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The abstracts that follow demonstrate the broad range of timely issues addressed in the contributed oral and poster presentations at ISBER's 2019 Annual Meeting & Exhibits.

INTERNATIONAL SOCIETY FOR BIOLOGICAL AND ENVIRONMENTAL REPOSITORIES

ORAL ABSTRACTS

O-01 Establishing Repository (Bio-Bank) of Biological Samples for Testing Biological Markers as Predictors of Important Maternal and Fetal Outcomes in a Developing Country Setting

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Background: Several genetic & other biomarkers have been identified that detect women at risk of adverse birth outcomes. However most studies have been carried out in developed countries and very few population based bio-repositories in developing country setting. With BMGF funding & WHO coordination, we aim to establish a repository of biological samples to facilitate future discoveries on maternal, fetal & neonatal health. The main objective is to identify biological markers to predict & facilitate future discoveries for prevention & improvement in care of pre-eclampsia, preterm births, IUGR & stillbirths.

Methodology: From 11 Aug 2014 to 18 Nov 2018 we enrolled 2500 ultrasound confirmed women at <20 weeks of pregnancy in a peri-urban fishing community in Karachi, Pakistan. Using standardized and harmonized methods maternal blood (15 ml) & urine (100 ml) are collected at enrolment, 24–28 or 32–36 weeks gestation, 42–60 days postnatal, placenta & cord blood at delivery. Other samples include paternal saliva, newborn saliva & stool, infant blood & stool. All samples are aliquoted and stored in −80 freezers with real time data entry and sample tracking. Detailed phenotypic & clinical data regarding maternal demographics, socioeconomic, pregnancy history, morbidity, depression & child health is collected at various visits.

Results: We have enrolled 2500 women from 11Aug 2014 to 18 Nov 2018. 80 women are awaiting outcome. Second antenatal blood & urine samples have been collected for 88% of the women. We collected placenta & cord blood in 806 pregnancy outcomes. The rates of completion for other specimens have also been high with maternal feces collected in 86% of the women post outcome, postnatal blood & urine collected in 89% of women, paternal saliva in 89% and newborn stool from 84%. Newborn saliva was collected in cases where cord blood could not be collected (1264). We recently started doing heel pricks and have done it in 821 newborns so far. Infant blood has been collected in 450 & stool samples in 580 infants. We have also shared our specimens with our international collaborators in the west for various transcriptomics, metabolomics and proteomics analysis to identify predictors for predict preterm births.

Conclusion: This developing country bio bank with detailed phenotypic profiling provides a great opportunity to answer important questions related to adverse maternal and neonatal outcomes within the framework of local context and regional applicability.

O-02 A Study of Integrated Biobanking Systems

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The field of biorepository has evolved from a simple collection and storage of frozen biological samples to the integrated biobanking system that accepts, records, classifies, processes, cryopreserves, stores, and distributes biospecimens and their associated data, in a systematic way, for scientific, medical, pharmaceutical, biological, or agricultural research and applications. Coupled with advances in biobanking, people are developing ''virtual biobanks'' based on specialized computer software, database, internet, and search engine, helping researchers locate biospecimens for testing and data mining from different biobanks all over the world. However, biobanking is still facing, at least, the following problems and challenges: (1) improving and standardizing the biospecimen access and regulatory policies (including quality control, legal and ethical issues, donor consent, privacy, safety, security, risk management, etc., (2) enhancing biobanking sustainability and economics, (3) increasing public awareness and knowledge on biobanking and its applications, gaining the support of general population and governments, (4) improving global communication and collaboration, (5) promoting research in biospecimen science and cryobiology to ensure the quality and usability of biospecimens, and (6) developing optimal technologies to cryopreserve cells, tissues and organs which are currently unable to preserve. The central theme of this presentation focuses on (A) a comparative analysis of various biobanking systems & models in the world to address the above challenges, and (B) a study of the China National GeneBank (CNGB, Shenzhen, China), the first national biobank established in 2016. The CNGB consists of five interactive units, i.e. ''Three Banks and Two Platforms'', including a biorepository (''Wet Bank''), a bioinformatics/omics data center (''Dry Bank''), a ''Living Bank'' for long-term cryopreservation of living biological materials, a ''Digitalization Platform'' for gene research deciphering the profound life science, and a ''Gene Synthesis & Editing Platform''. The CNGB demonstrates a unique biobanking system model aiming to integrate collecting, preserving, investigating, disseminating, and exploiting bio-resources, as well as to build a network fostering global communication and collaboration on biodiversity conservation and bio-resources utilization for the human health, environmental sustainability, and the advancement of science and technology.

O-03 Challenges When Moving Old Samples to New Systems

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In 1992 a rancher started a cryopreservation project to introduce specific genetic phenotypes into his cattle herd. The traits included a mutation in the myostatin (MSTN) gene that resulted in a desirable change in the phenotype. The MSTN mutation consists of a two base pair deletion in the third exon of MSTN; which causes a premature stop codon at amino acid 313. Cattle with only one copy of the MSTN mutation, have about 14% more muscle mass than other cattle; because they are double muscled. By increasing muscle mass, more beef can be harvested from the herd. Embryos and semen of a specific Hillcrest Aaron Piedmontese bull were preserved in liquid nitrogen for 27 years; by manually filling and measuring liquid nitrogen levels. We find that the viability of the semen currently has 70% of the cells still alive. This cattle rancher has given our team the responsibility of moving the old samples from old technology and methods, to new technology and methods. With this task our team faces many challenges. We must ensure the samples are not destroyed in the process of moving to a new system. Quality control checks must be in place and we avoid freeze thaw where possible. We have been given limited funding and resources. Each task must be completed exactly right the first time; to avoid damage or contamination of the samples and wasted resources. In conclusion, we are finding that the task at hand is very doable even with limited resources. So far, the project has been a success; we are looking at barcoding racks instead of individual samples to avoid damage to the cells. As our team moves forward, we are trying different ways to ensure that this research project meets all possible best practices from the ISBER Best Practices.

O-04 Mind Over Matter: Confronting Challenges in Post-Mortem Brain Biobanking for Glioblastoma Multiforme

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Brain cancer is the sixth leading type of cancer in Australia and appears to be increasing. The Mark Hughes Foundation (MHF) Brain Bank is facilitated by Hunter Cancer Biobank (HCB) and located at Hunter Medical Research Institute, Australia. The first post-mortem Brain Cancer biobank in the country, we are located within a well-established and resourced health network, however, the boundaries of service provided by the biobank extend well into the surrounding regional and rural areas. This presents a number of challenges both logistically and in terms of resources. By nature, brain biobanking is challenging, with conflicting international guidelines for best practice and many unanswered questions relating to scientific, psychosocial and operational practices. This is further complicated by the cancer specific nature of the program, as the few guidelines that do exist have been developed for mental health biobanking and do not account for the unique requirements of cancer brain banking – namely prologued agonal state, rising systemic pH and increased rates of necrosis in brain tissue.

Our best practice model has been developed to account for these concerns, while also addressing the challenges of operating within regional communities or resource poor settings. Establishing a partnership with NSW Health Pathology has been key to our success, along with the invaluable input from the local Brain Care Coordinators. At present we have a maximum post mortem delay of 12 hours between death and freezing of tissue, yet have facilitated the majority of recent donations within a 4 hour period. This is reduced from the 72 hour period accepted from many brain banks in the UK specialising in mental health brain banking.

Having successfully facilitated a recent donation from a participant located in a remote area, we have also developed solutions to the challenge of operating a program that requires 24 hour communication and services, within a community that does not have 24 hour health facilities. Obstacles overcome include long distance patient transport, lack of palliative care staff, death in the home and the absence of local general practitioners with limited rural outreach services.

With the support of the MHF and the dedication of HCB staff we have established a brain bank that provides an invaluable service to the community and ensures that local researchers have access to the tissues samples needed to facilitate much needed translational research in brain cancer.

O-05 National Liver Disease Biobank as an Important Tool for Biomarker Discovery

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Background: Background Biomarker or Biological marker refers to a medical indicator or sign, which are associated with particular medical conditions such as cancer. These indicators may be in form of protein, genetic alteration, metabolites that found in blood, tissue or other body fluids. Biomarker lends a hand in advancement of personalized medicine and patients care by disease diagnosis, prognosis and prediction of therapy. Discovery of biomarkers has string of phases that is biomarker identification, verification and clinical validation, are possible only on the availability of high quality of biosamples.

National Liver Disease Biobank (NLDB) is an entity, established by Department of Biotechnology, Government of India and Institute of Liver and Biliary Sciences to accelerate research and personalized treatment. Biobank collect, process, store and distribute biospecimens and associated data for use in future research. We have been involving in many research projects which results would be highly useful in patient care and cancer research, biomarker discovery and translational research.

Methods: The Biobank has collaboration with different hospitals and research institutes from all over India. It is following Decentralized collection, centralized storage and informatics. All centres are collecting biosamples as per SOPs of National Liver Disease Biobank.

Results: The Biobank collects, process and store a wide array of biospecimens (tumor tissue, adjacent normal tissue, blood, plasma, serum, buffycoat) using validated SOPs. Biospecimens are processed and banked within 30 minutes. We have involved in more than ten projects for research and biomarker discovery. It has collected 10719 biosamples and has involved in many research projects.

Conclusions: It is a first and biggest Liver Biobank in India, have network from different hospitals and research institutes across country. It has a direct impact on biomarker research. We have been involving in many research projects which results would be highly useful in patient care and cancer research,

biomarker discovery and translational research. We would like to acknowledge DBT for providing funds for the project.

O-06 Policies to Increase Utilization in Clinical Biobanks

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For clinicians, they should not only do the clinical work, but also be engaged in basic scientific research. They simulate the patient's disease through a large number of cell experiments and animal models. Every day large amount of samples and clinical data, which reflects the real condition of the disease, are produced from clinics. These valuable clinical resources are not fully utilized. More and more hospitals are realizing this problem and they are building their own clinical biobank. But majority of the hospitals lacks overall planning for the construction of clinical biobank. It directly leads to obstacles for clinicians to use clinical resources. Many of clinical biobanks become ''dead & non-circulating'' biobanks.

In the face of above problems, we focus on serving and helping clinicians to establish standardized, unified and well-informed clinical biobank. We guide them to collect biological samples purposefully under the framework of law and ethics. In addition, combined with different clinical departments, different biological samples, different collection purposes, we discuss with the clinicians development of personalized SOP. All processes can be linked through our information network platform. After the standardized samples from the clinic had been stored according to the corresponding SOP, the patient/volunteer information would be uploaded and matched after data cleaning.

At present, we have carried out extensive cooperation with the clinics and formulated a series of standards, management methods and SOPs to regulate the storage, sharing and usage of clinical biological samples. Through the information service platform, resources are integrated, optimized and managed in a unified way. In this way, most clinicians can accept it and their enthusiasm has also been mobilized. It indicates that the construction of clinical biobank has to include deep understanding and close cooperation between biobankers and clinicians, thus, clinical resources can be utilized better and more effectively, making the biobank alive.

O-07 Challenges and Solutions from Establishing India's First and Only Commercial Biobank: Use of Biospecimens and Data for R&D Services and Healthcare Products for Improving Patient Lives

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Sapien is India's pioneer in biobanking, being its largest and only commercial biobank. It has already acquired >80,000 unique cases & has access to 250,000 more cases. The biobank has been established in a unique partnership model with Apollo Hospitals which is a network of 55+ multi-specialty, high quality, private hospitals across India, hence the biobank has no regional bias. Sapien is expanding into other public and private hospitals also to increase capacity and diversity of patients. Challenges from streamlining and integrating multiple hospitals, each with its own workflow, IT databases, sample and data storage practices will be discussed along with solutions we have evolved to overcome them and gain synergy of scale.

The biospecimens and linked coded data have been used for establishing multiple platforms of interest to biotech, pharma, diagnostics or reagents/equipment companies that need biospecimens and data for product development, validation and marketing. Our platforms include a) Oncobloc, a systematic collection of FFPE blocks, surgical/diagnostic 'waste' samples that were acquired with appropriate ethical approvals in line with ICMR guidelines, b) OncoPrime, a panel of primary cells derived from breast and brain cancer patient tissues, from which 3D cultures enriched for cancer stem cells have been grown to mimic the original tumour, c) TruCell, a panel of primary cells derived from all types of normal or disease samples such as cancer-associated fibroblasts, dendritic cells, d) TruScreen, custom cell and molecular assays to test new drugs, drug targets, biomarkers, including using human skin to test novel formulations and drugs in an effort to decrease use of animals, e) TruData, a detailed database of thousands of breast cancer cases with demographics, diagnostic, receptor expression, treatment and outcomes data to mine for prognostic tools to optimize treatment for each patient, and f) Clinical diagnostics that are developed at Sapien or with partners to personalize medicine eg, myPlatelet test for PCI-plus-stent patients. Our services and products will be presented in the context of building a sustainable biobank in a LMIC resource-limited country where awareness of value of biobanking is low, and government support minimal for commercial biobanking. In summary, we will share how we are combining services to industry and academia for sustainability, whilst driving innovation into personalized diagnostics and treatment paradigms to benefit future patients.

O-08 Biobanking for Human Microbiome Research: Promise, Risks, and Ethics

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With the advancement of human microbiome research, it is inevitable that a growing number of biobanks will include a collection of microbiota specimens to characterize the microbial communities that inhabit the human body and explore the relationships between the microbiota and their human hosts. Biobanks of human microbiota and their associated genetic information may become a valuable health resource. But, this area of research also presents ethical and social problems, some of which are distinct from those faced by biobanks that store human tissue samples. This paper examines four core issues which are considered highly relevant to microbiome biobanking: the nature of human microbiome samples and how different understandings have an impact on benefit/risk evaluation, privacy, informed consent, and returning the result to participants. We argue that these issues should be addressed early on in microbiome research projects and also call for adjusting or developing new governance mechanism to better accommodate these changes.

As human microbiome research advances, more research initiative may require the participation of diverse and broad population across race, culture, and society while often exposing participants to very small risks. These changes may require a reevaluation of the benefits and harms ratio and design of new

consent and governance mechanism to better accommodate changes. We believe engaging with these challenges can foster a meaningful and collaborative endeavor to better formulate policy guidelines for human microbiome research and its applications.

O-10 Returning Genetic Results to Research Biobank Subjects – A Challenging Experience from the Colorado Center for Personalized Medicine

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Background: The Colorado Center for Personalized Medicine (CCPM) at the University of Colorado is enrolling and collecting samples from patients at UCHealth clinics to hasten discoveries in personalized medicine. The CCPM established a Biobank Laboratory to serve as both a research biorepository and a CLIA-certified genetic testing laboratory. A number of studies to date, as well as feedback from CCPM Biobank subjects, confirm that a majority of research subjects express a preference to receive individual genetic results. This preference, at face value, may seem easy to accommodate, but in our experience is a profoundly challenging endeavor.

Methods: The CCPM Biobank uses a custom genotyping microarray to simultaneously generate research data and clinical genetic results for return to subjects. To ensure that the Biobank is acting in an ethical and responsible manner in line with current clinical and research best practices, we have engaged clinicians, laboratory directors, genetic counselors, bioethicists, lawyers, researchers, clinical educators, and research subjects to determine our return of results process. Two committees, Pharmacogenetics Implementation Committee and Secondary Findings Review Board, were formed to determine clinical validity of and develop criteria for return of specific findings, and to establish the clinical and personal utility of genetic results. A Return of Results Committee was tasked with deciding by whom and how specific genetic results are returned to subjects. With committee guidance, we have developed a two-part consent model to ensure that research subjects understand their choices and the implications of receiving clinical genetic results. As we are using an online self-consent process, we continue to develop informational materials to help subjects make informed choices about genetic results.

Results & Conclusions: The CCPM Biobank has opted to return both actionable pharmacogenetic and ACMG secondary genetic findings to subjects. We are fortunate to have the administrative, genetic counseling, and clinical support to create a robust process to return these results to subjects. We believe the return of these results will serve to increase openness about research, motivate participation, and provide information of material benefit to the individual.

Here, we present detailed information on the experience of the CCPM Biobank in returning both pharmacogenetic and secondary genetic findings to Biobank subjects.

O-11 Legislation of the ABS Law in Korea and Its Implication for BRCs

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Background: The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting on 29 October 2010 in Nagoya. Republic of Korea enacted the ''Act on Access to, Utilization of, and Sharing Benefits of Genetic Resources'' (Genetic Resource Law) on January 17, 2017 and enforced on August 17, 2017. But one year grace period was allowed for preparation and awareness-raising about the compliance obligations. The Genetic Resource Law states the obligations on the users as well as providers of genetic resources. Biological Resource Centers (BRCs) collect, develop, preserve and distribute biological resources and play a role as an ex-situ conservation facilities. As providers of genetic material and depositories of biological resources, BRCs should be aware of the obligations in compliance with domestic and foreign laws and provide users with accurate information.

Methods: We conducted online and offline surveys about the awareness of Nagoya Protocol and the Genetic Resource Law. The questionnaire was sent to 101 directors and staff of the resource centers that are under KNRRC program and 44 responses were collected.

Results: For the awareness of the Nagoya Protocol question, 20% answered that they did not know, 71% knew only the main contents, and 7% knew the details. In the question about the preparedness, 74% of respondents said they were watching the trends, 21% were prepared or preparing, and 5% said they had no plans. Of the respondents 52% were distributing and 30% were acquiring resources from oversees but the proportion was low compare to domestic distribution/acquisition.

Conclusions: Even with the seminars and guidance materials about the Access and Benefit Sharing (ABS) of genetic resources and Korea's ratification of Nagoya Protocol provided, the respondents feel that they need more practical up-to-date information and clearer explanation of the approach and procedures that they should follow. The survey showed that more effective training program for BRC staffs are needed about the Nagoya Protocol and about collecting updated information. Also, the BRCs should recognize its role as an ex-situ conservation organization, and have guidelines and related documents for the implementation of the Nagoya Protocol in order.

O-12 Challenges and Practice on Ethical Governance in a Comprehensive Hospital Biobank in Western China

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Over the last decade, a number of population-rooted, disease-orientated and hospital-based biobanks have been emerging in China, which poses new challenges to the general guideline and regulation for biobanks, especially the ethical governance. Repositories of data and samples from human subjects have to operate under standardized ethical governance, to protect privacy, align with participant consent. Though regulations and policies regarding to biobanking have been developed and ethical guidelines for biobanking have been established worldwide, there is still lack of bespoken regulations, policies or guidelines related to ethical issues of biobanking in China, especially hospital-based ones. In this article, we articulate the challenges to ethical governance of biobanks, particularly among Chinese comprehensive hospitals. Then we review important policies and guidelines for the acquisition, storage, sharing and analysis of

biobank material, with focus on ethical practices including informed consent options, privacy and protection of participants. Finally, we present the standardized practice for ethical governance of our biobank, including different types of informed consent for various departments, diseases and sample types, privacy protection strategies, and ethical review process. As a large comprehensive hospital biobank in China, we collect various types of samples and data from multiple sources, such as clinical studies, cohort studies, and clinical departments with patients infected with wide range of diseases. To avoid complex ethical questions rising from a huge variety of biological sources, we developed a realistic protocol to guide our daily practice, which could provide an ethical governance model for comprehensive hospital biobanks and help develop suitable regulations and guidelines for Chinese biobanks.

O-13 Data Sharing and Protection in Biorepositories: Perspectives from a Small LMIC Biorepository in SA and Other African Countries

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With the implementation of General Data Protection Regulation (GDPR) and soon to be implemented, Protection of Personal Information, Act 4 of 2013 (POPIA), biorepositories in SA is revising or establishing new data sharing and protection policies to ensure that they are in line with these national and global legislations considering their international partners. Since data privacy policies are in place for some SA biobanks, the question remains how many other biobanks are POPIA/GDPR ready and take into account their african partners data sharing and protection legislation since it differs internationally.

Methods: Both current and prospective partner's regulatory frameworks will be taken into account. Therefore NSB current data sharing and protection policies along with POPIA and GDPR guidelines will be reviewed as a case study. Partners from various African countries such as Kenya and Nigeria will also be liaised with in order to analyse and review their data sharing and protection legislations to account for differences. Develop/Update a SA/African data sharing and protection summary of do's and don'ts taking into account all the required national and international legislation.

Preliminary Results: Using POPIA/GDPR as a reference, a coded sheet was generated of key points. Main focus points related to: 1) informed consent and REC roles, 2) MTA and DTA's, 3) the use of secondary data, 4) long term storage, 5) protection, 6) IT/LIMS perspective and 7) in between countries sharing along with 8) whom takes responsibilities in case of data breaches were focused on. The different sections covering the various points for the different countries will be summarised accordingly.

Discussion and Conclusion: With the coming into force of the GDPR and the soon to be implemented POPIA, many research laboratories and biorepositories had to introduce or update legislation to ensure compliance. However for researchers and biobankers these legislations is a challenge to interpret taken into account the many differences. Therefore the summarised guideline for LIMC African countries that would be generated focusing on the do's and don'ts related to data sharing and protection aims to help researchers and biobankers to become POPIA/GDPR complaint and to create awareness within their own setting.

O-14 Consequences of Applying GDPR for Data Transfer Agreement and Material Transfer Agreement

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Data Transfer Agreement (DTA) and Material Transfer Agreement (MTA) are the basis for the functioning of modern biobanks. Over the years, the models of these agreements have been unified due to the need for the safest and most efficient exchange of personal data and biological material between biobanks around the world. The harmonization of DTA and MTA in this area has developed without legally binding international documents. It meant that all of the content of these specific agreements depended on the will and decision of the biobanks. However, the introduction of GDPR has changed this situation.

There is no doubt that the regulations of the GDPR bind directly only European States, however, due to the global market of personal data transfer processed for research purposes, this European regulation becomes relevant for all biobanks and scientists using data and samples from Europe or conducting research in Europe.

The subject of the presentation will be to indicate the most important principles of personal data processing for the purposes of scientific research and to show the legal mechanisms that must be applied whenever scientific research on the use of human data is conducted in Europe or in cooperation with partners from Europe. The following concepts will also be analyzed: data controller, processor, anomimization, pseudonymisation in the context of biobanking and data processing for research purposes. Finally, the rules for the transfer of personal data for scientific research to countries outside the European Union will also be indicated.

O-15 Second Party Audits of Human Research Biobanking Organisations from a Responsible Sourcing Perspective

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Research using human biosamples (HBS) requires legitimacy of use and quality for consistency and reproducibility of results. As there was no international standard for governance and quality of organisations supplying/using HBS in research (''suppliers''), Novo Nordisk evaluates its suppliers to ensure that they meet high standards. The audit standard consists of 64 mandatory requirements, derived from existing laws and regulations, declarations, best practices, guidelines, conventions and quality management standards. The requirements relate to a range of topics: legal and ethical, quality and integrity of HBS, donor recruitment and consent, donor confidentiality, contract management, document control, infrastructure and outsourcing.

This study reports the results of audits conducted between November 2015 and the end of December 2017. Forty-nine suppliers from 12 countries were invited. The suppliers were from the public and private sectors and included biobanks, contract research organisations and research collaborators. Thirty-nine accepted the invitation and underwent full audit. There were no significant differences in the types of suppliers that agreed to be audited, and suppliers in all countries equally agreed, with the exception of the UK where suppliers were significantly less likely to agree. Eleven suppliers were in full conformity with all requirements on initial audit. Twenty-eight suppliers were initially non-compliant, with an average number of non-conformities (N/Cs) of 5.1. Twenty of these suppliers became compliant after correcting N/Cs. The rate of N/Cs did not vary by the types of supplier or the ownership type. Suppliers in the USA had a higher N/C rate in comparison to suppliers in other countries. Most N/Cs were related to biological safety, packing and transportation of HBS, or handling of liquid nitrogen. A lack of standard operating procedures for key processes was common, as was payments to donors or sub-standard consent documents. Novo Nordisk's approach to responsible sourcing of HBS, by conducting ''second party'' audits against an internationally applicable standard, benefits Novo Nordisk and also its suppliers by fostering working towards higher international standards. This assists Novo Nordisk to select suppliers from a responsible sourcing perspective. The success of the process predicts that ISO 20387:2018 will benefit both biobanking organisations and their stakeholders, particularly their end-user researchers.

O-16 Tumor Cell Content and RNA Integrity of Surgical Tissues from Different Types of Tumors and Its Correlation with Ex Vivo and In Vivo Ischemia

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Background: Tissues from tumor patients are important resources for promoting cancer research, and therefore many biobanks have been established to collect tumor tissues; however, the quality of tumor tissues after surgical resection has not been well documented.

Methods: A total of 896 cases of tissues from 12 types of tumors were chosen for this study. First, histopathological examination was conducted to evaluate the tumor cell content. Second, microchip electrophoresis was used to determine the RNA integrity number (RIN) in 466 cases of tissues with high tumor cell content (75%). Finally, a correlation test was used to analyze the effect of ischemia on RNA integrity in 384 cases of tissues with a recorded ischemia time.

Results: Tumor tissues from 12 different organs had different tumor cell contents and RNA integrity. The liver had the highest percentage (69.7%) of tissue samples with high tumor cell content (75%) and the highest percentage (96%) of samples with high RIN. RNA integrity was not correlated with limited ex vivo ischemia time (5–60 min) in any of the 12 types of tumors. In contrast, a significant correlation with in vivo ischemia time was observed in several types of tumors.

Conclusions: Not every sample of excised tumor tissue has a sufficient amount of tumor cells and enough RNA integrity. In vivo ischemia has a more significant influence on RNA integrity, and tumor tissues have different tolerances to pre-analytical variables. Those conducting translational research should pay attention to pre-analytical variables when collecting and utilizing tumor tissues.

O-17 RAVEN Biorepository and Panel Development for Comparative Evaluation of Ultrasensitive HIV Reservoir Assays

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Background: There is immediate need for rigorous evaluation of HIV reservoir assays for use in cure research. The Reservoir Assay Validation and Evaluation Network (RAVEN) developed an extensive biorepository of apheresis-derived, rigorously cryopreserved specimens including plasma, PBMCs, and CD4+ from HIV Clade B and Clade C infected RAVEN participants and HIV controls to develop and validate methods for quantifying HIV persistence. To include globally relevant isolates, the Clade C module included partnering with South African collaborators and thus building capacity and expertise for processing of apheresis collections to ensure quality outcome.

Methods: Leukapheresis collection yields 6–20 billion PBMCs and 250+ ml of plasma, allowing generation of identical panels for testing multiple HIV reservoir platforms in parallel. However, isolation of PBMC, CD4++ and plasma from apheresis collections is an intensive process requiring extensive optimization to minimize pre-analytic variability and ensure that differences in HIV reservoir detection are not due to sample preparation variability. Ongoing QC of sample integrity and composition spanning the multiple processing steps is necessary and include comparisons of pre and post cryopreservation viability, recovery, and subset frequencies by flow cytometry.

Results: Viability, recovery and cell subset frequencies were compared between whole blood, raw leukapack, freshly isolated PBMCs and CD4+ T-cells. In partnership with South Africa, in country training was provided and procedures were streamlined to accommodate capacity and expertise. Plasma and PBMC panels were constructed and designed to evaluate performance characteristics and limitations of HIV reservoir assays. Panels consist of pedigreed clinical HIV+ specimens, analytic standards of HIV− serum or PBMC spiked with high HIV reservoir plasma or PBMC, and HIV− controls, requiring parallel processing of multiple apheresis collections.

Conclusions: Determining the impact of HIV curative interventions requires assays validated to accurately and reproducibly detect and quantify the HIV reservoir and thus extensively validated and optimized procedures to ensure sample preparation consistency. Partnering with international sites allows inclusion of relevant circulating HIV subtypes and opportunity for capacity building. Distribution of high quality, blinded panels by the RAVEN program enables rigorous assessment of assays for use in cure research protocols

O-18 Quality Management Practices for Operations at NIST's Marine Environmental Specimen Bank

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In the 4th Edition of *ISBER's Best Practices*, Section D describes and outlines in detail the importance of Quality Management to specimen banking activities. Integrated systems for management (Quality Assurance) and technical (Quality Control) activities are integral to operational success in meeting objectives. Aside from the technical aspects of specimen archival to ensure fitness for purpose, these also encompass planning, implementation, documentation, assessment, and iterative improvements to ensure processes are of the type and quality needed for any given project. The National Institute of Standards and Technology has been involved in specimen banking since 1979 through environmental research and monitoring programs. As collections grow, QA/QC practices focused around day-to-day operational activities become increasingly important. In the last year, NIST has made efforts to drastically improve QA/QC practices at the Marine ESB through development of three data visualization, assessment, and quality control tools. Such tools improve or unlock the ability to successfully plan for future collections, address space utilization deficiencies, and provide candidate space for consolidation. In providing staff with a high-level intuitive visualization of space allocation and utilization, the Freezer Visual Information System (FreezerVIS) enables estimates of space used and remaining at repository, freezer, and individual container levels; this drastically reduces the time requirements around tasks such as freezer and container consolidation, metadata evaluation, and physical repository maintenance. To reduce data entry errors, the Freezer Validation for Import Data (Freezer VALID) enables automatic checking and reconciliation of metadata provided to the ESB against expected entries (for controlled vocabulary) and reasonable entries as well as automatically generating calculated fields and identifiers; this dramatically reduces the potential for data entry errors and streamlines the overall process of including stakeholder metadata into sample control databases for precise searching. Finally, the Freezer Check tool curates the process of physical location audits accelerating the process of identifying truly random locations and maintaining an ongoing tally of outstanding issues identified, overall progress, and issue resolution to meet the goal of improved QC in a manner that enables stricter QC guidelines without increasing overall cost of staff time.

O-19 Optimization of a Dual RNA/DNA Extraction Procedure from Flash-Frozen Brain Tumor Tissue Samples Representing a Large Pediatric Brain Tumor Cohort Containing a Range of Unique Tumor Types in Support of the Creation of a Pediatric Brain Tumor Atlas

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As part of a project undertaken by the Children's Brain Tumor Tissue Consortium (CBTTC) to create a Pediatric Brain Tumor Atlas containing genomic data (RNA and whole genome sequences) along with paired clinical, pathology, histology, and radiologic data, the Children's Hospital of Philadelphia's Biorepository Resource Center was enlisted to extract RNA and DNA from approximately 1400 banked samples of flash-frozen pediatric brain tumor tissue representing several unique brain tumor types. We chose the Qiagen AllPrep DNA/RNA/miRNA procedure using the QiaCube platform and performed optimization utilizing both mouse and human brain tissue. The dual prep procedure was chosen because of the importance of extracting the RNA and DNA from the same piece of tissue with regard to downstream genomic analyses. All samples and quality control measures were tracked with our laboratory information management system. RNA and DNA quality was evaluated by RNA Integrity Number equivalents (RINe), DNA Integrity Numbers (DIN), OD260/280ratios, and yields. Between 10–30 mg of brain tumor tissue was used for each extraction with our optimized procedure. The average RINe value for 1416 RNA samples was 7.0, with 76% of the samples having a RINe of 6.0 or higher. The average OD260/280 ratio was 1.98, and the average yield was 10.5ug. The average DIN value for 1416 DNA samples (extracted from the same tissue samples) was 7.8, with 92% of the DNA samples having a DIN of 7.0 or higher. The average OD260/280 ratio was 1.85, and the average yield was 22.7ug. Flash-frozen mouse brain tissue was included as a control in all extraction runs. The average RINe for 330 control RNA samples was 8.5, with 96% having a RINe of 7.0 or higher. The average OD260/280 ratio was 2.03 with 95% having a ratio of 1.9 – 2.1. The average DIN for 330 control DNA samples was 8.0, with 91% having a DIN of 7.5 or higher. The average OD260/280 ratio was 1.83 with 96% having a ratio of 1.7 – 1.9. Although it has been noted that surgically excised brain tumor tissue often exhibits degraded RNA, most likely due to prolonged ex vivo time before stabilization and tissue-specific effects, the optimized workflow we established here provided good quality nucleic acid in a timely manner for downstream genomic analyses. The first data set for the Pediatric Brain Tumor Atlas was released by CBTTC in September 2018 and represents data collected from more than 1,000 subjects and 30 unique brain tumor types.

O-20 Specimen Evaluation, Quality Assurance Project (SE'QAP): Assessing Quality Within the Historic Alaska Area Specimen Bank

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Background: The Alaska Area Specimen Bank (AASB) contains over 650,000 aliquots and 80% of these specimens are serum, dating as far back as the 1960s. Storage conditions and containers have changed over time raising concerns about the quality of historic specimens and their utility in future research. Modern biobanks utilize DNA as a prospective quality control (QC) measure; however assessing specimen quality of historic samples remains mostly undefined. Our aim is to determine fit for purpose of these valuable specimens. The AASB provides an opportunity to investigate physical storage conditions with nucleic acid, metabolite and protein quality measures that will expand knowledge for determining a useful QC sample measure in a historic bank.

Method: We designed an evaluation by measuring the quality of materials extracted (nucleic acids) from, or contained within (Basic Metabolic Panel (BMP) analytes and protein) serum. We randomly selected specimens stratified by: (1) storage container, (2) duration of storage, and (3) specimen condition (desiccation, ice crystal formation). Our preliminary analysis focused on quality evaluation of DNA and BMP analytes (BUN, Ca2, CO2, Creatinine, Glucose, Cl, K, and Na). DNA quality was measured by spectroscopy and electrophoresis. BMP analyte quality was measured by quantitative chemistry. The analytical quality

measures of DNA and BMP analytes were compared with the three physical specimen criteria using multivariate analysis. A comparison group of serum collected recently (>2010) stored in standard, polypropylene cryovials, was included.

Results: Results were available on BMP analytes for 236 specimens and for DNA quality on 111 specimens. Storage in glass trended with lower sodium levels ($p=0.04$). A longer duration of storage was associated with lower glucose ($p=0.001$) and chloride ($p=0.02$), and higher potassium ($p=0.01$). Specimen condition did not exhibit a significant impact on BMP analyte levels. Preliminary results indicated no association between DNA quality and the three physical specimen criteria.

Conclusion: Preliminary results suggest some effects from the storage container type and the duration of storage on BMP analytes, however, not for DNA quality. We continue to expand analyses to a larger number of specimens, and to include other material (Protein, RNA) quality evaluation. These investigations will lend further guidance for evaluation and inventory of historic specimen banks

O-21 Development of the Full Process Management System for Biological Sample Processing

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Background: To realize automatic recording of all aspects of sample processing, integration of hospital biobank and clinical resources, comprehensive information construction and international quality management, systematic construction of necessary research resources and interdisciplinary cooperation research on the biological sample information platform we developed a whole process management system for biological sample processing.

Materials and Methods: The front-end development tools Delphi XE5 system is connect to the SQL Server2008 R2 database platform through the ADOConnection control, and data access and control is implemented by Tclientdataset control, which enable to update the data directly. The sample traceability information code is established using the medical information, and the Hamilton Microlab Star+ I.D. Capper workstation is also integrated.

Results: After many years of continuous development, our biobank realize the whole process monitoring of the sample including collection, processing, quality control, storage and distribution. The sample management system consists of eight modules, including: peripheral blood samples, tissue samples, clinical information, quality control information, data and device interfaces. Peripheral blood samples including electronic doctor's advice, execution in nurse workstations, information codes generation, sample scan and IDs and sample basic information generation, informed consent scanning, sample dispensing and bottom two-dimensional code scanning. Tissue sample including the sample data match and storage, added sample registration management station in the dehydrator and the embedding machine, added slide writing instrument in the paraffin slicer and the frozen slicer. Clinical information including pathological information, tumor marker indicators, imaging, medication and surgical information; and discharge summary, etc. Quality control information including document quality control, preanalysis variables, information cross-matching, temperature control system and quality control.

Conclusion: The whole process monitoring system is able monitoring, control and record of the whole process of sample processing in our biobank, which reduces errors and improves efficiency, and ultimately improves sample quality.

O-22 Collection Strategy for Sustainability: A Study of Sample Use

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Background: Sustainability is a hot topic for biobanks and there are differing schools of thought regarding the most beneficial collection strategy to increase sustainability. Many feel that only collecting samples that have a known use is the most cost effective model, with others subscribing to the hypothesis of a more generalized collection to enable an archive of readily available material.

Methods: The Wales Cancer Bank (WCB) carried out an assessment of sample use over a twelve year period and the data will be presented. A variety of data points were examined to investigate; time from consent to first use of samples, time span of sample use, use of samples in multiple projects and average time to use of samples.

Results: The assessment showed the value of a ready archive of samples with samples from the first five years of collection still being used in projects up to twelve years later. It showed that the first sample from a donation is typically issued within one year of consent, but nearly a third of donations do not have their first sample used until at least two years after donation. Many donations have had samples used in multiple projects and, of the patients with samples used in seven or more projects, 90% were consented before the end of 2007 and the span of sample use (when first sample was used to when latest sample was used) has been as great as eleven years. The data for all samples issued identified that 66% were issued two years or more after the date of consent.

Conclusions: A greater number of projects have been supported via the archive than would have been possible if collection had been limited to known projects. Maturing data results in a higher percentage of consents from the early years having samples used, as the increasing depth of data enhances sample utility. Supporting an archive of samples and data with unpredictable use is undoubtedly more financially burdensome than having a steady state of incoming and outgoing samples. The decision is one for each biobank to make and is ultimately a balance between financial sustainability and operational sustainability. Biobanks are there to serve and expedite science and the availability of an archive collection of standardised, well-annotated biosamples ensures that future research can be supported without the delay of prospectively collecting samples. Funders need to be aware that a financially more sustainable model may not result in the most scientifically beneficial resource.

O-23 The Israel Registry and Biobank of Autism (IRBA)

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Autism Spectrum Disorder (ASD) is defined by deficits in social communication and the presence of stereotypical or repetitive behaviors. Its incidence increased tenfold over last 20 years in many countries, including USA and Israel. Of importance, there is no known biological marker of autism, no bio-

chemical or anatomical pathology, and no treatment which directly treats the core symptoms. An important step towards the treatment of autism is to understand its causes. Current data concludes that the etiology of autism is approximately 60% genetics, while the other 40% is unknown. It is widely believed that environmental factors are involved in the other 40%, although the exact environmental factors are unknown.

We founded the Israel Registry and Biobank of Autism (IRBA) in 2015, to promote the ASD research in Israel. The project is maintained with support of ''Teva Pharmaceutical Industries''.

Historically, the population of Israel has extremely high diversity, where many ethnic groups, sometimes with high endogamy, live in a relatively small territory. This factor, together with well developed ASD facilities, gives the IRBA an advantage to succeed in autism research.

The long term objective of IRBA is to find specific association between various ASD phenotypes, genetic and environment factors.

The participants are people who are 3–45 years old, ASD-diagnosed, or their siblings. The collected samples are salivary, blood and feces. The families fill an epidemiological questionnaire and receive an opportunity to perform ADOS test for quantification of autism traits.

The main challenges: 1) low compliance of target population. Management: a) education of target population (lectures, conferences, facebook, media sources) to stress importance of scientific research. b) personal attention to the families of every potential donor b) cooperation with ASD clinics and specialists.

2) a shortage of human resource. Management: education and training for achieving highly-qualified multifunctional staff.

Enrollment: 60 families are already enrolled and about 40 families are waiting for our visit.

Scientific Research: We are currently starting a research program of autistic children microbiome using samples from IRBA collection.

Future Perspectives: During the next steps of IRBA development, the most attention will be devoted to sample quality, data management and QA.

Conclusion: IRBA could open up the possibilities of complex genetic, biochemical and behavior studies of ASD.

O-24 St. Luke's Medical Center's Efforts in Establishing a Human Cancer Biobank, a First in the Philippines

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The completion of the human genome project and the consequential ''omic'' projects have driven medical research into an unprecedented pace. Biobanks are established to meet the need of generating huge of data in an effort to understand the etiology of human diseases. Asian countries like China, Japan and Korea who are leaders in the medical field have built several biobanks focused on collecting, storing various human tissues for research. The Philippines, a developing country has embarked on building its own modest human cancer Biobank. In 2013, responding to the ever increasing demand to study cancer among Filipinos, the Research and Biotechnology group of the hospital formalized the creation of the human cancer biobank, the first in the Philippines. The St. Luke's Medical Center-Human Cancer Biobank Reasearch Unit (SLMC-HCBRU) was largely due to the efforts of a dynamic group of medical oncologists and scientists who came together with a clear vision of what a Cancer Biobank for Filipinos should be. The project also went through rigorous scrutiny and eventual approval by the Ethics and Institutional Review Boards of SLMC. In May 2015, the SLMC-HCBRU was officially launched. The establishment of SLMC-HCBRU can be described in four phases: I. Consultation and Integration; II. Infrastructure and Resource Allocation; III. Activation of basic operations and IV. Conduct of researches. Phase I basically involved meetings among clinicians, researchers and administration brainstorming on the mission vision, objectives, policies and standard operating procedures. Phase 2 dealt with the space preparation, building of facilities, storage and processing system, personnel recruitment and training. Fund allocation was a challenge as this is solely provided by the medical center. Phase III was the exciting part when we operationalized what we have planned, from patient recruitment, collection, processing, storage of samples as well data encoding. Phase IV is underway as we open the use of stored samples to in-house researchers: residents, fellow and graduate students of the Molecular Medicine Program of the SLMC's Medical School. There are plans to do research collaboration with other hospitals and research institutions as soon as policies on research collaborations are finalized. SLMC-HCBRU on its 3rdyear of operations has collected and stored 2,500 various human cancer tissues. For now we move in small steps but towards a strong and sustainable future.

O-25 PHI and Prostate Cancer - Optimal Management

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Background: Prostate cancer is the fifth leading cause of cancer death among men. More than one million cases are worldwide diagnosed every year, and the mortality is over 300,000 deaths per year. Prostatic specific antigen (PSA) is a serine protease composed of 240 amino acids in a single polypeptide chain. In serum, PSA is primarily bound to alpha1-anti-chymotrypsin (95% of total PSA), to a lesser extent to alpha2-macroglobulin. 10–30% serum PSA occurs in the free form (fPSA). Since the 80s of the last century, total level of prostatic specific antigen (tPSA) is used as a tumour marker in the prostate cancer diagnostics. Most of the prostate tumours are diagnosed using biopsy based on the elevated levels of PSA. It is also useful to determine the part of PSA called proPSA. This part of PSA is more produced by tumour cells. Based on the levels of PSA, proPSA, and free PSA, the prostate health index PHI can be calculated. The aim of the study was to demonstrate usefulness of PHI in routine practice in University Hospital in Pilsen.

Methods: Cohort of 1865 patients was evaluated. The total of 800 biopsies, 1 448 MRI and 250 PET/MRI were performed in this cohort of patients. 5900 samples with the results of PSA, fPSA, -2proPSA, fPSA/tPSA calculated results and PHI during 1–3 years the follow-up period. Gleason score was established in all patients.

Results: By comparison of AUC sensitivity for each laboratory parameter, PHI achieved the highest value (0.8118). PHI achieved also the best correlation with the Gleason score (G6-G9) which allows PHI to be a reliable marker of aggressiveness of the prostate cancer. An optimal PHI cut-off value was 31 with specificity 20.4%, sensitivity 97.6%, PV+ 18%, PV– 97%,

RR 8.7. The correlation between laboratory methods and imaging techniques were discussed.

Conclusions: Determining PHI allows proposing the optimal diagnostic algorithm for prostate cancer, improvement of differential diagnosis of carcinoma vs. prostate hypertrophy, reducing biopsies and imaging techniques, more accurate prognosis estimation, optimizing the type of surgery, optimizing of the postoperative treatment, optimizing of follow-up.

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O-26 Challenges of Setting up a Bio Repository in a LMIC Setting in Pemba: An Island in Sub Saharan Africa.

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Statement of the Problem: Creating a bio-repository of biospecimens provides the opportunity in quick translation of biomedical research into practice for providing solution to many major health care and services. Alliance of maternal and newborn health Initiative (AMANHI) is a multi-centric study aimed to establish a Biobank from a community-based pregnancy cohort followed from conception till 42 days postpartum in LMIC countries (Bangladesh, Pakistan, and Tanzania). In Pemba Island, Tanzania where we have set up the first bio-bank in the region the problems are manifold. The concept of a biobank and its importance is not fully understood even at the higher levels of administration. Absence of a proper governing committee and rules makes it complex to identify and address the research gaps and utilization of the samples. Basic infrastructures like trained manpower, stable power supply, powers backup which are essential for the sustenance and viability of a bio-bank are not present. Absence of vendors in the region provided further challenges in procurement of essentials like cryo-freezers and other harmonized equipments, supplies required for collection of the bio-specimens.

Among the social issues included the challenges of setting up a community-based surveillance system, AMANHI being a community-based sample cohort involved recruitment, follow-up, collection of bio-specimens, clinical and phenotypic data at the community level. There was need to set up facilities for sample collection in the community with strong adherence to protocol, maintain higher compliance rate, behavioral change to maximize facility-based deliveries to ensure deliver sample collection and processing within a short time.

Solution: Establishing a governance body, community sensitization involving local leaders, religious leaders along with health officials helped introducing the concept of bio-bank both at community and with different stakeholders, a mobile clinic helped participants to visit a clinic for donating bio-specimen and introduction of an ambulance system helped improve the facility delivery, an in-house designed software enabled step by step guidance to the whole process of specimen collection to archival and easy retrieval.

Conclusion: We as part of AMANHI initiative were able successfully overcome most of these challenges and set-up a state of the art Bio-bank with strong adherence to international standards in Pemba Island, Zanzibar.

O-27 Implementing Personalized Medicine in the CCPM Biobank: Strategies for Cost Reduction and Sustainability in Biorepository-Based Genetic Testing

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Statement of the Problem: Recent years have seen the rapid adoption of institutional and collaborative biorepository initiatives among academic health systems. Institutions are interested in the potential of biorepository-generated data to benefit the health system in a number of ways, including reducing health care costs and elevating the health system's reputation among its peer institutions and with prospective patients. Data to date indicate that when given a choice, a majority of participants will consent to clinical genetic testing performed by the biorepository. One of the primary challenges in implementation of large-scale genetic biorepository testing is reducing operating costs to a level at which the potential benefits of the testing justify the expense, while complying with applicable regulatory requirements for clinical testing.

Proposed Solution: Here we describe the development and implementation of a scalable, cost-effective, automated system for clinical sample collection, genetic test ordering, and results reporting at the Colorado Center for Personalized Medicine Biobank. In this system, costs are reduced by implementing an online electronic self-consent model, automated ''add-on'' clinical sample order and collection, automated and simultaneous analysis of hundreds of samples, high-throughput and relatively inexpensive microarray-based genotyping for both research and clinical use, and a direct connection between the analysis software and the electronic health record system (EHR) that allows the simultaneous release of hundreds of laboratory reports in a CLIA-compliant manner.

Conclusions: Benefits of this system include test menu and sample volume scalability, a relatively high genotyping throughput of up to 1000 samples per week with 3.5 laboratory technicians, an analysis throughput of up to 1080 samples per hour per reviewer, and the reduction of opportunities for human error. Challenges include the significant effort required to establish the workflow, including custom software design, custom functionality in the EHR, extensive clinical validation, maintaining regulatory compliance for clinical testing, and establishing secure and HIPAA-compliant data connections between the Biobank instrumentation, the analysis software, and the EHR. Overall, we anticipate that this model for biorepository-based personalized medicine will increase participation rates for the CCPM Biobank and improve patient care at a sustainable cost.

O-28 Evolving Population Data Linkage Services to Transform Large-Scale Biobanking Services

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Background: Many population data linkage centres have been established to provide a mechanism for making linked administrative data available to approved third parties within robust governance frameworks. While current models support a wide variety of research, modifications are required for linked administrative data to better position biobanking research infrastructure.

Methods: We have sought to reconfigure population data linkage services to enhance the value of a newly established state-of-the art population and disease biobank embedded within a state based pathology network, equipped with robotic technology, with the capacity to store and process more than 3 million samples from participants consenting to data linkage and future unspecified research.

Results: Three data service streams have been developed: longitudinal data linkage, cohort management and targeted recruitment. Traditional infrastructure for population data linkage will support the longitudinal data linkage stream, making data and biospecimens available for research, without direct patient identifiers. Technical and governance changes are necessary to enable the rapid release of contemporaneous patient and health system data for cohort management and recruitment purposes. The cohort management stream seeks to significantly reduce the manual follow-up of administrative data by cohort managers. The newly developed targeted recruitment service will leverage on the jurisdictional data holdings and structure of the health system and pathology network, to identify optimal sites and service providers for patient recruitment at scale, in an expedited manner.

Conclusion/Implications: Modest changes to population data infrastructure have significant potential to enhance biobank research infrastructure. By fast tracking biospecimen accrual for diseases of population subgroups of strategic importance, this new service is intended to promote biobank viability, accelerate the pace of clinical trials recruitment and improve patient access to trials.

Innovative Technology

ITO-01 New Developments in NGS Sample Quality Control – from FFPE RNA to Cell-Free DNA

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Over the past years, Next Generation Sequencing (NGS) developed to a powerful tool in almost all genetic research and diagnostic areas. Key for the success of any NGS experiment is the quality control (QC) of source RNA and DNA samples as well as generated libraries. Most library preparations remain lengthy and therefore are expensive processes. Tight QC steps are required to avoid a ''garbage in-garbage out'' situation. The ideal NGS QC solution is easy-to-use, economical and provides fast and unambiguous results also for very low concentrated samples. One way to ensure that samples are ''fit for purpose'' is to apply a separation by automated electrophoresis followed by fluorescence detection and automatic data analysis. This talk covers the latest developments in the area of NGS sample QC and gives application examples.

Cell-free DNA (cfDNA), extracted from blood specimens (''liquid biopsies'') or other body fluids, gain more and more importance in the context of cancer research and prenatal testing. Accurate quantification of cfDNA samples is essential to determine suitable input amounts for cfDNA library preparation prior to sequencing. Dependent on preanalytical sample treatment or extraction method, cfDNA samples may contain larger DNA fragments e.g. genomic DNA contaminations. High molecular weight material can negatively influence library preparation and subsequently result in lower sequencing depth. Different examples for cfDNA samples will be shown and data will be discussed.

ITO-02 Introduction to Artificial Intelligence-Assisted Clinical Biobank Screening System

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We have applied the natural language processing (NLP) technology of artificial intelligence (AI) to structure electronic text data such as clinical electronic text, ultrasound inspection and CT detection reports, etc., and unstructured data was transformed into structured variable data. Furthermore, the clinical data including hospital information system (HIS), laboratory information system (LIS) and biobank information system (BIS) data were integrated, and the integrated data is used to assist the screening of clinical biospecimens, and the clinical biospecimen that meets the researcher's requirements are easily selected and provided to the researchers. So this screening system greatly improved the accuracy of clinical researchers' screening of samples, and improved the accuracy and speed of the researcher's collection of clinical data. In addition, this system will help clinical researchers to carry out clinical research.

ITO-03 A Model for Implementing a Network of Biobanks in a Country

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Background: In Mexico, nearly all sample collections are held by individual principal investigators and are used mainly for short-term local projects. Thus, samples are not necessarily being collected adhering to good biobanking practices. Aiming to promote translational research in the long term, we have begun the establishment of the first biobank network in Mexico.

Methods: Having INCMNSZ as our first partner, we were recognized as a National Laboratory by the National Council of Science and Technology (CONACYT) in 2015. With the grant funds, we were able to meet with key opinion leaders in leading medical research institutions to present our vision of a national network of biobanks. Moreover, financial support allowed these institutions to start biobanking operations and join us in building this network which allowed to sustain our biobanking efforts via collaborations with pharmaceutical and biotech companies, exclusively through one of the leading biospecimen procurement CROs, Trans-Hit Biomarkers (Montreal, Canada).

Results: In order to transition from National Laboratory to National Network, the members (ten biobanks) voted to operate

as a consortium (Mexican Network of Biobanks or REMBIOBAN, by its initials in Spanish) and drew Innbiogem SC to administer it and Innovita SA to provide logistics support. CONACYT funds were used to help member biobanks to renew their infrastructure, implement a Laboratory Information Management System, standardize the SOPs, and follow best ISBER biobanking practices. We have been successfully overcoming the different and numerous regulatory hurdles specific to Mexico (IRB, export of biospecimen). Our next step is to distribute common biospecimen management software to all participating biobanks and to help them develop a sustainable business plan which should allow them to share real-time information and data and improve international collaborations through our partnership with THB.

Conclusions: Starting from scratch, setting up good biobanking and biospecimens-sharing practices with the help of selected partners, will allow Mexican biobanks to be recognized internationally for their expertise and potential. Therefore, we believe that our model could be easily transferable to any country, especially from Latin America, who is willing to initiate biobanking activities and seeks to attain sustainability.

Acknowledgments: We thank CONACYT, Alberto Anaya, and the many volunteers and students that helped us launch the project.

ITO-04 Effective Annotation of Autopsy Specimens for Better Understanding of Tumour Heterogeneity

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Statement of the Problem: Rapid autopsy programmes are revolutionising research knowledge about the genetic heterogeneity of tumour lesions in an individual allowing us to learn about how tumours metastasise and how they may evolve to evade therapy. However where a supported rapid autopsy programme is not in place the establishment of such a system for a one off and unique opportunity is an ethical and logistical challenge.

Proposed Solution: Our New Zealand neuroendocrine cancer research program (NETwork!) was presented with such a situation in early 2016. A donor and her family initiated a study with the research team, where at the time of her passing over 300 specimens from her 89 lesions were collected for analysis. The road to gaining ethical approval and consent, coordination of and continued liaison with the parties involved, and the preparation of SOPs and consumables for the day was long. In conjunction with a multidisciplinary team we developed protocols for sample coding, photography, annotation and tracking and learnt that for a research project such as this to succeed accurate recording of this information is key. The collection has allowed the NETwork! team to be the first to investigate genetic heterogeneity in a rare lung neuroendocrine tumour, teasing apart the evolutionary development of lesions from the original site and beginning building models of metastasis. Further, we have begun to develop two digital tools to aid similar future studies. The first is a point of collection photographic annotation tablet or phone app designed to combine paper records with photographs in one system. The second is an augmented reality system that visually exhibits the spatial and genetic relationships between lesions in an interactive manner to aid communication among researchers and clinicians and to facilitate interpretation of the findings.

Conclusions: Not only did this opportunity provide us with an invaluable tissue resource it has enabled our research group to develop protocols to be able to undertake rapid autopsy collection and, as importantly, to develop computational and educational tools. These tools, when fully developed could be made accessible for researchers and tissue banks to allow accurate annotation and to visualise the spatial orientation of samples for the better understanding of tumour heterogeneity within a patient.

ITO-05 Holograms Can Aid the Manual Handling of Frozen Samples

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Statement of the Problem: Old biobanks are often kept in manual freezers. We manage the sample collection of the Northern Sweden Health and Disease Study (NSHDS), with over 150,000 plasma, erythrocyte and buffy coat samples stored in manual −80 degrees freezers. Sampling begun in 1985 and is still ongoing. Within NSHDS, several case-control studies are being performed. Most case-control studies entail 100–2,000 samples that are manually taken out of the freezers. This is sometimes referred to as 'cherry picking' and requires a list of the samples that should be taken. Paper printouts of these lists have to be handled manually while working in the cold freezers – a job that is quite time consuming. This all adds up to less than ideal working conditions for biobank staff.

Proposed Solution: By using augmented reality (AR) and holograms, a solution has been developed to facilitate the work. The application can be used on different mobile devices, but we have chosen smart glasses. Simply explained, it's a computer that can be worn on one's head and that interacts with speech and hand movements. Through a connection to the laboratory information management system, we can use the application to tell us where the sample is, and we can scan barcodes to confirm that we picked the right sample. The holograms give us guidance in the process of picking these valuable research samples, and the work can be performed without any other handheld equipment. This largely increases the efficiency of the work.

Conclusion: Holograms can aid the manual handling of frozen samples, vastly improving working conditions for biobank staff.

ITO-06 Application of Apoptotic Inhibitors on the Cryopreservation of Human Cultured T Cells

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A growing numbers of T cell based immunotherapy were developed these years and the effective cryopreservation of cultured T cells is urgent needed for the future application. The purpose of this study is to investigate the effects of apoptotic inhibitors on the viability, early apoptosis and the expression of apoptosis-

related genes of cryopreserved T cells. T cells were cryopreserved in 7.5% (v/v) DMSO as cryoprotectant solutions, the apoptotic inhibitor α-Zearalano was added into the medium of T cells before freezing or after thawing, or mixed with CPAs. Data showed that adding the apoptotic inhibitors into cryoprotectant directly did not improve the viability or inhibit the early apoptosis statistically ($P > 0.5$). However, the cell viability and recovery rate were significantly improved by incubating the cells with apoptotic inhibitors before and after cryopreservation. The 24h cell viability and recovery rate of cryopreserved human immune T cells incubating with apoptotic inhibitor α-Zearalano were 63.20% and 89.58% respectively, which were significantly higher than control group ($P < 0.5$). Similarly the flow cytometry result showed significantly reduction of early apoptosis rate for T cells incubating with apoptotic inhibitor α-Zearalano compared to control group (29% vs 40%, $P < 0.5$). Further study showed that after incubating with apoptotic inhibitors, the expression of proapoptotic gene BAX from death receptor pathway and mitochondrial pathway in human T cells declined significantly accompanied with the increase expression of anti-apoptotic gene BCL-2. These indicated that incubating human T cells with apoptotic inhibitor α-Zearalano before and after cryopreservation could be an alternative way for improving the activity of cryopreserved T cells.

ITO-07 Maintaining Chain of Condition in Automated BioBanks

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Statement of the Problem: Biobanks typically cryopreserve biospecimens to safeguard their biochemical composition. Exposing samples repeatedly to temperatures above −80°C for prolonged periods of time can degrade sample integrity. Automated sample management systems provide significant advantages over manual storage; however, many automated systems that store biospecimens at −80°C house their robotic components at warmer temperatures, typically at −20°C, to ensure reliable performance. As a result, the samples will transverse through temperatures above −80°C for sample processing. How can researchers ensure their chain of condition requirements are met during automated processing?

To address this question, we performed a case study to investigate the effect of the transient temperatures on samples during processing and evaluated the implementation of temperature control measures to maintain sample temperature below −60°C.

Proposed Solution: We established our threshold for temperature exposure by measuring the amount of time it would take samples to warm up from −80°C to −60°C in a −20°C environment. The warm-up time for 0.25ml saline samples located in the four corners of a 96-way rack was 2.5 minutes. We utilized this threshold to evaluate control measures that limit the exposure of samples in the −20°C environment. These control measures include software controls to physically limit the exposure of samples and hardware solutions to ensure all automated tasks are completed within our established threshold. In addition, independent and redundant temperature probes may be places alongside the samples to provide additional temperature measurements during processing.

Conclusions: By implementing software and hardware controls, we were able to complete the sample processing workflows above −80°C in less than 2 minutes; many processing workflows completed in less than 30 seconds. We tailored these control measures to meet specific chain of condition requirements and to maintain sample temperatures below −60°C. Acceptable temperature variance will vary by sample type, therapy area, workflow, and individual research requirements. It may become industry practice when evaluating automated sample management systems to assess temperature variance when optimizing storage workflow in line with downstream applications to ensure chain of condition requirements are met.

ITO-08 Biomarker Profiling by NMR Metabolomics: Using Biobank Partnerships to Build the Evidence-Base for Clinical Use

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Background: Advances in metabolomics now allow comprehensive biomarker profiling of entire biobanks and clinical trials. This provides a plethora of scientific opportunities such as discovery of novel biomarkers for onset of cardiovascular diseases and tracking their progression, as well as etiological insights into established cardiometabolic risk factors.

Methods: Nightingale Health Ltd has developed a high-throughput metabolomics platform for population-wide initiatives and screening programs. It is becoming a standard in the world's largest health resources, and it is now being applied to profile close to 1.000.000 biobanked blood samples with extensive electronic health care records, including the entire collection of the UK Biobank with 500.000 samples. In contrast to genomics, metabolomics provides a functional read-out of an individual's current health status. While reflecting the combined effects of lifestyle, environment and genetics, metabolomics provides a powerful tool for monitoring the health of individual patients over time.

Results: In this study, we demonstrate how metabolic profiling of large biobank collections paves the way for precision medicine. We show that the strong evidence obtained through large-scale collections helps guide decision making for the individual patient.

Conclusions: Here we showcase the benefits of metabolomic profiling in a precision medicine setting, for improved risk stratification and clear clinical interpretation of the biomarker results. We also illustrate the benefits of tracking the metabolomic effects in response to various lifestyle and pharmacological interventions. These results demonstrate how NMR metabolomics and large biobanks can be combined and the value further translated into precision medicine applications in primary prevention settings, providing enhanced cardiovascular risk prediction and novel means to track effectiveness of interventions.

ITO-09 Performance Comparison Between Micro Electro Mechanical Systems Tracking Tags and Other Labelling Strategies for Cryotubes

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Labelling is a critical issue in biobanking. There are many labelling methods available to be used in cryopreservation procedures. The Micro Electro Mechanical Systems (MEMS) tracking tag is a mechanical device based on mechanically resonating micro-structures used to encode an identification number. This number, along with tag temperature (placed in the base of the tube) can be detected by a reader. In a previous

study was assessed that MEMS tracking tags can reduce our biobank labeling time from 55 to 33 minutes per donation event. MEMS tracking tagged vials can be sterilized using two of the more common used methods.

Based on this preliminary result, the objective of the present work is to design a further study to assess the advantages of the implementation of MEMS chips based tracking tags as the standard labelling method at our biobank.

Two different tests were designed to check the suitability and advantages of this working scheme in our daily procedures: i) liquid and solid samples acquisition simulation: It consists in 10 liquid and 10 solid tissue aliquots storage simulation, comparing the currently used protocol and the MEMs based one. Each of the methods will be carried out by 4 different people (biobank workers) to obtain 4 replicates of the measures. This leads to a total number of 80 tubes for each method; ii) aliquot search procedure simulation: this test consists in searching specific aliquots mimicking a regular searching procedure at our biobank (in order to fulfil a sample order, to make inventory, to audit the state of the samples stored …). In this test not only time spent but also temperature difference between the beginning and finish of the procedure will be measured and compared. Tube sampling must take into account their distribution must be representative of all the positions of the box, i.e. there must be tubes in the border positions as well as in the inner positions.

These tests results will allow us to conclude if the MEMs method does or does not improve our current stablished protocol performance in storage and search processes.

ITO-10 Gene Delivery to Hearts During Ex Vivo Perfusion Storage

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Background: Viral vector mediated gene delivery provides an approach to biologically modify organs prior to transplantation or long term preservation. Cold static storage of organs remains an inefficient methodology for viral vector delivery since much of the viral vector transduction processes are temperature and metabolism dependent. Developments in the field of cardiac normothermic ex vivo perfusion storage have created an opportunity to overcome these limitations. For the heart, perfusion storage isolates the metabolically active cardiac graft and allows for intracoronary delivery of vectors with continuous recirculation. The aim of this study was to evaluate the utility of ex vivo warm blood perfusion as a method of viral vector delivery to the heart prior to experimental transplantation in the porcine.

Methods: The influence of the components of the Organ Care System warm blood perfusion system (Transmedics, Inc) on viral vector transduction was examined using a cell-based luciferase assay. Our ex vivo perfusion strategy was utilized to deliver 5x1013 viral particles of Adenoviral firefly luciferase vector with a cytomegalovirus promotor to porcine donor hearts prior to heterotopic implantation. We evaluated the overall levels of expression, protein activity, as well as the bio distribution of the firefly luciferase protein in a series of three heart transplants at five days post-transplant.

Results: The perfusion solution and the ex vivo circuitry did not influence vector transduction, but the serum or plasma fractions of the donor blood significantly inhibited transduction. Subsequent gene delivery experiments to the explanted porcine heart utilized autologous blood recovery to remove undesired components of the donor blood. Assessment of luciferase activity in tissues obtained post-transplant day five revealed widespread and robust luciferase activity in all regions of the allograft compared to the native recipient heart. The luciferase protein expression in the allograft appeared uniform and robust across all areas of the myocardium as well as in the coronary arteries.

Conclusion: We demonstrate a protocol to achieve substantial gene delivery to the cardiac allograft. This introduces a novel method of viral vector delivery that opens the opportunity for biological modification of the allograft prior to implantation that may improve post-transplant outcomes. Extension of this approach may be useful in long term organ preservation.

Note: Additional Oral Abstracts can be found on page A-73.

POSTER ABSTRACTS

Biobank Tools

PBT-01 Implementation of a Software Framework for Data Validation According to CEN/TS – a Proof of Concept

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Background: Prior to the release of the first Biobank-dedicated ISO-Standard in August 2018, the European Committee for Standardization (CEN) published nine technical specifications (TS) covering the handling, processing and documentation of certain specimen during the pre-analytical phase. Hitherto those CEN/TS were the only binding norms for implementation in biobanking processes. Ensuring the conformity of the specimen's documentation with the respective CEN/TS is a cumbersome manual task. To facilitate the process of data validation, the goal was to implement a supporting software tool.

Methods: Firstly the different CEN/TS were evaluated to extract the required and recommended data entries. Following the data fields were grouped by the steps of the pre-analytical phase to derive a suitable data model thereof. A software framework, consisting of database, validation layer and a web application, was designed and implemented. The database was realized as a document store (MongoDB) to offer a flexible data model. The validation layer was implemented in Ruby and contains validation rules and schemas for the individual CEN/TS. A simplified web application was written in Ruby to provide the user with a graphical user interface. A Java program for generating dummy data sets was implemented.

Results: Data sets were generated for the different specimen types as well as varying data field values and types. The implemented software framework validated the data sets for all suitable CEN/TS and stored the results and possible error messages in the database. Test cases were created for each type of validation rule and subsequently the expected result manually compared to the realized result. All test cases passed the verification. Missing data fields, faulty data and inconsistencies were detected by the validation algorithm and displayed in the web application accordingly.

Conclusion: The implemented framework compared the generated dummy data with the requirements of the different CEN/TS successfully. The exhibition of the validation results and error messages for the user via the web application demonstrates that such a tool provides a suitable support for data quality control. As a next step, the software should be refactored and expanded to be tested with real data sets, subsequently preparing it to be released as open source project for the biobanking community.

PBT-02 The Role of Prior Training in the Initial Operation of Specimen Collection in China

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Background: In recent years, the increasing demand for biological specimens in biomedical research has promoted the establishment of high-quality, large-scale and standardized biobanks. Based on the abundant clinical specimens, Zhongnan Hospital Biobank was built in September 2016 and approved as the first official member of ISBER-IRL in china on November 20, 2018.

Objective: To investigate the role of prior training in the initial operation of specimen collection, to summarize the experience of front-line staff of biobank and to provide reference for new biobankers in order to collect specimen as soon as possible.

Methods and Results: We started specimen collection on December 27, 2017 and collect specimen in 12 clinical departments at present. In the early stage, specimen collection was conducted by clinical staff without prior training, which was complemented afterwards and focused on the introduction of biobank and collection process to clinical staff. In this mode, 249 specimens were collected in one department within 202 days, with an average number of specimen 1.23 cases/day. Along with the gradual development and standardization, prior training was strengthened after fully analysis of the difficulties for clinical staff to participate in the process of specimen collection. The content of the prior training is more practical, including the introduction of our biobank, the value of biological specimen, the advantages of standardized collection and storage methods compared with the traditional way. The important role of clinical staff in the sufficient notification and guidance of signature on the informed consent was emphasized again and again. Continuous optimization of the training greatly improves the clinical staff's understanding and support, following with the mobilized enthusiasm. Up to now, the average number of specimen has increased significantly, reaching 6–9 cases/day in most departments and 14.82 cases/day in some departments.

Conclusion: Clinical staff in China know very little about specimen collection. Prior training is helpful and plays an important role in promoting the initial operation of specimen collection.

PBT-03 NMR-Based Quality Control and Generation of Standardized Spectral Information

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NMR for long time was considered a method for structure elucidation of unknown compounds. With the appearance of Metabolomics, NMR has proven as one of the 2 main technologies in the analysis of bio-specimens and entered the field of complex mixture analysis. Due to its reproducibility and transferability, NMR is especially suited to enable integrated studies on large specimen cohorts by multiple research groups. Standardization of the technology enabled efficient use of NMR e.g. in the International Phenome Center Network (IPCN) inaugurated December 2016. Biobanks with their large specimen cohorts can benefit in multiple ways from this technology:

- Quality Control of incoming specimens with regard to contaminations, impurities, non-reported drugs or food supplements,
- differentiate urine/plasma/serum
- check type of plasma (EDTA, Citrate, Heparine...),
- fasting state,
- multiple freezing cycles and others.
- Generation of spectral data to store in the Biobank generated as part of QC
- Generation of analysis results to be stored in the biobank along with spectra
- Quantification of a large number of metabolites and ions in urine
- Comprehensive Lipoprotein analysis in plasma/serum including Subclasses and particle numbers
- Quantification of small molecules in plasma/serum
- Results of using NMR assay analysis to be stored in the biobank
- Retrospective analysis on previously measured spectra with extended analysis routines
- Reducing the need of generating new specimens for clinical trials by using NMR spectra and results stored in different biobanks worldwide and generated under standardized conditions, such reducing cost and time efforts substantially

Examples for all aspects described will be given as well as an outlook to future possibilities generated by NMR technology.

Biobanking Profiles

PBP-01 The Australia and New Zealand Children's Haematology/Oncology Group (ANZCHOG) Biobanking Network

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The movement towards precision medicine for cancer patient care is placing increasing pressure on biobanks to deliver large cohorts of high quality biospecimens for research. Biobanking in childhood and adolescent/young adult (AYA) cancers presents an additional challenge for biobanks because these cancers are rare and therefore biospecimens are less accessible. Many biobanks lack the resources and infrastructure required to meet increasing research demands. As a result, researchers may waste valuable time applying for biospecimens from several biobanks, or be obliged to limit the scope of their research. Biobank networks are evolving as one solution to this problem, as they allow the establishment of streamlined, harmonised or shared biospecimen application processes, to provide researchers with easier access to larger sample cohorts.

The ANZCHOG Biobanking Network (ANZCHOG-BN) was established in 2017 as a subgroup of ANZCHOG, the organisation for Australian and New Zealand health professionals working to improve outcomes for children and adolescents with cancer through quality research, clinical trials and best practice in clinical care. The ANZCHOG-BN aims to promote and improve the biobanking of childhood and AYA cancer samples at hospitals, research institutes, and Universities in Australia and New Zealand. The network has obtained seed funding from philanthropic cancer organisations. The ANZCHOG-BN is governed by a Steering Committee, a subgroup of which is responsible for day to day operations of the network and reports to the ANZCHOG Executive Committee.

The ANZCHOG-BN was established as a unified approach to accelerating progress in childhood cancer research and improving clinical outcomes for patients. The network aims to improve the operations and sustainability of individual member biobanks through approaches such as sharing of information, particularly Standard Operating Procedures and expertise, and by gaining infrastructure funding for member biobanks. The network also aims to develop long-term collaborations with international biobank networks (eg, rare disease and paediatric cancer networks), patient registries (eg, the Australian Cardio-Oncology Registry), and research organisations (eg, the Cancer Cell Line Factory). In summary, ANZCHOG-BN is a relatively newly established biobank network in Australasia with the goal of improving and streamlining access to high quality paediatric and AYA cancer biospecimens for cancer research.

PBP-02 Establishment of Clinical Biobank for Women and Children in South China

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Guangzhou Women and Children medical center is the largest women's and children's hospital in south of China. The biobank has set up for 3 years, collecting the different kind of samples from four centers. In order to comprehensively improve the quality of samples, accurately search the location of samples in the biobank, completely collect clinical information of storage samples, and build a highly intelligent biobank, Guangzhou Women and Children Medical Center has accomplished in the following work. We have established standard quality management system according ISO15189 medical laboratory standard, to improve the biobank quality construction of sample database. We have set up series of cohort research for

severe diseases about women and children, collecting their clinical information and samples. The source of the specimens in our biobank has covered the south of China and South Asia. Including the first the biliary atresia cohort in the world, multicenter neuroblastoma cohort and Kawasaki disease cohort. In recent 2 years depending biobank sample resource, more than 50 related articles have been published, with a total IF value of 116. Since samples from children are rare and precious, we have made huge effort to increase the samples collection from the children limited blood. During this process, we solved some problems like as single sample category, omission of the special samples and the insufficiency of samples information and so on. We have explored about the informed consent mode with the increasing child's age. We want to provide a reference for the construction of pediatric biobank. We have extended construction of ''intelligent filtering'' informatization, to achieve a good running of automated sample storage, and intelligent search and standard operation. In addition, we have integrates the interface data of hospital examination, imaging, pathology, electronic medical record, hand anesthesia, nursing and other systems. Our new biobank management system could sort the information by the capture and integrate the sample source and corresponding sample information scientifically, to meet the needs of clinical research finally and improving the clinical research efficiency. Guangzhou women and children medical center will build seven sub-centers, import automated refrigerator to make the storage operation more convenient. We will provide more sharing of biosamples and bio-information, and Efficient support for more scientific research.

PBP-03 Biobank Profile - China National GeneBank

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China National GeneBank (hereinafter referred as ''CNGB'') is a non-profit organization supported by the Chinese Government. CNGB has stored over 20 million bioresources in the Biorepository, including human biospecimens and biodiversity resources. CNGB has also established world leading digitalization platform, and the annual data output capacity reaches 8PB.

CNGB is committed to develop a global biobank consortium to provide a platform for information sharing, Biobank materials exchanging, omics data acquisition, and Trans-omics scientific research. In order to contribute to the life science industry, CNGB has built an integrated infrastructure of ''Three banks and Two platforms'', that not only for bioresources and data storage, but also for data analysis and bioresources utilization. ''Three Banks'' represents the Biorepository, Bio-informatics Data Center and Living Biobank, while ''Two Platforms'' includes Digitalization Platform, and Synthesis and Editing Platform.

PBP-04 Primary Care Based Biobanking: A New Concept?

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Less than 1% of the population is seen in university based hospitals while most of the population seeking medical care are seen in a primary healthcare setting. Primary care (PC) fills a huge gap between the general healthy population and the university teaching hospital in provision of healthcare services. Patients seeking medical care in a primary setting present with symptoms that do not always render towards diagnosis. However, having a biobank in PC is key in studying trends, susceptibilities to disease and obtaining population data. A PC biobank can consist of a collection of biological samples and data to investigate disease, symptoms, signs and the relationship between environmental factors and diseases before it leads to pathological changes. It can facilitate earlier diagnosis presented in the general practice as well as elucidate their mechanism of production and their significance for the patient. A population biobank has the power to translate genetic discoveries into clinical practice. However, it is donated by thousands of individuals from the general population who might or not have disease or use a healthcare service. But, the challenges we face in a PC biobank is multifaceted. These can relate to the nature and organizational aspect such as patient sampling (population), governance and the type of collections (data and biospecimen) in a PC setting. A PC biobank can provide some reliable assessment of lifestyle, environmental and genetic factors as determinants of chronic disease.

PBP-05

Withdrawn

PBP-06 The NSW Brain Tissue Resource Centre: An Australian Brain Bank

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The NSW Brain Tissue Resource Centre (BTRC) has been operational since 2000 and housed within the Charles Perkins Centre at The University of Sydney, Australia. It was established to provide well-characterised, human post-mortem brain tissue for reseach projects studying psychiatric and neurological diseases. The complexity of the human brain, together with the absence of statisfactory models of many diseases, means that it is necessary to use human tissue to further research in these areas. The focus of the brain collection is alcohol abuse disorders, mental health disorders and neurologically normal controls. These cases are collected through the NSW Department of Forensic Medicine (DoFM) and a prospective donor program ''Using our Brains''.

Methods: Protocols relating to the consent, collection, processing, case characterisation, storage, data management, research applications and general management are regularly reviewed to ensure compliance and best practice. Brain tissue is prepared in a standardised manner for use with a variety of histological, molecular, genetic and ''omic'' techniques. Cases are allocated to main research cohorts based upon pathological and clinical findings. Subsets of cohorts can be provided based on other variables eg. lifestyle factors. Research applications are reviewed by a Scientific Advisory Committee and cost recovery for processing is implemented. Management tools, designed in Filemaker Pro and workflow planner systems encompass all the activities and reporting requirements to the governing bodies.

Results: Over 200 chief investigators around the world have accessed samples from the BTRC. Of the 600 approved projects, 237 are still in progress. Over 190,000 samples have been provided with a higher proportion of frozen samples requested (60%). Researchers are required to complete an annual report on outcomes, 560 journals and over 900 conference presentations have been reported. More than 200 data points for each case are notated allowing the ability of the BTRC to assign cases to cohorts according to variety of variables. The UoB brain donor program has 619 participants, 31% followed from 2002.

Conclusion: Brain banking is complex and labor intensive. Managing stakeholder expectations is important and the use of management tools aids in the delivery of positive outcomes. Community support has been strong and continued involvement in research projects assists in broadening the knowledge of participant and researcher.

PBP-07 Role and Mission of Non-Profit Boundary Organization, CIBER, to Promote Biobanking as a Business

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Council for Industrial Use of Biological and Environmental Repositories (CIBER) was established in January 2018 as a non-profit boundary organization,* aiming to become a hub for Japanese industry-government-academia biobanking research groups by adopting the model of International Society for Biological and Environmental Repositories (ISBER). Generally, in biobanking, the academic medical institutes are supposed to provide biospecimens and associated data, and bio-industries are thought to become users of those biorepositories for their R & D purposes. The network of biobankers is gradually coming into shape. However, it lacks a framework for the participation of users. In line of this context, CIBER was established by industrial members to become a hub for users, and to connect users and biobankers.

In October 2018, a five-year national project was launched by Japan Agency for Medical Research and Development (AMED) aiming primarily to establish a search engine for accessing major Japanese biorepositories, which is believed to activate the utilization of bioresources stored in different biobank nationwide; to create genome research infrastructure; and to link the results to precision medicine. CIBER joined this project as a sole member of non-biobankers and was given the task of ''international cooperation.'' Under the CIBER-ISBER partnership framework, CIBER's mission is to contribute to the project by making it acknowledged world-wide.

Biobanking is business and management that transacts bioresources such as biospecimen and associated data based on market principles. Therefore, it is predictable that debates on biobanking business models will be a common issue in the future. However, biobanking has a uniquely high publicness, and the most important and never-to-be-forgotten priority lies in the benefit of general citizens who are both donators of bioresources and recipients of biobank.

CIBER was established very timely to support the creation of biobanking environments which are destined to become essential infrastructures for global research and development. In our poster presentation, we will be introducing CIBER's activity plans.

PBP-08 Biobanking as Basis for Biomarker Research: Model of Biobank Graz

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*Non-profit boundary organization: organization that acts as a mediator between governmental regulatory sectors and innovative industrial private sectors that are normally in the form of pre-competitive institutions.

Background: In the last decades, sample analysis technologies have become increasingly sophisticated. Concomitantly, access to high-quality well-documented human biospecimens has gained importance in the field of biomarker research. Therefore it is of particular importance for biobanks to know about the requirements of biomarker research.

Methods: Biobank Graz is one of the largest biorepositories in Europe comprising approximately 20 million of well-organized human blood and tissue samples and their associated data (see http://bbmri.at/catalog). To foster medically relevant research discoveries, Biobank Graz supplies stored samples collected from selected patients who have signed an informed consent form along with their anonymized data to biomedical scientists and researchers worldwide. Regular consultations with Biobank Graz' partners in biomarker research as well as continuous observations of literature on this topic are carried out to be in line with latest developments and demands.

Results: The most important requirements for samples used in biomarker studies are:

Cohort size:

Cohorts must be large enough to guarantee statistical significance.

Longitudinal samples from each patient enable the detection of changes of a biomarker over time.

Sample quality:

High sample quality is a prerequisite for reproducible results and is ensured by standardized sample collection, processing and storage.

Data quality:

Clinical data and follow-up data are necessary to generate valuable outcomes in biomarker studies.

ISO-certified clinical biobanks are able to fulfil these requirements and to support researchers with large and homogeneous cohorts of high-quality biospecimens together with their anonymized data.

As an example, the samples from Biobank Graz were used for a wide range of biomarker studies from academia as well as industry. 192 publications using samples, data or services from Biobank Graz were counted in 2017 only. The respective cohorts, publications and clinical studies are listed on the homepages of the Medical University of Graz, Biobank Graz and BBMRI.at.

Conclusion: Biobanks are a valuable source for high-quality data-rich biospecimens in biomarker research. To fulfil the needs of biomarker research biobanks have to consider three major conditions: cohort size, sample quality and data quality. Biobank Graz has comprehensive experience with biomarker studies and constantly strives to comply with emerging needs of the biomarker research community.

PBP-09 Biobank Sweden – The Implementation of a New Swedish Biobank Infrastructure

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Statement of the Problem: In Sweden, over 150 million samples are stored in biobanks with a yearly increase of 3–4 million. Approximately 90% are in healthcare biobanks, and the remaining 10% are in universities and private companies. Thanks to the use of unique personal identifiers, biobank samples can be linked to health-related endpoints registered in nationwide health data registries, working as a foundation for the long tradition of longitudinal studies in Sweden. We have organized ourselves into a new national biobank infrastructure: Biobank Sweden. This is a joint initiative founded by Swedish healthcare and universities with a medical faculty, also including industrial partners through their trade associations. Additionally, county councils from those regions in Sweden without university collaboration have joined the infrastructure, as well as representatives from patient advocacy groups. Biobank Sweden is a continuation of BBMRI.se and a member of BBMRI-ERIC. Our work is now in the intense phase of implementation.

Proposed Solution: Our overall goal is to build a sustainable national biobank infrastructure where we provide a nationally accessible, cost effective biobank network securing access to high quality samples. To attain this, we work on national harmonization of several aspects of biobanking. We have a joint web portal, a communication strategy, and a biannual national biobank conference. The regulatory support function is being digitized and has been expanded with an ELSI helpdesk for research support. Operative support is being established through Sample Service Coordinators and Hospital Integrated Biobanking for high-quality samples. National project managers are addressing the question of how to increase the value of healthcare biobanks for research. A national IT strategy group has created a road map of the wide array of IT solutions needed, such as catalogs on sample and sample collection level, standardization of parameters used in LIMS, and case management on the national level. Much effort has also been put into enhancing sample retrieval, by means of projects addressing annotation, technical improvements in freezer hotels and the development of IT systems.

Conclusions: The implementation of the various plans within the infrastructure of Biobank Sweden is well underway and is an important building block on the way to fulfilling the goal of offering coordinated access to biological samples and data for medical research and clinical trials.

PBP-10 Biobank Graz – Hub of Cooperations in Clinical Research

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Background: In terms of sustainability and customer orientation biobanks should strive to clarify their profile and present themselves with their unique service portfolio. As one of Europe's largest hospital-based biobanks Biobank Graz considers itself as service provider and hub of cooperations in clinical research.

Methods: To raise awareness within the biobank and to conclude a strategy and service profile Biobank Graz performed multiple brainstormings, a SWOT analysis as well as an illustration of the organisation's value chain. After internal discussions and consultation with the rectorate the Biobank Graz' profile and service portfolio has been established.

Results: Key characteristics of Biobank Graz are 1) embedment into the clinical routine system of the University Hospital Graz and therefore central interface to clinical/medical specialists and lab-service-platforms, 2) quantity of more than 20 million biospecimen (FFPE, Cryo and Liquid samples) from over 1 million donors, collected for more than 30 years with according longitudinal clinical data, 3) commitment to highly standardized and quality assured sample handling and storage – efforts in implementing CEN/TS-conform workflows, 4) accessible samples and data for academic and industrial researchers worldwide.

Due to many years of experience Biobank Graz is able to provide services such as 1) project development and project coordination, 2) state-of-the-art sample storage under controlled conditions and high-end infrastructure, 3) integration of pre-existing sample collections into the Biobank Graz, 4) support in clearing ethical and legal conditions, 5) connection to the national biobank network via BBMRI.at and the pan-European biobank network via BBMRI-ERIC, 6) several education possibilities, such as the Master's programme (MSc Biobanking), Biobanking courses (basic & advanced), individual coaching and consulting possibilities, guided tours through the Biobank Graz facilities.

Conclusion: Through increasing self-awareness about the biobank profile and the added value Biobank Graz is able to perform a straightforward approach in addressing the research community. Being conscious of the organizations key characteristics and service portfolio are indispensable requirements for the sustainability of a biobank.

PBP-12 Telethon Network of Genetic Biobanks: High-Quality Service for Rare Diseases

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Access to well annotated and properly preserved samples is pivotal for biomedical research, particularly in rare diseases (RDs) context. RD-Biobanks are critical resources for samples and data collected, stored, processed, and distributed.

Recent advances in molecular biology and genetics have promoted the demand for samples and data and have contributed to raise the awareness of the importance of coordinated biobanking activity through the creation of networks.

TNGB is the first national, coordinated resource of biospecimens from patients affected by RDs. Created in 2008, it is currently composed of 11 Italian non-profit repositories and stores more than 90,000 biological samples representing approximately 950 distinct rare genetic diseases.

The main aims of TNGB are to i) centralize rare samples and data to facilitate access to large collections; ii) minimize biases potentially arising from heterogenity in the sample quality by developing and sharing SOPs and policies; iii) develop and share a sample access policy based on predefined criteria, ensuring transparency and impartiality; iv) promote biobanks within patient organisations and foster their active participation and engagement in developing procedures concerning ELSI aspects.

To achieve its main objectives, TNGB has created a website (http://biobanknetwork.telethon.it/) and adopted a common IT infrastructure, managing all data collection, sample request submissions and inventory. Aggregated data are published on the online catalogue. The IT platform manages and monitors the complete in/out workflow of samples via a request control panel shared by all TNGB partners. Samples are made available to users only for research purposes. In addition, TNGB has become, over the years, a leading player in the European biobanking framework thanks to its active interaction with BBMRI-ERIC infrastructure (and the National Node BBMRI.it), EuroBioBank network and RD-Connect platform, EU-project aimed to connecting databases, registries, biobanks and clinical bioinformatics for RD research.

The results of 10 years of TNGB activities how networking was the most effective action for satisfying the growing demand of RD samples and data.

Notwithstanding these achievements, data harmonisation, SOPs update and maintaining the public trust and interest in biobanking still remain the most compelling challenges for RD biobanks in order to provide the scientific community with high quality services.

PBP-13 Human Biospecimens Collection for Bio-Medical Research: Obstacles and Solutions. The NYU Langone Health (NYULH) Experience

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Background: Banking of human biospecimens linked to prospective, well-annotated clinical information is critical for advancing biomedical research. However, the establishment of an efficient biobank encompasses many issues including adherence to federal regulations, institutional policies and governance of the relationship between the biobank, investigators and funding agents. Here we report on the efforts of the Center for Biospecimen Research and Development (CBRD) at NYULH to establish a state-of-the-art biobank.

Methods: In 2015, we identified the need to establish a centralized infrastructure to facilitate research collaborations and support clinical trial studies. The four main considerations were: 1) creating a centralized mechanism to consent, collect and bank human biospecimens 2) Organizing, de-identifying, and annotating subjects' samples linked to their clinical data 3) Establishing multidisciplinary involvement of pathology departments 4) Enhancing quality control measures to achieve CAP and NYS DOH accreditation. To address these considerations, we created a Universal Consent (UC) form; developed a Laboratory Information Management System that assists in specimen organization and links subject samples to clinical data in their electronic medical record and fostered a partnership between the pathology department, individual researchers and the CBRD to develop best practices in biobanking.

Results: Since June 2016, using the UC, 18,906 of 27,355 (70%) subjects agreed to use their specimens and data for research. 9,054 patients had specimens collected using the UC and additional specific consent if needed. We collected 4,178 unique samples (tissue, blood and fluids) - 13,969 aliquots by the UC method and 7,713 samples from fresh and archival collections for specific research studies or clinical trials. The CBRD supported 93 research projects and 251 clinical trials.

Conclusions: Establishment of the CBRD permitted the increase in absolute number of patients approached for research; enhancement of specimen quality and organization and introduction of the electronic crosslink to minimize the time and

overhead needed for clinical data retrieval. Building on this success, we are upgrading our IT infrastructure to expand upon the data collected, digitalizing tissue slides to improve quality control and building an automated molecular genotyping database using existing NGS data to increase the number of translational research projects.

PBP-14 Improvement of the Service Quality Promotes Sustainable Development of Biobank

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Objective: The researchers' requirements on the biobank are raising with the comprehensive development of scientific research work in our hospital. How to improve the service quality for the scientific research become the first tasks of the biobank.

Method: First, to provide high-quality samples with accurately related data timely, we collect and process biological samples and related information strictly according to the standard operating procedures of our biobank, and communicate with the surgeon in time to make works more efficient. Second, to provide the fast service for researchers, we optimize and streamline the application and procurement process. Third, we provide statistics analysis result on the volume and hispathological types of all samples stored in our biobank to researchers in time, which can help to increase more research ideas. Fouth, we continuously improve the professional ability of the biobank staff, and improve the sense of responsibility and professionalism of all staff through daily training and practice. Finally, all staff were actively participated in the discussion and construction of biobank standards, and timely correct and improve the work flow.

Results: At present, 61393 cases of tumor tissue samples, 1000 cases of body fluid samples and 137274 cases of peripheral blood samples have been collected and stored in the biobank. Among them, 117738 samples have been provided for research, which supported 443 projects and related scientific research services, and published 937 articles. The SCI paper was published with a total impact factor of 3851, and the high-impact factor article increased significantly in the past 10 years.

Conclusion: High-quality biological samples are the soul of the biobank. Our biobank is regulated and operated in strict accordance with the standard operating procedures, which can effectively improve the service quality of the sample library and improve the domestic scientific research level.

Keywords: scientific research services; biological samples; quality of service; biobank

PBP-15 Truman Medical Centers Biobank: Biobank Participation Disparities Within a Catchment Area

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Statement of Problem: The University of Kansas Cancer Center (KUCC) is in a unique geographical location as the metropolitan area it resides in, Kansas City, is split between two states, Kansas and Missouri; but this also presents unique problems. While KUCC is based out of the Kansas side and can provide access to its underserved, it can be challenging to provide the same access to the underserved on the Missouri state side within the catchment area without the support of statewide infrastructure programs. This trickles down to the problem of disparity in biobank participation for challenging catchment areas.

Proposed Solution: This was the scenario presented to Truman Medical Centers (TMC), a safety-net hospital located in the Kansas City Metro on the Missouri state side and within KUCC's catchment area. TMC wanted to provide its population access to an NCI-Designated institution and by having KUCC within the same catchment area of the Kansas City Metro, they decided to partner with KUCC through its outreach network, Midwest Cancer Alliance (MCA), giving its population access to NCI designated cancer care and research. This partnership led to the design and construction of a biobank laboratory. This biobank is able to host KUCC's NCI designated biobank protocol through agreements between TMC's and KUCC's institutional review boards (IRB). TMC's underserved population now have the opportunity to represent themselves with biobank related studies and activities from an NCI-Designated Cancer Center.

Conclusion: TMC's biobank was able to have significant impact by enrolling 235 from when operations began in December 2014 through the year 2017. This increased minority enrollment to the KUCC biobank protocol by 25% over that same period. Not only was this collaboration able to increase minority enrollment into the biobank, which is a common challenge and disparity; it was able to incorporate an entirely different minority population from a safety-net hospital representing other social economic disparities. This would not have been possible without the commitment TMC has to provide everything possible to its population concerning health care and health research. Lastly, TMC's biobank highlights the importance that institutions within the same catchment area should and are able to collaborate with one another.

PBP-16 Biobank Issues? Put a Sample Service Coordinator into Your Research-Life

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The long tradition of registers and biobanks in Sweden has generated a propitious climate for research and clinical trials within the country using human biological samples. Given the importance of samples for biomarker research for diagnosis, prognosis and treatment for patients, there has been a clear increase in the development and use of biobank services.

However, the field of biobanking is complex and demands specific skills to support researchers not only for starting new sample collections, but also for accessing the existing ones, fulfilling all the requirements established by the Swedish Biobanks in Medical Care Act.

For this purpose, the newly formed national biobank infrastructure, Biobank Sweden, has incorporated in their structure the role of Sample Service Coordinators (SSCs) in order to meet the demands and needs of researchers. SSCs are spread around

the country in the seven different universities with university hospitals, employed by the Medical Faculties, and serve and act in their correspondent biobank facilities within the region. Therefore, SSCs can be found in Gothenburg, Linkoping, Lund, Orebro, Stockholm, Umea and Uppsala.

The main SSC role is to operate by facilitating the workflow for researchers interested in starting a new national study involving new sample collections or cohorts. It is a special logistical challenge to ensure that preanalytical sample handling is performed in a standardized way to assure comparable sample quality regardless the site of sampling. Moreover, SSCs will provide researchers with advice and guidelines to get access and retrieve samples from existing sample collections/cohorts, as well as to encourage the scientific community to collaborate, use and give value to all the collections stored in the different biobanks within the country.

Apart from the national scope, SSCs will also have a regional strategic function by developing a local workflow which fits in a tight manner within the national coordinated biobank services.

All this together make the SSC a key resource for researchers to create, find, access and retrieve samples for local, regional and national research studies that could lead to the discovery of better biomarkers and therefore, to better health and quality of life.

PBP-17 Training Future Experts in Next Generation Biobanking. MSc Biobanks and Complex Data Management at the Université Côte d'Azur, Nice, France

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Statement of the Problem: Biobanks are essential tools for translating research into clinical practice for global healthcare treatment. The rapid growth of personalised medicine has increased demand for biological resources along with the clinical and biological associated data. However, despite significant progress in responding to several issues of Biobanking, operational and sustainability challenges still remain.

Preparing the future experts in Biobanking should be one of the main goals for the Next Generation Biobanking. The high demand for instructing specialists in the field of Biobanking has made the requirement for well-structured postgraduate training and education frameworks. Future leaders of biobanks worldwide require abilities and specific training in management as well as deep analysis of new challenges.

Proposed Solution: The University Côte d'Azur in Nice, France, faced this essential need with its newly launched MSc Biobanks and Complex Data Management, (http://univ-cotedazur.fr/MSc Biobanks-complex-data). The main goal of this Master is to provide knowledge and practical skills that will qualify graduates for the management of the multidisciplinary field of Biobanking (humans, animals, plants, and other living organisms) and complex data including intelligence artificial approaches. Master's students will be confronted to world leaders operating in the Biobanking sectors including quality, ethics, legislation, social issues, safety, project management, economic model, complex data management, international networks, communication and marketing. The program is completed over 2 years, with 2 internships of 6 months in Biobanks worldwide. The Master program is supported by Academic institutional partners such as the University Hospital Federation «OncoAge», ''Biobanques'' Infrastructure, Nice University Hospital, the French National Institute of Agricultural Research (INRA), and the French Institute for Research in Computer Science and Automation (INRIA), as well by industry partners.

Conclusions: The skills that the graduates of the ''MSc Biobanks and Complex Data Management'' obtain through education and then through application within internships and continued development in their working lives will make them resilient to and thrive on the inevitable impact of disruptive changes in biomedicine. Next Generation Biobankers will be the new key players in a rapidly growing list of 21st century biomedical organisations.

PBP-18 Bio-banking Platform for Precision Cancer Medicine at the Southwest Hospital

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Background: The ''Precision Medicine Initiative'' is considered to be a new era of medical care and has been listed as key projects by many countries. Cancer research, due to its heterogeneity and complexity, is one of the best fields for the practice of precision medicine. The successful development of this research requires a variety of omics-based big data, which is based on the collection and management of a large number of patient samples and complete clinical information. To this end, Southwest Hospital, one of the best hospitals in southwestern of China, established a clinical biobank in 2014.

Methods: Biological specimens were collected from the tumor patients at Southwest Hospital in accordance with the ethical rules of Southwest Hospital. Based on the preoperative diagnoses, surgeons determined the specimens including fresh human pathologic and normal tissues, blood and urine for sample collection. Samples were collected, treated, stored and registered by experienced residents following our standard operating procedures. Further processes such as paraffin section, frozen section, HE staining, DNA, RNA and tissue microarray will be done by inquiry.

Results: In total, 36 tumor specimens including glioma, breast carcinoma, rectal cancer, hypophysoma, lung cancer, etc. were collected with the total number of cases reached 4,970 and the total sample copies reached 114,359 (41,657 frozen tissues, 6,025 paraffin embedded tissues, 32,789 blood specimens, 729 patient derived primary cells and others) from 2014 to 2018. Among them, nearly half of the samples (53,430) are gliomas, which greatly promoted the clinical and translational medicine research in the field. For example, the biobank fully assisted the research of 70 projects and 6 domestic and international awards of the Institute of Pathology (one of the pioneers in glioma research), Southwest Hospital. In addition, we also supported 12 articles published in well-known magazines such as Nature, Nature Neuroscience, Science Translational Medicine, Cell Research, etc.

Conclusion: We have successfully established a set of mechanisms for the collection, processing, storage and use of clinical samples, and promoted the scientific research of cancer biomarkers, molecular mechanisms of tumor initiation and development, laying a foundation for clinical medical transfor-

mation. This will greatly promote the development of precision cancer medicine and benefit patients.

PBP-19 A Brief Introduction of CHCMU BioBank Center

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Background: A major roadblock in pediatric research in China is the unavailability of high quality biosamples with standardized clinical annotations. The Children's Hospital of Chongqing Medical University (CHCMU) is one of best top children's hospital in China, and undertook the initiative to establish the southwest pediatric biobank in 2018.

Method: Based on the standardized procedures for establishing biological specimen banks, the operational processes and quality management system were formulated. At the early stage, children were enrolled for the collection of healthy physical examination specimen, respiratory disease system specimen and primary immunodeficiency disease specimen.

Result: Until 2018, 11,000 clinical data and biological samples are being collected from primary immunodeficiency disease children and during the same period a total of 41,700 biological samples have been collected from respiratory disease children, including sputum, blood, serum, plasma, PBMC, and clinical data. Meanwhile, healthy children samples were collected, and cryopreserved as serum, plasma and whole blood.

Conclusion: CHCMU has established a standardized clinical biobank based on children's biological samples. With the use of these samples and clinical transformation of research, it will help promote the pediatric research and improve children's health.

PBP-20 Successful Integration of Biobanking in Hospital Workflow

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Statement of the Problem: In a hectic hospital day with focus on patient care, it can be challenging to collect high quality biobank material in an efficient manner.

Proposed Solution: In the central part of Norway, we have established one clinical research biobank, Biobank1®, which is meant to serve the whole region.

Thematic research biobank for cancer, organized by Biobank1®, is an assembly of various collections from patients who are under investigation or diagnosed with cancer.

This is a general biobank, meaning that material is collected for future cancer research, with not yet defined hypothesis. The groups of patients included suffer from one or more of these types of cancer: kidney, prostate, bladder, colon and rectal, lung, testicular, lymphoma, pancreatic, multiple myeloma and leukaemia. The material collected is fresh frozen tissue, pre- and postoperative blood samples (serum, plasma and buffy coat).

The intention with this biobank is to collect samples with minimal intervention for the patients. Diagnostics is the most important focus for the patient, and this aspect will be taken care of when the biobank material is collected synchronously with the patient care program. Due to this, we have organized an applicable room for biobanking tissue next to the operation theatres. This makes the logistics effective and maintains the quality of the samples. Blood samples are taken at the same time as routine tests and sent directly to the hospital routine laboratory, which takes care of the biobanking procedures.

We have successfully integrated the biobank sampling within the hospital workflow!

Dedicated personnel register sample and patient information, according to the CEN/TS technical specifications prepared in the BBMRI-network. This information is securely stored in a biobank data system, BIOBYTE®, and is necessary for retrieval of samples for future research projects.

Conclusions: In Thematic research biobank for cancer, Biobank1® has organized efficient collection of biological samples from cancer patients, with minimal intervention and maintenance of sample quality. This will contribute to increased research on cancer in the health region. The purpose is to increase knowledge about the causes and mechanisms of cancer in order to improve prevention, diagnosis and treatment.

PBP-21 Past, Present and Future of the Victorian Cancer Biobank

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Past: The Victorian Cancer Biobank (VCB) is one of the most prominent not-for-profit biobanks that has evolved over the years, its biobanking model has been widely used in benchmarking analysis in the industry. The VCB was established in 2006 as a consortium with support from the Victorian Government, in order to provide high quality clinically annotated biospecimens to the academic and commercial cancer research sectors. Members of this consortium included five major Victorian health precincts (25 hospitals) with Cancer Council Victoria as the lead agency. Since 2013, VCB has transformed from the all-kind collection model to a supply and demand model whereby collection is tailored to researcher requests and replenishing high demand tumour streams. As of 2016, VCB transitioned into a more efficient web-based biobanking informatics platform known as OpenSpecimen, to allow for better management of biospecimens and associated clinical data.

Present: To date, VCB has recruited more than 27,000 donors, with more than 430,000 specimens banked. VCB is currently supporting 40 active projects with 11 papers published last year acknowledging the contribution of VCB. Such services include provision of retrospective biospecimens and associated clinical data, project specific collection and processing, construction of tissue microarray, and support of multiple clinical trials. Currently VCB is undergoing modernisation and harmonisation of operational practices to develop a quality management system that will emulate accreditation standards. The approaches include enhancement of the existing informatics and data management platform to incorporate all aspects of the

biobanking workflow, data linkage with the Victorian Cancer Registry (VCR) to improve data quality and enhance annotation of new cases, and adoption of ISO standards.

Future: Academic and commercial engagement is one of the main priorities that VCB is striving to maintain and improve. VCB will utilise the social media and workshops to improve and strengthen stakeholder relationships with the researchers, funding body, biobanking community and the consumers. The integration of the VCB into VCR provides opportunities to improve the interoperability of the annotated clinical data for translational research. As a not-for-profit biobank, the VCB will continue to aim for excellence in service by continuous improvement of the biobanking processes in a sustainable setting.

PBP-22 Biobanking for Clinical and Translational Research Programs: An Integrated and Innovative Model for a Hybrid Academic-Community Cancer Center

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Statement of the Problem: Human biospecimens (tissues and fluids) are an essential foundation for effective translational and genomics-based cancer research and have proven to be critical for the development of personalized cancer medicine. The demand for more high quality and clinically annotated biospecimens and the challenge of finding them to conduct clinical research or validation studies have grown rapidly, primarily due to an unprecedented level of genomic, post-genomic and personalized medicine research. The increased complexity of biospecimen requests in terms of linked pre-clinical variables, biospecimen types, and multidimensional longitudinal clinical data has created new challenges but also opportunities for adapting collection and annotation strategies to meet the biospecimen supply requirements of the future.

Proposed Solution: In response to this critical need, and after identifying a distinctive niche, the Miami Cancer Institute established the Biospecimen Repository Facility as part of its Center for Genomic Medicine. The Institute is a hybrid academic-community cancer center that enhances patient access to quality cancer care and clinical trials. It serves one of the most ethnically diverse populations in the continental United States: 67% of the population is of Hispanic ancestry. Biospecimens obtained from cancer patients are managed through a standardized, reliable and cost-effective approach and are used to support translational and clinical research programs. An innovative operational model uses master workflows that articulate standard operating procedures, a backbone laboratory information management system and highly specialized technical staff to support three operational areas: default biobanking activities, targeted collection and biospecimen management for clinical trials and correlative science.

Conclusion: The Miami Cancer Institute Biospecimen Repository Facility provides resources and services to expedite discoveries and their translation to more effective diagnostics, prognostics and therapeutics. In a unique hybrid setting, it operates using a model that adapts to the complex and ever-shifting oncology research landscape and makes available biospecimens from an ethnically diverse population.

Biodiversity/Environmental/Animal Repositories

PBE-01 Biodiversity-Pathogenic Microorganisms

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Pathogenic microorganisms cause a wide range of infections diseases including pneumonia, UTIs, bloodstream infections, and sepsis, and even death. These infections are particularly a problem among neonates, elderly and immunocompromised individuals. Despite early triumphs over infectious diseases with the development of vaccines and antibiotics, new and F are continuously emerging. The increasing isolation of multidrug resistant strains has significantly narrowed, or in some settings completely removed, the therapeutic options for the treatment of infections. Not surprisingly, this pathogen has then been singled out as an 'urgent threat to human health' by several organizations. Overall, hypervirulent and multidrug-resistant pathogenic microorganisms is a critical health care concern. However, the lack of the collection and preservation of those strains are common. Therefore, it is important to establish a system of preservation of pathogenic microoganisms.

The isolates from patients should identified by 16S rRNA. The identification of the isolates should be used the Vitek II system and manual biochemical identification when necessary. Antimicrobial susceptibility testing should performed on all isolates by the Vitek II system or Etest. Susceptibilities should categorize according to Clinical and Laboratory Standards Institute (CLSI) guidelines. And the strains should to subject to whole genomic sequencing and analysis.

In summary, surveillance of pathogenic microoganisms especially in multidrug resistant and hyper-virulence is urgently required to generate essential information for preventing their spread.

PBE-02 Of Mice and Men: Establishing a Sustainable Pre-Clinical Biobank for the University of Newcastle

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The Hunter Cancer Biobank (HCB) was established in 2012 in partnership with the University of Newcastle (UoN), Local health district hospitals, and NSW Health Pathology. HCB is actively working towards diversification and innovation to ensure economies of scale and resource efficiency. Integration with existing infrastructure, and the development of mutually beneficial initiatives, is key to sustainability and HCB have explored a number of challenges faced by its partners including expenditure on pre-clinical research models.

UoN invests approximately $380,000 a year purchasing pre-clinical models – excluding maintenance or administrative costs. Given pre-clinical research is predominantly driven by interest in a specific phenotype, anatomical location, tissue or genotype – the majority of tissue, not integral to the specific study, is often discarded.

Many researchers have developed their own biobanks in an attempt to preserve resources and mitigate waste. Many of these collections are stored in individual laboratories, uncatalogued or documented in paper-based files and are in danger of being discarded. There is no system in place for managing this resource at UoN and thus this growing repository cannot be utilised to its full potential. The UoN Pre-Clinical Biobank is a collaboration employing HCB infrastructure and protocols to catalogue, store and re-distribute animal tissue for future research.

Once catalogued, samples will continue to be stored in their current locations until they can be moved to a central storage facility. Tissue requests will be managed by Biobank staff and the scientific review committee who will assess donations–ensuring only quality tissue is banked.

Engagement with key stakeholders is essential for success and these conversations are progressing well, with resource incentives planned to avoid a reliance on altruism for donors. We are negotiating an opt-in field on all UoN animal ethics applications for the storage of excess tissue, complemented by existing guidelines stating approval for new models will only be granted when banked alternatives are unsuitable.

The UoN pre-clinical biobank will open new frontiers for HCB, expanding our scope and diversifying workload, while also ensuring economies of scale across the university. The provision of this service will attract further collaborations in both local research communities, international institutions and industry – a substantial step towards sustainability.

PBE-03 Biobank at Biomedical Primate Research Centre (BPRC), Rijswijk, The Netherlands: Implementation of the 3Rs Principles (Replacement, Reduction and Refinement)

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Tissue and genetic material obtained from non-human primates (NHP) represents a valuable resource in biomedical research. However, offering and obtaining this type of material is often limited, time demanding and needs high expertise. As pressure grows for reduction of numbers of animals used in research, the Biobank is becoming an attractive alternative source for testing scientific ideas, pathophysiological mechanisms and testing new vaccines and biologicals before proceeding to pre-clinical studies.

The BPRC's Primate Biobank is the biggest nonhuman primate Biobank in Europe and it is based on the principals of the 3Rs: refinement, reduction and replacement (3Rs). The aim of the Biobank is to provide rare and valuable primate specimens both for internal use and for external scientists who can use the material for biomedical research as well as for conservation studies.

BPRC's nonhuman primate biobank consists of:

1. Tissue bank: organs, tissues and cell lines. Organs without morphological alterations from clinically healthy retired animals and tissue samples from animals of different species with experimentally induced or spontaneously developed pathological conditions and syndromes are available. The organ- and tissue- collections include snap frozen tissue samples stored at −80 C, samples fixed in 10 % neutral buffered formalin (NBF), formalin fixed paraffin embedded (FFPE) tissues and cell lines frozen and stored in liquid nitrogen. Scientifically valuable resources are available for the research community and are comprised of catalogued frozen tissue collections such as: a/brain samples from different brain regions of young and aged NHPs and apes; b/reproductive organs from different NHP' genders; c/bone collections, d/lymphoid organs and collections of all internal organs

The primary focus is on the following primate species: Rhesus macaques (Macaca mulatta), Long-tail macaque (Macaca fascicularis) and Common marmoset (Callithrix jacchus). Samples from endangered species such as great apes - Common chimpanzee (Pan troglodytes) and Orangutan (Pongo Borneo) are also collected.

2. Blood, Serum and Gene bank: Serum and plasma samples are available. DNA, RNA, cDNA samples are adequately stored at +4, −20 or −80°C. The species identity and the quality of the materials are tested by standard laboratory-based technologies. PBMCs and/or immortalized B-cell lines of macaques, marmoset and chimpanzees are stored in liquid nitrogen.

PBE-04 Biobanking of Indian Wild/Endangered Species

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Natural breeding is the best method to increase/restore the diminishing population of wild/endangered species. The advancement of reproductive technologies in domestic species have been provided a tool to increase the wild/endangered animal population when natural breeding is ineffective, but the success in terms of the live offspring is very low. This may be attributed to the lack of basic knowledge about the reproductive functions of wild animals and its gametes. The ability to rescue and preservation of gametes and tissues immediately after the death of wild/endangered species is one of the promising approaches for building basic knowledge of gametes for development of species-specific protocols for assisted reproductive techniques, holds tremendous potential for conservation of wild/endangered species. Generation of embryos using these gametes would be helpful to regenerate the species by embryo transfer when the need arises. Somatic cell nuclear transfer / cloning is one of the existing reproductive technologies to regenerate the species even after extinct. This technology depends on the availability of somatic cells of the species to be regenerated. To establish National Wildlife Genetic Resource Banks (NWGRB) for Indian wildlife, we have been working on collection and preservation of tissues, cells and gametes from the wild animals that have been died due to accidents, medical or old age. So far we have developed primary cells of various wild/endangered species (no: 23) and preserved in National wildlife Genetic Resource Banks at Laboratory for The Conservation of Endangered Species (LaCONES) for future applications. Oocytes were also collected and preserved from the ovaries collected postmortem of different wild animals (chousingha, rusty-spotted cat, mouse deer, etc.) postmortem and their developmental ability was also tested by in vitro maturation and fertilization in few species. The cells or gametes preserved in this bank will be useful to specie specific reproductive methods as well as research in wild species. NWGRB at LaCONES has all the facilities to preserve various biological samples such as DNA, RNA, blood tissues and gametes.

Biospecimen Research and Science

PBR-01 Cryopreservation of Whole Tumor Tissue

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For years, researchers have been exploring different methods of cryopreservation. Whether it be for single cells, whole tissues or even whole organs, scientists are still coming up with newer and safer methods of freezing and thawing viable tissue. The most common form of cryopreservation for research labs today is digesting tissue into single cell suspensions and freezing them in media containing 5–10% DMSO. While this may be a good method for a lot of single cell assays, it is both time and resource-intensive for the biobank. Single-cell suspensions may also no longer be 'fit-for-purpose' for PDX or organoid model creation.

As science advances and evolves, biorepository methods must also evolve. Researchers have been requesting viable tissue and cells for downstream assays, ie. single cell RNA seq, organoid, and primary cell culture development. Locally, our biorepository is becoming a ''living'' Biobank, storing viable human tissue samples in a manner that can be used for many applications requiring live cells.

We sought to develop a general, quick and inexpensive method to cryopreserve tissue. After an extensive literature review, we proposed to test the success rate of our proposed protocol. For the study, we procured samples of sarcoma and prostate tumor tissue. Working in a laminar hood, we finely minced each sample with a sterile razor blade to about 1mm3 chunks and placed them into two separate cryovials since the starting material was relatively large at ~1cm3. We added 1.5mL of our freezing media made up solely of 20% DMSO/FBS, then placed them in a slow freezing cooler at −80°C. The following day samples were placed in the liquid nitrogen vapor tank for storage.

For viability testing, we pulled one sarcoma and one prostate sample from the liquid nitrogen tank. Tissues were placed into sterile petri dishes and further minced with scissors, then incubated at 37°C in a special digestion media (collagenase-hyaluronidase/dispase/F-Media) for 5 hours, vortexing for 30 seconds every 30 minutes. Trypsin was then added to the samples at a concentration of 2.5% and incubation/vortexing continued for another hour. Cells were subsequently plated and left at 37°C ON to recover. The following day cells were counted using Trypan Blue exclusion. Both samples were at 80% viability, making these samples more than suitable for assays and procedures requiring live cells.

PBR-02 Frequencies of HLA Class I Alleles in HIV-1 Infected SM Cohort and MSM Cohort of China

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Background: Human Leukocyte Antigen (HLA) is reported with the progression of disease, especially in HIV infection. However, the distribution of HLA alleles varies amongst different populations. Here, we report the HLA class I alleles in HIV-1 infected SM cohort and MSM cohort of China.

Methods: 258 samples of ShuangMiao (SM) cohort and 448 samples of men who have sex with men (MSM) cohort were collected from the AIDS biobank of Beijing YouAn hospital. SM cohort were infected more than 10 years and MSM cohort is more rapid progression. Genomic DNA was used to determine HLA types. HIV Molecular Immunology Database HLA Analysis Tools (http://www.hiv.lanl.gov/content/immunology/tools links.html) were used to analysis the HLA molecular typing.

Results:

1. HLA class I alleles in SM cohort

HLA-A alleles is dominated by HLA-A*02 (52%), HLA-A*11 (25%), A*24 (29%). HLA-B*40 is most prevalent at 26%, and a diverse array of other commonly expressed HLA alleles are observed at a frequency of 10–20% (including HLA-B*13, -B*15, -B*46, -B*51 and -B*58). HLA-Cw*03 as the dominant allele contributed 32%, followed by HLA-Cw*07 (29%), HLA-Cw*06 (28%), HLA-Cw*08 (22%) and HLA-Cw*01(19%).

The most common HLA-B/C haplotypes are HLA-B*40/Cw*03 (4.56%). The highest frequency of HLA-A/B haplotypes are HLA-A*02/B*40(5.36%). The most frequent HLA-A/C haplotypes are HLA-A*02/Cw*03(8.19%).

2. HLA class I alleles in MSM cohort

The HLA-A alleles dominated by HLA-A*02 (51%), HLA-A*11 (37%), A*24 (29%). HLA-B*13 in MSM cohort is most prevalent and the frequency is at 19%, the frequency of HLA-B*46, HLA-B*60 and HLA-B*62 at 14%. HLA-Cw*07 as the dominant allele contributed 30%, followed by HLA-Cw*01(27%), HLA-Cw*06(23%). The most common HLA-B/C haplotypes are HLA-B*15/Cw*03(14.28%). The highest frequency of HLA-A/B haplotypes are HLA-A*02/B*15(19.64%). The most frequent HLA-A/C haplotypes are HLA-A*02/Cw*03(24.55%).

3. Compare the HLA Class I Allele Frequencies between SM cohort and MSM cohort

An increase in alleles HLA-A*11, HLA-CW*01 in MSM cohort and a decrease in HLA-A*30,-A*33,-B*15,-B*40,-B*51,-B*57,-B*58 and -CW*03 in MSM cohort, compared with SM cohort. In SM cohort, there were about 17.90% were HLA-B51 positive, the percentage of HLA-B51 in MSM cohort was only 10.94%.

Conclusions: HLA-B51, HLA-B57, HLA-B58 are associated with better disease outcomes. So, the difference of HLA typing in SM cohort and MSM cohort may partly explain why MSM cohort is more rapid progression of HIV-1 infection.

PBR-03 Optimization of Human Skin Biopsies Derived Fibroblast Culture for Reprogramming into Induced Pluripotent Stem Cells

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Background: Human induced pluripotent stem cells (iPSC) offer an unprecedented opportunity for disease modelling and drug development. However, the variability of the iPSC quality attributes remains a severe limitation. Here we report the selection of an optimal processing method for culture, passaging and cryopreservation of fibroblasts after isolation from skin biopsies to obtain cells that can be successfully reprogrammed into iPSC using the SimpliconTM RNA Reprogramming kit.

Methods: The method optimization was performed in two phases: the assessment of feasibility followed by the optimization of specific processing parameters. These parameters were the dissociation technique used to isolate fibroblasts from skin biopsies and the cryopreservation conditions of these fibroblasts.

Skin biopsies were disrupted by different dissociation techniques using either a chemical separation, a physical separation or a combination of both techniques.

Fibroblasts were cryopreserved using either supplier-based or home-made cryopreservation media, containing 10% Dimethyl sulfoxide (DMSO).

Results: The selection of the optimal dissociation technique was based on growth curves, post-thaw recovery (%), viability (%) and karyotyping analyses of the fibroblasts.

The selection of the optimal cryopreservation condition was based on growth curves, post-thaw recovery (%), viability (%) and efficient reprogramming of fibroblasts, as assessed by the number of iPSC colonies obtained at the end of the reprogramming. iPSC were characterized by immunofluorescence, real-time PCR and three-germ layer differentiation.

Conclusions: The combination of the physical separation technique and the home-made cryopreservation conditions were selected as the optimized conditions for high yield and suitable quality of the output fibroblasts. Standardization of the fibroblast culture processing method would allow researchers to minimize factors contributing to variability in iPSC behavior.

PBR-04 Effect of −80°C Storage on RNA from Snap Frozen Placental Tissue

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Background: Cryopreservation is integral to biorepository operations but inherently stressful to tissue. Ribonucleic Acid (RNA) is a vital part of biomedical research but because of the ubiquity of environmental RNAase and the fragility of RNA, researchers prefer to use fresh tissue for requests. However, fresh tissue can be difficult to offer given the limitations of tissue transport, study inclusion criteria, and biorepository staffing. Being able to offer researchers frozen tissue with an estimated RNA quality would expand opportunities in maternal research.

Methods: The Medical College of Wisconsin (MCW) Tissue Bank undertook a quality control (QC) study to assess the RNA quality of cryopreserved placenta samples stored for differing amounts of time in −80°C. Samples were collected as 75–100-micron sections using a Leica Cryostat from OCT embedded snap frozen placenta tissue and isolated using a QuickGene 810 and Kurabo RNA from Tissue Kit. Quality and quantity of RNA was assessed using a NanoDrop 2000 spectrophotometer. Analysis of Variance (ANOVA) was performed to compare the ratios among the three groups and a t test was used for comparison between two groups. A $P < 0.05$ was considered significant. The three cohorts of six samples each were stored for >18 months, 13–18 months, and <12 months for a total N of 18.

Results: There was no statistically significant difference among the three cohorts in A260/A280 ratio ($P = 0.066$) or in A260/A230 ratio ($P = 0.21$). Comparing the >18-month cohort to the combination of the other two cohorts <18-months old showed that the older cohort had a significantly lower A260/A280 ratio (1.91 ± 0.07 vs 1.78 ± 0.13, $P = 0.018$) but there was no significant difference looking at the A260/A230 ratio ($P = 0.13$). The range of A260/A280 ratios across all 18 samples was 1.58 to 2.01; ratios close to 2.0 are considered pure. The A260/A230 ratios ranged from 0.18 to 1.26 across all 18 samples; high A260/A230 ratios relative to the A260/A280 ratio or ratios higher than 2.0 are considered pure.

Conclusions: These results suggest that RNA quality is resilient in −80°C up to 18 months and that banked normal placenta specimens can be used for RNA acquisition. Further testing is necessary to determine full research applications of RNA from frozen tissue and factors contributing to sample quality.

PBR-05 DMSO Protects Protein from Degradation During Exosome Storage

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Background: Exosome has received more and more attention in recent years. Therefore, established the optimal storage method to avoid the molecules in exosome from degradation is extremely valuable.

Aim: To investigate the effect of Dimethyl sulfoxide (DMSO) and Freezing-Thawing on the protein amount of exosome.

Methods: Exosomes were extracted from ten cases of pleural effusion collected from patients with lung cancer, and then were freeze–thawed by three times in PBS buffers with or without 10% DMSO. The specific protein CD63 and CD9 were determined by western blot. The gray intensity of each band on a western blot was measured by Image J software.

Results: Totally, the CD63 and CD9 protein levels are significant higher in 5/10 and 6/10 cases in the PBS with 10% DMSO group than those in the PBS control group by western blot, and the gray intensity of CD63 and CD9 protein qualified Image J software in the PBS with 10% DMSO group were higher than those in the PBS control group whether they are treated with repeated freeze/thaw or not.

Conclusion: Taken together, the above data suggest that exosome protein is more stable in the solution supplementary with 10% DMSO, but not affected by repeated freeze/thaw cycle. Adding extra DMSO may be useful for exosome preservation.

PBR-06 The Mechanism Underlying Sperm Cryoinjury for Semen Cryopreservation in Small Ruminants

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Semen cryopreservation is an important tool to maintain the genetic diversity and preserve endangered species. Development of an efficient sperm cryopreservation procedure will contribute to long-term conservation of small ruminant genetic resources. However, mammalian sperm are susceptible to cryoinjury induced by ice formation and lipid peroxidation. Particularly, lipid peroxidation causes functional and biochemical changes in sperm, consequently leading to the formation of reactive oxygen species. Therefore, research efforts are focusing on finding a well-defined freezing protocol to mitigate oxidative stress on sperm. But, approximately 50% post-thaw sperm lose their viability. In sheep, only 20%–30% post-thaw sperm are biologically functional. Small ruminant sperm are well known to be sensitive to oxidative stress, owing to the high membrane concentration of unsaturated fatty acids and to its limited antioxidant and membrane repairing capacity. Currently, little is known about the molecular mechanism regulating sperm

cryoinjury. The effects of cryopreservation on several specific proteins or genes of sperm have been tested in some sporadic studies. However, these studies cannot completely reflect the molecular nature of sperm cryodamage. Recently, the fast development of proteomics or transcriptomics gives some inspirations to explore this problem. Different from traditional molecular methods, proteomics or transcriptomics can get an enormous amount of genetic information. Via the omics analysis, some biomarkers potentially used for assessment of frozen sperm quality may be identified. However, how to make use of the vast information derived from proteomics or transcriptomics remains a great challenge. For instance, some proteins or RNAs which may function as biomarkers have been identified. However, the efficiency of these markers still needs tests.

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PBR-07 Influence of Different Collection Conditions on RNA Integrity of Tissue Samples

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During the collection of samples, the quality of tissue samples could be affected by many operations, including ischemia time, transport mode, the duration of temporary storage and the size of tissue block. Molecular biology research usually requires high quality of total RNA, so the purpose of this study was to observe the effects of different collection conditions on the quality of total RNA. In this study, the kidney tissues of mice were used and the effects of four factors mentioned above on the quality of total RNA were observed. A single factor experiment was conducted to explore the collection conditions which ensured that the quality of total RNA was best for tissue samples. After comparison, tissues should be collected within 30 minutes after being resected and immediately put into the liquid nitrogen for storage. The tissues should be cut into small pieces and the size of each piece was preferably about $0.5 \times 0.5 \times 0.5$ cm. In addition, it was best to transport the tissue samples in the −20 degrees Celsius transfer box. Once the tissue sample is resected, RNA degrades soon. Therefore, tissues should be cut into suitable pieces as soon as possible and immediately transferred to liquid nitrogen for temporary storage. In the process of transport, the tissue samples should be placed at a relatively low temperature as much as possible, which can protect the sample from degradation.

PBR-08 The Effects of Resveratrol on Goat Sperm Quality Parameters During Cryopreservation

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Currently, it is necessary to develop a standard sperm cryopreservation procedure for preservation of small ruminant genetic resources. However, the membranous structures of the sperm, such as plasma membrane and outer acrosomal membrane, are sensitive to cryoinjuries. Additionally, sperm membrane structure contains rich unsaturated phospholipids which lead to their high susceptibility to lipid peroxidation. Lipid peroxidation results in the formation of reactive oxygen species, finally damaging sperm structures and functions. The aim of this study was to evaluated the protective effects of resveratrol on frozen goat semen. Semen was collected from eight Yunshang Black bucks using artificial vagina. The semen was extended with optidyl supplemented with resveratrol at 0, 0.1, 1, 10, 20 μM. Following equilibration, the straws were frozen, and then plunged into the liquid nitrogen. After thawing, sperm motility, acrosome damage, membrane integrity, and distribution of phosphatidylserine (PS) were measured. The percentages of progressive sperm motility and plasma membrane integrity were significantly higher when the semen was frozen in optidyl supplemented with 10 μM resveratrol ($P < 0.05$). But, the post-thaw PM in the 20 μM resveratrol group was significantly less than those in other groups ($P < 0.05$). However, no differences were observed in total motility, acrosome integrity, and PS distribution between all extenders ($P > 0.05$). Based on our findings, resveratrol improve progressive motility and plasma membrane integrity during cryopreservation. Future efforts are needed to find the appropriate concentrations of resveratrol in order to improve post-thaw sperm parameters and fertility.

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PBR-09 Separation and Clinical Value of Immune Cells in Ascites and Hydrothorax

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Background: Malignant ascites and hydrothorax are one of the most significant clinical features of various intra-abdominal carcinogenesis. The components of malignant ascites are complex, including cellular components and supernatant. To investigate the immune profile of malignant ascites and hydrothorax, the SOP of separation of immune cells from these samples was established and the number and proportion of immune cells in ascites and hydrothorax were determined by flow cytometry. One of immune cell components in the tumor microenvironment is myeloid-derived suppressor cells (MDSCs), which promote tumor growth and metastasis directly or indirectly by recognizing other immune cells, producing cytokines and exerting their immunosuppression functions. The distribution and number of MDSCs and lymphocyte subsets could provide an important methodological support for clinical evaluation both in diagnosis and prognosis.

Method: Ascites and hydrothorax specimens were collected from pancreatic and lung cancer respectively. The proportions of MDSC and T cells in ascites and hydrothorax were detected by flow cytometry. The cytokines were measured by BDTM cytometric bead array from the supernatant of ascites and hydrothorax.

Results: A certain type of immune cell components and supernatant were successfully separated by centrifugation, and the isolated cell components were surface-stained including MDSCs (CD11b+CD33+HLA-DRlow) and T lymphocytes (CD3+CD4+, CD3+CD8+). It was found that the proportion of MDSCs in ascites decreased and the proportion of CD8+ T cells increased accordingly upon treatment. In summary, we successfully isolated

MDSCs and T lymphocytes from ascites and hydrothorax, and investigates a certain correlation with the treatment effect of patients, which shows the great significance for evaluating the prognosis.

Conclusion: For the biobank, the SOPs of conventional blood and tissue specimens have been established, but the SOPs for separating and analyzing ascites and hydrothorax are still missing. In this study, immune cells were separated from ascites and hydrothorax samples successfully, and lay the foundation for SOP of the other body fluid specimens. For clinic, the proportions and numbers of MDSCs, T cells and inflammatory factors in ascites and hydrothorax can reflect the therapeutic effect and prognosis of patients to a certain extent, which can be used as a supplementary indication for clinical diagnosis.

PBR-10

PBR-11 Optimizing Thawing Temperature to Improve the Quality of Cryopreserved Human Peripheral Blood Mononuclear Cells

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Thawing is an important step after cryopreservation, suboptimal thawing leads to the impaired viability and functionality of recovered cells. However, literatures on the thawing of cryopreserved human peripheral blood mononuclear cells (PBMCs) are limited. Although protocols usually advise rapid warming in a 37°C water bath, it is necessary to make a better understand on the critical parameters in thawing process, especially on the temperature used to de-freeze cryopreserved PBMCs.

Our findings uncovered the fact that using 65°C as an alternative temperature improves the cell viability and recovery of PBMCs. Furthermore, we performed the phenotypic and functional analysis to assess the consequences of thawing at elevated temperature. Results showed that elevated thawing temperature at 65°C or 42°C did not impair the population distribution of PBMCs, activation and expansion. In addition, IFN-γ and IL-2 secretion level in response to PHA stimulation at 5 ug/ml were much higher in 65°C thawed PBMCs than that in 42°C and 37°C. These data suggest that using 65°C as thawing temperature for PBMCs has better protective capacities in PBMC cell viability, recovery and functionality compared with 37°C.

PBR-12 Utility of Serum Indices for the Quality Control of Biobanked Serum Samples

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The serum index of hemolysis, icterus or lipemia (HIL) is one of the common factors affecting analytical results in clinical laboratory practice. Most biobanks frequently encounter serum samples showing different levels of HIL measurements. However, few studies has been conducted to assess the utility of the HIL index for the quality control of biobanked serum samples. To assess the impact of the serum indices on analytical results and find a better way to control the quality of serum samples, we investigated clinical and pre-analytical variables associated with the HIL indices obtained from subjects (n = 12,000) in a large population-based cohort study. Next, we analyzed proteomic profiles of selected serum samples (n = 240) with low and high levels of HIL measurements. We found the hemolysis index was associated with some SPREC (Standard PREanalytical Code) conditions, but not icterus and lipemia indices. In addition, a proteomic approach using multiple reaction monitoring(MRM) method showed that the level of some proteins including complement C3 was significantly different between groups of HIL and the control group of normal HIL measurements. This results suggest that serum indices of HIL

can be a good surrogate marker for assessing the serum quality in the analytical phase.

PBR-13 Analysis of Feasibility and Stability of Single Cell Transcriptomics in Patient Derived Cryopreserved Blood Cells

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Scarcity of fresh samples from pediatric patients with rare diseases warrants the use of frozen samples and thus creating a critical need to define the single cell transcriptomics in frozen cells. Freeze thaw events and prenalytical variations can impact the gene expression differently in each cell. Here, we performed single cell RNA-seq (scRNA-seq) on both fresh and cryopreserved peripheral blood mononuclear cells (PBMCs) derived from a pediatric patient with congenital heart defect undergoing surgical treatment to determine the feasibility of cryo-preserving PBMCs for use with single cell transcriptomics. Density gradient centrifugation was utilized to isolate PBMCs. scRNA-seq on freshly isolated PBMCs as well as PBMCs from the same patient that were cryopreserved for several weeks, thawed, and washed was performed. Single-cell RNA sequencing was done using the 10X Genomics Chromium Single Cell Controller system, a high-throughput droplet based microfluidic capture technology. Strikingly, we found that both fresh and frozen samples produced highly similar single cell transcriptomes that were of comparable and equally high quality. The average gene expression as well as genes and UMI counts per cell in both data sets (fresh and frozen) were remarkably similar indicating that freezing did not alter the transcriptional profiles. In addition, the cellular identity and proportions were similar indicating the feasbility of our method on both sample types. Through this study, we have generated a protocol for cryopreserving isolated PBMCs indefinitely to capable of producing high quality single cell transcriptomes.

PBR-14 Preanalytical Impacts of FFPE Specimens on Next Generation Sequencing (NGS) Analysis

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Background: The NCI-sponsored Biospecimen Preanalytical Variables (BPV) Program has generated a comprehensive set of molecular profiling data to assess the impacts of cold ischemic time (delay to formalin fixation (DTF), time in formalin (TIF)), freezing methods, and storage temperatures/durations. This study reports 1) the quality of RNA and DNA from the human FFPE tumor specimens collected under DTF and TIF conditions by NGS analysis with matched fresh frozen controls; 2) investigation of the demodification (a DEMOD method) for its potential to mitigate the formalin effects occurred in FFPE sequencing.

Methods: Cancer patients with 4 primary cancer types (kidney, colon, ovary and lung) were consented to donate specimens to BPV program. The surgical resection tissues and matched blood from eligible patients were collected following pre-defined preanalytical manipulations. RNA and DNA from biospecimens collected under these conditions was analyzed via NGS. FFPE specimens were also treated by organocatalyst (DEMOD) during nucleic acid isolation to see if it increases DNA quality in NGS analysis.

Results: We observed a consistent and dramatic shift in the proportion of reads corresponding to intronic/exonic/untranslated regions in FFPE specimens, with doubled reads mapped to intronic regions, and half of the reads mapped to exon regions in FFPE relative to matched frozen tissues. In the DTF group, 82% of samples exhibited differential expression compared to the matched frozen, regardless of the DTF duration. In the TIF group, high concordance in variant calling exists between FFPE (<= 24hrs) DNA and frozen control, but discordance was observed in 72hrs-FFPE samples. These results point to a clear quality defect caused by formalin fixation. Previously, EPA studies demonstrated that the DEMOD method improved RNAseq data quality from mouse FFPE samples. Our current collaboration at HESI consortium is applying the same approach to DNA isolation from human FFPE samples. Preliminary results showed that DNA behaved differently from RNA in the DEMOD treatment and additional experiments are ongoing to optimize the procedure.

Conclusion: Genomic analysis from FFPE specimens by NGS can generate reliable and reproducible results through careful and consistent analysis. The DEMOD approach could be an important tool to mitigate FFPE impacts on NGS analysis.

PBR-15 Assessment of the Suitability of RNA Extracted from Archived FFPE Tissue Blocks for Use in qRT-PCR

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Background: Formalin-fixed paraffin embedded (FFPE) tissue hold enormous potential as a source of RNA, but challenges still exist. FFPE RNA undergo severe chemical modification and fragmentation thereby limiting RNA extraction, quantification and quality. Several commercial kits are available that yield RNA of acceptable quantity and quality for molecular assays. However, verification of the suitability of such kits remain imperative as quantity and quantity of RNA may differ between kits. The aim of this study was to determine whether the quantity and quality of RNA extracted from FFPE tissues archived at our facility are fit for use in quantitative real-time PCR (qRT-PCR).

Methods: Forty FFPE cervical tissue blocks with verified diagnosis of cervical intraepithelial neoplasia, invasive squamous cell carcinoma and adenocarcinoma stored at our facility between 2015 and 2017 were used. RNA were isolated with the Qiagen miRNeasy FFPE tissue kit. RNA quality indicators for purity were A260 nm/A280 nm of between 1.80 and 2.0 and A260 nm/A230 nm of between 2.0 and 2.2. Quantification were done with a Qubit fluorometer. RNA integrity was determined with an Agilent bioanalyzer using RIN (between 2 and 3) and DV200 (> 30%) values. Detection of human GAPDH mRNA trancripts were used to assess RNA integrity and presence of high abundant transcripts. HPV 16 and HPV 18 E6/E7 mRNA expression were used to detect lower abundant transcripts. The detection of U6, miR-21 and miR-595-p were also investigated.

Results: Eighty five percent of RNA samples had sufficient yield for cDNA conversion using 300 ng of total RNA in triplicate. Only 75% of samples fitted the A260 nm/A280 nm and A260 nm/A230 nm quality criteria. GAPDH mRNA were de-

tected in all samples tested, indicating that the integrity of the isolated RNA were sufficient for qRT-PCR analysis. HPV 16 mRNA transcripts were amplified in 20% of tested samples, whereas 8.5% were positive for HPV 18, thereby demonstrating the ability to detect lower abundant transcripts. For miRNA detection, only 71% of the RNA samples could be tested, all of which were positive for U6 and miR-595-5p, whilst miR-21 was detected in 69% of these samples.

Conclusion: The quantity and quality of RNA isolated from the FFPE cervical tissue blocks archived within our division between 2015 and 2017 were suitable to detect high and low abundant mRNA transcripts and miRNAs. Therefore, isolated RNA is fit for use in sensitive molecular assays such as qRT-PCR.

PBR-16 A Comparison of Quality Assessment Methods Specified in SOPs Contributed to the Biospecimen Research Database's SOP Library

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Background: Advancements in medical research, including those that can improve patient diagnosis, prognosis, and treatment options are reliant upon the quality of biospecimens used. Biospecimens collected using variable or suboptimal collection and processing practices can yield irreproducible data or lead to false biomarker discovery. While the call to improve, standardize, and harmonize biospecimen handling practices are crucial to increasing the availability of high quality biospecimens, we questioned if quality assessment is included in biobanking standard operating procedures (SOPs) and whether quality assessment methods are harmonious across biobanks.

Methods: We surveyed the National Cancer Institute's Biospecimen Research Database (BRD)'s SOP library for procedures that included quality assessment. The BRD (http://biospecimens.cancer.gov/brd) is a publicly accessible database tailored to the field of human Biospecimen Science that contains a curated literature repository and a library of SOPs contributed by biobanking organizations. SOPs returned using the applied search criteria were examined, the type of quality assay specified was noted, and their frequency was tallied to identify prevalent quality assessment methods for DNA and RNA isolated from tissue and fluid biospecimens. To better understand the effects of different quality assessment methods, the BRD's literature repository was screened for articles that experimentally compared DNA and RNA quality assays.

Results: The BRD's SOP library contains more than 470 protocols contributed by more than 70 source organizations, including U.S. government agencies, private, nonprofit, and international biobanking organizations. Of these protocols, 179 mentioned quality assessment. Quality assessment methods frequently specified among the SOPs surveyed included electrophoresis, PCR, spectrophotometry, bioanalyzer generated electropherograms, and RNA integrity number (RIN). A search of the BRD's literature repository returned 14 articles that evaluated DNA and RNA quality assessment methods, and meta-analysis findings will be summarized.

Conclusions: Quality assessment is a key step that is included in the majority of topic-relevant SOPs contributed to the BRD's SOP library. While some level of discordance was observed among SOPs regarding the quality assessment method used, choice is also reliant on the technology available at each institution and the research intent for the specimens collected.

PBR-17 Quantification of the DNA Integrity Affecting the Genome Data Quality in the Analytical Phase

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National Biobank of Korea (NBK) has distributed about 430,000 genomic DNA samples for genetic and genomic research projects from 2003 to 2017. Most of the distributed DNA samples were applied on large-scale genomic analysis platforms such as single nucleotide polymorphism (SNP) array and next-generation sequencing (NGS). The high quality of DNA sample is one of important prerequisites for good results of the genomic analysis. For DNA quality control, the NBK performs not only an agarose gel electrophoresis method to qualitatively determine the DNA integrity but also measures OD260/OD280 for the DNA quantity and purity. In order to determine the quantitative criteria of DNA integrity for genome analysis platforms, we analyzed three pairs of genomic data of SNP arrays ($n=50$), methylation arrays ($n=50$), NGSs ($n=50$) obtained from the same DNA samples ($n=50$) of a different quality ranging from 0 to 10 values of the Genomic Quality Number (GQN), metrics of DNA integrity. This study showed that the most important factor affecting the data quality of the genome analysis platforms was the proportion of double stranded (ds) DNA as well as the higher GQN value of used DNA samples. This study would help set the quantitative criteria of DNA integrity for genome analysis platforms, and provide an evidence of disposal SOPs.

PBR-18 CR Cells from Pleural Effusion Identifies Therapy for NSCLC Patient With Primary Resistance to TKI

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Here we reported a preclinical model that can propagate cells in vitro that are derived directly from human tumors or healthy tissues. With this model, an in vitro drug sensitivity test can be performed on a personalized cell model, including single drugs and drug combinations.

A 62 year old woman was diagnosed with metastatic NSCLC, with a comprehensive physical examination, the tumor was EGFR positive and had a clinical stage of T3N3M0. Specimen of the right upper lobe and the right neck neoplasm were obtained by virtue of fine needle aspiration. Pathological examination shows the typical characterizations of pulmonary adenocarcinoma.

Object: To establish a conditional reprogramming cell line derived from a NSCLC patients with primary resistance to TKI. To find a suitable combination of chemotherapy drugs by performing a chemosensitivity test on CRC.

Methods: The tumor cells were separated from the pleural effusion. Under the conditional reprogramming culture environment, certain amount of cancer cells were collected for a drug sensitivity test.

A group of single drugs and drug combinations were tested including both chemotherapies and targeting drugs.

Results: Based on the drug combination index, we found that cisplatin had a synergistic effect with pemetrexed, whereas other groups, produced no such effect. The inhibiting ability of combinations was dose dependent because higher concentrations. Combination of Cisplatin and Pemetrexed produced a similar effect with the group of Cisplatin and Gemcitabine in our new cell model. Significant difference was observed in the group of Cisplatin and Docetaxel which was compared to Cisplatin and Gemcitabine but with lower inhibitive effect.

Conclusion: Apparently, according to the clinical effect, the previous first line targeted gene therapy schemes had been unsuccessful for this patient. Hence, Platinum based drugs as a therapeutic strategy, were provided for her with EGFR mutations primary resistance and deteriorated progression. An overall consideration of individual differences and medication safety, the combination of Cisplatin and Pemetrexed was the most promising therapeutic regimen in previously to select for the advanced NSCLC patient without operative treatment. This suggested that functional analysis with patient-derived cell models provides practical option for the patients with NSCLC, especially for those patients with primary or acquired resistant to targeting therapies.

PBR-19 Combined TCGA Database Retrieval and Analysis with Experimental Verification of Clinical Samples in Biobank to Find HCC Related Genes

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Background: Liver is an important metabolic organ of human body, and fatty acid metabolism is an important metabolic pathway. Abnormal fatty acid metabolism pathways exist in liver cancer. We searched for abnormal genes related to lipid metabolism of liver cancer through TCGA database analysis and combined with inventory sample detection.

Methods: RNAseq data of 377 patients with hepatocellular carcinoma and their related clinical data (each patient included 36 entries of basic information, clinical-pathological information and follow-up information) were downloaded from the TCGA database to compare the expression differences of 47 related genes in fatty acid generation pathways in hepatocellular carcinoma and paracancer tissues and their relationship with prognosis. Paraffin tissues and clinical data (30 entries for each patient) of 82 cases of hepatocellular carcinoma were collected from Nanjing Muti-center biobank, for immunohistochemical experiments of lipid metabolism-related gene ACSL1 and ACSL4. The correlation between expression level and clinical data was analyzed.

Results: TAGA database analysis showed that most of the genes in the lipid metabolism pathway were down-regulated, such as ACOX1, ECSH1, HADH, ACAA1, ACSL1, CPT1A, etc. ACSL4 and CPT1C were abnormally up-regulated. Immunohistochemical results of tumors and paracancer tissues of 82 HCC patients showed that ACSL1 expression was down-regulated in liver cancer, and ACSL4 expression was up-regulated in liver cancer. The correlation analysis between the clinical data of the patients and the expression of ACSL1/ACSL4 showed that the expression of ACSL4 was positively correlated with AFP ($n=20$), Pearson correlation coefficient was 0.608, $p=0.004$. ACSL4 is correlated with fibrosis, and there is no significant correlation between the other indexes.

Conclusions: TCGA data show that most gene expressions of fatty acid metabolism pathway are inhibited in liver cancer, among which ACSL family is closely related to lipid metabolism of liver cancer. Combined TCGA database retrieval and analysis with experimental verification of clinical samples in biobank is a feasible method to find HCC related genes.

PBR-20 Histomorphometric Quality Assessment of Tissue Samples Before Distribution Promote the Service Effectiveness

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Objective: The morphological quality of tissue samples are important impact factors on the quality of biological samples, which may lead to the bias of molecular marker research. To provide high quality biological samples for FUSCC and NCI's Cooperation on Clinical Proteomic Tumor Analysis Consortium, we performed morphological quality assessment on tissue samples before distribution.

Methods: A case-matched representative FFPE H&E section, from the original anatomic pathology diagnostic block (125 mg/sample) of the tumor, were produced and scanned for digital image. The morphological quality were evaluated by two pathologist with double-blind methods. By default for any cancer, the following tissue cellular composition cutoff values were used: of viable cell nuclei present, on average, $\geq 80\%$ should be tumor nuclei for sarcoma, head and neck squamous cell carcinoma (HNSCC) and clear cell renal cell carcinoma (ccRCC); $\geq 60\%$ should be tumor nuclei for non-small cell lung cancer (NSCLC) and glioblastoma (GBM); $\leq 20\%$ of viable cells present may be normal stromal, inflammatory or immune cells. The necrosis may comprise $\leq 20\%$ of the total sample area of the histological slide. Of the total sample area of the histological slide, at least 50% must be comprised of viable cells (tumor or otherwise, not extracellular matrix).

Results: Among the 116 collected paraffin samples corresponding to seven kinds of tumor, including 2 GBM, 59 NSCLC, 28 PDAC, 20 ccRCC, 7 HNSCC and 6 sarcoma. For all cases, the average total cell percentage, total percentage of tumor tissue, total percentage of tumor cell nucleus was, and percentage of necrosis in each tumor types were: 78.75%, 95.00%, 81.25% and 0 in GBM; 83.09%, 84.02%, 78.48% and 6.50% in NSCLC; 60.36%, 66.98%, 41.82% and 4.50% in PDAC; 89.55%, 91.63%, 89.45% and 0.05% in ccRCC, 87.86%, 93.50%, 84.29% and 5.00% in HNSCC; 86.25%, 90.25%, 84.585 and 3.33% in sarcoma, respectively. The failed case was a PDAC, which have no tumor in the whole samples. These 115 morphological qualified samples were delivered to the Quality Management System of the CPTAC project, and besides of two NSCLC and one ccRCC samples,

all the other 112 samples pased the further quality assessment for CPTAC project.

Conclusion: Morphological quality assessment is critical for biological samples, the case-matched representative FFPE H&E section from the original tumor showed a certain representativeness of the overall quality assessment of the tumor.

PBR-21 Fully Cold Chain in an Automatic Cryopreservation System Reverses the Reduction of Cell Viability and Functional Activities Caused by Temperature Fluctuation

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Temperature fluctuation caused by the explosion of cryopreserved cells to room temperature is well recognized as a critical issue impairing cell viability, recovery and functionality in a long term. Here we focused on the umbilical cord-derived mesenchymal stromal cells (MSCs) and cultured T cells, both of which are the most important cell types for cell-based therapies, to figure out the influence of temperature fluctuation on the viability, recovery and bioactivities. Cryopreserved MSCs and cultured T cells were taken out from the liquid nitrogen tank until the sample temperature rise to 60oCand then put back into the tank repeatedly to mimic sampling process. Our data showed that MSCs viability, recovery and capacities in multilineage differentiation were negative correlated with the times of sampling process ($P < 0.05$). Although there was no significant difference in the viability and recovery of cultured T cells within first 50 times, the lymphocyte proliferation (LPA) capacity and subsequent cytokine secretion level were significantly reduced ($P < 0.05$). Notably the reduction either in MSCs viability, recovery and multilineage differentiation or in T cells bio-activity could be reduced or even reversed when the whole sampling process was under −150oC within a fully automatic cryopreservation systems. All these results indicated that the temperature fluctuation should be avoided during the sampling process and a protective temperature under −150 oC in a fully automatic system can be a solution for the development of a biobank in a large scale.

PBR-22 Comparative Analysis of the Advantages and Disadvantages of Different Storage Methods of Tissue Samples

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Objective: To assist in the selection of appropriate methods for tissue sample stroage, we comparative analysed the difficulty level of three methods for incision of tissue samples under the same storage conditions.

Methods: Thirty fresh tissue samples stored in a refrigerator at −80°C were randomly selected, each group contains 10 samples and stored using specific methods: samples were chopped into small tissues with a maximum diameter of 0.2–0.5 cm and placed into the cryopreservation tube; samples were chopped into small tissues with a maximum diameter of 0.2–0.5 cm, immersed in liquid nitrogen for 10 s, and then placed in the cryopreservation tube; samples were cut into 1.2*0.3*0.3 cm^3 strips and placed in the cryopreservation tube and sticked the tube wall. Sample serial section was performed in a freezing microtome at −30°C.

Results: Among the three different storage methods, the longest and most inconvenient methods was the first one, the average dispose time was 60 s. The reason is that the chopped tissues were adhered to each other again in the cryopreservation tube when it is taken out, and needs to be re-chopped. The shortest and most convenient time is the second kind, the average time is 20 s. The reason is that the chopped tissue will not freeze again with the same tube tissue after quick freezing. In the third method, the long fresh tissue strips are placed in the cryopreserved tube, and the time-consuming is between the first two mothods, taking an average of 30–40 s. However, its advantage is the form of the cut-off tissue sample is relatively regular, and the sample can be morphologically quality controlled before release.

Conclusion: Different tissue cutting and preservation methods should be selected according to tumor types, which can more effectively and rationally exert the resource advantages and assist in the research of basic and clinical translational medicine.

PBR-23 Exploring the Improvement of Cryopreserving Human Peripheral Blood Mononuclear Cells

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Human peripheral blood mononuclear cells (PBMCs) are usually collected for functional analysis in various infectious diseases and clinical vaccine studies, as well as serving as precursors for potential immunotherapy development in translational medicine. Therefore the cryopreservation of PBMCs is a critical issue in the field of cryopreservation, and lots of problems need to be resolved to improve the viability and recovery of frozen PBMCs. To fulfill this purpose, we carried out a systematic investigation of relevant factors linking to the collection, transportation, freezing, thawing and their effects on the final survival and function of PBMCs.

During the collection of PBMCs, the content of red blood cells (RBCs) and platelets in individual blood was first taken into consideration. It turned out that more than 0.5×1012 RBCs per liter would significantly reduce the cell recovery than that of lower RBC concentration. Additionally, it seemed that the concentration of platelets was not a big issue because similar survival rates of frozen samples with differential concentrations of platelets were observed. We also analyzed different conditions of temperature and vibration during the transportation, and found out that low temperature and less shaking rate than 200rpm would benefit for PBMCs. Furthermore, we investigated the optimal cell concentration and volume of cryomedium in each vial, and the formulation of cyromedium. For a cryovial of 2.0 ml, 1×107 cells in 1.5 ml cryomedium was the best option which was of near 95% cell viability while the number reduced to less than 90% when the concentrations were higher than 5×107. Finally, we testified that PBMCs did not t need to be frozen immediately after their collection but could be stored at 4 degrees for one day before their cryopreservation without any unfavorable effects, demonstrating the alternatively operative convenience. In conclusion, our current work comprehensively evaluated the key parameters in cryopreservation of PBMCs and shed new lights on potent strategy for optimizing this procedure.

PBR-24 Clinical Use of Cryopreserved Whole Adipose Tissue

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Background: Autologous fat grafting has now been used extensively and successfully for more than two decades. Although most adipose grafts and adipose-derived MSC therapies are done with fresh tissue, cryopreservation of tissue allows much greater flexibility of use.

Methods: Over the course of six years, more than 250 cryopreserved adipose samples were thawed and returned to the collecting physician for subsequent autologous applications. Samples were stored with the mean cryogenic storage time of 10 months with some samples being stored as long as 46 months. The volumes of tissue stored varied from 12 cc to as large as 1440 cc.

Results: Upon thaw the volume of recovered whole adipose tissue averaged 67% of the amount stored. This recovery yield ranged from a low of 46% for some patients to a high of 100%. Recovery yield was not found to be a function of patient age, collection volume, amount of tissue thawed, or length of time in cryopreservation. Viability of thawed cells remained high with a mean value of 91%.

Conclusions: While an average recovery of 67% of volume frozen indicates that the use of banked and thawed tissue requires a larger amount of sample be taken from the patient initially, this requirement is easily accomplished by an experienced clinician. As cryopreservation of adipose tissue becomes more commonplace physicians will find it helpful to know what will be the likely amount of tissue that will be available after thaw procedures.

PBR-25 Techa River Population Cancer Morbidity and Mortality and Mayak Worker Cancer Mortality

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The Mayak worker cohort (MWC) includes about 26,000 workers who worked at the Mayak Production Association (Mayak), located in Ozersk, Russia, which was the first Soviet nuclear weapons production facility. This cohort presents one of the very few opportunities to estimate radiogenic risks related to prolonged exposure to both low-LET external exposure (primarily gamma-rays) as well as exposure to high-LET alpha-particles emitted by inhaled 239Pu.

The Techa River Cohort (TRC) includes nearly 30,000 residents of villages along the Techa River, which was heavily radioactively contaminated by effluent from the Mayak facility.

While there are some fundamental differences in the dosimetry systems adopted to estimate dose for the two cohorts, both systems (MWDS-2016 and TRDS-2016) now describe uncertainty in dose by means of a Monte Carlo algorithm that produces many possible realizations of true dose, with variation in the realizations incorporating shared and unshared uncertainties.

Using specialized statistical techniques we can now incorporate complex shared uncertainties into the analysis of radiation-dose response for cohorts as large as the MWC and TRC. Currently we are working on lung cancer analysis in the MWC, fitting risk models involving (1) plutonium, (2) gamma-rays, and (3) smoking to reduce confounding and to determine how smoking interacts with radiation exposure. We show, that dose uncertainty has an important effect on inference regarding lung dose response due to plutonium. Confidence intervals for dose response parameters fit using models that ignore dosimetry error must be lengthened to capture the dosimetric uncertainty of plutonium exposure, a much smaller effect is seen on the confidence intervals for internal expose In the TRC we are using similar methods in analysis of risk of all solid cancer types and of leukemia. It appears that uncertainty in internal exposure is larger than for external exposure, and the effect of the uncertainty on inference about leukemia risk, is greater than for solid tumors.

Other recent work is focused on leukemia risk among the MWC. Since plutonium is not an important contributor to red bone marrow exposure, the focus is entirely on external dose, which is evidently less uncertain than internal plutonium dose.

PBR-27 Living Biobanking of Human Solid Tissues as Highest Possible Quality Method of Cryopreservation

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The availability of viable human tissues is critical to support translational research focused on personalized cancer care. Most studies have relied on fresh frozen or formalin-fixed paraffin-embedded tissues for histopathology, genomics, and proteomics. Yet many basic, translational, and clinical research downstream assays such as tumor progression/invasion, PDX, organoids, immuno-profiling, vaccine development still require viable tissue which are time sensitive and rare commodities. We present the validation of a viable freeze cryopreservation technique as standard method of highest quality specimen preservation.

Patients were consented under UCSD IRB# 181755 (Ex-090401). After surgical resection, specimens were cut into 3mm fragments and placed in Cryostor media, processed using slow freezing method (−1°C/minute in −80C) and after 24 hours stored in liquid nitrogen. After 15–18 months, tissues were thawed and dissociated using a gentle MACs Dissociator into single cell suspensions and cell viability was measured. To generate primary 2D lines, cells were plated onto Collagen and Matrigel coated plates. To develop spheroid lines, the cells were plated in reduced serum RPMI media on non-adherent plates, or in Matrigel matrix. To evaluate growth of Tumor Infiltrating Lymphocytes (TIL), the tissues were minced and plated with IL-2 supplemented media. Cell proliferation was evaluated in primary lines using IHC for KI67 antibody; the epithelial nature was corroborated with cytokeratin expression. TIL were characterized by staining for CD3, CD4, CD8 and CD56. DNA and RNA isolation was performed using QIAGEN AllPrep kits.

Cell viability was 42% ±21%. We developed primary lines (2-D and 3-D) of colon, thyroid, lung, and liver cancers that were 30–50% positive for KI67 and cytokeratin staining. 3D lines were developed from same cohort of tumor types in both suspended media and Matrigel matrix. In addition, four/six (sinus, thyroid, colon cancers) tissues developed TILs. TILs were positive for evaluated antibodies. Multiple freeze-thaw cycles did not significantly alter viability and growth of TILs, 2-

D and 3-D lines. DNA/RNA recovery was similar to its fresh frozen cohort.

In this study, we demonstrate the feasibility of viable preservation of tumor tissue. This proof-of-principle study, if more widely implemented, should improve accessibility of human viable tumor tissue/cells in time independent manner for many basic, pre-clinical, and translational assays.

PBR-28 Establishment and Characterization of Patient-Derived CIN Cell Model Containing Episomal HPV18 Virus

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Human papillomavirus (HPV) is the smallest circular double-stranded DNA virus. HPV infection can cause cervical cancer. Although the preventive vaccine has been developed and applied, there is no effective anti-HPV drug or anti-tumor drug available. It's extremely hard to establish and expand primary cultures from normal or diseased tissues. HeLa, Caski and SiHa cells are integrated HPV16 or HPV18 cervical cancer cell lines. After heavily used and cultured in vitro for many years, these cell lines can not stand for patient-derived tumor biology anymore. In addition, the HPV virus exists as integrated form in these cells. Till now, there is no proliferative cells containing episomal HPV virus.

Thus, an appropriate cell model in vitro which is close to in vivo physiological function is highly desirable. This study has successfully isolated and cultured a CIN cell line derived from Chinese female cervical intraepitheilial neoplasia (CIN) tissue. We characterized cells as below. (1) Establishment of patient-derived CCH18 cells. Conditional reprogramming (CR) technology was used to establish the CIN cell line derived from cervical intraepitheilial neoplasia (CIN) tissue without any transduction of exogenous viral or cellular genes. Subtyping was done by PCR and the result showed that cells carried HPV18 virus. This CIN cell line was named Chinese Cervical Intraepithelial Neoplasia (CIN) HPV18, CCH18 for short. (2) The subculture, genetic identification and karyotype analysis of CCH18 cells. (3) Biological characteristics analysis of CCH18. (4) Histological analysis of CCH18. (5) Reconstruct of CCH18 3D model using Matrigel and Air-liquid (ALI) 3D cultures. (6) Identification of HPV18 in CCH18 cells.

We have established the first HPV18 cell line containing episomal HPV18 for the first time. CCH18 is also as an integrated HPV18 cell line. CCH18 can mimic the dynamic process of viral infection and integration in patients to some extent. It provides an ideal research model for cervical cancer and anticancer drug screening. The 3D ex vivo model derived from the patient CIN cells has been constructed using ALI culture system. The reconstituted cervical epithelium mimics the tissue structure in vivo. In addition, CCH18 cells carry episomal and integrated HPV18. This 3D model can visually study the whole life cycle of HPV replication. It provides a unique and novel model to investigate the mechanism underlying HPV infection and cervical cancer.

PBR-29 Effect of Vitro Ischemia and Delayed Processing Time on Quality of Fresh Tissues in Biobank

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Background: Maintaining stability and integrity of RNA is a major problem in tissue banking. The impact of ex-vivo ischemia time on RNA quality and genes expression involved in hypoxia, stress, apoptosis and autophagy remains elusive.

Methods: A total of 18 carcinoma tissues from different organs were collected to detect the RNA quality. Fresh tissues were cut into pieces at aseptic condition and kept at room temperature for seven different time courses (15 min, 30 min, 1 h, 2 h, 4 h, 8 h, 24 h) before snap frozen and cryopreservation. RNA integrity andpurity were analyzed, and gene expression was analyzed by real-time polymerase chain reaction.

Results: Majority specimens banked using a standardized protocol yielded RNA with an RNA integrity number of ≥7 (8.03 ± 0.699, 7.69 ± 0.656, 7.81 ± 0.682, 7.59 ± 0.624, 7.23 ± 0.681, 6.93 ± 1.274, 6.41 ± 1.199 during the five storage periods, respectively). RNA remained stable in carcinoma tissues kept at room temperature for up to 4 h whereas degradation was found in tissues left for 8 h and 24 h. SPSS analysis of RIN indicated RNA remained intact afterischemia for 2 h at room temperature ($p < 0.001$). Expression of genes PI3K, AKT, AMPK, Caspas8 in corresponding functional pathways of hypoxia, stress, apoptosis and autophagy changed during ischemia storage for 8h and 24 h ($p < 0.001$).

Conclusions: Fresh tissue biospecimen should be processed within 2 h to avoid a major reduction in RNA quality. Except for RIN and tissues morphology, gene expression of PI3K, AKT, AMPK, Caspas8 should be considered as biomarkers to evaluate tissue quality at gene level. The presented data provide attempts to further standardize tissue biospecimen collection, processing and banking.

PBR-30 CircRNAs Expression and the Association with Clinicopathological Characteristics in Human Papillary Thyroid Carcinoma

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Background/Aims: Papillary thyroid carcinoma (PTC) is the most common type of thyroid cancer. Some protein-coding genes associated with PTC pathogenesis have been evaluated as diagnostic or prognostic markers. CircRNA is a novel class of RNA, and would be applicate as a new clinical diagnostic marker. The objective of this study was to explore the expression patterns of circRNAs in five pairs of PTC tissues and adjacement normal tissues.

Methods: So we would like to explore the expression patterns of circRNAs in five pairs of PTC tissues and adjacement nontumorous with RNA-seqsequencing was used to identify the expression profiles of circRNAs in five pairs of PTC tissues, and verified in 45 cases with qRT-PCR was employed to verify the sequencing results in 45 cases. Then, we explored and accessed the relationship of circRNAs mRNA expression and clinicopathological characteristics of PTC with non-parameter analysis and Receiver operating characteristic (ROC) curves.

Results: Our results showed comparing to adjacement nontumoroustissues, there were 45 circRNAs upregulated and 8 downregulated in tumor tissuescacinoma, and mRNA expression level of 8 circRNAs were consistent with RNA-seq data ($p < 0.001$ and $p < 0.01$). Among them, the expression of chr5:161330882-161336769- ($p = 0.015$), chr9:22046750-22097364+ ($p = 0.041$) and chr8: 18765448-18804898- ($p = 0.036$) were obviously correlating with BRAF V600E mutation, chr12:129699809-129700698- had relation with capsular invasion ($p = 0.025$), and chr5:38523418- 38530666- were was varied in different stage

of tumor ($p = 0.037$) and coupled with lymph node metastasis ($p = 0.002$) respectively. Besides, these findings were confirmed by ROC curves.

Conclusion: To include, the circRNAs expression could have relation with the mutation and lymph node metastasis of PTC, which would be a putative biomarker for the diagnostic and progression of PTC.

PBR-31 PD-L1 Expression and the Association with Malignant Behavior in Pheochromocytomas/Paragangliomas

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As the immunosuppressive effect of the PD-1/PD-L1 pathway plays an important role in the treatment of variety of tumors, such as lung cancer, breast cancer and others, but there is little literature about PD-1/PD-L1 and pheochromocytomas/paragangliomas (PCC/PGLs). So we would like to explore the relationship of PD-L1 and malignant behavior in 77 cases of PCC/PGLs with IHC at protein expression level, and detect mRNA expression level with RNAscope in 20 cases. The IHC data showed 59.74% of PCC/PGLs expressed PD-L1, and the expression is highly correlated with Ki-67 ($p = 0.019$) and hypertension ($p = 0.013$), but has no relation with age, sex, tumor size, capsular invasion, tumor necrosis, relapse/distant metastasis, secretion of noradrenaline/adrenaline/dopamine or diabetes. In addition, we found an excellent correlation of PD-L1 mRNA and protein expression levels with RNAscope and IHC, that was 0.828 of κ-coefficient, and the further stratified IHC and RNAscope showed highly consistent (Pearson's coefficient = 0.753). To include, the correlation of PD-L1 and Ki-67 indicated that PD-L1 could be considered as a tumor malignant proliferation biomarker for PCC/PGLs, which would be a putative biomarker for anti-PD-L1 therapies.

PBR-32 Diversifying Biosample Collections to Fuel Immuno-Oncology Research Studies. The Experience of the Nice University Hospital Biobank (BB-0033-00025)

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Background: Immune checkpoint inhibitors (ICIs) have changed treatment paradigm of locally advanced or metastatic non-small cell lung cancer (NSCLC). However, despite the durable clinical benefit observed in NSCLC patients, the majority of patients are either refractory or develop resistance after an initial response. Similar to the targeted therapy paradigm, the success of immuno-oncology depends on choosing patient populations most likely to benefit. The plasticity of the immune system under immunotherapy has weakened single biomarker-driven approaches and currently used predictive biomarkers are unable to accurately identify the subset of patients that benefit from these therapies. We established a large collection of blood-based samples to enable immunomonitoring during immunotherapy in patients with NSCLC.

Methods: Since January 2018, every patient with NSCLC treated with 1st or later lines of immunotherapy in our institution is prospectively included in this study after obtaining informed consent. A control population of 35 age-matched healthy donors has been included. Before and after 6 and 12 weeks of immunotherapy, each NSCLC patient is donating 20 ml of peripheral whole-blood drawn in EDTA tubes and 2 ml of blood collected with the TruCulture system (Myriad RBM, Inc., Austin, TX, USA). The EDTA tubes are then used to collect and cryopreserve i) peripheral blood mononuclear cells (PBMCs), ii) plasma after a two-step centrifugation, and iii) the remaining pellet. TruCulture, a syringe-based device for whole-blood collection, incubation, and stimulation of PBMCs, is used to enable the study of induced immune responses.

Results: The preliminary 1-year results show that 105 patients have been donated all types of samples during each visit (inclusion and 2 follow-up visits). After 1 year, the collection included 255 PBMCs pellets, 1275 vials/2 ml of plasma, and 510 TruCulture vials. The TruCulture vials are currently being used to measure the levels of 30 circulating cytokine levels on the Luminex™ MAGPIX™ platform (ThermoFisher Scientific). The collection of follow-up clinical data is ongoing.

Conclusions: The essential need to accurately identify the subset of NSCLC patients who benefit from immunotherapy will be covered only by integrating multiple biomarker-driven approaches. For this purpose, we established a large blood-based collection with multiple types of samples to enable immunomonitoring of NSCLC patients during immunotherapy.

PBR-33 Subsets of T Cell Expression on Hand-Foot-Mouth Disease Children with Enterovirus 71 in Different IFITM3-rs12252 Genotypes

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Background: The interferon-induced transmembrane protein 3 (IFITM3)-rs12252-CC/CT are associated with rapid progression of acute HIV and severe influenza. However, the effects of IFITM3-rs12252-CC/CT genotypes on hand-foot-mouth disease (HFMD) are not clear. The aim of this study was to explore the relationship between IFITM3-rs12252-CC/CT genotypes and HFMD, and to find the difference between HFMD with IFITM3-rs12252-CC/CT genotypes and TT genotype in the subsets of T lymphocytes when infected by human enterovirus 71.

Methods: Forty-four children diagnosed with EV71 infected patients with HFMD were enrolled. All the children's IFITM3-rs12252 genotypes were tested by BGI. The IFITM3-rs12252 CC/CT genotypes include 35 children, and the IFITM3-rs12252 TT genotype include 9 children.

Results: Firstly, we found the percentage of lived CD3+T cells in HFMD patients with CC/CT genotypes was markedly lower than TT genotype; Secondly, the percentage of PD-1+CD8+T cells in IFITM3-rs12252 CC/CT group were significantly increased. Thirdly, the percentage of CXCR5 on CD4+T cells in HFMD with IFITM3-rs12252 CC/CT genotypes was remarkably lower than TT genotype.

Conclusions: These data illustrate differential expression of makers on T lymphocytes surface of hand-foot-mouth disease children with EV71 in different IFITM3-rs12252 genotypes, and the frequency of Tfh was associated with the IFITM3-rs12252 genotypes and the progression of HFMD.

PBR-34 Optimal Cryopreservation of Viable Buffy Coat Using the New CoolCell Device

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Cryopreservation of viable buffy coat cells would greatly reduce the blood processing time compared to PBMC isolation. This process needs validation for reliable and reproducible results in the scope of functional assays. Additionally, improved reproducibility can be achieved by freezing using the new CoolCell device (Biocision) which eliminates the problematic use of isopropanol associated with the ''Mr Frosty'' procedure.

Here we evaluated the CoolCell device for cryopreservation of PBMCs and applied it for optimised buffy coat cryopreservation conditions. We found no statistical significant difference in viability between PBMC cryopreservation with Mr Frosty and the CoolCell device, as measured post-thaw by flow cytometry.

Buffy coat cells automatically isolated from whole blood on a TECAN platform, were cryopreserved using different volume ratios of cellular (buffy coat) fraction / Cryostore CS10 medium (Biolife), with the CoolCell device. The post-thaw cell viability and functionality were compared to iso-donor derived frozen PBMCs by flow cytometry and IFN-y Elispot.

Results and conclusions concerning the optimum ratio to be used for viable buffy coat cryopreservation, as well as the evaluation of the CoolCell device in this processing method will be presented.

PBR-35 Long Non-coding RNA LINC02487 Is Differentially Expressed in Head and Neck Cancer and Acts as a Tumor Suppressor Through Regulating USP17

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Objective: This study is aimed to determine the expression pattern of long non-coding RNA LINC02487 in head and neck squamous cell carcinoma (HNSCC) specimens and cell lines, and to preliminarily explore the functions and its mechanisms.

Materials and Methods: Relative expression levels of LINC02487 in HNSCC cell lines and samples were examined by qRT-PCR. LINC02487 was cloned into pCMV-puro vector, and transfected into HNSCC cell lines HN6 and HN30 by lentivirus. Cell proliferation, apoptosis, cell cycle, migration and invasion were examined subsequently. RNA binding protein was explored by ChIRP-MS. And protein expression was determined by western-blotting assay.

Results: LINC02487 was found downregulated in HNSCCs using microarray analysis. In this study we tested the expression pattern and confirmed the downregulation of LINC02487 in 50 OSCC samples comparing with paired adjacent normal tissues (data from sharing platform for the tissue sample and bioinformatics database of oral maxillofacial tumor, Shanghai, http://mdl.shsmu.edu.cn/OMNDB/page/home/home_en.jsp), and in 6 HNSCC cell lines comparing with immortalized normal oral epithelial cell line(HIOEC). Overexpression of LINC02487 significantly suppressed cell migration and invasion, increased the ratio of cells in G1 phase, with a minor influence on cell proliferation and apoptosis. Furtherly, LINC02487 was found directly binding to USP17, a deubiquitinating enzyme that was found to be associated with cancer metastasis, and regulating cell migration and invasion through USP17 expression.

Conclusion: Our study confirmed that long non-coding RNA LINC02487 was downregulated in HNSCC samples and cell lines. It acted as a tumor suppressor through its directly binding protein USP17. This work was supported by the National Program on Key Research Project of China (2016YFC0902700) and Shanghai Municipal Science and Technology Commission Funded Project (18DZ2291500).

PBR-36 The Evaluation of Genomic Identity of the Cell Specimens in the TMM Biobank

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Background: For the realization of next generation genomic medicine, the contribution of biobank is rapidly increasing in supplying a huge number of samples for research analysis. The assurance of these biobank sample correctness is important. However, it is hard to completely eliminate human errors. Our Tohoku Medical Megabank biobank (TMM biobank) is the first major population-based biobank in Japan established as a part of the reconstruction program from the Great East Japan Earthquake and Tsunami of 2011. The TMM biobank has generated thousands of Epstein-Barr virus (EBV)-transformed lymphoblastoid cell lines (LCL) and proliferating T cells derived from our cohort participants. The evaluation of correctness of these cells is essential for further functional studies.

Methods: For the evaluation of genomic identity between EBV-LCLs/proliferating T cell specimens and the same participants' blood, we designed MassArray probes for 37 common genetic variants in Japanese genome. The genomic DNA were isolated from each EBV-LCLs' and proliferating T cells' pellets, and the variant information of MassArray analysis was compared with the information of whole genome sequencing (WGS) data derived from the same participants' blood.

Results: Most of the designed MassArray probes worked well and the majority of the variant genotypes in MassArray analysis were consistent with that of whole genome sequencing. We confirmed that our MassArray analysis is a useful tool for the evaluation of the genetic identity of specimens and data obtained from identical participant. Five out of 767 MassArray investigated T cell specimens showed high genetic inconsistency of specimens and WGS data, and were suspected of sample mix-up during their culture stage. These findings enabled us to correct or eliminate the mismatch samples appropriately for further functional studies.

Conclusion: To eliminate the possibility of sample mix-up and ID mislabeling, we set up the MassArray analysis and applied it to the management our biobank cell specimens. We found the majority of investigated samples were correct, however, some samples were suspected of mix-up. The MassArray

analysis could evaluate genomic identity easily and inexpensively, and would be useful for the correction/elimination of mismatch samples. Application of the MassArray analysis to all our cell specimens would improve the quality and reliability of the TMM biobank for the realization of next generation genomic medicine.

PBR-37 A Novel Gene Panel for Detection of Oral Squamous Cell Carcinoma

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Purpose: At the early stage of oral squamous carcinoma (OSCC), only may partial tissue turn into typical carcinoma under pathological observation. Missed diagnosis remains a true possibility especially in early OSCC by biopsy. We aimed to identify genes panel for diagnosing OSCC combined with pathological observation.

Patients and Methods: Gene expressions were investigated with four independent cohorts including 666 tissue samples recruited from 3 medical centers. First, we analyzed microarray data named GSE6631 profile in Gene Expression Omnibus (GEO) and used PubMed dataset search engine to screen total 78 genes for diagnosing OSCCs. Quantitative reverse transcriptase polymerase chain reaction analysis (qRT-PCR) was applied to evaluate the expressions of candidate genes. We then built an eleven-gene panel using a logistic regression model. The diagnosis accuracy of this panel was validated in both the internal testing group of 122 patients, and an external independent group of 91 patients.

Results: We identified an eleven-gene panel, including PLAU, SPP1, MMP1, NMU, HOPX, KRT13, KRT15, IL1RN, TGM3, MAL, and EMP1, that provided a high diagnosis accuracy of OSCCs. And the AUCs were 0.9674, 0.9538 and 0.9306, for training, internal testing and validation data set, respectively. The excellent diagnostic performance of gene panel persisted regardless of disease status, such as AUCs for T1-T2, T3-T4, lymph node positive, lymph node negative, perineural invasion, non-perineural invasion, well differentiated, moderately-poorly differentiated were 0.9391, 0.9402, 0.9444.0.9349, 0.9764, 0.9524,0.9006 and 0.948, respectively.

Conclusion: We built a gene panel that has potential clinical value in OSCC diagnosis. Thus, patients who have otherwise missed diagnosis can benefit from optimal molecular diagnosis and therapy.

This work was supported by the National Program on Key Research Project of China (2016YFC0902700) and Shanghai Municipal Science and Technology Commission Funded Project (18DZ2291500).

PBR-38 Human Leukaemia Cells (HL-60) Proteomic and Biological Signatures Underpinning Cryo-Damage Are Differentially Modulated by Novel Cryo-Additives

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Background: Cryopreservation is a routinely used methodology for prolonged storage of viable cells. The use of cryo-protective agents (CPAs) such as dimethylsulfoxide (DMSO), glycerol or trehalose is paramount to reduce cellular cryo-injury but their effectiveness is still limited. The current study focuses on establishing and modulating the proteomic and the corresponding biological profiles associated with the cryo-injury of human leukaemia (HL-60) cells cryopreserved in DMSO alone or DMSO ± novel CPAs [e.g., nigerose (Nig) or salidroside (Sal)].

Findings: To reduce cryo-damage, HL-60 cells were cultured prior and post cryopreservation in RPMI-1640 media ± Nig or Sal. Shotgun proteomic analysis showed significant alterations in the levels of proteins in cells cryopreserved in Nig or Sal compared to DMSO. Nig mostly affected cellular metabolism and energy pathways, whereas Sal increased the levels of proteins associated with DNA repair/duplication, RNA transcription and cell proliferation. Validation testing showed that the proteome profile associated with Sal was correlated with a 2.8 fold increase in cell proliferative rate. At the functional level, both Nig and Sal increased glutathione reductase ($0.0012 \pm 6.19E\text{-}05$ and $0.0016 \pm 3.04E\text{-}05$ mU/mL, respectively) compared to DMSO controls ($0.0003 \pm 3.7E\text{-}05$ mU/mL) and reduced cytotoxicity by decreasing lactate dehydrogenase activities (from −2.5 to −4.75 fold) and lipid oxidation (−1.6 fold). In contrast, only Nig attenuated protein carbonylation or oxidation.

Conclusions: We have identified key molecules and corresponding functional pathways underpinning the effect of cryopreservation (± CPAs) of HL-60 cells. We also validated the proteomic findings by identifying the corresponding biological profiles associated with promoting an anti-oxidative environment post cryopreservation. Nig or Sal in comparison to DMSO showed differential or additive effects in regards to reducing cryo-injury and enhancing cell survival/proliferation post thaw. These results can provide useful insight to cryo-damage and the design of enhanced cryomedia formulation.

Ethical, Legal, and Social Issues

PE-01 What Egyptians Think? Knowledge, Attitude, and Opinions of Egyptian Patients Towards Biobanking Issues

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Introduction: Biobanking as a structural core facility is a relatively new concept in Egypt. Several biobanks have been established in the last few years. Building and maintaining a good relationship with different stakeholders, including patients or potential participants, is essential for the social sustainability of biobanks and hence their success. To establish this relationship, it is essential to assess and evaluate the knowledge and attitude of different groups towards this concept.

Methods: We designed a structured survey of 28 questions to be administered to patients coming to the outpatient clinics in 3 institutions in different regions of Egypt. The survey included questions estimating the level of knowledge about the term ''Biobank'', together with several questions about attitudes and opinions about related issues.

Results: Two hundred and fifty-nine patients participated in the survey. Eighty-one percent of participants reported that they have never heard about the term before. There was a significant correlation between the knowledge about the term and the higher educational level ($p < 0.001$) and with the male gender ($p = 0.012$). About 85% expressed that they would be willing to donate their samples for research and about 87% thought that sample donation did not contradict their religious beliefs. A lower perecentage (58.3%) were willing to participate in a research project related to heredity and genes, 45.6% were not in favor of sharing their samples with pharmaceutical companies, and only 32.4% agreed to share their samples with persons or institutions abroad.

Conclusion: Although there is limited knowledge about biobanking among Egyptian patients, many had a positive attitude towards sample donation in general and didn't show any cultural or religious concerns against it. However, they showed concerns regarding participation in genetic research and with sharing their samples across borders or with pharmaceutical companies. Public education about biobanking in Egypt is possible, taking into consideration the specific cultural and legal framework in Egypt.

PE-02 Consent, the Pivot in Research in Ghana; Breast Care International Best Approach

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Background: Breast cancer is becoming a major public health challenge in Africa and most countries do not have cancer registries, nevertheless, the World Health Organisation estimates that the incidence rate of breast cancer in Africa has steadily increased over the years. According to 2018 Globocan report; Ghana recorded 4,645 (20.4%) new breast cancer cases. Although, it is acknowledged that early detection reduces mortality, 80% of newly diagnosed breast cancer patients delay presentation. Early detection and prompt treatment has been the focus of Breast Care International (BCI). Since its inception, in 2002. BCI has developed a well-structured outreach program that reaches a significant portion of the population with the goal of receiving the consents of the masses to enhance research and other projects such as biobanking.

Objective: To explore the effectiveness of informed consent that promotes education, treatment and research in breast cancer for further evaluation and treatment.

Methods: Using the Ghana Breast Health Study as a case study, BCI collaborates with opinion leaders, organized groups and local community to explain the project purpose and importance, role of individual, stakeholders and community; and increase their knowledge on consent. A consent form is provided by the sponsor with the study protocol or created by the site investigator. The consent form is personalized by each site, adding local contact names and numbers. The consent is approved for use by Institutional Review Board. The investigator or designated study personnel informs the participant about the study purpose, risks, and potential benefits. The patient is allowed time to read the consent form, ask questions, and consider participation. Participant or representative signs and dates the consent form. The sponsor and/or Institutional Review Board may require additional signatures. The participant is given a copy of the consent and taken to the phlebotomy unit for sampling.

Results: The BCI method has improved the knowledge, attitudes, and involvement of individual, organized group and opinion leaders regarding consent for a project.

Conclusion: A short community-based education on consent might influence huge participation in a project in Ghana.

PE-03 The National Measure for Biological Research Resources in Korea

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Biological resources are the fundamental material for biotechnological studies and industries. Due to the importance of the biological resource, developed and developing countries have been encouraged collection and management of biological resources. Due to consider the importance of biological research resource in Korea, the biological research resources are newly defined as raw materials which form the basis of biotechnology research, consisting of living organisms for industrial uses, such as animals, plants, microorganisms, and human-derived research materials, and the related information. The Act on the acquisition, management, and utilization of biological research resource was entered into force on November 9th, 2009. Consequently, biological resource centers are designated and managed by governments under these Act. In Korea, 218 biological resource centers are designated as a biological resources center for collecting, preservation, and distribution of biological resources. The competent authority which is a headquarter of biological resource centers is designated among each ministries. In Korea, there are 12 competent authorities in 7 ministries. The competent authorities organize a consultative council of competent authorities and it works for technical cooperation, exchange of information, linkage, and so on. In the information integration perspectives, the information center of biological research resource center is designated among ministries and the national information center of biological research resources center is designated in the ministry of Science and ICT. In this study, we introduce a harmonized national measure for biological research resources in Korea.

PE-04 ELSI Helpdesk

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The Swedish Research Council-funded research infrastructure Biobank Swedensupports healthcare providers and universities with medical faculties working towards national harmonization in biobanking.

Research on human tissues raises ethical, legal and social issues. For example, how do we protect data when sharing samples? How do we protect the integrity of research participants?

To assist researchers and biobanks navigating through the ethical, legal and societal landscape, Biobank Sweden launched an ELSI Helpdesk in October 2018. This support service offers researcher and biobankers in Sweden advice on ethical topics relevant in biobanking and biomedical research, such as informed consent and data protection.

The ELSI Helpdesk also offers trainings in ELSI related questions, research ethics and provides preparatory materials to support universities and research consortia in their dialogue with Swedish authorities, such as answers to referrals on government inquires and policy documents.

The ELSI Helpdesk is managed by researchers and experts of biomedical ethics, administrative law and public law connected to the Centre for Research Ethics & Bioethics (CRB) at Uppsala University. Several of CRBs experts are also part of the BBMRI-ERIC Common Service ELSI. By sharing their expertise through the ELSI Helpdesk, Biobank Sweden will contribute to the integrity of biobank research.

PE-05 Communication with Biobank Participants-from the Experience of Tohoku Medical Megabank Project

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Tohoku Medical Megabank (TMM) Project runs one of the largest biobanks in Japan, collecting biospecimen and health related information including analytical data of biospecimen since 2013. The biobank is based on two types of prospective cohort studies, and it grows continuously by adding biospecimen and information from the follow-up studies of cohort the contents.

TMM recruited over 150,000 participants through the period of 2013–2017 and maintained relationships with them for follow-up studies since 2017, including a second visit to the assessment center. TMM paid considerable attention to communicate and involve the community, and the strategy evolved during the phases of pre-requirement, recruitment, and follow-up.

During the first phase, which was the pre-recruitment phase that ran from around 2012–2013, the project had just started and lacked notoriety. We tried to inform as many people as possible and connect our project with our university's name. In the second phase, around 2013–2017, the recruitment for cohort studies (which means the recruitment for the biobank directly) had begun, and we had to communicate with general residents on the content of cohort studies and biobank. In the third phase, after 2017, we finished recruitment and called back cohort participants, facilitating their return to our assessment center for examination. We also communicated with the general public the contributions the program made to community health.

In each phase, the difficulties and stress of communication to the people who participate in the cohort and biobank are slightly different and we need to build different strategies for that. On the poster, the major activities for community involvement during each phase of our cohort and biobank will be shown and the strategy will be discussed.

PE-06 Using Our Brains Donor Program Supporting Neuroscience Research

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The NSW Brain Tissue Resource Centre's (BTRC) brain donor program ''Using our Brains'' was launched in 2002. The pre-mortem program invites the general public to consent to brain donation via an opt in approach. Information about the program is on websites, brochures and discussed at a variety of meetings. There are currently 619 consented donors, of which 428 have registered their interest to participate in a variety research studies (70%).

Aim: A pilot study to assess the effects of aging, nutrition, sleep and depression on brain function.

Method: The Cambridge Neuropsychological Test Automated Battery (CANTAB), a semi-automated computer interface, was chosen for assessment of memory and executive function. Participants underwent face to face testing for approximately 45 minutes, completed the following tests: Reaction Time Test (RTT), Paired Associate Learning (PAL), Spatial Working Memory (SWM) and Verbal Recognition Memory (VRM). Participants also completed surveys on nutrition (Food Frequency Questionnaire, Cancer Council Victoria), exercise (Goodwin), sleep (PSQI), depression (PHQ_9 depression scale) and biochemistry.

Results: The group comprised of 64 donors (25M, 39F) aged between 33 and 91 years for males (mean 69y SD 10) and 33 and 89 years for females (mean 67y SD 13). CANTAB raw scores were adjusted for age, gender and education. Females had a higher probability of poor sleep quality ($p = 0.05$). Females scored higher in the PAL ($p = 0.0005$) and SWM tests ($p = 0.0002$). Females had higher levels of cholesterol than males ($p = 0.008$). More males (96%) were drinkers than females (82%). Blood results indicated higher levels of creatinine ($p < 0.0001$), bilirubin ($p = 0.0002$), AST ($p = 0.019$) and ALT ($p = 0.0009$) for males. Males had lower folate levels although this did not reach significance ($p = 0.07$). Feedback showed that the donors found no difficulty in using the IPad, but length of time was tiring and should be considered in future studies.

Conclusion: Having baseline cognitive data on our donors for researchers would definitely enhance the BTRC research potential and outcomes. Many of the participants have been enrolled in the UoB program for a number of years allowing the opportunity to conduct follow up assessments determining any deterioration of brain function with aging and/or lifestyle factors.

PE-07 Donor Privacy Protection: From the Perspective of Front-Line Staff of Biobank

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Privacy and benefits are two major concerns that affect donors' willingness to donate their biospecimens. This paper mainly discusses the issue of donor privacy protection from the perspective of front-line staff of biobank. At present, many biobanks use information systems to connect the hospital information system and the laboratory system and other institutions. With the system, biobank can directly or indirectly access donor medical and personal information, and the information may be stored in the system. Biobanks play an important role in the collection, processing, storage and use of samples, meanwhile, the donor's personal information may inevitably be exposed to these links of information transmission, which maybe infringe the individual privacy of the donor.

In the front-line staff of biobank opinion, when the donor's information was first entered into the biobank's information system, it should be completely de-flagged in the first step. With a number as its identification mark in all subsequent links, biobank should set the original correspondence file to a high authority, allowing access to only the subject under review in several specific cases. It can avoid the exposure of donors'

personal information to a large extent and would not have a great impact on the daily work of the biobanks. The awareness of privacy protection of biobank staff can be strengthened through reviews and supervision by ethics review committees and third-party bodies. In addition, the reviews and supervision can help biobank to acquire the donor's trust and willingness to donate samples.

PE-08 The Efficiency of Different Preaching Schemes of Consent Informing in Biosample Collection Event from Newly Enrolled freshmen

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Purpose: Since a bulk of biobanks in china are hospital biobanks, which collect biospecimens from patients and donators from hospital-affiliated health checkup centers. Biobanks dedicated to collect and manage biospecimens from volunteered citizens from all over the country are rare. So we need to develop an efficient preaching scheme to consent the citizens who may knows little about the meaning of biobank and biosample donation. Here we compared the efficiency of two different preaching schemes utilized in 2017 and 2018, respectively, in the collection of first three-day stool, middle-segmented urine and blood samples from newly enrolled freshmen of Central South University.

Methods: In 2017, we spread the knowledge of biobank, and the significance of donation and longtime preservation of fecal microbiota from an very early life stage during the period of freshmen registration. We set up a welcome station in the welcome region and distributed leaflets to the students and their parents who walked by. We call this method welcome-station-and-leaflets method (WSL). In 2018, we employed the force of instructors and started our preaching work two weeks before freshmen registration through QQ group by instructors. The instructors are teachers responsible for life assistance to the freshmen, and each instructor corresponds to a set number of students who are almost from one major. During registration days, we set up an welcome and consultation station for further preaching and explaining. We call this method instructor-directed and qq group-based preaching method (QQ-based-IDP).

Results: In 2017, we collected 253 qualified stool samples with 253 valid consents from 8352 freshmen. The collection efficiency index is 3.03%. In 2018, we received 1050 qualified stool samples but only 730 valid consents,1200 urine samples with 730 valid consents among which there are only 350 morning urine. We also collected 7786 donations of blood samples with 7786 valid consents from all 8460 newly-enrolled Chinese freshmen. The efficiency of qualified fecal microbiota collection is 8.63%, which is significantly improved compared with that of 2017.

Conclusion: QQ-based-IDI preaching scheme has higher efficiency when applied to popularize the knowledge and significance of biobank establishment and bio-specimen donation from all stages of life to a population who knows little about biobank, but needs further evaluation of economic efficiency.

PE-09 Broad Consent for Use of Tissues in Future Research in Singapore

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Statement of the Problem: In both clinical and research settings, biospecimens (also referred to as human biological materials) have been collected and stored. Researchers have been using variable processes and practices to obtain consent for the future research use of biospecimes. These include obtaining consent at the time of biospecimen collection for a specific use, with re-consent for subsequent uses; general consent that covers broad uses; or no consent.

With the enforcement of Human Biomedical Research Act (HBRA) in governing donors' decision to be involved in biobanking, the legislation mandate the need for donors to be appropriately informed, including a list of essential information, and that the information are organized in a way that facilitates the prospective participant's or legally authorized representative's understanding of the reasons why one might or might not want to participate. Uncertainty about the format of information and the application of understandable consent process may result in decisions to not use certain bisopecimens and consequent loss in public benefit from research.

Proposed Solution: It is critical to identify the best approach which balance the burden of obtaining consent for future research and minimise harm for the donors (disrespect, lost of autonomy and lack of transparency). Within an academic institution, a policy of broad consent has been proposed. This broad consent permits institutions to collect, store and use participant's data and identifiable biospecimens for unspecified range of future research with and will be separated from study specific consent.

Once broad consent is obtained, any subsequent storage and secondary research uses of the biospecimens and data consistent with broad consent will not require additional consent. This avoid the burden for researchers and donors of making a decision for each new study. However there may be concern for individuals who are willing to have their samples used only for a few type of research and logistics for tracking broad consent. The applications of broad consent will be evaluated, including assessing the ethical acceptability and oversight process.

Conclusions: A framework for appropriate broad consent, which includes development of appropriate consent template with mandatory elements, guidance on initial consent, independent oversight and future review will be established, so as to ensure compliance with HBRA in Singapore.

PE-10

Withdrawn

Hot Topics

PHT-01 Covering Your Assets: A Survey of US Academic Biobank Continuity Planning

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Background: Academic biobanks in the US face a number of natural and man-made challenges that call out for continuity planning. Current regulations do not require such planning, so it is unclear how biobanks are preparing for future crises. Nevertheless, it seems critical to have good practices and procedures that allow for efficient recovery and promotion of long-term sustainability.

Methods: This exploratory study employed mixed methods to understand the state of continuity planning in US biobanks. It first reviewed the current regulatory and implementation requirements driving and challenging continuity planning, then developed a survey instrument, which was critiqued by a focus group of experienced practitioners in biobanking. The refined survey collected responses from a targeted group of US biobanks.

Results: Most respondents were associated with relatively mature biobanks operating for more than six years. and having some form of continuity plan in place. These mostly had some form of continuity planning focused on natural disasters rather than organization- or personnel-related disasters or crises. However, nearly 25% of surveyed biobanks did not have a continuity plan in place Principal amongst several reported challenges associated with continuity planning were limitations due to financial and personnel resources. While many respondents appeared to be aware of some national and international guidance documents and standards for continuity planning, many reported they did not consult or reference those documents when constructing their biobank continuity plans. Although no specific requirements currently exist for continuity plans, 61% of respondents were concerned that such mandated plans may be required in future.

Conclusions: Continuity plans are recognized by most as important but difficult to develop and maintain. Many of the biobanks appeared reluctant to endorse additional oversight of continuity planning in part perhaps because of the level of resource allocation that might be needed. However, most were amenable to having access to templates and best practice guidelines. Considerations of such materials should consider scalability related to economic constraints, size, collection type, and research utility if they are to be broadly useful yet.

PHT-02 Differential Diagnosis of Cancer in Animal Model by Urine Proteomics

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Urine has been proposed as a sensitive early biomarker source which deserves more biobankers' attention. The power of urine as early biomarker source of various disease types has been shown before. But the power of urine for differential diagnosis has never been shown. In this report, the differential diagnosis by urine proteomics of different cancer types at different organs will be demonstrated in animal models. The results suggest that urine proteome can be used to differentiat different cancer types grown in different organs.

PHT-03 Small, but Mighty: The 20 Year Journey of a Hospital Embedded Paediatric Tumour Bank

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Problem: Sustainability is currently a major challenge for biobanks. Although biobanks have emerged as key resources for translational research, their role as drivers for improved future healthcare is rarely recognised. Due to the necessity of high quality and meaningful numbers of consistently collected human samples for translational research, establishing biobanks within healthcare systems should see biospecimen driven research evolve. How this is achieved and would it best be recognised?

Proposed Solution: The Tumour Bank in The Children's Hospital at Westmead (TB-CHW) was established in 1998. Operating as a single institutional biobank within CHW, within 20 years practice, TB-CHW has supported 100 research projects and distributed 8994 samples to researchers globally, which represented 2324 patients and many disease types. As a result, TB-CHW has been recognized with 82 journal publications with authorship and acknowledgement. Despite this activity, the role the Tumour Bank provides as the 'tissue handling experts' for these studies has not always been recognised and in some cases, completely ignored.

In this review, we summarise the 20 years' experience of TB-CHW by exploring 3 pertinent questions: 1. What can biobanks do for themselves in regards to their structure, operational model

and daily practice to maintain their sustainability? 2. What can biobanks do for researchers to build up their academic credit and community confidence, eventually help with their sustainability? 3. What can researchers/research community do to promote biobanks' sustainability through recognition of the role played in translational investigations?

Conclusion: In the light of these data, we will convey two messages. Firstly, to bolster your claim to be sustained, biobank can be small in size, simple in structure, but mighty with regards to their contribution to academic outcomes and the meaningful impact of the research. Secondly, to help biobanks' sustainability, researchers need to acknowledge the contribution of biobanks, not only before the dispatch of samples, but more importantly after the projects' conclusion through recognition of the future impact the research has to healthcare. Only then will biobanks be able to justify claims for ongoing financial support.

PHT-04 Next Generation Living Biobanks for Precision Oncology

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Originally, precision medicine takes into account the influence of patients' genomic changes, environment and life style exposures to tailor interventions. Genomics-based targeted cancer therapies have produced substantial clinical responses in the past decade, but most tumors develop resistance to these drugs. Biomarkers are urgently needed to predict response to immunotherapies including checkpoint inhibitors, adaptive T cell therapies (TIL, Car T, TCR T, etc), and cancer vaccines as well. Functional testing is an unmet need for the majority of patients without targetable driver genes as well as patients who become resistant to targeting- and immune- therapies. We developed a method which allows us to establish rapid functional analyses of patient-derived tumor cells (including CTCs and urine cancer cells), especially for predicting drugs/drug combinations, using Conditional Reprogramming (CR) technology. This rapid and efficient method for generating cancer cell cultures (non-invasion approach for culturing bladder cancer cells) can be used potentially for high-throughput drug screening, predicting patient clinical responses, and for monitoring tumor initiation and recurrence. Together with other Patient-Derived Models (PDMs): patient-derived xenografts (PDXs), iPSCs, cancer associated fibroblasts (CAFs), patient-derived organoids (PDO), CR cells represent a novel and more attractive field of biobanking: living biobanks. These types of models or living biobanks better represent the structure and complexity of human tumors than traditional cell lines do. The living biobanks will serve as a resource for public-private partnerships and for academic drug discovery efforts. The living biobanks can be clinically-annotated with molecular information available in an easily accessible database and should be available to the all cancer research communities, including academy, clinics and industry. Recently, there are several reports in ''Science'' ''Cell'' ''NEJM'' showing a critical role of these living biobanks in precision medicine.

PHT-05 Practicability of Next Generation Sequencing in a Low Income African Setting with a Focus on Whole Genome Sequencing of Multi-Drug Resistant M. Tuberculosis Isolates from Uganda

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Background: Next Generation Sequencing (NGS) technologies offer valuable tools for detection of microorganisms, understanding diversity, knowing virulence mechanisms or drug resistance. They deliver quick, accurate and cheap options for Nucleic acid sequencing yielding results that are comparable with those of Sanger platforms. The technologies also provide novel ways of addressing scientific questions to advance genomics, medical research, science and molecular biology globally. However, in our settings, even with improved analysis machineries, mysteries like massive cost implications, inadequate expertise, insufficient facilities and lack of improved infrastructure for massive data analysis may derail smooth usage. Nonetheless, we highlight the feasibility, challenges and practicability of NGS in low income settings, with a focus on executing Whole genome sequencing (WGS) for analysis of drug resistance variants in known genes of Multi drug resistance tuberculosis (MDR-TB) strains.

Methods: Twenty archived MDR-TB strains from patients who participated in the National Drug Resistance Survey (Lukoye et al., 2013) were analysed. The isolates were recovered, DNA extracted, and WGS done on a MiSeq at H3Africa Genomics facilities at Makerere University. Sequence data were validated against Sanger data focusing on drug resistance variants in rpoB and inhA/KatG genes in drug resistant M. tuberculosis.

Results: WGS data for rifampicin resistant isolates showed 19 (95%) isolates had resistance variants in rpoB/RRDR gene region whereas 1 (5%) isolate had no mutation. The 19 isolates revealed mutations in five codons; 531, 526, 516, 513 and 511; with Ser531Leu representing 8/20 (40%), 526 representing 5/20 (25%), 516 representing 4/20 (10%), 513 representing (5%, 1/20) and 511 demonstrating 1/20 (5%). katG genes revealed mutations in Ser315Thr (75%, 15/20), Ser315Asn (5%, 1/20) and Trp191Gly (10%, 2/20). Two (10%, 2/20) isolates had no mutations in katG whereas the inhA gene promoter had no mutations in all the 20 isolates. The three isolates with no katG mutations also lacked mutations in inhA gene promoter, even after displaying phenotypic resistance to Isoniazid. After carrying out Sanger sequencing, all these results were very similar.

Conclusions: We report the first successful validation and execution of Next Generation Sequencing that analysed resistance variants in MDR-TB strains from a low income setting.

PHT-07 The Intelligent Database for Clinical and Molecular Classification of Oral and Maxillofacial Cancers

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The Intelligent database for clinical and molecular classification of oral and maxillofacial tumors is an online resource integrating genetic, epigenetic and clinicopathological data of malignant tumors in oral and maxillofacial regions. Our collaborative efforts in China have been mainly focused on correlation analysis between clinical features and multi-omics data, which currently involve over 350 human oral cancer exome DNA libraries/full-length cDNA libraries. The multi-omics data and relevant patient details is uploaded to the database by study administrator using the database's web Interface. The R pack-

age is used to import database mutation and expression values and perform a series of statistical analyses including t-tests, correlation coefficients and hierarchical clustering. Values from all statistical analyses can be queried through tranSMART-based tools and website interface. Query results are embedded with graphical capabilities as well as with links to other databases containing valuable gene resources, including GO, KEGG, and dbSNP. The database is helpful for revealing the relationship between omics data and clinical parameters, as well as discovering the molecular targets for prevention, diagnosis and treatment of oral cancers. Data for other levels of omics such as WGS, micro-RNAs and DNA methylation information will be added in the near future. This work was supported by the National Program on Key Research Project of China (2016YFC0902700) and Shanghai Municipal Science and Technology Commission Funded Project (18DZ2291500).

PHT-08 DNA Fingerprinting – An Innovative Way to Re-Identify Clinical Trial Biospecimens with Missing Labels

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Background: Missing labels have long been challenging to clinical trials rendering biospecimens unidentifiable, causing loss in crucial data, and impacting study timelines. During registration of 10 OCT tissue samples for an early phase Celgene clinical trial, labels fell off and the blocks could not be associated with their respective subjects. Given the potential donor matches could be narrowed down to 6 subjects (4 subjects had 2 blocks each). DNA fingerprinting using SNPTrace™ was performed on both the blood and blocks to match blocks to corresponding subjects with the precision required to identify each sample without question.

Methods: Single nucleotide changes, known as Single Nucleotide Polymorphisms (SNPs) are the most common form of genetic variation found in the genome. DNA fingerprinting was performed by high-throughput Fluidigm BioMark Genetic Analysis system using the SNPTrace™ identity and sample quality panel. DNA from tissue samples was extracted using Qiagen QIAamp DNA Micro Kit following standard procedures. A 10 µL aliquot from each subject, using DNA extracted from OCT blocks and EP-DNA from whole blood biospecimens, were run on the SNPTraceTM panel, with controls and known sample pairs on each plate. Genotype call were made using the Fluidigm SNP Genotyping Analysis software. The resulting genotypes were analyzed using a sample quality and identity algorithm developed at RUCDR to match skin biospecimens with their corresponding whole blood samples through concordant comparison identification. When performing concordance analysis, loci with a ''no call'' were considered invalid for that biospecimen and were not included in the comparative analysis. The cutoff for concordance between all biospecimen SNP profiles was set at 90% amongst valid calls to confirm sample identity pairs.

Results: All 10 OCT block biospecimens exceeded the 90% concordance cutoff when analyzed with the whole blood EP-DNA biospecimens. Out of 10 OCT blocks, 5 showed 100% concordance. Therefore, all 10 blocks were matched to their original donors resulting in no loss of sample identity in clinical trial.

Conclusions: In cases where mislabeling or sample identity loss does occur, DNA fingerprinting can be used reliably and efficiently to identify the donors of biospecimens or link a primary biospecimen with any of its biological derivatives. This technique is an innovative way to support to clinical trial operations and ensure sample identity on a molecular level.

PHT-01M Healthcare Integrated Biobanking Explained-Reaching Researchers and the Public by a Short Information Film

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Background: Reaching out on many levels is always challenging. The knowledge of what a biobank is and the process of biobanking is limited among the public. This also includes the different steps of scientific research leading to a scientific report. The researchers have a clear idea of their research but often lack knowledge about the biobanking process. With focus on the patient or sample donor but with the aim to benefit staff, researchers and others that come in touch with biobanking, Uppsala Biobank decided to produce a short film explaining the most essential steps when it comes to sample access through healthcare integrated biobanking.

Methods: After gaining support from the principals of Uppsala Biobank and securing the funding needed to take on the project, a film production company was contacted. In the preproduction stage, a manuscript was written, locations for filming was decided upon, and casting took place. It was of high importance that those who on daily basis worked in biobanking related processes had the opportunity to be involved, and engaged in the project. Therefore, anyone who was interested in a role was given the chance to audition for that part. The shooting was carried out on multiple occasions, followed by rounds of editing, and sound recording. Finally yet importantly English subtitles was added.

Results: A short film was produced explaining the essential steps of sample access through healthcare integrated biobanking. The film is starting with the research idea, and then continues to follow the chain of custody of the sample-the ethical application, the application to the biobank, the consent from the research participant, the automated sample handling process at the laboratory, and finally the long-term storage of the samples.

Conclusions: The film easily explain the requirements for sample access, and the highly automated process of collecting samples through healthcare integrated biobanking. It is now distributed to research projects, and schools as educational material. It also serves well as an introduction to biobanking for new researchers seeking advice from Uppsala Biobank.

PHT-02M

Human Specimen Repositories

PHS-01 Assessment of Feasibility of Investigation of Non-Targeted and Transgenerational Effects Among Offspring of Radiation Exposed Individuals

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Background: Findings of animal experiments suggest that high levels of radiation (>1.0 Gy) may induce genetic and epigenetic alterations in offspring of radiation exposed species (Little M. 2013). However some studies of offspring of radiation exposed parents reported no increased risks of any health outcomes. Additionally, it should be noted that data on health effects in offspring of individuals chronically exposed to ionizing radiation, and specifically internal radiation, at low dose rates remains sparse.

Methods: A cohort of Mayak Production Association (PA) workers and their families provides a unique source to perform such studies, and one of the main advantages of the cohort is availability of biological specimens contributed by cohort members.

Results: To date the Russian Radiobiology Human Tissue Repository (RRHTR) stores biological specimens for 1415 family triads (119 families with an exposed mother, 650 families with an exposed father, 497 families with both spouses being exposed and 150 control unexposed families). The range of preconception gonadal absorbed doses from external gamma-rays was wide (0 - 5.7 Gy). The mean cumulative preconception gonadal absorbed doses from external gamma-rays were 0.74.

Conclusions: Available individual medical information, data on parental reproductive health, non-radiation factors and other variables, as well as individual measured annual (in some case, monthly) doses from chronic radiation exposure and sufficient statistical power enable investigations of non-targeted and transgenerational effects among offspring of radiation exposed parents.

PHS-02 Assessment of Feasibility of a Study of Lung Cancer Pathogenesis in Mayak Workers Internally Exposed to Alpha-Particles

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Background: One of the most significant effects observed in a cohort of workers at the Russian nuclear production facility Mayak Production Association (PA) is an increase of lung cancer risk following internal alpha-particle exposure from inhaled plutonium-239 as well as external gamma-ray exposure over prolonged periods. Stored biospecimens from these workers and controls, together with annotated occupational and medical data, are critical to support.

Methods: The Russian Radiobiological Human Tissue Repository (RRHTR) was established at the Southern Urals Biophysics Institute in Ozyorsk, Russia and is currently maintained and extended with the support and collaboration between the US and the Russian Federation. The RHTR stores biological specimens collected from Mayak PA workers and residents of the Ozyorsk city located close to the nuclear facility who had never been occupationally exposed to ionizing radiation.

Results: To date the RRHTR stores biological specimens from 343 individuals diagnosed with lung cancer, among who 286 individuals are Mayak PA workers (83.4%) and 57 individuals are unexposed Ozyorsk residents (16.6%). These specimens include lung tumor tissue fixed in paraffin (1250 tissue blocks), slides (2447 slide samples), and stored in formalin solution (188 samples). Lung tumor tissue samples are complemented with normal lung tissue samples free of tumor lesions (3444 tissue samples) collected from the same registrants and with blood component specimens (1865 samples).

Conclusions: This inventory of biological specimens stored in the RRHTR is more than sufficient to support research on radiogenic lung cancer pathogenesis. Specimens provided by Mayak PA workers are annotated with occupational history information, individual lung absorbed doses from external gamma- and internal alpha-radiation, as well as data on disease history and non-radiation risk factors including detailed quantitative characteristics of tobacco smoking habits. Altogether, this opens the door for complex investigations of mechanisms

involved in lung cancer development following prolonged ionizing radiation exposure using state-of-the-art techniques.

PHS-03 HIV Biobanking in Ukraine: From the Strategy to Action Plan

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Background: Samples collection from people living with HIV remains the crucial issue of HIV/AIDS translational science. The development and integration of a network of national biobanks into research in Ukraine is a key tool for localizing not only production of modern medicines, but also new methods for early diagnosis of socially significant diseases. We aimed to establish a systemized HIV biobank in Ukraine with well-rounded clinical data, thus to expedite the translational research into this infection.

Methods: The HIV biobank was based on the platform of Laboratory of Molecular Genetic Studies at Sumy State University (Sumy, Ukraine). The peripheral venous blood from HIV-infected patients were collected and fractionated into plasmas and DNA according to standardized operational procedures since 2014. All donations were from subjects who have given ''open consent''. The Information Management System was applied to input of the clinical data and samples.

Results: Totally donations from 112 HIV-positive individuals were included in the HIV biobank in Sumy Region. Stored samples were linked to the dataset of each particular patient (including sociodemographical, epidemiological, clinical and laboratory indices). The component of the HIV Biobank contains samples from HIV-1 infected European Ukrainians: 68 % males, 32 % females, age at diagnosis (33,35 ± 0,76) years, 40 % ART-naive. The samples in HIV biobank were used in the studies of genetic factors of immune response to antiretroviral therapy, including the role of cytokines genes polymorphism in HIV/AIDS immunopathogenesis.

Conclusions: To our knowledge, this is the first report of creation of HIV biobank in Ukraine. The establishment of HIV biobank provides qualified resource for HIV infection research in the country with limited resources.

PHS-04 Development and Validation of an Immune Related, Prognostic Signature and Nomogram in Ovarian Cancer

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Background: The present study aims to develop a immune related prognostic signature and nomogram of ovarian cancer.

Methods: OC gene expression studies was used to construct immune relate gene pairs (IRGP). Log-rank based survival analysis and Lasso Cox proportional regression analysis was conducted to identify prognostic IRGPs to construct a IRGP index based prognostic signature. An immune-clinical prognostic index (ICPI) was generated by applying Cox proportional hazards regression analysis. An ICPI-containing nomogram was developed and validated. Decision curve analysis (DCA) of the nomogram was performed.

Results: 21 OC gene expression studies were obtained and 23 prognostic IRGPs containing 34 IRGs were identified. Survival analyses suggested IRGPI was an independent prognostic factor in the training and test set. Unvariate survival analysis suggested that patients with advanced OC, low grade OC and high grade OC in IRGPI low risk group had better OS compared with those in IRGPI high risk group in the training and test set. The prognostic performance of IRGPI was significantly better compared with that of three other prognostic signatures. The C-index of the ICPI-containing nomogram for predicting the OS was 0.671. Internal and external validation of the nomogram confirmed the robustness of the nomogram with the original and corrected C-indexes for the nomogram were 0.66–0.67. External calibration analysis showed good agreement between nomograms' prediction and observed outcomes. DCA suggested that the nomogram could be translated into clinical practice.

Conclusion: A prognostic immune related, prognostic signature and nomogram for OC was developed, which could be translated into clinical practice.

PHS-05 Four Novel Biomarkers for Bladder Cancer Identified by Weighted Gene Co-Expression Network Analysis

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Background: Bladder cancer (BC) is the commonest malignancy of the urinary system. And currently, there are no specific diagnostic biomarkers for BC. The purpose of this study is to screen novel and prognostic biomarkers for patients with bladder cancer.

Methods: DEGs was detected by using GEO2R. TCGA-BLCA data was used to construct co-expression networks using ''WGCNA'' package in R. We constructed the protein-protein interaction (PPI) network of common DEGs and genes in hub module. GO and KEGG pathway enrichment analysis were in progress by means of clusterProfiler software. By using various datasets and databases, the validation of hub genes was conducted using one-way ANOVA, Pearson's correlation, survival analysis, diagnostic capacity (ROC curve) and expression level revalidation.

Results: 258 DEGs which contained 33 up-regulated and 225 down-regulated genes were screened out in total. Yellow module with $R2 = 0.27$ ($P = 6 \times 10 - 8$) was regarded as key module. We picked out 13 candidate hub genes (BIRC5, BUB1, CCNB1, CDC6, FOXM1, KIF4A, MCM4, NUSAP1, RNASEH2A, RRM2, TPX2, TRIP13, TROAP) from the PPI network and co-expression network. A total of 4 real hub genes (CCNB1, KIF4A, TPX2 and TRIP13) were eventually identified by using 5 different methods. The validation of transcriptional and translational levels made sense. Functional enrichment analysis suggested that all the real hub genes played crucial roles in many events during cell mitosis. Moreover, the genetical alteration showed that 3 of the real hub genes bade fair to be potential targets of cancer drugs.

Conclusions: We identified 258 DEGs, a key module and 4 real hub genes. The real hub genes might be candidate prognostic biomarkers in patients with BC, three of which might be therapeutic targets of BC.

Keywords: Bladder cancer, co-expression, WGCNA, hub genes, histologic grade, prognosis

PHS-06 Establishment and Management of Urogenital Tumor Biobank in Chinese Population

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Background: With the development of science and technology, people have a deep understanding of the pathogenesis of disease, but it can not be applied to early warning, diagnosis, and treatment. A very important reason is that basic research and clinical research do not establish real communication and cooperation. Non-renewable biological samples contain both basic research information (sample entities and genetic information) and clinical research information (disease progression and treatment efficacy) which has been acting as a bridge and link between basic research and clinical research. In 2009, the cover of TIME magazine listed ''Biobank'' as the fourth of ten ideas changing the world. In 2016, the National Thirteenth Five-Year Plan of china explicitly listed ''building a national resource bank of biological information and samples'' as one of the important tasks of ''supporting the development of medicine.''

Research Contents: In order to meet the needs of clinical and scientific research, Department of Biological Repositories, Zhongnan Hospital of Wuhan University (Human Genetics Resource Preservation Center of Hubei Province) established urogenital tumor biobank based on the abundant clinical resources of the hospital. The aim is to study the pathogenesis of urologic diseases, to explore effective early warning, diagnosis and clinical treatment, and to reduce the morbidity and mortality of urogenital diseases.

Results: A biobank of urogenital tumors was established, which covered the collection, processing, preservation, quality control, sample information management, and ethical regulations of tumor samples. The goal of our biobank is to achieve complete preservation, long-term storage (maximization of preservation period), strict quality control, and information management for cancer samples from clinical research center of endoscopic urology in Hubei province.

(1) The construction of biobank has reached the international leading level which has been approved by international ISBER-IRL certification.
(2) It is necessary to establish a feasible organization implementation mechanism, set up a complete operation standard and execution standard, and form a resource advantage integration and sharing mechanism.
(3) As a bridge between basic scientific research and clinical scientific research, the biobank promote collaborative research, produce a series of scientific research results, and finally form a virtuous circle.

PHS-07 Effects of Temperature on DNA Quality and Stability: Some Practical Considerations for DNA Banking in Low to Middle Income Countries

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Tissue banks have provided an important resource of tissues for genetic researches on cancer. However, to low and middle income countries (LMICs) the challenge of putting up facilities to store tissues and DNA can be challenging because of resource limitations. Factors such as, lack of funding for infrastructure and equipment, insufficient numbers of trained staff to develop and use appropriate tools, non-utilization of biobank IT, and the absence of quality assurance programmes were some of the identified factors in the underutilization biobanks in LMICs. We investigated the effects of temperature on extraction of DNA from the buffy coat and stability of the extracted genomic DNA in varying storage temperatures. To be able to propose some practical considerations to LMICs in terms of processing and storing their collected samples for genetic researches. Whole blood samples were drawn and buffy coat was separated by density gradient centrifugation. Cell count was determined to establish quantity of starting material that was separated into three groups: 1) same day extraction, 2) Store at 40C, and 3) Store at −200C. Those stored at 40C and −200C had DNA extraction after 1 week and 2 weeks of storage. After extraction, all of the DNA was re-assessed for DNA quantity and stability. Our results show that, best way to get high yield of DNA from buffy coat is to extract DNA on the same day of blood draw. Also the amount of DNA and its stability is not affected by storage temperature. Therefore, LMICs can consider putting up DNA banks using 40C refrigerators which are much cheaper than biofreezers and will only occupy a small space in their infrastructures. Such way, researchers can have access to genomic DNA readily available for use especially in cancer research.

PHS-09 Establishment of a National Health Laboratory Services Biorepository in Uganda

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Introduction: Uganda National Health Laboratory Services (UNHLS) receives a variety of specimen types such as Dried Blood Spots (DBS), plasma, microbiological and outbreak specimen from health facilities across the country. Due to the absence of a bio-repository both DBS and microbiology specimen have been inappropriately stored and can hardly be retrieved for future research and other lawful usage. Therefore, there is need to establish a banking bio-repository at UNHLS in order to store remnant DBS, plasma and public health threat specimen under appropriate conditions that conserve the integrity of the specimen. These clinical specimen will be readily availed to researchers and dual-use in clinical, public health and other programs.

Specific Objectives: To seek consent for long term storage and utilization for research of remnant clinical samples

To process, cryopreserve and store bio-specimens derived from remnant clinical samples, public health surveillance and biomedical research in Uganda.

To establish a BRGC to oversee the activities of the bio-repository, provide direction on priority samples to store and regulate access to the repository resources on the behalf of the government of Uganda.

To promote specimen access and sharing by university and research institutions and enhancing health research collaborations.

To provide education and training in bio-repository science with a special emphasis on health and safety biosecurity in Uganda.

Methodology: The bio repository will be established in UNHLS located on plot 106-1062 Luzira - Butabika Road, opposite Butabika National Referral Hospital. Target specimen will include HIV infected patients for viral load testing, HIV exposed infants for Early Infant Diagnosis, specimen from cases and their contacts with confirmed agents for disease outbreaks, antimicrobial resistance isolates, specimen from Hepatitis B positive patients, sickle cell patients sickle's and variants specimens, specimen from clinical trial participants and specimen from epidemiology and health survey participants. Biological specimen will be stored at −80oC for long term storage or according to the standard operating procedure/research protocols and the environmental conditions will be monitored routinely. Electronic Laboratory Information Management System with backup.

PHS-10

PHS-11 Trust—The Building Block for a Successful Biorepository

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Background: Trust is a fundamental building block for biorepositories to solicit support from it users. Yet, trust is often compromised in low and middle income countries (LMIC) due to lack of knowledge of biobanking and a history of personal harms. Harms are rooted in colonialism, unethical exploitation, corruption, and helicopter research. In the Human Heredity and Health in Africa (H3A) consortium, trust was a major barrier to principal investigators (PI) agreeing to deposit DNA at H3A biorepositories, despite a mandate by H3A. The Institute of Human Virology Nigeria- H3A Biorepository (I-HAB) sought to overcome mistrust through several strategies.

Methods:

I-HAB's strategy:

*Educate-Developed themes for advocacy and communication, highlighting the purpose and benefits of biobanking; and addressing myths and misconceptions head-on.

*Advocate-Presented oral and poster presentations echoing themes of education.

*Communicate- Sought PIs and arranged meetings echoing themes of education and probing to determine areas of misconception and need.

*Dedicate- Provide services; support growth of users through site assessments, training and mentorship.

*Replicate- Continuously seek opportunities to educate, advocate, communicate and dedicate.

New community engagement program- flyers, focus groups, online videos, questionnaires, and meetings with leaders in research, medicine, ethics, and the community.

Results:

I-HAB:

*Presented at H3A, African Society for Laboratory Medicine, and local scientific meetings; and participated in a regional taskforce to promote biobanking in Africa.

*Met routinely with users.

*Provided assessments, and customized training and mentorship in 20 topics for 51 persons at I-HAB and on-site.

*Received 11,751 DNA from the five assigned H3A projects and one requested for storage and shipment of an additional 15,333 non-DNA samples.

*Gained four non-H3A clients.

*Design, staff and train a national biorepository for government of Nigeria.

Conclusions: Distrust is an adversary to biobanking, especially in LMIC where past harms and lack of knowledge spur skepticism. Trust can be built by purposeful messaging, probing, directly addressing misconceptions, and providing services such as training and mentorship. Trust builds mutually beneficial relationships between the biorepository and its community and provides a foundation for high quality samples for science and public benefit.

PHS-12 Research and Development of Biobank Network and Operational Support for Promotion of Utilization of Biobank Toward Realization of Genomic Medicine

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We have started the project aiming at research and development of biobank network connecting the three major biobanks (Biobank Japan, Six National Center Biobank Network, and Tohoku Medical Megabank) and the university hospital's biobanks in Japan. This project also aims at research and development of operational support for promotion of utilization of biospecimen and data stored in biobank toward realization of genomic medicine. For this aim, we are developing a biobank cross-search system on biospecimen and data stored in biobanks in biobank networks, utilizing our experience of development of prototype of this system. Our biobank network will be developed for utilization of biospecimen and data across biobanks which are various ones. We are working on this advanced project with all major stakeholders including the three major biobanks, the major university hospital's biobanks and related academic societies in Japan. To develop biobank cross-search system, at first, we are investigating user needs, and we are examining advancement of the biobank cross-search system including addition of quality control data of biospecimen to search item, that is the minimum common data of biospecimen and data in biobank, with paying close attention to the international trends. After development of the biobank cross-search system, we will operate the system, and then will examine the coordination function of fast access to biospecimen and data to meet the requests by academic/commercial users. After examination of coordination function, we will start support of matching between academic/commercial users and biobanks. To accomplish aims of this project, utilization across various biobanks will be promoted by our biobank cross-search system and support of matching between academic/commercial users, and researches and developments toward realization of genomic medicine will be expected to be accelerated.

PHS-15 Generating and Banking Patient Derived Cell Lines: Adding to the Biorepositories Repertoire

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Statement of the Problem: Biorepositories fulfill an important function in aiding clinical, basic, archival, and translational research. By facilitating the collection and storage of blood and tissue samples from patients across hospitals and clinics, these facilities contain an array of samples used for DNA/RNA analysis, IHC, proteomics, genomics and other studies. Unfortunately, samples such as FFPE and OCT tissue blocks have a finite life span. This depletion of non-renewable patient samples is one of the most critical issues facing all biorepositories today. Viable cryopreservation of PBMC'S from blood has been one method developed but cryopreservation of tissue to use as a renewable resource has been more challenging. Thus, new methods and strategies must be developed that allow biorepositories to not only secure and bank samples but to facilitate the renewal of these important samples.

Proposed Solution: In 2015, the Duke Cancer Research Institute partnered with the Duke BioRepository and Precision Pathology Center to address this problem. The Primary Tumor Cell Culture (PTCC), was created with the goal of generating and banking primary malignant and normal epithelial cell lines from fresh patient tissue utilizing the ''conditional reprogramming'' technique developed by Schlegel and colleagues at Georgetown University (Am. J. Path. 2012, 180: 599). This method enables the efficient generation of cell lines from malignant and normal epithelial tissues under culture conditions that include irradiated fibroblast feeder cells and media containing a Rho kinase (ROCK) inhibitor. It has been shown that a large fraction of primary epithelial tissue samples, and individual cells within those samples, are observed to proliferate indefinitely under these conditions while maintaining the key genomic features and drug sensitivities of the parental tissues. Additionally, most commonly used, commercially available cancer cell lines are believed to possess limited genetic or functional heterogeneity relative to the corresponding human disease while also commonly harboring de novo features emerging from long-term selection in in vitro culture conditions.

Conclusions: To date we have generated over 347 uncharacterized cell lines. We are now pursuing our secondary goal and begin characterizing these lines with respect to the parent tissue. This will ultimately allow the Duke research community to utilize primary cell lines that best fit their research needs.

PHS-16 Quality Control Mechanisms for Establishment of BioRepository of Mother-Child Cohort in Pemba Island: Africa

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Statement of the Problem: Bio-banking is emerging as a complex science involving multiple disciplines by providing a platform for the rapidly evolving era of technological advances in the field of genomics, proteomics, metabolomics, and epidemiological studies. It is very important to ensure that these bio-specimens guarantees that samples distributed to industry or academic researchers are comparable and without institute-dependent intrinsic bias and to ensure the accuracy of the results obtained from the samples. However, this is a challenge especially in a community-based setting and needs several measures to guarantee the maintenance of the quality standards set by international bodies.

The Alliance for Maternal and Newborn Health Initiative is a BMGF funded multicentre study monitored by the World

Health Organization (WHO/MCA). It is a community-based pregnancy cohort involving three countries Bangladesh, Pakistan and Tanzania. In Pemba, Tanzania site 5,000 women are currently being recruited, followed from early pregnancy till 42 days postpartum. Blood, urine, placental tissue and cord blood samples are collected during the follow-up period.

Solutions: Standard Operating Procedures (SOPs), harmonized sample collection tools and techniques have been developed in consultation with international experts and WHO. Internal quality control checks involving random spot checks, rapid test for analysis of sample quality have been developed. Videotaping of the sample collection process enables reviewing the process and filling the gap through refresher training. In-house designed real-time data capture software ensures recording the details of the whole sample collection and processing with date and time stamp.

As part of external quality control, a team of experts appointed by the WHO/MCH periodically visit the site for monitoring; a ''walking with the sample'' approach is followed to ensure feedback and corrective measure at each stage of the process. Randomly selected (loss to follow-up) samples are sent to international certified laboratories for external quality check. In addition, fortnightly conference call with external monitoring team of experts to discuss progress and issues helps in immediate corrective measure.

Conclusion: So far all our samples have been reported to provide high yield and high quality of analytes.

PHS-17 Genomic and Biological Comparison of Conditionally Reprogrammed Cell Culture with Their Parental Patient-Derived Xenografts

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Current efforts for cancer drug discovery have predominantly been deterred by the lack of appropriate preclinical cancer models that recapitulate the characteristics of this complex disease. Patient-derived xenografts (PDXs) are widely recognised as a more physiologically relevant preclinical model than organoids and standard cell lines, and often resemble the original tumor histology, genetic profile, and gene-expression patterns. Despite these benefits, PDX models are limited by their variable engraftment rate, lack of sustained growth in vitro, low throughput for drug screening, less amenability of experimental manipulation and high cost. In this study, we utilized our recently discovered conditional reprogramming (CR) technology and have successfully generated four CR cell (CRC) lines from bladder cancer PDXs. All the established CRC lines maintain parental mutations and allele frequencies without clonal drift. Moreover, the drug responses of the parental PDX tumors in vivoare retained in the established CRC lines in vitro. Altogether, this CR technology offers the ability to generate cell lines and expand PDX cells without compromising fundamental biological properties of the model, as well as for use in in vivoto reduce animal usage, variability and study cost. We propose that the CR cell lines established here can not only potentially be used for high-throughput drug screening towards personalized therapy, but also for studying drug resistance mechanism, testing against a panel of approved drugs and developing new drugs.

PHS-18 Best Practices for Establishing a Biobank in an Academic Institution in Singapore

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Statement of the Problem: In Singapore, all research using human biological materials is regulated under the Human Tissue Framework of the Human Biomedical Research Act (HBRA). Any individual or organization that are involved in removal, collection, storage, supply, import, export activities of human tissues for future research will be required to comply with the HBRA for tissue banking.

As the institutional or investigator-driven collection of biospecimens are precious, an appropriate set up of biobank is an initiative response to the needs of researchers in terms of quality, access and transparency. Being the custodian of the biospecimen, a biobank will also need to be adequately equipped with management of data associated with the biospecimens, linkage to biospecimens, policies and procedures for appropriate banking management. An academic institution may be large with various banking facilities across the institution. This composition of banking facility, resource, policies and procedures necessitates a harmonization of workflows within institution and a changing mindset of researchers willingness to share and collaborate.

Proposed Solution: In order to establish a biobank for the custodianship of high quality biospecimens and data compliance with HBRA, best practices will be adopted from established biobanks and international biobanking guidelines, including the ISBER best practices. Structured biobank governance framework and policies will be developed to oversight the biobank operations. The workflow pertaining to collection, storage, processing, access and utilization guidelines as well as compliance monitoring strategies will be set up. The composition of biobanks will include satellite banks across the large institution. This set up requires a harmonization of workflows including defining clear roles and responsibilities between the biobank and its satellite banks. Transparent and open communication will be vital among stakeholders across institution, leading to trust and engagement. Policies for sharing of biospecimens and associated data should be developed, consistent with HBRA.

Conclusions: The biobank's governing body, biobank business plan and documented policies covering the full biobanking lifecycle including its satellites will be established.

PHS-19 Facilitating Rare Cancer Biobanking in Manchester, UK

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Background: The Manchester Cancer Research Centre (MCRC) Biobank is a multi-centre Biobank set-up to collect human tissue samples from cancer patients in the Greater Manchester area. Access to biological materials for research into rare cancers, where access to high-quality samples and associated clinical data remains limited, is particularly vital as outcomes for patients with rare cancers is significantly worse than those with common cancers.

For each rare cancer, the MCRC Biobank has collaborated with the clinical teams to establish a high quality biobank with a

range of sample types, including whole blood, plasma, serum, fresh/frozen tissue, saliva, stool, ascities and pleural fluid. These samples are being actively used in translational research projects within the Manchester Cancer Research Centre.

Method: Individual collection models have been developed using the robust MCRC Biobank infrastructure and tailored to work alongside diverse clinical pathways for patient management, to ensure effective sample collection.

The MCRC Biobank's flexible working approach to sample collection has allowed adaptation to the variations in the clinical management pathways of each cancer group, including:

- hepatopancreatobiliary
- head and neck and salivary gland tumours
- sarcoma
- penile malignancies

The MCRC Biobank also accepts applications for secondary biobanking activity for rare cancer subtypes, including banking of translational material as part of a clinical trial for a future unspecified use, which builds the rare sample collections and enables best use of these samples at the end of a trial or study.

Results: The collaboration of the MCRC Biobank with the clinical teams has increased the availability of rare cancer tissue samples for approved research applications, including:

- Serial timepoint blood samples for CDX mouse models
- Unprocessed (fresh) tissue samples for PDX mouse models
- Mining of the vast pathology archives available to construct large cohort tissue microarrays linked to clinical data
- Genomic profiling of tumour DNA

Conclusion: The strong working relationship between the various clinical teams, researchers and the MCRC Biobank has been paramount in establishing successful sample collection pathways from patients with rare cancers. It has improved the accessibility of high quality tissue samples for researchers with the ultimate aim of improving understanding of the underlying mechanisms of these diseases and improved treatment options in an area of unmet need.

PHS-20 Image Processing to Capture Informed Consent Data

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Statement of Problem: The Cooperative Human Tissue Network Eastern Division (CHTN-ED) is an NCI sponsored biorepository. The CHTN-ED collects a wide variety of biosamples for multiple IRB approved projects which result in the use of multiple consent forms. The consent process is performed with paper consents. Once signed, the forms are digitally scanned as a whole PDF image into the database. All efforts are made to protect donor confidentiality as outlined by ISBER Best Practices. Selected responses to the consent questions effect the final distribution of biosamples (e,g, can samples be used for genetic research). Staff require access to the consent responses to determine proper utilization of the biosamples. The responses to questions become more meaningful when the data (opt-in/out responses) are available for data-mining and the images do not need to be read directly. This can only be achieved if the individual consent responses are captured digitally within the Specimen Management System (SMS) database. Manual entry of these responses leave significant room for human error during hand entry. In addition, this increases the administrative burden for the collection of this data for use in data-mining.

Proposed Solution: In response to this problem, data elements were created in the database to replicate the consent form questions and responses. The responses all require predetermined data values (Yes/No/No response). The CHTN-ED developed and is testing an autonomous PHP-server application based on the php-extension library (PDFlib) which monitors a directory. When a pdf file is scanned and uploaded to this directory, the application reads the file and determines by the geography of the text layout, which consent form is being uploaded. Once the geography is determined, the application identifies extraneous markings within the defined geographic boundaries of the document. These boundaries define the placement of opt-in/opt-out check marks/responses. Upon completion of the processes; the application converts the PDF document to a base64-encoded object for capture within the database; saves found opt-in data to to the biosample record; and alerts staff to review the recorded data.

Conclusion: Exploiting a single-step automated workflow data processes whenever practicable, reduces administrative burden and removes the opportunity for human error. This in turn leads to increases in efficiency and a more meaningful and useful dataset.

PHS-21

Withdrawn

PHS-22 The Vanderbilt Pediatric Biorepository for Congenital Heart Disease

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Background: Congenital Heart Disease (CHD) is the most common types of birth defects. It affects 1% of births per year in the United States. There are some factors that are associated with an increased susceptibility to CHD, such as: genetic or chromosomal abnormalities in the child with Down Syndrome, DiGeorge Syndrome and Williams Syndrome; taking certain medications, alcohol or drugs during pregnancy. The risk of having a child with CHD is higher if a parent or a sibling has CHD, the risk increases from 8 to 16 in 1,000. Though genes such as GATA-4 and NKX-2 have been associated with the formation of some cardiac defects, much about the underlying genetic and molecular mechanisms of CHD are still unknown. We initiated the Pediatric Heart Tissue Biorepository in early 2010, and have been actively collecting blood, DNA, and heart tissue samples. These samples provide us with rare opportunities to study the etiology and biology of CHD across various disciplines.

Methods: In collaboration with pediatric cardiac surgeons, we have established infrastructure and Standard Operating Procedures to build a well characterized pediatric cardiovascular tissue biobank with plasma/DNA collection for biomarker discovery and genetic studies. Patients' clinical information associated with the specimens was collected into the Research Electronic Data Capture (RedCap) database, and the Freezerworks was used as inventory database.

Results: To date, 321 patients were enrolled. More than 300 pediatric cardiac tissue specimens have been collected including 78 explanted hearts. A total of 262 blood and DNA samples from the matching tissue donors were collected making it a powerful resource for studying somatic mutations and biomarker discovery associated with clinical outcomes. Samples collected ranging from all four chambers and major arteries of the explanted heart, aortic valves, apex from patients implanting Ventricular Assistant Device, to specimens from Norwood, Ross and TOF repair procedures. We have also established 37 fibroblast cell lines derived from the cardiac tissue and generated iPSC cell lines from congenital dilated cardiomyopathy patients.

Conclusions: We have established a well characterized pediatric heart tissue Biorepository supplemented with clinical information. With these resources, we supported many investigators on translational research projects at Vanderbilt University Medical Center.

PHS-23 The Pathological Dissection and Biobank Collection of Whipple Radical Specimen

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Background: Pancreatoduodenectomy or Whipple surgery, is the most complicated surgery, high surgical complication and mortality. The cancer mainly includes pancreatic cancer, distal cholangiocarcinoma, ampullary cancer and duodenal cancer. In order to accurately diagnose tumor and pathological staging and improve postoperative survival rate, standardized pathological examination is particularly important. This article mainly introduces our experience. The pathological dissection and sample collection in biobank can meet the needs of clinical evaluation of tumor biological behavior and scientific research.

Methods: Before the dissection, the relationship between tumor location, the pancreatic duct and the bile duct was predicted based on the clinical data. After the specimen was obtained, first restore the normal position of the specimen, determine the ventral and dorsal sides of the pancreas, and predict the location, size and surrounding relationship of the tumor by palpation. The duodenum was dissected along the duodenal papilla, and the stomach wall was cut along the big curve. Then, combined with the position of the common bile duct, the main pancreatic duct and the mass, the anatomy is cut from the front of the pancreas or the rear. Each specimen was photographed using a black background and a white ruler. The biobankers cut the specimen into pieces if the tumor size is larger than 2 cm. To avoid repeated freezing and thawing, the tissue should be divided into small pieces and placed in different tubes. The specimens are frozen in liquid nitrogen and placed in a −80 °C refrigerator for long-term storage.

Results: Since May 2017, 50 cases of whipple surgery radical have been received. Each tissue has been standardized and photographed with gross photos to meet the needs of research. The specimens in biobank are stored in liquid nitrogen within 1h after the tissue is isolated which means the cold ischemic time is less than 1h. The quality of the tissue samples is ensured.

Conclusions: The standardized dissection and photograph of the whipple surgery radical tissue can ensure the accuracy of the pathological diagnosis. The standardized sample preservation of biobank can further improve the scientific research value. As the development of the tumor biology, more and more new technologies are applied to tumor research, such as PDX and PDO. Standardized sample collection can play an important role in PDX and PDO model construction.

PHS-24 Setting up a Transplant Research Biobank at an Academic Medical Center

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Background: The J.C. Walter Jr. Transplant Center at Houston Methodist Hospital performs more than 500 different solid organ transplant surgeries, including kidney, lung, liver, pancreas and heart, annually. The Houston Methodist Research Institute's (HMRI) transplant and immunobiology group pursues cutting edge research in transplant science. The HMRI Biorepository in conjunction with the Transplant Center has established a Transplant biobank to collect and store high quality biospecimens from transplant recipients and donors to foster innovative transplant translational research.

Methods: Multiple discussions between the Biorepository management and Transplant Group, to decide on biospecimens to be collected and design SOPs, were conducted. A decision to initially start collecting biospecimens from live donor renal transplant cases followed by deceased donor renal transplant cases and after hours' renal transplant cases was taken. A protocol was written, consent form designed, and IRB approval obtained for collecting pre-surgery, during surgery and long-term post-surgery biospecimens from the recipients and from donors during surgery. The Transplant Center operating room staff was trained on the upcoming biobanking collection including the consenting and the specimen collecting process. The Biorepository staff was added to the Transplant Group email list for easy access to patient information. A detailed collection form, designating different locations within the OR from where the recipient and donor biospecimens are being collected, and including SPREC parameters was designed.

Results: Till date, the HMRI Biorepository has collected and stored over 200 sample aliquots from 12 live donor renal transplant cases. The process has been streamlined, minor issues like, timely information of consent to the biorepository and communicating the collection process to all transplant OR staff, have been resolved. Very soon, we will be moving to collect the deceased donor and after office hours renal cases as well as other organ system cases.

Conclusion: A Transplant Research Biobank has been successfully established at the Houston Methodist Hospital. This is a complex biobank collection requiring close interaction between the HMRI Biorepository and the Transplant Center at Houston Methodist Hospital. Once fully established this unique resource will benefit transplant researchers not only at Houston Methodist but also at other institutions in the US and, even, globally.

PHS-25 Tumor-Associated Antigen Specific T-cell Immunity in HBV-Associated Hepatocellular Carcinoma

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Background: Hepatocellular carcinoma (HCC) is a worldwide major health problem and there are few studies on the immune status of HCC. This study is about tumor-associated antigen (TAA) specific T-cell immune response in HBV-associated HCC.

Method: We obtained 40 HBV-associated HCC samples from AIDS biobank, isolated peripheral blood mononuclear cells (PBMC), used enzyme-linked immunospot assay (ELISPOT) with different TAAs including suoluo trees sample 4 protein gene (SALL-4), melanoma associated antigen A1 (MAGE-A1), MAGE-A3, New York esophageal squamous cell carcinoma associated antigen 1 (NY-ESO-1), synovial sarcoma breaking point X gene protein 2 (SSX-2) and alpha-fetal protein (AFP) to detect the immune response.

Results:

1. Screening immunocompetent T-cell antigen: Observing the response frequency of T cells corresponding to 6 TAAs, AFP presented the highest response frequency(73%). Second, SALL-4 was higher (58%), and MAGE-A1 (38%), MAGE-A3 (35%), SSX-2 (20%) and NY-ESO-1 (18%) decreased.
2. Screening high response magnitude antigen: Regarding response magnitude, AFP is the highest, followed by SALL-4, MAGE-A1, MAGE-A3, NY-ESO-1 and SSX-2.
3. Analysing the relationship between HCC stage and TAA response: According to the Barcelona (BCLC) stage, 40 patients were divided into 0, A, B, C and D phases, where 0 and A phases were classified as early stage, B phase as intermediate, C and D phases as late. The positive and negative samples were counted for every TAA at different stages, the relationship with disease stage was analyzed. Results showed that there was no difference in the response frequency of each TAA between different stages. The result of total response is as same as the result of TAA.
4. Analysing the relationship between HCC stage and the number of responsive TAA species: The staging method is described above. Count the number of responsive TAA species in 3 stages of each patient. Results showed that the majority with early stage response to 2 TAAs (early, intermediate and late stage was 40%, 23.08% and 25%, respectively), the response of 1 kind of TAA at intermediate stage (13.33%, 30.77% and 16.67%), most patients appear no response to TAA at late stage. (13.33%, 0 and 25 %).

Conclusion: The response frequency and magnitude of PBMC to AFP were higher in HBV-associated HCC. With the progression of HCC, the number of responsive TAAs also decreased which may imply the importance of TAA specific T-cell immune response in HBV associated HCC.

PHS-26

PHS-27 Quality Assessment of Cryopreserved Cancer Biospecimens in Context of Storage Period

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Background: Quality assessment of biobanked specimens is an essential intervention to ensure implementation of good laboratory practices for carrying out translational research. Quality of genomic DNA is assessed by conventional spectroscopy and gel electrophoresis and long length PCR for housekeeping genes.

Methods: 120 fresh frozen tissues of oral, breast and colorectal cryopreserved over a period of 3–8 months (short term) and 3–4 years (long term) were collected by Department of Biorepository, TMC, ACTREC, India. Histopathology analysis was carried out by the Pathologist and tissues with range of viable tumor percent and <50% necrosis were included in the study. Genomic DNA extracted from the tissues was quantified using absorption and fluorescence spectroscopy while the quality was assessed by gel electrophoresis.

Results: Quantification of genomic DNA confirmed high yield while qualitative analysis by gel electrophoresis showed intact bands of genomic DNA for 94% and 87% of short and long term cryopreserved tissues. Statistical analysis of purity ratio by Bland-Altman plot showed overlapping groups of genomic DNA of short and long term cryopreserved tissues ascertaining the quality of DNA being preserved irrespective of storage period.

Conclusions: Biobanked fresh frozen tissues yielded high quality genomic DNA irrespective of the storage period. To the best of our knowledge this is the first Indian biobank study reporting quality analysis of biospecimens cryopreserved at different time periods.

General Significance: Quality control of biospecimens cryopreserved at Biorepositories is crucial for carrying out high quality, reliable and reproducible bench-to-bedside research.

PHS-28 Establishment of Beijing Biobank of Clinical Resources (BBCR) for Mental Disorders

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Background: Beijing Biobank of Clinical Resource for Mental Disorders (BBCR-MD) was established in 2009. BBCR is a research infrastructure project which funded by Municipal Science and Technology Commission of Beijing, is focused on management system, quality control and standard operating procedures (SOPs) of processing, storage and distribution of clinical resource and biological material with human disease research. We want to report construction process and current state of BBCR-MD.

Methods: According to the third edition of Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research and certification documents of International Organization for Standardization to establish BBCR-MD, including quality control, informed consent, clinical resource and specimen collection and preservation. Special standardized operational procedures for BBCR-MD were development, we also collected clinical data and venous blood samples after sign informed consent. The BBCR-MD appointed an Approval Committee which reviews all applications received and grants permission to access the stored samples and data for research.

Results: Between June 2012 and December 2018, more than 8,000 participants were enrolled in BBCR-MD, most of them with major depressive disorder. In July 2014, other disorders such as bipolar disorder, schizophrenia, anxiety disorder were start to enroll. High risk population of mental disorders and health control were also taken into account. Over 90,000 tubes of blood derivatives were collected and stored. Specimens including plasma, serum, erythrocyte, leukocyte and DNA.

Conclusion: The construction of BBCR-MD is a systematic work. It's functions will be increasing in exploring pathogenesis, developing technological innovation for early detection, novel therapeutic strategies and individualized therapy.

PHS-29 Current Status of Resources and Work Performance of the Korea Gynecologic Cancer Bank

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Background: Human-derived specimens emerged as important resources for basic and transitional research in gynecologic cancer which is critical in accelerating development of molecular-based diagnostics and therapeutics for precision medicine. In spite of the expanding needs for adequate human-derived specimens in gynecologic cancer studies, there was no well-established biobank for gynecologic cancer. Biobanking requires effective and efficient management of not only tissue sampling and storage, but also systematic management of bioinformatics and distribution of utilize high-quality research materials. We would like to introduce a biobank experiences for biospecimens of common gynecologic cancer.

Methods: Human-derived specimens and data stored in the bank target primary gynecologic cancer tissue, serum, plasma,

urine, saliva, ascites and paraffin blocks. Recently, we also started to service tissue microarrays (TMAs). Specimen extraction was administered starting from 2012, and it was administered before or after the treatment using the less-invasive method with the patients agreement. Specimen quality and quantity was identified by classifying specimens by cancer types and their characteristic.

Results: Currently, specimen and data in the bank numbers total of 58,503. Starting from May 2012 to Dec 2018, 20,130 serum, 15,679 plasma, 4,159 lymphocyte, 99 whole blood, 3,124 frozen tissue, 6,306 ascites, 36 HOSE, 4,181 urine, 350 saliva, 1,200 thin-prep, 440 cervicovaginal fluid, 8 TMAs and 2,791 paraffin block units were stored. As for the data on the research source distribution, they include 2,051 serum, 510 plasma, 440 lymphocyte, 631 frozen tissue, 264 ascites, 32 OCT, 3 HOSE, 20 urine, 46 whole blood, 400 cervicovaginal fluid, 32 TMAs and 4,254 Unstained section (paraffin block)units. As for the paper using the distribution of research sources, there are 52 papers published on SCI journals from 2012 to 2018.

Conclusions: Resources of gynecologic cancer bank is continuing to grow steadily since 2012, and quality resource is being developed through proper management.

As such, these resources are utilized to publish a number of outstanding research papers. It is necessary to continue to acquire and manage resources continually to establish the mechanism and the treatment method of the gynecologic cancer that are not confirmed to this point.

PHS-30 Macquarie University's Neurodegenerative Disease Biobank

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Motor Neuron disease (MND) is a fatal neurodegenerative disease characterised by progressive loss of motor neurons, which control muscle movement and function. From symptom onset, patient typically die within 2 to 5 years. Currently, there is no treatment to slow progression.

In 2013, Macquarie University's Centre for MND research and Macquarie Neurology clinic joined forces to establish the Neurodegenerative Disease (ND) Biobank. MND patients and healthy controls are invited to participate in the biobank. Participation involves donation of blood, urine, hair and skin biopsies, which are processed into DNA, RNA, PBMCs, serum, plasma, urine and fibroblasts. The biobank collects extensive clinical data from each participant. Participants are also invited to complete an online environmental and lifestyle questionnaire. Data is stored within a custom build database system.

This resource has grown rapidly with approximately 900 participants, 1,900 collections and 33,000 sample aliquots available for research. It is one of the largest ND biobanks in the world, with a collection of well-characterized samples and extensive clinical and lifestyle data.

The biobank attained NSW Health biobank certification status in 2019. Access to biobank resources is obtained via a biobank access committee and a cost recovery fee applies.

Since 2013, 17 internal and collaborative research projects have availed of this resource. Multiple biomarker projects study longitudinal collections of plasma, serum, urine and hair, to identify biomarkers for diagnosis and prognosis. Fibroblast cells grown from skin biopsies are used to investigate protein degradation. DNA samples are used to identify new genes and to develop new models for investigating MND biology. This team has been involved in most of the major MND genetic advances identified.

Project MiNE is an international whole genome sequencing effort to identify rare gene variations contributing to MND. SALSA is a national research effort into the sporadic onset of MND. Environmental projects search for evidence of neurotoxin and pollutant exposure in plasma and hair samples from patients living within geographical MND clusters.

The ND biobank is an excellent example of a medium-sized biobank with a collection of high quality samples, interdigitdated with extensive clinical records that can support numerous complex research projects to make major advances in understanding the pathogenesis of a complex disease.

Innovative Technology

PIT-01 A Novel Computational Drug Repositioning Approach Based on Integration of Transcriptoms and Drug-Target Mapping

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We report an original computational pipeline aiming for drug repositioning by integration of transcriptoms and drug-target mapping, which follows six major steps.

Step I: For a given disease, from in-house and public resources (GEO, ArrayExpress, TCGA, etc.), we collect and prepare transcriptomic datasets containing phenotype data (disease status, severity of disease, treatment response, recurrence, metastasis, survival, etc.) and gene expression profiling matrices.

Step II: For each phenotype, we calculate a phenotype-expression correlation matrix with two vectors (point-estimates and precision measures) for each dataset; for continuous, binary or ordinal phenotype, correlation coefficients with sample size; for time-to-event phenotype, Cox regression βs with standard errors. We then meta-analytically synthesize the vectors. In this step, we can filter out genes showing significantly heterogeneous (inconsistent directions among datasets and/or large I2 statistic) and/or inadequate (by threshold or select top n genes) correlation with phenotype. Across-phenotype synthesis may also be performed.

Step III: We create biological networks with eligible genes identified from previous steps. The edges can be protein-protein interaction, co-expression relationship, regulatory / co-regulatory relationship, or derived using other specific methodologies.

Step IV: We apply node prioritizing algorithms (eg. GeneRank) to re-rank the genes, with pooled correlation measures as the primary node weights.

Step V: We prepare the target gene lists of drugs tested, based on information from public databases (DrugBank, DGIdb, etc.).

Step VI: We verify by resampling test if the target genes of a given drug significantly ranks on-top of the ranked gene list. If so, the drug is considered having repositioning potential for this disease.

As a case study, we tested our methods with 6 multiple myeloma datasets and used proteosome inhibitors (PIs) widely used in myeloma treatment as the reference. The targets of PIs were enriched on-top of the ranked gene list, indicating the effectiveness of our method. We identified Rapamycin, an mTOR inhibitor with potent immune inhibitory effects, may be repurposed for

myeloma treatment. We found supporting evidence from literature and by analysis of GDSC drug sensitivity profiles. Our method can be of use for various diseases and extended for repurposing of combination regimens. It is currently under evaluation as National Invention Patent.

PIT-02 Construction of "DEEP FACTS" Tumor Intelligent Research Platform Based on Biobank

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DEEP FACTS is based on the data repositories of Zhongnan Hospital Biobank which is registered as the Human Genetics Resource Preservation Center of Hubei Province (HGRPC-Hubei). We focus on the construction of large tumor database and data deep mining and dedicate to build a multidisciplinary big data intelligent service platform composed by a large biomedical database and data intelligence analysis platform.

A cloud analysis platform is established for tumor big data with the support of the HGRPC-Hubei to provide systematic and intuitive data analysis results toward scientific researchers by using an independently designed tumor data analysis system. This platform is built to solve the problems such as incomprehensible data, difficult analysis, low efficiency and so on, that is, to avoid problem that big data changed into large garbage, and finally to achieve the goal of rational and accurate medical treatment and the independent development of tumor targeting drugs. Morevoer, the global researchers are welcome to share data and resources and communicate with each other in our platform. Our purposes are to break the closed-door model and to establish the industrial platform of ''Internet plus medicine''.

PIT-03 Living Biobanks and Precision Medicine

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Statement of the Problem: In the past decade, clinical oncology has gradually entered the era of precision medicine. Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person, finally realizes the individualized accurate treatment in patients with disease and specific purposes, improve the efficiency of the disease diagnosis, treatment and prevention. Formalin fixed, paraffin embedded whole tissue sections are ideal candidates for localizing DNA and protein markers in pathological diagnosis. However, this type of tissue cannot be used for further proliferation and subsequent drug screening. Traditional tissue processing method is not conducive to the development of precision medicine.

Proposed Solution: Living biobank should enable to identify populations of patients that we can predict will be most likely to benefit from a specific drug. The main techniques as below.

1. Patient-derived conditional reprogramming

Normal or tumor human epithelial cells could coculture with irradiated mouse fibroblast feeder cells in the presence of a Rho kinase inhibitor. Conditional reprogramming cells can be used for various applications, including regenerative medicine, drug sensitivity testing, gene expression profiling and xenograft studies.

2. Organoid cultures

Organoids derived from tumor tissues could largely retain the biological characteristics and structure of the tumor tissues in vivo. Organoids could be used for translational medical research and drug sensitive tests.

3. Patient-derived xenografts (PDXs)

A PDX model was established by direct transplantation of tumor tissue into immunocompromised mice. The new tumor tissues retain the most characteristics of the primary tumors at the level of histopathology, molecular biology and genome. It has good clinical efficacy predictability. PDX model could be used for gene sequencing and drug screening.

Conclusions: Establishing and maintaining a living biobank could benefit individual patients for development of tailored therapy, since high-throughput drug screening results would be available within weeks of initial tissue derivation.

PIT-04 Sample Quality Control of Cell-Free DNA

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Sequencing of cell-free DNA (cfDNA) is possible due to the establishment of low input library protocols for next-generation sequencing workflows. Accurate quantification of cfDNA samples is essential to determine suitable input amounts for cfDNA library preparation prior to sequencing. The main component of cfDNA samples is the mononucleosome with a size around 170 bp, sometimes with additional species representing nucleosome multimers. Further, cfDNA samples may contain larger DNA fragments dependent on preanalytical sample treatment or extraction method. High molecular weight material can negatively influence library preparation and subsequently result in lower sequencing depth. Therefore, reliable quantification of cfDNA requires a method that separates DNA fragments by size, such as electrophoresis. This poster shows the use of an automated electrophoresis platform performing cfDNA quantification with region analysis. Moreover, the results include a score to qualify cfDNA samples according to their contamination level with high molecular weight material. This allows defining a threshold for objective sample qualification prior to library preparation. The analysis features are described with examples of typical sample patterns.

PIT-05 The Nightingale Experience — Biomarker Profiling by NMR Metabolomics: Using Biobank Partnerships to Build the Evidence-Base for Clinical Use

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Background: Advances in metabolomics now allow comprehensive biomarker profiling of entire biobanks and clinical trials. This provides a plethora of scientific opportunities such as discovery of novel biomarkers for onset of cardiovascular diseases and tracking their progression, as well as etiological insights into established cardiometabolic risk factors.

Methods: Nightingale Health Ltd has developed a high-throughput metabolomics platform for population-wide initiatives and screening programs. It is becoming a standard in the world's

largest health resources, and it is now being applied to profile close to 1.000.000 biobanked blood samples with extensive electronic health care records, including the entire collection of the UK Biobank with 500.000 samples. In contrast to genomics, metabolomics provides a functional read-out of an individual's current health status. While reflecting the combined effects of lifestyle, environment and genetics, metabolomics provides a powerful tool for monitoring the health of individual patients over time.

Results: In this study, we demonstrate how metabolic profiling of large biobank collections paves the way for precision medicine. We show that the strong evidence obtained through large-scale collections helps guide decision making for the individual patient.

Conclusions: Here we showcase the benefits of metabolomic profiling in a precision medicine setting, for improved risk stratification and clear clinical interpretation of the biomarker results. We also illustrate the benefits of tracking the metabolomic effects in response to various lifestyle and pharmacological interventions. These results demonstrate how NMR metabolomics and large biobanks can be combined and the value further translated into precision medicine applications in primary prevention settings, providing enhanced cardiovascular risk prediction and novel means to track effectiveness of interventions.

PIT-06 Color Two-Dimensional Code

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The Data Matrix code is widely used due to its high coding density and small size. However, with the increasing applications of Data Matrix code, the information capacity required for code is increasing. However, the space available for marking two-dimensional codes is very limited in some fields. For example, storage tubes for holding pharmaceutical compounds, nucleic acids or other biological samples are small in volume but large in number and cannot be repeated. Limited by the resolution of the reading device and the limitation of the tube bottom area, increasing the number of two-dimensional code matrices to increase the encoding information capacity is near the limit, and it is impossible to increase the encoding information capacity by increasing the number of encoding matrices. By introducing 8 colors to construct a color two-dimensional code, the coding capacity is increased to several times, that is, under the condition that the coding matrix and the symbol size are constant, the two-dimensional code originally encoding 12-bit information can accommodate 36–48-bit information, that will completely solve the problem of insufficient coding capacity of small-area two-dimensional code.

PIT-07 Industry Accelerators and Components Assist in Implementing CLIA Diagnostic Labs Best Practices into Production Faster

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LabVantage Solutions Inc. is rolling out a new line of industry accelerators including Diagnostics in addition to our already existing Guaranteed Biobank solution. Whether you operate a clinical or molecular diagnostics lab, hospital core facility or are a contract diagnostic provider LabVantage will describe how to get into production faster. We will review best practices in informatics functionality, documentation and workflows through preconfigured components. Turning your paper SOPs and 'traveler sheets' into electronic forms that provide better control and oversight into the data and sample handling especially in CLIA validated environments. Along with samples, tracking all your lab consumables in the Lab Consumables Management module will help to maintain accurate inventory, provide notifications about expiry and inventory limitations ensuring that lab operations are not disrupted by supplies on hand. Graphical workflows allow you to quickly set up your standard procedures, allow traceability of your processes, visibility into bottlenecks and the ability to pinpoint potential failure areas. This component library solution, which is free of charge to our customers, includes workflows for Sanger and Next Gen Sequencing, which can be modified to fit your specific needs. Tracking information about your controls over time to trend your data using SPC control cards and a set of the Westgard rules will help to illuminate what works and what does not, and if a specific lot of controls is out of spec over time.

PIT-08 New Technology for Automated Decapping of Large Volume Labware

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Problem: As the trend in the market to use larger labware continues to grow, laboratories need the ability to process these samples quickly and efficiently. Many researchers prefer the large format tube geometry as it enables storage of solid and liquid samples up to several milliliters, with easy access using forceps or standard-length pipette tips. However, decapping these caps manually is a time consuming process, and has the risk of sample mishandling or contamination.

Solution: The new 6-channel decapping head on the LabElite decapping devices is the first in the market to automatically decap and recap large-format tubes such as the Nunc™ Low Profile 5.0 mL Externally-Threaded Universal Tubes.

The LabElite decapping device is 240% faster at decapping large-format tubes than a manual process, and recapping (with optional secure mode enabled) is 120% faster.

Conclusion: The automated processing step allows researchers to increase sample throughput, refocus attention on higher value activities, and reduce or eliminate the risks of sample mishandling or contamination compared to manual methods.

The 6-channel head is ideal for applications in biobanking, agriculture, genomics, biotechnology, pharmaceutical, clinical, and more.

PIT-09 Towards a Mental Health and Friendly Biobanking Environments: Psychological Feeling Based Biobank Repository Planning and Space Design

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Statement of the Problem: The mission of the biobanking is to improve physical and mental health not only for human beings but also for the environment and the whole world. Physical environment can affect our cognition, problem-solving ability, and mood. Reasonable biobank site planning and space design have

the role of guiding, mapping and feedback on stakeholders' and biobankers' spirit and behavior. However, there is no report on the architecture and design on psychiatric biobank available.

Proposed Solution: Renji biobank founded in 2008, now it is under reconstruction. Instead of traditional biobank design and facilities only taking into account of its function, physical and physiological needs, this research pioneers the human psychology and ethics through a series of ''naturally like'' interventions. Such interventions could take the form of orientation and place, naturally like color and daylight, temperature and outdoor views and green setting. The new site of the Renji Biobank is located on the first and second floors of a new research building, which is easy for participants and stakeholders to identify and access; the interior color of the biobank will use visible blue space as it was reported that residential exposure to visible blue space associated with lower psychological distress and a significant relation was found between a calm mood and preference for blue; the illumination of the office area and follow up area are intended to use natural light and a view from a window to a green setting; we aim to design a open bench seating instead of private offices and cubicles, since the open bench seating based office design could be a health-promoting factor; a temperature and humidity regulator will also be installed in the office area to ensure the air neither 'too dry', nor temperature 'too variable'.

Conclusion: The psychology world's role in human well-being is an essential, yet often forgotten, aspect of healthcare associate facilities design. Reincorporating the naturally like world into the design of settings in biobank is one way to complement conventional preserve biospecimen and move biobank building and space design toward being more friendly. By doing so, the biobank will reduce the stress and mental fatigue of the stakeholders or participators who participant the biobank facilities as well as the many individuals who live or work there.

PIT-10 Issues Related to IT Security in Adopting Specialized Commerical Biobanking Systems for Managing Patient's Data

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Diseased-biobanks are usually managed within healthcare Institutions. Biobanks may be using specilized commercial off-the-shelf biobanking system for data management which may include patient's data. If not adequately managed, these systems may pose various risks to the institutions as there may be sensitive patient data and medical records stored in these systems. Inadequate controls in external IT systems and services may pose serious cyber risks as well as reputation, data confidentiality and patient safety risks to the institution. The biobanks need to ascertain adequacy of internal controls on whether there is compliance with relevant policies, procedures, standards and guidelines established. We will discuss the various measures for biobank's system internal controls for IT security.

PIT-11 Data Privacy: Achieving Compliance and Efficiency via Configurable Data Masking

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Biobanks must comply with a variety of data privacy requirements and regulations, such as PII, PHI, HIPAA, and GDPR. To protect the privacy of individuals, labs must anonymize, hide, or mask sensitive information so that unauthorized users cannot access such data.

Data masking – shielding information from certain views without altering the database – can and should be a highly configurable feature within laboratory information management systems in which researchers, scientists, physicians, and others gather, store, record, and manage data on human specimens.

Enabling data masking at the LIMS administrator level, versus coding or engineering, makes laboratories and workflows within biobanks highly productive while ensuring compliance. Particularly for biobanks with multiple studies, and multiple internal and external users across departments and organizations, the ability to configure data masking for users, departments, or studies is essential to efficiency and compliance.

This poster, Data Privacy: Achieving Compliance and Efficiency Via Configurable Data Masking, explores the benefits of data masking, why it is necessary, and the steps involved in masking data and establishing data masking policy.

Data masking obscures sensitive information, required by regulations or standards to remain private, so that it is not exposed to unauthorized personnel. Data masking involves determining what information is considered sensitive, identifying database tables or records that contain sensitive information, and how to prevent the sensitive information from being presented to unauthorized users, as well as determining who has the authority to view sensitive information, by role or department.

A configurable LIMS should be able to mask any field an organization considers private health information and provides full, none, or limited dataset access by user or role to these fields, as approved by the Institutional Review Board. Data masking can obscure the entirety or a portion of text or numbers in certain formats or patterns, such as Social Security, age, or date of birth; or provide ranges. Advanced masking with complex expressions can be applied that are sensitive to context, user, and permissions; and user and study subjects can by anonymized.

For biobanks looking to improve productivity while remaining compliant with the latest data privacy regulations, a configurable LIMS is more efficient than solutions requiring coding and engineering to mask data.

PIT-12 Higher DNA Yield for Epidemiological Studies: A Better Method for DNA Extraction from Blood Clot

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Blood clots are an economical and easily accessible source of DNA, many biobanks and cohort studies accumulate a large number of blood clot samples during their work. Blood clots can be used to extract DNA, but they are not used as widespread as whole blood or buffy coats. Not only because of the relatively low DNA yields and quality, but also because of the liquefaction and sampling of solid clots prior to DNA extraction, it is more difficult to use blood clots than to use liquid blood samples. To solve these problems, we compared several clot liquefaction methods, determined the four most feasible methods, and subsequently evaluated them experimentally. We compared the yields and optical density (OD) ratios of the re-

sulting DNA samples and assessed their integrity using agarose gel electrophoresis, PCR and next-generation sequencing. Each of the four examined methods has advantages and disadvantages, But in general, higher yields of DNA with better quality and integrity were obtained using the high-shear homogenization method than using the other three methods. Additionally, this method is cost-effective and feasible at large operational scales. The DNA yields and A260/280 ratios were optimal and stable, the operation time and labor costs were acceptable, and the success rate of next-generation sequencing applications was 99.74%. Furthermore, we developed a simple and rapid method for cleaning the homogenizer head to remove residual samples. According to our experiment results, our cleaning method effectively avoided possible cross contamination caused by the homogenizer head.

In summary, we recommend high-shear homogenization as a superior method for clot liquefaction. We believe this method is worthy of large-scale application as it can improve the efficiency of DNA extraction from clots, thus reducing labor and economic costs.

PIT-13 Let Your Tubes Fly! Re-Imagining Established Technology for Efficient and High Quality Biobanking

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Statement of the Problem: Within biobanking, much effort has focussed on establishing best practice for sample collection, processing, storage and retrieval. Organisations such as ISBER have published guidelines and generally, Institutes take great care to develop well documented procedures that ensure samples are handled or processed consistently. However, an overlooked weak link often remains. Typically, samples are transferred from the collection/processing point to the biobank manually in batches, with some samples being held longer than others. Centres can mitigate risk by placing samples into temporary freezers, but this process introduces inconsistencies with respect to freezing profiles. When full racks of tubes are introduced into manual freezers, as much as a two-hour difference can be observed between the time taken for inner tubes to reach −80°C versus outer tubes. Whilst not ideal, this is generally accepted as a necessary compromise due to the fact storing tubes without racks is not practical.

Proposed Solution: TTP Labtech's automated storage solutions (ambient, +4°C, −20°C and −80°C) are designed to address these weak links to ensure sample handling consistently throughout. Having pioneered the use of pneumatic technology to transfer 2D barcoded tubes reliably in and out of high-density storage units, a new development will see this same tube transfer capability extended outside the store. A small remote benchtop device has been designed to transfer samples from the collection/processing laboratory directly into the biobank via a pneumatic pipe that easily fits into a building's existing piping and electrical cable conduits. Capable of transporting tubes over long distances, this solution is ideal for remotely located biobanks. By providing a direct link from collection/processing to store, the time between sample collection and banking becomes much more consistent and by placing tubes into individual storage locations within the biobanks each sample is exposed to the same freezing profile eliminating the edge effect issues associated with rack storage.

Conclusion: While much care has been taken to refine sample processing protocols, the mundane task of transporting samples has generally been overlooked. Proven pneumatic transport technology has been adaptated to fit this need, enabling faster, more consistent and reliable transfer of samples directly into the biobank, bringing significant sample quality and workflow efficiency benefits.

PIT-14 Unlocking the Value of Human Biospecimens via an Interoperable, Ontologically Unified IT System for Clinical, Biosample Analyses and Patient Health Status Data and Biosamples

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Problem: In the era of personalized medicine, technology for biomedical research has evolved, but as stated in multiple scientific reviews, systems for tracking, acquiring, recording, storing and providing human biospecimens and data used for that research have not kept pace. The biobanking industry operates with a vast array of ad-hoc systems, non-harmonized, with limited interoperability or sharing capacities. Established processes for sample procurement are fragmented, ontologically diverse, and as a result often static. As multiple systems co-exist in siloed environments, biobanking services do not consistently provide annotated specimens with clinical and preanalytical data, thus limiting research impact. Use of such poorly-characterized specimens is one of the main reasons for the high cost of drug development. Absence of real-time multi-criteria queries and technologies that cannot be adequately mined by integration, interfacing, or efficiently linked to data from alternate sources, produce structural problems for research.

Solution: Metabio developed and validated an interoperable system for biobanks that works seamlessly with existing legacy systems. The system integrates data (patient, biosample, clinical) from multiple sources, for a data-product that is ontologically (HL7, open EHR) unified and longitudinally synchronized. As verified by biobanks, this data brings a much higher degree of accuracy and value for research and biobanks. Metabio's system records and integrates data from each step of the collection process, establishing a chain of characterized, relational timeline data/donor. The system's online platform will receive data from, and offer it to: patients, biobanks, healthcare providers, and researchers. The platform adds value to specimens and acts as a biospecimen vendor and biobank aggregator. Pools of specimens and associated data from distinct biobanks are enriched and brought together in disease specific cohorts, thus increasing inventory turnover margins, efficacy and value throughout the research cycle, leading to faster drug development.

Conclusion: This unique technology creates a one-stop system for biospecimens and data, gathering data from multiple biobanks (disease-specific), patients (disease-progression), and hospitals (patients' clinical data). This approach equips biobanks with the ability to provide collections of specimens that cover the entire cycle of diseases, thus raising value for all members of the healthcare chain.

Repository Automation Technology

PRA-01 Application of Automated Storage System in the Operation of Biobanking

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Biobanks play an increasingly important role in the development of precision medicine. The automated storage system has the advantages of ensuring sample quality, convenient operation, efficient storage and saving labor cost and plays an important role in the construction and operation of biobank. Department of Biological Repositories, Zhongnan Hospital of Wuhan University, the first provincial level biobank in China, was put into operation in 2017. With the automated storage system, the entire process of scanning, storing, using and docking of related sample information of each sample can be managed automately. The system can manage a total of 48 tissue samples at a time and the whole process takes 20 minutes. Compared with the manual storage of tissue samples into liquid nitrogen tanks, it shortens the exposure time during the operation. Moreover, the automated storage system can accurately catch each cryotube and avoid repeated freeze-thaw cycles of the sample as well as errors in manual management.

PRA-02 Comparison of the Capacity of Stationary Liquid Nitrogen Storage Tank to Supply Liquid Nitrogen to Storage Devices in Different Operating Modes

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Background: Low temperature storage with liquid nitrogen (LN) is an effective way to store biological samples for a long time. Moreover, LN can reduce the dependence on electromechanical refrigeration device. Since gaseous LN has been applied, the risk of cross-contamination during storage can be avoided. The stationary LN storage tank is one of the ideal LN storage containers for gaseous LN supply at present.

Objective: To summarize the LN consumption of the 10m3 stationary LN storage tank (CIMC Sanctum) and analyze the capacity of stationary LN storage tank to supply LN to storage devices in three different operating modes.

Methods and Results: With steady operation of 318 days until Nov 22, 2018, the stationary LN storage tank has replenished the LN with 99.99% purity for 30 times. From Jan 08 to July 26, six semi-automatic gaseous LN tanks (TANKA Biosystem 94500) were operated simultaneously. The LN supply was controlled by LN pipeline through main valve A and branch valve B. We compare the LN consumption of two modes: mode 1 is automatic with all valves open, and mode 2 is manual with A open and B closed. The average LN supply interval for mode 1 and mode 2 was 10.62 days and 19.67 days and average daily LN consumption of each tank was 116.50 L/D and 54.32 L/D, respectively. The consumption difference between the two modes shows the LN consumption for pipeline system is comparable to the tanks themselves. With LN volume and temperature ensured, mode 2 can be recommended as the preferred method. Since July 27, a full-automatic gaseous LN storage device (ASKION C-Line HS200s) has been set up and put into operation on Sep 17. The LN supply of HS200s depends on valve B as well. Mode 3 is automatic with all values open but TANKA tanks are set as manual mode. Up to Nov 22, the total consumption of LN was 58.57 m^3, average LN supply interval was 8 days, and average daily LN consumption of each device was 131.44 L/D.

Conclusion: To sum up, full-automatic device increased the LN consumption significantly, which is due to ASKION C-Line HS200s can guarantee below −110 degrees centigrade during the whole operation. When designing the LN transfer pipeline, branch value for semi-automatic device can be installed after the full-automatic device so as to decrease the LN consumption. In either mode, the LN volume needs to ensure at least three additional days of normal usage.

PRA-03 FW2018 Meets Biorepository Need for Automation, Accuracy, and Efficiency

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Background: A laboratory information management system (LIMS) is critical to sample management. The Institute of Human Virology Nigeria- Human Heredity and Health in Africa (H3A) biorepository (I-HAB) employed Freezerworks 2015 (FW) for sample management. However, FW 2015 was limited in its ability to perform a number of functions required by a biorepository such as creating varied numbers of aliquots per biospecimen; adding and modifying data without going through a server; and scanning racked barcoded tubes. The FW 2018 is a great improvement and provides the flexibility and high-throughput LIMS required at I-HAB.

Methods:

1) Two I-HAB staff were trained at the Freezerworks Users Education Conference 2018 in Seattle, Washington, USA for 3 days on FW 2018.
2) Trained I-HAB staff piloted FW 2018, comparing it to FW 2015.

Results: Compared to FW 2015, the 2018 was able to perform many more functions as follows:

Creating aliquots automatically: FW 2018 created varied numbers of aliquots and reformatted to I-HAB's customized template. This reduced hands on time by 90% and increased productivity. With FW 2015; aliquots were created manually as it numbered aliquots with the same number.

Web client: It was possible to add and manipulate data only with the FW2018.

Scanning of 2d barcoded tubes: While sample were scanned individually with the FW 2015; the FW 2018 could scan a rack of 96 2d tubes at once using a flatbed scanner thereby increasing operational efficiency and accuracy. Hands-on time reduced by 99%.

Advanced Search: FW 2018 feature allowed searches to be scheduled and results received by email, retrieved on signing in and/or on user defined intervals. The automated reports eliminated redundancy.

Reports: Graphical representation unavailable with the FW 2015 is available with the FW2018 in the form of charts.

Conclusion: LIMS should be flexible enough to allow users to manipulate the software to fit the need of the biorepository. Customization, automation, and high-throughput features are critical for high-volume biorepositories in the selection of LIMS.

PRA-04 Automation in Biobanking: Biospecimen Data Entry Using a Custom Script

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Statement of Problem: Research sample tracking and annotation are fundamental components of biobanking, where much of data entry is manual. We propose that digital technology may be used to improve efficiency and functionality of these processes. Towards this, we have developed a Python script for the bulk upload of data into our biospecimen database.

Proposed Solution: A custom script was programmed for the bulk upload of frozen plasma samples into our biospecimen management system, CaTissue Suite-University Health Network (caTS-UHN). The Python script employed three modules; Selenium WebDriver for interaction with webforms, OpenPyxl for Excel interaction and PyAutoGUI for simulating mouse clicks. The use of these open-source Python modules makes this script readily adaptable and reproducible. The script was run through command line, prompting the user to select an Excel file that contained target data. These data included patient identifiers (ID's) such as Medical Record Number (MRN) and study ID, and specimen processing information such as collection date and initial storage location. The browser session was next directed automatically to the caTS-UHN webpage and the user was logged in. Patient MRNs from the excel file were pulled by the script to register the donor into the system. Once registered, a venipuncture event was created. Collection date and required fields were then populated including collection site (UHN) and specimen collection container (EDTA blood tube). Frozen plasma aliquots were derived, annotated by study ID and then assigned a new cryostorage location in caTS-UHN, which was recorded by the script into the original Excel sheet along with accessioning status (complete or error).

The script was validated in the caTS-UHN test environment using 1760 plasma samples from 220 patients. Some of the patient samples initially failed. These were due to consistency errors in the Excel sheet. When these were corrected, all samples uploaded successfully. In total, 20% of patient samples that were accessioned automatically were cross checked with the original file, and no data entry errors were found.

Conclusions: A custom Python script was used for the automated bulk upload of banked samples into our biospecimen management system. Data entry was accurate and operator time was reduced from hours to minutes. Digital technology such as custom scripts may be used to facilitate biobanking workflow including database entries.

Repository Management

PRM-01 Leveraging Cloud-Based LIMS for Managing Tissue Samples at RGCIRC Biorepository to Facilitate Cancer Research

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Background: The Biorepository at Rajiv Gandhi Cancer Institute and Research Center (RGCIRC) is crucial for meeting the needs of researchers focusing on cancer research. They have collected and stored over 15,000 bio-specimens across various cancer types such as breast, kidney, ovary, gallbladder, head and neck, gastrointestinal and prostate cancers from over 3500 donors. They provide a variety of clinically annotated samples including tumor tissue, adjacent normal tissue from surgical resection specimens, associated blood and their processed derivatives (buffy coat, serum, plasma) to researchers based in India as well as overseas to find diagnostic molecular markers, prognostic indicators, and therapeutic targets. To manage this large number of bio-specimens and associated clinical annotation, a Laboratory Information Management System (LIMS) was imperative.

Method: RGCIRC Biorepository uses donated bio-specimens in research in such a way that it is compliant with most current Best Practices for Biorepositories as recommended by International Society of Biological and Environmental Biorepositories (ISBER) and follow ICMR Ethical norms for patient consenting. This hospital integrated Biorepository has pathology as its operational core with quality, safety, service, researchers satisfaction, and a sustainable revenue cycle. Leveraging the benefits offered by a cloud-based LIMS, the RGCIRC biorepository is able to overcome the challenges of patient privacy, consent management and real-time sharing of bio-specimens to match with regulatory norms.

Results: Deploying a cloud-based LIMS at RGCIRC Biorepository helped manage the complete life-cycle of tissue samples including cryo storage, long-term archiving, patient consent, patient demographic details, investigatory profile, clinical details, follow-up data, and sample location. Managing a variety of tissue requests, building disease-specific or mutation specific cohorts was also made possible. RGCIRC was able to manage quality control data and audit trails as well.

Conclusion: Clinically annotated samples are one of the most valuable resources for enhancing basic and translational research for cancer and other disease processes. RGCIRC Biorepository is now able to provide researchers access to high-quality samples, helping them to find targets to intervene in cancer treatment and to develop cancer therapies for future use.

PRM-02 An Economics Approach to Defining Cancer Biobank Outputs

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Background: Human tissue biobanks are an integral research infrastructure. However despite increasing demands for tissue by researchers, there is a paucity of literature on biobank outputs, as well as reported sustainability challenges. We hypothesise that a lack of output data, and their value, represent threats to biobank sustainability. Our project aims to determine the costs, investments and outputs of a cohort of Australian cancer biobanks, to provide explicit and accountable economic data to all biobank stakeholders.

Methods: From a cancer biobank cohort (n = 22) identified in 2013 (Rush et al 2015), we invited Expressions of Interest to participate in a face to face interview. We designed and piloted a survey to collect information on the costs of biobank operations, funding, cost recovery, and research and clinical outputs. Where

possible, monetary values were assigned to biobank costs and outputs before cost:consequence analyses were undertaken.

Results: In the 5 years since 2013, 5/22 (23%) biobanks had closed. Each of these 5 biobanks had restricted-access policies supporting a single investigator. Of the operating biobanks, 12/17 (63%) agreed to participate. Six participating biobanks each had open- and restricted- access policies, respectively. Of the 5 biobanks that did not participate, 4/5 (80%) cited lack of resources as a barrier. Taking monetary and equivalent in-kind staff/equipment costs into account, over three quarters (76%) of a participating biobank's costs were allocated to paid human resources. Biobanks supported a range of outputs including basic research publications, research training, and contributions to personalized medicine, oncology clinical trials, clinical testing and clinical registries.

Conclusions: We describe the first comprehensive investigation into the costs, investments and outputs of Australian cancer biobanks. Biobank sustainability remains a challenge, with almost one quarter of cancer biobanks operating in 2013 closing in the past 5 years. Furthermore, lack of resources prevented a similar number of biobanks from participating in research. Nevertheless, our economic study of open- and restricted-access cancer biobanks will document a broad range of biobank impacts, and provide a better understanding of the costs, outputs and value of biobanking. This will allow improvements in biobank business plans and modelling, identification of benchmarks, and enable stable funding to be leveraged.

PRM-03 Using e-Data Linkage for Clinical Annotation of Samples in Cancer Biobanks: A Pilot Study

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Background: Comprehensive and accurate clinical information is essential to achieve the full research potential from banked biospecimens, however this information is labour-intensive and costly to obtain. In Australia there are several national and state-based routinely collected, population-based administrative health data collections. These may provide the required clinical information, but there is little reported information about the use of these data collections for annotation of samples held in open-access cancer biobanks.

This project aimed to investigate the feasibility, practicality and utility of obtaining common clinical data variables required by biobanks and researchers, through linkage to selected administrative data collections. The data collections included the following state based registries; the New South Wales (NSW) Cancer Registry, the NSW Admitted Patient Data Collection, the NSW Registry of Births, Deaths and Marriages along with the national Australian Bureau of Statistics Mortality Data. These data were compared with clinical data held in the Westmead Gynaecological Oncology Biobank (n = 559) and the Australian Breast Cancer Tissue Bank (n = 4923) for more than 75 individual data fields.

Methods: Records from the two biobanks were probabilistically linked to the administrative datasets by the Centre for Health Record Linkage (CHeReL) using a best-practice approach to linkage while preserving privacy. Linkage was carried out using the ChoiceMaker open-source probabilistic record linkage software.

Results: Overall there was agreement between administrative and biobank data for diagnostic information such as tumour site, grade and morphology; some treatment data; and survival information. However, not all data items required by the biobanks were held in administrative data sets, including important information related to relapse/progression; menarche, menopause and oral treatments for breast cancer; and residual disease and tumour marker results such as CA125 for ovarian cancer.

Conclusion: This study provides valuable information on the capacity of record linkage to value-add or augment the clinical data holdings of Biobanks. The results are promising for certain aspects of clinical annotation however, not all key data are covered and data access, date coverage, timeliness and data management remain as potential barriers.

PRM-04 Reusing Leftover Sera Obtained During the Health Care Process as Prospective Samples for Research Purposes or Technical Validations

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Statement of the Problem: Obtaining prospective samples is a Biobanks big challenge because they need very often collaboration of physicians or health care personnel that are not interested in obtaining these samples if they are not involved in the project. So that, it would be very useful to find an ''automatic'' solution that allows the biobank obtaining these samples without external collaborations.

On the other hand, the hospital Clinical Analysis Service needs very often samples (mainly sera) from patients, to check new equipment or analyzers, or to test or validate new diagnostic kits. Also, Biotech companies need these serum samples for similar purposes.

This kind of proofs of concept, validations and tests using these leftover samples are not strictly research projects but they are neither for the patient particular benefit. Furthermore, it is not known if, from these technical protocols, patents or scientific publications could be derived in the future. So that, the main issue is to be sure that they are using all these samples fulfilling all the ethical and legal conditions.

Proposed Solution: Leftover sera obtained during the healthcare process are stored routinely at the Clinical Analysis Service for a security period of time of 8 months reserved for reanalyzing samples if necessary for the patient care.

Taking the advantage of this process, our MARBiobanc has established a protocol where leftover samples are stored for a longer period of time to can use them for research if the informed consent is available. After this security period, the Biobank is in charge of managing the transference of these samples to researchers or to external companies for their tests or technical validations.

When these stored leftover samples linked to the clinical records are required for purposes other than those related to the health care process, a request must be submitted to the biobank and consequently to the biobank external committees.

Conclusions: We have established a useful strategy for obtaining prospective samples without external collaborations, based on a long storage of leftover sera obtained at the hospital during the health care process. The Biobank takes responsibility of managing these samples when requested for research purposes. Moreover, Clinical Analysis Departments and external Biotech Companies can apply a request to the Biobank in order to get samples for their technical tests and validations, accomplishing all the ethical and legal rules.

PRM-05 Discovering Hidden Biobanks in Our Public Hospitals

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The Tumour Bank at the Children's Hospital at Westmead (CHW) is a semi-embedded hospital biobank that has successfully facilitated translational cancer research since 1998. Deeper integration within the hospitals pathology service is predicted to make available larger collections of high quality biomaterial for research. To explore this environment, the Tumour Bank conducted a workflow analysis of the biospecimen supply chain, between strongly collaborative partners within the CHW: Pathology and Cancer Centre for Children.

The ultimate goal aim of this project was to increase biospecimen accrual rates for rare diseases, such that biomaterials are procured in diagnostically significant timeframe and available for every cancer child who may be eligible for inclusion in research studies.

Existing biobanking workflows that procure residual biomaterial were reviewed. A deeper understanding of the supply chain was gained and shortfalls identified. Medical records data from 60 oncology patients were analysed to determine the availability of residual biomaterial within pathology suitable for biobanking. Of specific interest were specimens collected at diagnosis, relapse and at significant treatment time points. Solid tumour specimens that are of particular value to translational cancer researchers but often challenging to find sufficient specimen numbers. Therefore, our focus was directed at tracking the journey of solid tissue from operating theatre to Tumour Bank storage, whilst simultaneously monitoring patient's clinical journey.

The results indicated high existing biomaterial procurement rates, 74.2% and 82.8% for fresh frozen tissue and liquid samples respectively. Actively tracking solid tissue biomaterial supply chain revealed that 44.8% of diagnostic tissue was archived within the anatomical pathology laboratory between 2011 and 2016. This tissue was effectively ''banked'' for future unspecified needs. This legacy resource was subsequently transferred to the Tumour Bank, adding value by boosting banked solid tissue inventory with 173 new cases and realising the research potential this biomaterial holds.

PRM-06 Adoption of an Open Source Biobanking Informatics Platform to Streamline the Tissue Repository Data

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Background: SingHealth Tissue Repository (STR) was established in 2009 with the goals to develop an acclaimed human biospecimen repository of superior tissue quality, compliant with the law of Singapore and benchmarked to international best practices, to facilitate the conduct of basic, translational and clinical research. We primarily collect human biological materials. The specimens are distributed to researchers for their approval IRB studies. We currently collect specimens for over 10 protocols and have about 120,000 specimens in our repository.

Right at the beginning, we realized that biospecimens without high quality annotations is of not much use. We had to make sure that the data we collect is inline with the very disparate set of research needs of our community.

Method: After evaluating variety of tools, in 2009 we decided to adopt caTissue. caTissue was developed by National Cancer Institute (USA) and fit our needs. Over the course of the last 8 years, caTissue has transformed from being a NCI led cancer specific database to a much widely adopted database across variety of biobanks across the globe.

STR collects human biological materials from the hospital operating theatre through the contributing surgeon with patient consent. At STR biobank, we use OpenSpecimen to collect all type of patient and samples information.

Results: OpenSpecimen has helped us collect data and later search for specimens based on these clinical and pathology parameters. It allows us the flexibility of tailoring future protocols to any new studies that we would take on board. The ease-of use facilitates the high throughput rapid data entry into the database to streamline our sample retrieval process. The ability to continually add new features such as DNA quantity and quality to our samples has helped to keep a single source for all of the specimen-related data.

Conclusion: We expect a substantial growth in our biobanking operations due to the recent changes in the Singapore biobanking regulatory guidelines. We are now implementing an eConsent module within OpenSpecimen to enable collecting consent information in the clinics. We also plan to integrate it with our freezers to monitor temperature changes on specimens. With now over 120,000 aliquots of specimens within our biobank, without a tool such as OpenSpecimen we would not be able to maintain an audit trail of the specimens from point of collection right down to usage, shipping, or disposal.

PRM-07 Sink or Swim: Facing the Burden of Sustainability in Biobanking

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The Hunter Cancer Biobank (HCB) was established in 2012 in partnership with the University of Newcastle (UoN), Local health district hospitals, and NSW Health Pathology (NSWHP). Sustainable biobanking is an ongoing concern for the biobanking community, yet the rate of progress towards finding solutions seems incongruent with the rapid withdrawal of funding opportunities nationwide. Industry involvement, consolidation into larger facilities, collaborations, node networks and the development of elaborate cost-recovery models have all been proposed and have achieved varying degrees of success, however each is accompanied by limitations that pose further obstacles to full sustainability.

HCB is pursuing a multifactorial model of sustainability, developed to integrate with local health services and partner organisations – while also facilitating organic growth opportunities within industry and secure its place as a UoN core service. Initial steps included the development of a cost recovery model which instituted pricing based on activity based costings, but also recognised the limitations of local researchers to engage with the service at exorbitant prices. Our leading partner, NSWHP is at the core of our model, providing phased support for HCB over the next 5 years, subsidising prices to ensure that costs are not prohibitive to the growth of our customer base, while also assimilating our workflows into their own to ensure economies of scale and avoid duplications in effort. As the research partner of NSWHP Hunter we have alleviated strain on the diagnostic laboratory by facilitating research contracts, both university, investigator initiated clinical trials and industry sponsored trials. Industry engagement continues to grow and we have specific initiatives in place to increase industry sponsored work while at the same time, diversifying our scope of services within the local research community. The establishment of a local biobanking network, intended to reduce resource expenditure and share learning, is a cost-minimisation strategy and will be implemented on an institutional level to ensure maximal benefit.

While support from government bodies such as the Cancer Institute and philanthropic groups is still an essential part of our business model, we foresee a not too distant future where the HCB will be a fully self-sustaining operation – balancing a commitment to local researchers while also maintaining its place as a valued industry partner.

PRM-08 Comparison of Tissue Samples Collection and Storage in Biobank and Clinical Departments

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With the development of precision medicine, the collection and preservation of tissue samples become more and more important for medical research. Although sample collection and storage in clinical departments have some convenience, there are still a lot of problems. Firstly, sample collection by clinical staff has large variability, different standards and low sample collection rate. Secondly, the tissue samples usually store at −80 degrees centigrade or small liquid nitrogen tanks, which may not meet the needs of long-term preservation requirements for tissue samples. Furthermore, the cross-contamination of tissue samples in the liquid nitrogen tanks is inevitable. In addition, the information related to the samples are always missing, such as collection situation and storage location, which result in the problems of sample identification, retrieval and repeated freeze-thaw cycles. These problems have greatly limited the sample utilization rate and even made the samples become a dead biobank. In our biobank, we modefied the workflow of sample collection as below. Firstly, specialists of biobank collect specimens from the operating room in order to reduce the cold ischemia time and improve the quality of samples. Secondly, cooperate with pathologists to ensure the nature of specimen. Lastly, standardized operation procedures and advanced equipment such as large gaseous liquid nitrogen tank, automated storage equipment and information system can ensure the sample quality and information integrity to the utmost extent. Taken together, the professionalism of biobank has great advantages in the collection and storage of tissue samples and can better serve the clinical and medical research.

PRM-09

PRM-10 Repository Operations Management

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Biorepository Management at Clinical Laboratory Services.

Clinical Laboratory Services (CLS) biorepository is an entity that collects, receives, processes, stores, and distributes biospecimens.

CLS biorepository plays a vital role for local and international clinical trials by storing biospecimens in a well-established, ISBER compliant biorepository.

The aim is to maintain the integrity of biospecimens through the provision of high-quality storage and data management systems.

To ensure biospecimen of the highest quality and integrity are provided for downstream analysis, CLS biorepository carefully monitors the collection, receipt, processing, transportation and storage of biospecimens.

A robust management system ensures efficiency in planning operation, implementation, reduces costs, minimize risk and is central to the biorepositories sustainability plans.

There are five components of a Robust Management System for biorepositories.

Operational Procedures

Management
Business Sustainability plan
Quality procedures

Policies and Procedures
Quality policy
Risk assessment.
Complaints.
Safety.
Sample processing protocols.

Documents and Databases

Quality manual
Standard operating procedures
lData management system
Document management system.

Facilitating Agreements

Service level agreements

Material Transfer Agreements

Compliance and Improvement.
Audit program.
Inspection program.
Management committee.

PRM-11 Challenges of Bringing Together Multiple Individual Biobanks: Implementing a New Centralised Service Model

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The Westmead Research Hub (WRH) in Sydney, Australia, is comprised of several partner Clinical and Medical Research organisations. Close to 30 biobanks based across the Westmead hub collectively represent a major resource for translational research, yet their reliance on external grants highlights the inherently unstable funding base for this essential resource. To address the challenge of sustainability for the campus biobanks, a new core facility for biobanking has been established. With so many co-located biobanks operating independently, extensive duplication of operations and facilities represents a significant opportunity for cost-benefits with centralisation.

In 2017, a questionnaire study of the WRH biobanks revealed 3 main areas of confluence in which central support could offer benefits of economies-of-scale: IT support, staff support and infrastructure. The survey results also indicated areas of divergence representing challenges for transitioning to a centralised model, however significant opportunities for enhanced operational efficiencies and quality improvement through standardisation were evident.

One of the partner organisations, the Westmead Institute for Medical Research (WIMR) initiated and funded a 1-year pilot to launch a service-model biobank as part of its existing Scientific Platforms. In February 2018, the project commenced with a new team recruited to establish and run the service.

During the initial planning phase, tasks for the year and infrastructure requirements were determined. In stage two, user consultation aimed to refine and modify a plan for introductory service offerings. Meetings with Research Centre Directors gathered input about which biobanking services would be of most value. In the third stage, services were developed by working with individual biobanks, and starting to deliver bespoke services in response to several requests. This was followed by a phased launch during August, and in September 2018, the new facility 'Westmead Biobank' was officially announced with the launch of its introductory services and fee schedule. The first services focussed on downstream processing and storage facilities. In future, Westmead Biobank will expand services to cover the management of multiple collections under a unified governance structure and streamline researcher access to materials to ensure that the strengths in biobanking at Westmead are maximally translated into research outcomes.

PRM-12 Needs and Requirements in Biobanking – Facing Challenges Far Beyond Biosamples

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Background: Recording of biosamples results in large datasets, which requires an IT-system enabling efficient and secure handling of data information. Tracking demographic and analytical data associated with these samples claims high standards. The Heidelberg Cardiobiobank developed an individualized solution using a customized research portal for biobanking and beyond named CentraXX (KAIROS).

Methods: The focus of our information system is the structured data acquisition by using the modules ''Biobanking'' and ''Study Management'' of the CentraXX System. All collected sample information, clinical data and all study related data will be aggregated in the electronic patient record within CentraXX.

Results: Beside sample and study information further structured data like diagnoses or data from hospital stays (clinical data) and informed consents are combined in one file. Additionally the standard CentraXX masks for collecting patient and sample data, the embedded form engine provides the flexibility to create forms to capture all additional documentation points needed. The hospital integrated Biobank uses interface standards HL7 (health level 7) for direct data connection to the hospital information system. Other data transfer via interfaces such as those for liquid handling platforms (TECAN), automated cryogenic storage (LICONIC) and multiple scanners are integrated in the system.

Conclusion: Embedding the customized CentraXX into the Heidelberg Cardiobiobank allows functional data modeling and enables an efficient search between clinical, study and sample related data. Even today features such as age, diagnoses, therapy,

pathological descriptions and laboratory values are no longer sufficient to compare diseases in the context of personalized medicine.

PRM-13 Experience of Organizing First National Tumour Tissue Repository in India

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Background: National Tumour Tissue Repository (NTTR) was commissioned in the year 2005 at the Tata Memorial Centre, Mumbai, India with a mandate to store all types of diseased as well as normal tissues and components of blood and distribute the biospecimens to researchers. Clinical information and follow up record of all patients whose biospecimens are maintained in the repository are provided to investigators, whenever required, Anonymised, coded biospecimens are stored in the biobank in order to protect the confidentiality of data and privacy of specimen donors.

Methods: The process of organizing NTTR is classified into various tasks viz. operational, administrative, and ethical/ legal aspects. Standard operating procedures are established & practised for collection, storage, retrieval, disbursement, and quality control. The biospecimens are collected following an administration of broad informed consent. The indigenously developed software is being used to anonymize the biospecimens and facilitate storage and retrieval of biospecimens. Disbursement of tissues is done for an Institutional Ethics Committee approved projects through NTTR Technical Authorization Committee. A Material Transfer Agreement is sought for disbursement of biospecimens to non-institutional investigators.

Results: During the period of 13 years from May 2005 to October 2018 2016, a total of 46,690 tissues are collected from various anatomic sites from 35,011 patients.5870 biospecimens (Tumour & Normal) are disbursed to investigators for various IEC approved projects.

Conclusions: Central tumour tissue repository has many advantages like better control of biospecimens, the easy availability of various types of tissues, and an increased opportunity to participate in intramural and extramural research projects. A repository can be easily implemented in a pathology laboratory. High quality and well annotated biological samples are valuable institutional assets for translational research.

PRM-14 Do We Need an Expiration Date for Biobanks?

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Background: All over the world billions of biospecimens are stored in the archives of biorepositories for future usage in research projects. Despite the huge number of samples, only a few publications are available discussing the expiration date of these collections. The currently available literature focuses on single aspects, such as the expiry date of informed consent, financial issues (e.g. lack of funding) or sample quality issues of specific types of biomaterials. So far in the biobanking community, only a few ideas have been developed about the expiration date of biorepositories, although situations and circumstances exist where this topic becomes relevant. Typical scenarios include a.) Closure of a biobank, b.) Planning a biobank inventory and c.) Starting a new collection or a new biorepository.

Methods: In order to determine the expiration date of a biobank or the lifetime of a biospecimen, a global approach taking into account different perspectives is necessary. To address this topic, we have identified different factors that have to be considered when defining whether a biological resource is usable for a particular purpose or not.

Results: Here we show that five main factors (1. access policy, 2. collection strategy, 3. quality, 4. data availability and 5. intended application) provide a sound basis for a decision how to select the best suitable samples of a study, when to discard biological samples or when to end up a collection.

At institutional level of a biobank the access policy (including ethical, legal and financial issues) and the biobank's collection strategy are important. On the level of single biospecimens, the ''expiration date'' also depends on various factors including sample quality, data availability and suitability of the sample for the intended application.

Conclusion: Rapid advances in biological and medical research have enabled the usage of human biomaterials in an increasing variety of new ways. As an example, sequencing technologies became more rapid, sensitive and less expensive in the last years. Consequently, biological samples may become (re-)usable both from a quality as well as quantity point of view. Finally, we conclude that bioresources do not have fixed expiration dates, but rather flexible and strongly dependent life cycles depending on the specific research plan and intended downstream analysis.

PRM-15 Education in Biobanking: Training and Knowledge Transfer for a Highly Interdisciplinary Field

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Background: Building up and managing a biobank is challenging since biobanking is a highly interdisciplinary field. The extensive growth of biobanks requires training of highly qualified personnel in the area of biobanking and the different disciplines linked to it (e. g. managers, engineers, biologists, lab technicians, quality managers, etc.). Hence information, training and know-how transfer from experienced biobanks to newcomers is needed for all disciplines.

Methods: An overview of biobanking education opportunities has shown that there are offered various types of trainings differentiated according to 1) Duration: Short duration trainings (courses for a few days) and long duration trainings (master programs one to two years); 2) Kind of completion – certificate, ECTS, degree; 3) Location – worldwide or in Europe; 4) Delivery model: On-site, Online or both; 5) Target group: is the course covering each individual disciplines in the field of Biobanking or all disciplines.

Results: Biobank Graz, as internationally renowned biobank, offers different educational opportunities for international biobankers to meet all the needs in biobanking education. As short duration trainings various biobanking courses have been developed - on the one hand a 3-day biobanking course for those who are involved in setting up a new biobank and on the other hand a course for those who are advancing the activities of established biobanks. In these practice-oriented courses participants gain comprehensive knowledge and profound hands-on experience in most of the mentioned interdisciplinary fields of biobanking. As a long duration training Biobank Graz offers a part-time postgraduate programme for biobanking as a distance

learning course, which can be completed alongside full-time work within the four semesters of the study. This university course imparts knowledge on biobank facilities, infrastructure, management and practical implementation of a biobank.

Conclusion: The goal of all offered educational opportunities is to acquire knowledge, experience and practical skills which will qualify for the work in the multidisciplinary field of biobanking.

PRM-16 Biobanking in a SA Context: Implementation and Setup Challenges in a Developing Country

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Statement of the problem: Despite ongoing and growing efforts to establish biobanking in South Africa, there is still a lack of clearly defined ethical and legislative frameworks to govern the implementation and setup of biobanks in the country. Currently, the research ethics committees (REC's) are attempting to incorporate numerous acts, bills and regulations for the setup of a biobank. The lack of a clear framework and specific requirements with regards to biobanking has led to different requirements by different REC's in the country. Furthermore, this causes the requirements and application process to be subject to continuous change from a REC view point.

Proposed solution: In order to find a solution for the stated problem, it is critical to identify all contributing factors. The factors identified include a lack of clear governing legislation in the National Health Act (NHA), a lack of clear guidelines and protocols by the National Health Research Ethics Committee (NHREC), a lack of communication between the different institutional REC's to adopt a uniform application approach and the lack of a biobanking network in the country to facilitate cooperation and collaboration.

Since a proper solution for the problem requires big institutional and governmental changes, the following intermediate solutions were implemented in order to overcome the limitation in the guidelines: Efforts were made to establish a connection between various registered and operational biobanks in the country in order to receive their input regarding requirements for biobanks. Furthermore, the latest version of the ISBER Best practices document were applied in setting up the CHM Biobank according to international best practice and to have a broader setup covered in the event that the institutional REC's application requirements may change.

Conclusion: Unless clearly defined ethical and legislative guidelines are incorporated in South Africa, all new biobanks will have to go through the same setup and implementation challenges stated. As an interim solution, the setup of a country-wide network of biobanks would be beneficial in order to facilitate collaboration and to help others gain from operational experience.

PRM-17 Stakeholder Analysis of a Clinical Academic Biobank

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Background: By delivering high-quality biological samples and data, a clinical biobank acts as a service provider for different areas between diagnostic and research, thus involving different kinds of stakeholders. The aim of the study is to assess the level of influence and interest of key stakeholders and formalize an engagement plan.

Methods: A power/interest matrix has been created and distributed to the internal biobank staff and external partners. The survey has consisted to assess the level of power and level of interest of each of selected 13 key stakeholders (such as ''Patients'', ''Researchers'' ''Funders'' etc.). Following the average classification, an engagement plan, stating stakeholders' expectations and respective achievements, has been issued.

Results: In total, 65 matrixes have been filled in. The respondents have considered seven stakeholders with high-interest and high power regarding the biobank such as sample users, sample suppliers, biobank staff and funders. The classification led to an engagement plan based on an adapted and ongoing collaboration with each key stakeholder.

Conclusion: This analysis has been helpful to find a fair balance between stakeholder satisfaction and optimal biobank operation. In the long-term, greater involvement of key biobank stakeholders' needs in decision-making would promote scientific collaboration for the benefit of research and public health.

PRM-18 Dasman Diabetes Biobank Kuwait – Operations Overview

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Background: Dasman Diabetes Biobank (DDB) established in 2009 to support the research community among Dasman Diabetes Institute (DDI) to provide research resources by providing high-quality biospecimens and comprehensive and reliable data to research entities within Kuwait and regional. DDB developed with a clear and comprehensive biorepository management structure including biospecimen design, processes, a quality management system, and sample tracking system linked to research participants.

Methods: The DDB operations are aligned with DDI's research strategy to support the various researches. DDB is equipped to handle variety of samples including urine, saliva, and blood components to support research needs. Biospecimen processing was designed according to international guidelines, literature review, and SOPs. Risk and contingency design were considered for sample storage. The DDB storage design consists of −80° freezers, liquid nitrogen storage, and enough backup −80°C freezers. All the storage devices are connected to a temperature monitoring system. Research projects are reviewed and approved by ''Research Audit and Review Committee'' and ''Ethical Review Committee (ERC)''.

Result: DDB is handling more than 60 research projects which are mainly related to diabetes and its associated complications. Samples of 35,000 research participants who consented to use their samples for research from various research projects, accumulating a bio storage of 379301 samples (plasma n = 51317 serum n = 38959 urine n = 23902 PBMC n = 13127 RBC Pellet n = 3,395 saliva n = 88634 saliva with RNAlater n = 37740 DNA n = 31601 RNA n = 976 Hair n = 5080 and Tissues n = 5720).

Moreover, 64,482 samples were shipped to collaborating institutions for various biomarker analysis. In addition, DDB distributed variety samples (n = 18,964) to the investigators for their research activities within DDI. Phenomenal growth in our research activities, that evidenced more than 325 publications.

Conclusion: The DDB operations structure is recommended to be a sufficient model for promoting the Omics and other clinical biomarkers data, in addition to active sample utilization, for multi-disciplinary research approach. Align with DDI's current research strategy, DDB is continuing to support the following major scientific directions – Genetics and Genomics of Diabetes and Metabolic Disease; Pathophysiology of Diabetes and its complications; Clinical Care Research and Trials; Epidemiology and Public Health.

PRM-19 Getting Involved in Clinical Research in a Large Comprehensive Research Chinese Hospital: How Can Biobanks Help?

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Statement of the Problem: In recent years, basic research has been greatly developed, however there is little progress in clinical research which plays an important role in promoting clinical diagnosis and treatment. The primary challenges in the field of clinical research include lack of high quality clinical sample/ data and centralized quality management infrastructure. Biobanks, the cornerstone of the translation medicine, are an important resource for facilitating clinical research which provide a procedures and facilities to ensure standardized sample collection and handling, and to guarantee a collection of samples of high and reproducible quality.

Proposed Solution: Standardized workflows and comprehensive management systems for clinical research programme management, clinical sample and data collection/ preprocess/ storage/ quality control are paramount together by the clinical departments and the biobank. The clinical researchers and doctors were trained, so that they could manage better clinical research biobanking based on routine clinical work. Then a team of clinical research assistants which may included CR associates (CRAs), CR nurses, non-nursing CRAs, data managers and scientific research secretaries was created. A clinical research support platform, including biobanking professionals, epidemiologist, biobank infrastructure and clinical database management system were constructed and maintained. The clinical research programs and the follow-up plan were mainly formulated by the clinical departments and reviewed by the professional technical committee of the Renji biobank. Clinical samples and information were collected by the trained clinical research assistants, and preprocessed, stored and quality controlled by the biobank.

Conclusions: In recent years, Renji Hospital Biobank has supported 30 clinical research programs and enrolled more than 20,000 patients as subjects in cancer, brain disease, autoimmune disease and cardiovascular disease prospective cohort study. A series of forms were designed for collecting the necessary data at baseline and at follow-up visits. In parallel, we collected, at regular intervals, 200,000 biospecimen including serum, plasma, urine, cerebral fluid, tissue and other sample types. 95.4% RIN values of those 1% tissue samples were above 7. 86% clinical information and biospecimen information were intact. More than 100 peer-reviewed articles have been published in the famous international journals.

PRM-20 Creating a Toolbox for Standardized Project Management in a Rapidly Growing Biobank

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Project management is a skill that can be used across multiple industries and fields, however the tools that are used by project management professionals can vary widely. In a rapidly growing biobank that requires many Project Managers, this can result in inconsistent study execution, study monitoring and risk mitigation planning which can negatively impact the study and the customer experience.

We developed a Project Management Toolbox that is used by all Project Managers across our organization, which manages >1,500 active collections and >10,000 unique collections. Standardized project definition specifications are used to define the planned accrual rates, define project specific data elements and special handling instructions required for particular sample groups. Change control procdures are used to track revisions to the project specifications. Communication plans provide clear definition of roles and responsibilities of all parties involved in the trial, along with primary and secondary contacts and escalation paths. Risk mitigation plans are established for all projects to document any anticipated issues/problems, estimate impacts, and the define mitigation strategies employed. Project management software is used to track progress of the project and to define and monitor key performance and key quality indicators. Study transition checklists were developed for use when a project is transitioned from one owner to the next. A well-defined checklist will help the new owner of the project better understand requirements and client expectations.

Finally, a robust mentoring program is critical to achieving the goal on consistent project management for study biospecimen collections. Junior Project Managers and new Project Managers are assigned a mentor. This mentor ensures the mentee is successful in learning the biobank processes and in the application of the tools within the Project Management Toolbox. Both the mentee and the mentor are held accountable for the success of the programs managed by the mentee.

In conclusion, the Project Management Toolbox helps our Managers plan, execute and control all aspects of the project management process for studies collecting and preserving biospecimens and associated data. The Toolbox also ensures all projects within our biobank our managed in a consistent manner, resulting in clearer communication and study documentation and a better customer experience.

PRM-21 Accurate Modeling of the Institution-Wide Impact of ULT Freezer Assets on Energy Use and Electricity Costs

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Our work presents a method to model energy use, costs, and savings from ultra-low temperature (ULT) freezers which incorporates algorithms that account for electrical specifications, freezer age, and the collateral impact on HVAC systems. Our measurements fit our model's predictions and show that simply using the manufacturer's electrical specifications for a freezer to determine the kWh of energy consumption results in an inaccurate low estimate of impact on energy use. The use of our

empirically-tested model will enable strategic decisions about freezer assets to be based on information which accurately captures both the current state of energy use and the impact of changes to the mix of freezer types. At the University of California, San Francisco we have embarked on a mission to develop strategies for optimal management of our cold storage. ULT freezers are a workhorse technology for storage of biological materials; however, these units use as much energy as a typical household. A campus-wide inventory of ULT freezers has found roughly 1,200 ULT units of greatly varying age. The total electrical consumption of our large fleet of freezers burdens the university with millions of dollars per year in electricity costs. Our modeling show that conversion of our fleet of units to Energy Star models will result in a future state where the same number of units have roughly one quarter of the impact on energy use and costs than our current mix of freezer types. UCSF has also committed to achieve carbon neutrality by the year 2025. Therefore this model captures the true impact of, and avoids understating, the benefits of UCSF initiatives intended to replace older freezers with newer Energy Star-rated models.

Repository Standards

PRS-01 Establishing a QA/QC Unit at MIDGAM: A Key to Standardization and Successful Downstream Applicability

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The Israeli Biorepository Network for Research (MIDGAM), was established in 2014, to create a national infrastructure to promote biomedical research in Israel, supporting academia and industry. MIDGAM operates under the auspices and supervision of the Chief Scientist of the Ministry of Health. Biosamples donated in a number of medical centers in Israel are collected, processed and preserved in order to provide scientists access to human samples annotated with relevant health information. Biobanks need to ensure that samples are interchangeable, without institution-dependent intrinsic bias, offering researchers an assurance of the accuracy, reproducibility and comparability of results. Sample quality underpins the accuracy of subsequent studies conducted and can impact on the reproducibility and robustness of data obtained. For these purposes, the QA/QC unit was established at MIDGAM. Biobank repositories in Israel are relied upon to standardize tissue/fluid collection for improved scientific quality and research for future precision medicine treatments. The systematic collection of human samples of high quality is a key element in the success of future treatments.

As a part of our QA/QC program, the first step which included sterility tests, nucleic acids (DNA and RNA) purification and sample volume accuracy were performed by a certified laboratory (ISO 17025, GMP) during March 2018. Blood, bone marrow and tissue samples from consented donors diagnosed with various GI malignancies undergoing surgical resection, were randomly chosen for this examination.

We found that despite implementation of homogeneous protocols for sample collection, differences in sample quality were observed. Following sterility testing, bacterial contamination was observed in 25% of the examined samples. Streptococci, Pseudomonas, Actinomyces and other types of human flora were found. In addition, following DNA and RNA purification data analysis, a direct and strong correlation between RIN values, 260/280/230 parameters, and sample concentration was obtained. Low nucleic acid concentrations were associated with decreased quality values.

In conclusion, the implementation of a QC program is a mandatory requirement for the network's success.

PRS-02 Survey Amongst the Downloaders of the ISBER Best Practice 4th Edition

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Background: ISBER Best Practices (BP) 4th edition was launched on January 31, 2018, and is available to download from the ISBER website for free (www.isber.org/bestpractices). This update of the BP was translated into different languages that are also available for free via the website. The goal of the BPs is to facilitate improvement within biobanks who may apply some or all of these guidelines. Therefore, the goal of the survey described here was to evaluate the impact of the 4th Edition of the BPs on biobanking practice in the year that it's been published.

Methods: Those who downloaded the ISBER BP had to provide their email address as well as answer a few questions: including country of origin, repository type, whether or not they were an ISBER membership yes or no, and reason for downloading.

We used the emails that were provided when the BP was downloaded to re-contact the downloaders to ask additional in-depth questions. This survey was only conducted in January 2019 with a reminder sent out in February 2019 since the official launch of the Russian and Chinese translation took place at the end of November and the beginning of December 2018, respectively.

Results: As of the end of September 2018, 1600 people downloaded the ISBER BP 4th edition from the ISBER website. From the data collected at the time of download, 721 are located in the US and a quarter 26% are repository managers. One-third are current ISBER members and when asked their reason for download, 56% said they will use the BP for reference or education, 33% to develop protocols/policies, 4% for academic coursework, and 7% cited 'other' reasons. Results of the follow-up survey will be evaluated and presented during the ISBER conference.

Conclusions: The follow-up survey will collate stakeholders' views and assess the use and impact of BP at a local level. Feedback will help to inform future editions and the development of ISBER's suite of educational tools.

PRS-03 The International Standard (ISO/AWI 20388 & 23105) for Animal and Plant Resource Collection, Processing, Preservation and Transportation in Biobank

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For the in-depth studies of the nature nowadays, genetic research of animal and plant resource plays more and more important role in various fields such as species identification and functional application. Thereby, it is crucial to have standards to specify animal and plant resources' collection, processing, pres-

ervation and transportation. They will help biobanks and related organizations to obtain high efficiency in sample collection/processing and sample transfer among possessors.

China National Genebank (CNGB), the fourth largest national-level biobank in the world, has developed a series of specifications and standardized documents in sample collection and management. In 2014, CNGB experts became members of ISO/TC 276/WG2 and participated in the preparation of the first ISO/TC 276/WG2 standard, ISO 20387:2018 ''Biotechnology-Biobanking-General requirements for biobanking''. Since 2016, they have specifically developed two technical specifications (ISO/AWI TS 20388 and ISO/AWI TS 23105) under the framework of ISO 20387:2018 with experts worldwide.

The two standards recommend required quality and competence in biobanking for animal/plant resources from collecting to transporting. The standards try to cover as more sample types as possible. Each step, including collection, processing, preservation and transportation is addressed in detail.

These two standards have been reported in Beijing in TC276 plenary meeting and revised for several rounds before being submitted to Secretariat for consultation in WG2. They will be reported in Potsdam meeting on 12th Dec for further development.

PRS-04 Assessment of Standardized Processes - A Retrospective Analysis on Quality of DNA Samples from the Heidelberg CardioBiobank (HCB)

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Background: The Heidelberg CardioBiobank (HCB) operates as a hospital integrated biobank as well as a core Biobank for several national and international studies and research projects. The Biobank started with a cluster of standard −80°C freezers in which biological samples (predominantly liquid samples) have been stored in a study specific way. Therefore the collection of the biological samples has been performed according to study specific guidelines and not in a standardized generic structural system. In the year 2014 the HCB was restructured and a large fully automated storage systems (customized by Liconic AG, Liechtenstein) as well as fully automated sample processing systems have been implemented. To ensure biosamples ''fit fur purpose'', we evaluated and optimized the entire workflow for sample collection, logistics and storage. It was then possible to define specific Standard Operating Processes (SOPs) for all preanalytical processes achieving highest quality of samples, which are mandatory for cutting edge translational research. To show the impact of SOPs in Biobanks, we analyzed the quality and quantity of DNA samples from the years 2010 until 2018.

Methods: First we measured the quantity of the DNA samples (all assays: 20 samples from each year) with different methods and compared the results with the initial measurements before freezing. By doing this it was possible to analyze and compare also the outcome of different DNA extraction methods (manual vs automated extraction). Additionally, we analyzed the quality (DNA integrity number, DIN) of DNA samples and analyzed the results considering the different preanalytical sample processing procedures during the years.

Results: Changing the DNA extraction method from manual to automated extraction increased the quantity of DNA in a 2.3 fold change on average. By analyzing the quality of DNA (DIN) we found that since using automated processes and strict SOPs the DIN of the tested DNA samples are of high and constant quality (DIN >9) whereas samples collected before 2014 show a higher variation of quality.

Conclusion: Retrospective analyses of DNA quality and quantity from samples collected over the last 9 years clearly showed that the implementation of SOPs and automated sample processing and storage systems lead to a significant improvement of sample quality and quantity. As the highest sample quality is needed for personalized and precision medicine, standardized processes are mandatory for Biobanks.

PRS-05 Definitive Guidelines for Blood Collection Volumes in Human Research: A Collaborative Multicenter Experience

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Statement of the Problem: Advances in medical research continuously increase the need for quality biological materials from human participants. Presently, whole blood and its derivatives comprise a major portion of biospecimen collection due to their relative accessibility, ease of procurement, and the plethora of valuable information they contain. Despite the importance of this type of biospecimen to clinical and translational research, there is lack of standardization on volume requirements for various analyses, which represents a significant challenge to researches, regulatory bodies, and clinical sponsors. Moreover, the absence of blood collection guidelines for research purposes introduces unwanted variables in specimen collection, increases collection and storage costs, and has the potential to compromise the health of research participants. In this work, we propose guidelines for volumes of human blood collection that are reflective of current research needs and available technologies.

Proposed Solution: In this work, we plan to analyze literature, subject matter recommendations, and findings from different biobanks worldwide to derive workable guidelines for blood collection volumes for genomics, transcriptomics, proteomics, and metabolomics research. Preliminary data collected by the group shows variation in collected volumes across similar analytes and platforms.

Conclusions: The published recommendations will be useful in standardizing blood collection volumes across different omics research studies and eliminate the prevalent arbitrary collection. It will also enhance the protection of research participants and avoid excessive blood draws.

PRS-06 Research in RNA Preservation of Pancreas Tissue

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Background: RNA plays a vital role in basic research. Analysis of RNA isolated from tissues is widely used in biomedical research and molecular pathological diagnostics. The extraction of nucleic acids followed by downstream sequencing provides fundamental principles of scientific studies. Since polymerase chain reaction (PCR) and sequencing technologies are widespread, a method for high-quality RNA preservation is significantly important, especially for pancreas tissues, which are self-digestive. Currently, there is a lack of effective method in RNA preservation of pancreas tissues due to multiple enzymes contained in pancreas. Our aim was to optimize the preservation method of high-quality RNA from frozen pancreas tissues.

Methods: Male Sprague-Dawley rats (about 400 g) were obtained from Vital River Laboratories (Beijing, China). Rat pancreas was dissected and divided into three parts. One was put into liquid nitrogen(LN) directly. Another one was soaked into RNAlater (Invitrogen, USA) and put into liquid nitrogen (L0N) immediately. The other was infiltrated into RNAlater for 24h at 4 degrees of centigrade, then put into liquid nitrogen (L24N). RNeasy Mini Kit (50) (Qiagen, Germany) was used for total RNA extraction according to manufacturer's instructions. And quality of RNA was tested by Agarose gel electrophoresis and Agilent 2100.

Results: Although better RNA preservation was reported by using RNAlater, L0N and L24N showed no significant difference in RNA quantity as well as quality compared to LN in this study.

Conclusions: To our knowledge, this is the first time that usage of RNAlater has been discussed in the field of pancreas tissue. It is convenient, efficient and affordable in collecting tissue samples if RNAlater is abandoned. However, further validation of RNA preservation of human pancreas tissue are still warranted, while more modifications are also required to be investigated continuously for high quality RNA preservation.

PRS-07 Implementation of ISO 20387 in Swedish Healthcare Integrated Biobanks

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Statement of the Problem: The Swedish national biobank infrastructure, Biobank Sweden, is implementing a nationally coordinated Healthcare Integrated Biobanking (HIB) procedure which involves more than 20 hospitals from seven different counties. This procedure ensures a standardized handling of research samples from sampling to freezing all over Sweden. The goal is to facilitate for patients to participate in research studies regardless of their residency, and for researchers to create larger cohorts where the samples are comparable. In addition, with the great number of quality and healthcare registries, all with the common denominator of the Swedish ''personal number'', HIB creates a unique opportunity to conduct extraordinary research in Sweden. Setting up standardized routines with controlled processes, standard operating procedures (SOPs), and well-documented sample records has been of great importance from the start. Since the new biobank standard ISO 20387 was released in the autumn of 2018, the question has been if and how the standard can be implemented and used in the Swedish HIB procedure to further increase the quality of the sample collections.

Proposed Solution: To facilitate the implementation of ISO 20387 in Swedish Healthcare Integrated Biobanking, the standard and the corresponding implementation guide ISO/TR 22758 have been translated into Swedish. A working group consisting of representatives from all participating biobank facilities has been formed. The group will evaluate the possibilities of full implementation of the standard at different facilities, but also how it can be used even if full implementation cannot be achieved. Recommendations for the implementation of ISO 20387 will also take specific Swedish regulations into account, as well as if there are any limitations regarding the HIB procedures.

Conclusions: Sweden is currently well underway to set up a large network of healthcare integrated sampling and storage opportunities for researchers. Sample handling and storage are conducted according to several SOPs to achieve high quality samples. In order to further strengthen the quality of samples stored in the biorepositories, a national working group has been formed to aid in the implementation of the new ISO 20387 standard. The combination of quality controlled Healthcare Integrated Biobanking and unique registries, based on the Swedish personal number, creates great opportunities for state-of-the-art research.

PRS-08 How Much DNA Quality Is Necessary for Biobanking?

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Background: Together with a growing number of blood stem cell transplantation- and collection centers the non-profit organization DKMS has established the 'Collaborative Biobank - CoBi'. Characteristic of CoBi is the collection of samples and corresponding data from transplanted patients including follow-up as well as samples from their healthy donors (related/unrelated). CoBi has also taken over DNA samples from a previous register which was implemented in 2005 and stopped 2016 with partly unknown storage condition and sample quality information. The donor samples were used for a study on the subject of whether the donor KIR-genotype predicts outcome after unrelated hematopoietic stem cell transplantation for acute myeloid leukemia.

Methods: Donor samples were mapped to patient outcome data extracted from the German Registry for Stem Cell Transplantation. DNA was isolated using different methods and DNA concentration was measured. DNA was usually stored at -20°C for up to 18 years. For a KIR typing project DNA was normalized and a high resolution amplicon-based next generation sequencing (NGS) method was performed. The impact of the KIR/HLA ligand classifiers of the donor on relapse-free survival was tested in a Cox regression model adjusted for patient age, a modified disease risk index, performance status, donor age, HLA-match, sex match, CMV match, conditioning intensity, type of T-cell depletion and graft type following previous publications.

Results: A total of N = 2278 donor samples and mapped patient data were analyzed. From the samples 740 were stored for over 5 years. In most cases the storage conditions were no longer comprehensible. In total, 56 samples (2.5%) could not be sequenced, 20 due to insufficient DNA concentration or volume and 36 due to insufficient DNA quality. Still, 2222 samples had the necessary quality to perform NGS on KIR.

Conclusion: Although there was no complete information on sample quality and sample origin, we were able to provide good quality and reproducible results using NGS. Thus, once again, the question arises, how much qualitative data on DNA must be collected in advance for a biobank. Depending on the research question, even minimal information might be sufficient when combining different data sources.

PRS-09 Implementing ISO20387 in a Systems Toxicology Test Facility

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Philip Morris International's (PMI) Biomedical Research department has a strong focus on Systems Toxicology assessment of biospecimen collected from clinical and pre-clinical, including in-vivo and in-vitro, studies. Application of Systems Toxicology to product assessment is an emerging approach that is based on a variety of high-throughput molecular measurements, including genomics, proteomics, metabolomics, lipidomics and others. These experiments are often associated with large sample sizes, require rich sample annotations, and often involve many sample events leading to a complex sample management task.

As PMI is using this assessment approach not only for research purposes but also for submissions to regulatory, a high level of quality and standards compliance is required. Over the course of the past years a quality management system was implemented and integrated together with lab automations through computerized systems and instrument automations.

Although PMI's systems toxicology test facility is neither a biobank nor biorepository, a sophisticated sample management process is key to success. To our knowledge, these sample management processes are best described in the new ISO20387. It is therefore our goal to understand these requirements and develop an integration plan specific to our organization.

We will present our ISO20387 integration plan and give an overview on where we stand, what tools and solutions were and will be used to ensure compliance and what points we consider not applicable nor feasible to integrate in our setup.

ADDITIONAL ORAL ABSTRACTS

PHT-02M Chinese Culture Specific Multi-Social Media as a Platform for Biobanking and Clinical Research-Related Researchers and Public Education Campaign in the Small Video Era

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Statement of the Problem: Biobanking is a relatively new concept to Chinese audience and different stakeholders of biobank. Chinese biobank faces repetitive construction and the sample usage is relatively low. Social media can act as an important platform for debating, discussing, and disseminating information about human health and well-beings associate biobanking. Chinese specific national culture, philosophical and social conditions and the subtle doctor-patient relationship call for the biobanking associate public education more humanitarian and full enlightening the public's spirit of social welfare. However, till now only a little biobank have made a public education campaign and few Chinese biobank have taken advantage of small video platform to educate their stakeholders.

Proposed Solution: On July 11, 2017, the State Council of China issued a bold plan to revolutionize medical education and promote collaboration between medical education and practice for Healthy China 2030. According to this plan, a ''Biobank Aware'' campaign included three major new media platforms (Tik Tok, Volcano video, National video) Small video platform, WeChat public platform and a website was instituted to train biobanking professionals and audience. Investigation of the utility of Tik Tok, Volcano video and National video small video platforms in biobanking field before November 1, 2018. was conducted. Then a SWOT (strengths, weaknesses, opportunities, and threats) analysis was used to evaluate the biobanking positioning of Renji Biobank. We designed a sustainable education marketing plan to maintain high continuous attention of our campaign. The first stage education plan was to promote usage among clinical researchers and then follows the public education. A investigation among the scientific researchers was done to analysis their real potential needs.

Conclusion: The investigation shows that there was no biobanks had created a small video platform account before November 1, 2018, some clinical researchers are not aware of the importance of biobanks and most of the clinical researchers have a need of clinical research and clinical cohort study consultation and special clinical sample preparation. The scientific researchers and public based education video is in progress.

PHS-26 Activities of Biobank at Tertiary Cancer Centre in India

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Background: According to various epidemiological studies Cancer is amongst the one of major emerging cause of mortality in world as well as India. Cancer research is dynamically progressing to conquer this dreadful disease. With the development in the technology now Cancer research is heading more and more towards the translational and precision medicine directions. Rapid development of High throughput sequencing and need of personalized medicine in Cancer research has tremendously increased the demand of Biospecimens. Hence, there arises the need of Biorepositories. In the developing country like India we have very few Biobanks and Tata Memorial Center ACTREC being the renowned cancer treatment and research Centre we have established the Biorepository in 2007.

Aim: The basic aim of this Biorepository facility is to facilitate the collection, proper storage and providing high quality biospecimens to Scientists for translational research.

Methods & Results: With prior consenting the tissues and blood is collected from as many patients/as possible without compromising the Pathology diagnosis. Samples are collected

from Operation Theatre, Wards, OPD and surgical pathology. Till date we have collected 25000 samples from various sites like Breast, Brain, G.I. and Oral. Samples are distributed to various in house projects which are approved by Institutional Review Board. SOPs followed are in compliance with the Indian Council of Medical Research (ICMR) guidelines of Biobanking. Also ISBER 2018-best practices and International Cancer Genome Consortium (ICGC) recommendation and guidelines for sample quality standards are followed at ACTREC biorepository. The ICGC was initiated in 2007, which involves different countries globally. India focuses on oral cancer as a part of the ICGC activities. The ICGC biobanking is done at ACTREC biorepository where we have collected 395 cancers with recommended criteria. Details of ICGC biobanking will be presented. ACTREC Biorepository work flow of consent, collection, storage, data entry, review of request and distribution will be discussed including the SOPs, key points and issues faced. Brief data on quality control testing will be presented. Detailed data for tissues collected from various site will be presented.

Conclusion: ACTREC Biobanking has facilitated collection for more than 30 research projects including the ICGC and many other leading to significant contribution in Translational cancer research field.

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