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"Collection of a lifetime: A practical approach to developing a longitudinal collection of women's healthcare biological samples"☆

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ABSTRACT

Objective: The objective is to develop a biorepository of samples that represent all stages of a women's life. Importantly, our goal is to collect longitudinal physical specimens as well as the associated short and long-term clinical information.
Study design: The Women's Health Tissue Repository was established to encompass four tissue banks: Well Women Tissue Bank, Reproductive Endocrinology and Infertility Tissue Bank, Maternal Fetal Tissue Bank, and the long-established Gynecologic Malignancies Tissue Bank. Based on their health status, women being seen in Women's Health at the University of Iowa are recruited to contribute samples and grant access to their electronic medical record to the biorepository. Samples are coded, processed, and stored for use by investigators.
Results: The Maternal Fetal Tissue Bank was the first expansion of our department's biobanking efforts. Approximately 75% of the women approached consent to participate in the Maternal Fetal Tissue Bank. Enrollment has steadily increased. Samples have been used for over 20 projects in the first 3 years and are critical to 7 funded grants and 3 patent applications.
Conclusion: Patient samples with corresponding clinical data are initially important to women's health research. Our model demonstrates that many research projects by faculty, fellows, and residents have benefited from the existence of the Women's Health Tissue Repository. While challenging to achieve, longitudinal sampling allows for the greatest opportunity to study normal and pathological changes throughout all phases of a women's life, including pregnancy. This bank facilitates and accelerates the development of novel research, technologies, and possible therapeutic options in women's health. The establishment of more longitudinal biorepositories based on our model would enhance women's health research.

Introduction

Cell culture and animal studies have been important resources in advancing biomedical research. However, these systems are not perfect reproductions of human biological systems. As it is not always feasible or ethical to perform studies using humans, one of the most ideal means to perform translational research is to have a large repository of biological samples with corresponding demographic and clinical information.

Under ideal preservation conditions, these samples serve as indispensable resource for experimental research in numerous areas such as genetics and proteomics. Cancer biology has demonstrated the advantage of tumor banks. However, there are few banks designed to collect samples in order to answer questions about normal physiologic as well as pathologic processes that occur throughout the life of a woman and to address studies related to personalized medicine.

There are few biobanks in the United States dedicated to collecting samples longitudinally from participants throughout their pregnancies. The benefits to such collection are the ability to study changes that occur before the onset of clinical evidence of disease and to study how normal and disease processes change during gestation. However, such an effort is expensive and time

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consuming as it requires the participation of many women in order to have a substantial number of samples from women of different ages, race, BMI, socio-economic background, and family medical history who will develop pregnancy-related issues.

The Department of Obstetrics and Gynecology at the University of Iowa Hospitals and Clinics (UIHC) began its biobanking initiative over 30 years ago with the collection of gynecologic tumor samples. This collection has been under the direction of the Gynecologic Oncology division and has led to numerous projects, grants, and publications. However, to more fully explore all of the stages of a woman's life, we expanded our tissue repository to include 3 additional banks: Reproductive Endocrinology and Infertility (REI), Maternal Fetal, and Well Women Bank. Additionally, we obtain male samples from the fathers through the Paternal Contributions to Children's Health (PATCH) biorepository. Each bank has its own Institutional Review Board (IRB) approval and falls under the infrastructure of the umbrella "Women's Health Tissue Repository" (Fig. 1). This infrastructure provides rigor in patient consent, sample handling and processing, and comprehensive coverage of clinical annotations of samples from electronic medical records. Centralization has proven useful in other large prospective collections, but also poses ethical, societal, and technological challenges [1–3]. For large centralized multi-institutional biobanks, ethical issues relate to ownership and distribution of samples as well as how personal data are published and de-identified. Societal challenges include the development of regulatory frameworks for these multi-institutional or commercial biobanks. Ethical considerations relate to ownership, but also consider how samples may be used in the future and the clarity of long term storage and use in the consent process [4].

Logistically, having a centralized process within the department has supported standardized processes, but also allowed for focused recruitment of our patient population with an enhanced understanding of the clinical flow to patient visits, standard of care samples, and engagement of our faculty, staff, and learners in the collection and usage of samples. Thus, our model represents a hybrid of a large centralized biobank and a focused recruitment effort.

The first expansion of our tissue collection beyond the Gynecologic Oncology Bank began in March 2010 with the implementation of the Maternal Fetal Tissue Bank (MFTB). The REI and Well Woman Bank followed in 2011 and 2012, respectively. We now report on our successful efforts to expand into banking samples in the Maternal Fetal Tissue Bank and on the use of these samples. Expansion of this format of biobanking into other institutions would greatly enhance women's health research.

Materials and methods

IRB approval (#200910784) was obtained to develop a biorepository of samples taken at the same time as clinically indicated samples of maternal blood, maternal urine, and amniotic fluid. Permission was also obtained to collect umbilical cord blood and placental tissues. This collection strategy eliminates the need for any study-specific procedures that are outside of routine clinical care. Further, we obtained permission for long term limited-access to the mother's and child(ren)'s medical records at UIHC. The mother provides consent for their child(ren) at the same time as they consent for themselves.

Ethical and regulatory considerations

Samples from patients that consent, but are later found to meet at least one of the exclusion criteria are discarded and not retained by the Tissue Repository Core. All participants are informed that they are free at any time in the future to withdraw their specimens from further scientific research. A patient's decision to participate in our tissue banking efforts has no effect on the clinical care that she or her child(ren) receives.

Patient consent

One research assistant is primarily responsible for obtaining informed consent. The tissue banks have a partial Health Insurance Portability and Accountability Act (HIPAA) waiver that allows us to view patient scheduling information to identify patients that are eligible for participation. Before or after a clinic visit, patients are approached in the exam room and asked if they would like to hear about a research opportunity. The biorepository is described and all elements of the consent form are explained. After patients ask any questions, they are given the opportunity to enroll, decline, or to speak with a member of our research team at a future visit.

We are especially careful to inform patients that we may not know what projects or assays for which their samples will be used and that we may follow up their health indefinitely and that of their child (until age 18) through our electronic medical record. Patients are not contacted for follow-up. Patients have the choice to participate in a registry to participate in future studies.

The inclusion criteria for MFTB are: pregnant women who are at least 18 years old, English speaking, receiving care at the University of Iowa Hospitals and Clinics (UIHC), and able to provide informed consent are eligible to participate.

The exclusion criteria for MFTB are: women who are less than 18 years of age, ward of the court, HIV positive, or are Hepatitis C

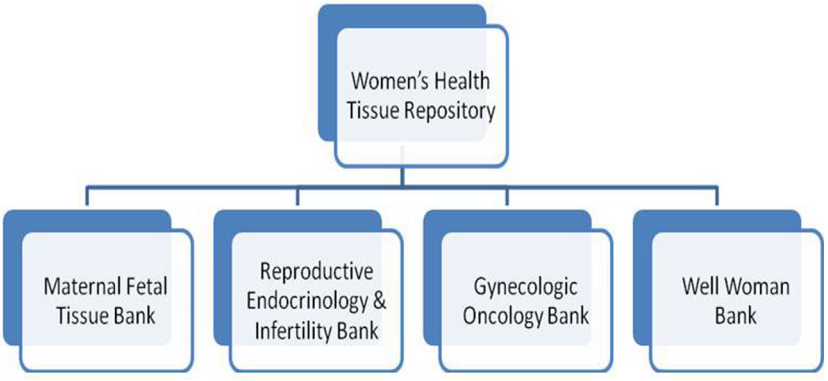

Fig. 1. Schematic of Organizational Structure of the Women's Health Tissue Repository. Each individual repository has IRB approval and a unique consent form to best address the issues related to each patient population.