic analysis.

Results: Nine interviews were conducted with biobank managers (Six from Egypt, one from Jordan, one from Qatar and one from Sudan). Eleven themes were identified. Five biobank managers said that the main challenges they faced with establishment were related to the novelty of the concept, lack of experience, limited fund, and resistance of several stakeholders (e.g., physician colleagues). While six biobanks were funded from local funding agencies, others collaborated with foreign partners to secure funding. Six biobank managers said that they do not have a current business plan. Although three biobank managers described the process of sample access, which included review of an ethics board and other committees, only two of them reported that they started giving access to samples and health data. Biobank managers stated that only a few activities related to community engagement were carried out by their biobanks. Seven biobanks used a broad consent to obtain samples for storage and future use preferred it over tiered consent. Most managers refused collaboration with pharmaceutical companies at the current moment due to community concerns. Five biobank managers said that they do not have clear policy for return of research results to participants.

Conclusions: Although biobanking is growing in the Arab region, biobanks still face common problems. Funding, stakeholders' engagement, absence of efficient governance systems, and robust community engagement activities represented the main common challenges in Arab biobanks. Consensus over these issues through discussions with key stakeholders in the biobanking and research communities as well as the community is needed to follow best practices in biobanking and to enhance trust among all stakeholders.

24. Characterization of Frozen Tissues from the PROCURE Prostate Cancer Biobank

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Background: Future OMIC studies on prostate cancer will hopefully lead to better understanding and treatments of this cancer. Their success however relies on the availability of biological specimens and clinical data of high quality. A team of investigators in four University Hospital Centres of the Québec province joined in 2007 to build the PROCURE Prostate Cancer Biobank. This biobank includes fixed and fresh frozen prostate tissues, blood, urine and updated clinical follow-up data from 2,007 men who underwent radical prostatectomy. In this investigation, we characterized the tumour content of frozen prostate tissues in the biobank.

Methods: Freshly resected prostates were rapidly processed in order to freeze in OCT at least four tissue samples, two presumed cancerous and two presumed benign. H&E-stained sections of frozen tissues were scanned and analyzed by pathologists. Tumour foci were identified, mapped, measured and graded. Nucleic acids and proteins were extracted to ascertain quality by agarose gels, RIN and RT-qPCR, and SDS-PAGE.

Results: A total of 7,808 frozen tissue samples from 1,835 participants (91% of the cohort) were analyzed. Tissue preservation and

tumour architecture were excellent with less than 1% of non-interpretable slides. Based on sample dimensions, it is estimated that ~ 5% of the prostate was banked as frozen tissues. Among the 7,808 tissue samples, 3,496 (45%) contained tumour while 4,265 (55%) were benign. Hence, for 1,583 participants (86%), at least one tissue sample contained tumour. The surface occupied by the largest tumour increased with Gleason grade group (GG). The surface of the tumour ranged from < 5% to 25% in 49% of GG1 cases and from 55 to 100% in 73% of the GG5 cases. Grade concordance in frozen tumours and overall cancer in pathology reports were observed for 64%, 66% and 71% of GG1, GG2 and GG5 cases, respectively, and for 42% and 40% of GG3 and GG4 cases, respectively. DNA, RNA and proteins extracted from frozen tissues were proven of high quality for molecular analyses.

Conclusions: Tumours were found in frozen tissue samples of a majority of participants and their size increased with GG. The well-characterized frozen tissues samples and the database with long follow-up information of the PROCURE biobank represent an excellent resource for prostate cancer research. This precious material is available for research to better understand the disease and improve its management.

25. Investigators' Perspectives Regarding Ethical Issues of Biobank Research in the Arab Region

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Background: Genomic biobanking research is rapidly emerging in the Arab region. However, the establishment of biobanks faces several legal, ethical, and cultural issues. There is a paucity of studies regarding the perceptions and attitudes of Arab investigators regarding these issues. The aim of this study was to explore perceptions and attitudes of investigators regarding biobanking research.

Methods: A quantitative survey was used for this study. We recruited investigators involved in biological sample research from universities and research institutes in Egypt, Sudan, Morocco, and Jordan. All participants completed a self-administered online questionnaire. In addition to demographic data, the questionnaire contained perceptions and attitudes about protection of human subjects in genomic research, ethical review process, acceptance of broad consent right to sample withdrawal, return of results to sample donors, data security, data sharing, and community engagement. Correlations and multiple logistic regression were used to identify association of independent variables and positive attitudes.

Results: We recruited 383 investigators. The majority of investigators (66.8%) agreed that potential donors have the right to withdraw their specimens after donation. A similar percentage (65.8%) had concerns that improper use of stored samples could cause harms (i.e., stigma) to communities from which samples were collected. Overall, respondents had positive attitudes about importance of data security (91.4%), reconsent of participants (81.7%), data sharing with national and international partners (83.2%), and to a lesser extent community engagement (64.2%). Positive attitudes correlated with working in academic institutions, serving in RECs, and receiving research ethics training. Logistic regression analysis revealed that potential predictors of positive attitudes included working in an academic institution and longer duration of being involved in biobank research.

Conclusions: Investigators involved in biological sample research in the Arab region have positive attitudes about subject protection, data sharing, reconsent and return of results. However, they have concerns about data protection and the social consequences of breaches in measures of confidentiality.

26. Perceptions and Attitudes of the Arab Public towards Biobank Research. A Quantitative Study.

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Background: Population-based biobanks have proven valuable in the identification of novel and rare genetic variants that are associated with diseases. While High-Income Countries (HICs) have established biobanks with clear governance structures informed by public views of biobanks, the situation, however, might be different in Arab countries where public-based studies are deficient.

Methods: Using a validated questionnaire, we assessed public perceptions and attitudes towards biobanks in Egypt, Jordan, Morocco, and Sudan. The questionnaire comprised of five sections: perceptions about biobanks; aspects important to participation in biobank research; preferences for the type of informed consent; attitudes toward biobanking; and willingness to participate in biobank research. We used descriptive statistics and bivariate analysis of the data.

Results: We collected 967 responses. Less than one-third of respondents knew of the term "biobank". A considerable proportion (44.6%) expressed willingness to participate in genetic studies. Regarding informed consent, a majority of respondents (65%) preferred to be re-contacted every time their biospecimens would be used in any future research, whereas less than half opted for a broad consent that is either anonymized (44.6%) or coded (48.4%). Approximately, three-quarters of respondents indicated their refusal to participate in biobanking research.

Conclusions: These results suggest the need to initiate strong campaigns to increase awareness and trust about biobanks and their importance in public health.

27. Perspectives of Research Ethics Committees Towards Research involving Human Biological Specimens and Health Data for Biobanking and Genetic Research

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Background: Understanding the genetic basis of disease among different populations is central to improving healthcare. Despite initial efforts to establish biobanks in developing countries, challenges remain including logistical and infrastructure problems, and training needs. This study aimed to investigate the perspectives of research ethics committee (REC) members regarding the collection, storage, and future use of the biospecimens and health data.

Methods: We administered a survey to REC members in four countries; Egypt, Sudan, Jordan, and Morocco. The survey covered opinions regarding elements of informed consent, attitudes about information provided in the consent form, and opinions about the information that should be provided in a material transfer agreement form.

Results: We collected responses from 83 participants. The majority of surveyed REC members agreed on the importance of involving information about; confidentiality of data (92.7%), withdrawal of consent in future research (95.1%), prior approval from an ethics committee in any future research (93.8%), the possibil-

ity of re-contact if data shared with other institutions from inside (78.2%) or outside the country (80.7), sharing with commercial companies (72.1%), ownership rights (85.5%), and informing participants about their research results (77%). Most of the REC members (66.2%) agreed that broad consent is acceptable only with de-identified and coded samples without sharing codes. Further, the majority of members believed it is ethically to obtain re-consent from patients to do research on their samples that have been stored for medical care (83%) and to investigate a different, but related illness of the original study (72.2%). Regarding information provided in the material transfer agreement, most members agreed that information should be provided about any identifiers (55%), the plans for ensuring the confidentiality of any identifying information (65%), and how benefits will be shared fairly among all countries (81.9%).

Conclusion: Most of the surveyed REC members showed positive opinions on the importance of detailed informed consent elements and held positive attitudes towards the importance of the abundance of information and details on the use, storage, and sharing of data.

Keywords: Biobank; Biospecimens; Broad consent; Data sharing; Research ethics committee

28. The Ethical, Legal and Social Implications (ELSI) of a Fertility Biobank During the COVID-19 Pandemic

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Background: The CReATe Biobank, established in 2015 as an adjunct to the CReATe Fertility Centre in Toronto, is Canada's first biobank to focus entirely on human reproductive biology-related samples. It is among a handful of certified biobanks dedicated to fertility treatment-related specimens in the world. What makes the CReATe Biobank stand out among others is the unique collection of data including preimplantation genetic screening results and pregnancy outcomes using a comprehensive consenting process. Here, we outline the ELSI of the CReATe Biobank during the COVID-19 pandemic.

Methods: To address the ethical and legal issues and comply with the Canadian Assisted Human Reproduction Act (AHR act), we upgraded our one-size-fits-all consent form in early 2020. We developed six forms to consent three different populations including intended parents, donors and gestational carriers. The implementation of the new and very complex process coincided with COVID, where all the communications with patients became virtual through emails and phone calls.

Results: We reached out to 1383 patients in the past year and observed a 56% drop in patient engagement during the pandemic. Our main challenge was unanswered phone calls and emails that had to be followed up in the clinic on the day of procedures. On the other hand, as per the AHR act, both partners' consents are required for embryo research. However, due to COVID related restrictions, follow ups were challenging and our TBD (to be determined) cases increased by 6-fold. The gap in Ontario provincial law and ethics board principles caused legal issues handling consents from individuals in polyamorous relationship where our forms only identified two persons as intended legal parents. As much as we wanted to build up an inclusive biobank, we also struggled in engaging non-Caucasian patients in the biobank. Finally, reaching out to anonymous sperm donors was a huge challenge and we never managed to recruit patients in that category.

Conclusion: The ELSI in fertility biobanks carries extra weight due to moral status with respect to gametes and embryos. The CReATe Biobank has developed a comprehensive and ethical process to enroll patients in the biobank program. Although the COVID-19 pandemic has imposed various challenges, we have been able to continue to serve the fertility research community. We have plans to further educate our patients to build up an inclusive biobank in the field of reproductive biology. We're also considering to amend our consent forms to fill gaps in the law.

29. Enabling Space Biology Knowledge Discovery Through Biospecimen Sharing: The NASA Biological Institutional Scientific Collection

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NASA and international partners have conducted experiments in space to understand the biological impacts and address hazards to health. The resulting basic and applied science is imperative to enabling humanity to venture back to the Moon and then to Mars and beyond. Sending organisms into space is a costly endeavor. All biospecimens not required by spaceflight-relevant Principal Investigators are harvested, preserved, and archived in the NASA Biological Institutional Scientific Collection (NBISC) to maximize the scientific return. The NASA Biological and Physical Sciences (BPS) Division 'Open Science' endeavor includes NASA Genelab, the Space Biology Program's Biospecimen Sharing Pro-

gram, Physical Sciences Informatics, the Ames Life Sciences Data Archive, and NBISC to integrate extensive data and biospecimen resources from spaceflight and/or ground-based analog experiments. NBISC biospecimens are collected and preserved according to well-established standard operating procedures to maintain scientific quality and are available on-request by the international scientific community. NBISC currently stores over 32,000 biospecimens from Shuttle, International Space Station, and ground-based space analog investigations. Tissue sharing has resulted in at least 33 publications since 2011 and 48 requests since 2016. Many requests for NBISC biospecimen come from first-time investigators who subsequently submit grants as the port-of-entry into the field of space biology. Some NBISC biospecimens have been awarded to NASA Genelab, who then generate various 'Open Science' -omics data sets on their platform for bioinformatics. Other NBISC biospecimen awards have led to multiple studies such as fecal microbiome analysis, DNA damage analysis using single-cell DNA sequencing, enzymatic-pathway identification involved in spaceflight muscle atrophy, and characterization of ocular morphological changes. Of note, NBISC has expanded to include a new Space Microbial Culture Collection (SMCC) for the collection, identification, documentation, long-term preservation, and distribution of space-related microbial isolates.

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