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Integrating a Learning Health System Framework Into a Large Academic Medical Center

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OBJECTIVES/GOALS: The Learning Health System (LHS) framework at Columbia University Irving Medical Center (CUIMC) aims to optimize health system performance through enhancing the patient and care team experience, reducing inequities, costs and improving population health outcomes, through a collaborative, interdisciplinary and data driven approach. METHODS/STUDY POPULATION: In alignment with the Quintuple Aim, the LHS program at CUIMC is composed of five critical components: data integration (particularly using Epic EHR and real-time informatics data), utilization of evidence-based practices, a methodology for continuous improvement, and leadership commitment. Our methodology incorporates an iterative process improvement project cycle into an integrated infrastructure and governance of an academic medical center and its hospital partners to fulfill rapid project design and implementation. The LHS at CUIMC aims to bring a cultural shift through stakeholder engagement, symposia, training, accelerated pilot award opportunities, and building external partnership engagement. RESULTS/ANTICIPATED RESULTS: At CUIMC, our definition of a successful integration of a LHS framework is a cultural shift in thinking, method, and continuous improvement. The LHS program has developed multidisciplinary teams that are involved in defining and sharing data, design, and project management resources. In 2021, the first annual symposium was launched and brought together over 200 stakeholders from across the organization to support continuous education, training, and scaling of the framework. As a result of this foundation, two pilot initiatives have been funded and launched, the innovation accelerator model developed and is supporting over ten unique innovative and transformative clinical and operational programs, and several research grant applications have been submitted citing learning health system methodologies. DISCUSSION/SIGNIFICANCE: Our LHS framework has broken down silos and institutional barriers, creating a network of stakeholder groups. Our interdisciplinary approach has enabled us to create sustainable processes, resources and training on rapid, rigorous design, evaluation and implementation of interventions using real-time informatics data and digital health tools.

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Living Review of World Trade Center Health Effects

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OBJECTIVES/GOALS: The goal of this project is to develop a strategy to collect and extract published evidence in real time and to house and model these data for efficient downstream application to Program activities such as targeted reviews, grant evaluation and partner engagement. METHODS/STUDY POPULATION: We created the World Trade Center Health Effects Library in 2016. Today, this living review is ongoing and is fueled by daily systematic searches of online publication databases. Each day we screen new references for health effects of 9/11. The publication must include measurements, reports, or discussion of 9/11 health effects. If a publication meets these criteria, it is categorized by outcome and funding category. Primary outcome category data, reference metadata, and funding data are then made immediately available for programmatic analysis. All reference data are entered into a data pipeline and modelled for targeted reviews. RESULTS/ANTICIPATED RESULTS: The WTC Health Effects Library curates 1932 references and adds an average of 60 new references each year on a wide range of study populations, exposures, and conditions. The completeness of the library has been verified by comprehensive literature searches for 9/11 health outcomes conducted externally and by CDC Library staff. As a result, the curated library is a proven alternative to a lengthy literature search and allows the Program and stakeholders to explore the data and engage immediately in targeted reviews on curated topics. The data that are collected in the screening and categorization process are merged with publication metadata and funding data to inform a data pipeline that supports outputs such as interactive visuals, charts, reports, and curated bibliographies for structured review. DISCUSSION/SIGNIFICANCE: This living review allows the Program to rapidly conduct focused reviews, to evaluate grants, and to communicate accurate data to partners. By using the curated data, we have reduced the time required to perform mandated evidence reviews by weeks, have conducted two structured reviews, and defined gaps in research maturity and health equity.

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Moving from observational studies to a clinical trial: the impact of obesity and surgical weight loss on breast imaging, tissue, and cancer screening experience: the B-BRITE study

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OBJECTIVES/GOALS: Obesity is associated with increased incidence of breast cancer (BC), yet is not included in many lifetime-risk calculators. Obesity may impact breast cancer screening sensitivity. Retrospective studies show that bariatric surgery is associated with a lower risk of BC, but the effects of surgical weight loss on breast tissue are poorly understood. METHODS/STUDY POPULATION: We proposed a mixed-methods before and after study design to investigate the effects of surgical weight loss on breast tissue via pre- and post-weight loss breast tissue biopsies and imaging. In addition, we aimed to better understand barriers to BC screening for patients with obesity by conducting qualitative interviews. With institutional review board approval, we have begun recruiting 14 cisgender women who plan to undergo Roux-en-Y gastric bypass or sleeve gastrectomy. Participants must be at least 40 years old, with no prior history of breast biopsies or breast cancer and will undergo comprehensive breast cancer screening including mammography with quantitative density assessment, breast MRI, as well as breast core biopsies. RESULTS/ANTICIPATED RESULTS: We hypothesize that obesity and its associated metabolic changes lead to altered breast stroma, including increased inflammation, and tissue stiffness, with subsequent risk of carcinogenesis. If true, we expect to find

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obese women will have measurably increased inflammatory markers in their breast tissue, which are reduced after bariatric surgery. We expect that change in mammographic density may correlate with fibroglandular volume change on MRI; there are little data on change in background parenchymal enhancement in the setting of obesity and weight change and quantifying this will provide preliminary data for future work. Last, we expect that undergoing BC screening will be easier for patients after weight loss due to constraints of imaging equipment and potential bias in the screening process. DISCUSSION/SIGNIFICANCE: Screening for BC is paramount to improving outcomes yet people with obesity are screened less with worse outcomes. Studying the effects of weight loss on the breast may improve interpretation of breast imaging in the setting of obesity and identify markers of risk. Understanding barriers to screening may help us develop strategies to improve screening.

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Quality by Design: A Framework for Study Success

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OBJECTIVES/GOALS: The SC CTSI Quality by Design (QbD) program aims to improve the execution of clinical research studies identifying and addressing possible issues before implementation. The program's overall goal is to optimize operational design to achieve an 80% on-time completion rate. METHODS/STUDY POPULATION: Adapted from the Clinical Trials Transformation Initiative, our QbD program applies principles of quality management, project management, and team science to SC CTSI-funded studies. The process begins with a Design Studio for systematic review of critical-to-quality factors and a discussion of risks and mitigation plans. Studio attendees generally include the research team, SC CTSI faculty, and at least one community member. Outcomes include mitigation plans, a study project plan, and continued support from the project-tailored advisory board. We will iteratively evaluate satisfaction, quality improvement, and study completion rates. RESULTS/ANTICIPATED RESULTS: In an evaluation of the pilot phase, QbD participants responded that careful planning and expert input added value to their studies. The QbD process improved the quality of their studies, and all participants plan to apply QbD tools and resources to future studies. Beyond quality improvement, other anticipated outcomes include higher on-time study completion rates and uptake of QbD resources by other research teams. We also plan to assess the comparative benefit of QbD by study type. DISCUSSION/SIGNIFICANCE: Broader application of the CTSI QbD program has the potential for widespread benefit on research processes and outcomes. Studies implemented with minimal avoidable errors are more likely to complete on time, helping ensure efficient use of valuable resources and participant time.

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Raising research awareness through StudyFinder

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OBJECTIVES/GOALS: To increase public awareness and access to research opportunities at the University of Minnesota (UMN) utilizing StudyFinder, a public-facing website that features actively enrolling UMN research studies and directly connects website visitors with study teams. METHODS/STUDY POPULATION: Promote the University of Minnesota CTSI's StudyFinder website to the public via social media ad campaigns and community outreach. Upon completion of the latest StudyFinder enhancement project in 2021, CTSI focused 2022 efforts on marketing and promotion of the site. CTSI created three StudyFinder social media ad campaigns in January, June, and October. CTSI also planned outreach events during the week of Clinical Trials Day, the Minnesota State Fair (1.8M attendees over 12 days), and the UMN's Urban Research and Outreach-Engagement Center Community Day. RESULTS/ANTICIPATED RESULTS: Website traffic data from Google Analytics indicated a 72.76% increase in StudyFinder sessions from 2021 (Jan 1, 2021 to Nov 1, 2021) to 2022 (Jan 1, 2022 to Nov 1, 2022), with 16,262 sessions to 28,094 sessions, respectively. Direct emails from potential participants to study teams increased 89% in that same timeframe, from 3,082 emails to 5,819 emails. Targeted marketing campaigns and attending community events can improve the visibility of an institution's research and connections of potential research participants to research teams. DISCUSSION/SIGNIFICANCE: Recruitment remains a main challenge in clinical and translational research. StudyFinder is an important patient-facing tool to connect individuals to specific studies. Future directions include expanding marketing efforts, events, and public feedback.

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Successful Implementation of a Cross-Institutional Clinical Research Coordinator Pool to Support Georgia Clinical and Translational Science Alliance (Georgia CTSA) Investigators

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OBJECTIVES/GOALS: In 2020 the Georgia CTSA Clinical Research Center site at Emory University developed a highly trained, credentialed research coordinator pool with a goal to expand the pool to include clinical research coordinators from our partner institutions with the ability to work across institutional barriers in support of Georgia CTSA investigators. METHODS/STUDY POPULATION: Fall 2022, an Emory Investigator requested Georgia CTSA Biorepository samples with supporting clinical data for a NIH funded study. This provided a pilot opportunity to utilize clinical research nursing support offered by the UGA Clinical and Translational Research Unit (CTRU). De-identified samples were collected from our Biorepository while Emory's coordinators and lab collaborated with UGA's nursing support for data collection. Our obstacle for cross-institutional support was access to Emory Healthcare (EHC) medical records that would be needed by the UGA nurses, but partnerships created with the Georgia CTSA allowed us to overcome this, granting access to the electronic medical records (EMR) needed to complete the study. RESULTS/ANTICIPATED RESULTS: As expected, the process of credentialing and gaining access to the EHC EMR for the UGA team was the most time-consuming in the development of the pool. Discussions began in June 2021 to determine needs to allow the UGA research nurses to support the Emory coordinator pool. Requirements included acquiring an EHC network ID, completion of required Emory research training, letters of support from the Georgia CTSA outlining the collaboration between institutions, and a credentialing application. All

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