education programs. In 2020, MU recruited an Executive Vice Chancellor (EVC) for Health Affairs and subsequently Dean of the SOM who initiated programmatic steps to develop and establish a centralized clinical and translational research (CTR) infrastructure. METHODS/STUDY POPULATION: In order to develop and establish a CTR infrastructure, the EVC/Dean of the SOM created and recruited to the combined position of the Associate Dean (AD) for CTR and Associate Director (ADR) of clinical research (CR) for the Ellis Fischel Cancer Ctr. (EFCC) in 2021. The AD CTR was appointed the Chair of the Clinical and Translational Science Unit (CTSU) Steering Committee with the charge of establishing a 10,000 sq. ft. CTSU to be housed in the newly built $225M Roy Blunt NextGen Precision Health Bldg. and for re-building the Clinical Trials Support Office (CTSO), and the Clinical Trials Office (CTO) at the EFCC in his other role as the ADR CR. The AD CTR was also charged with implementing the OnCore clinical trial management system (CTMS) to centrally track and fiscally manage SOM clinical trials. RESULTS/ANTICIPATED RESULTS: Between 2021 and 2023, a CTR infrastructure was developed and established at the MU SOM. A total of 25 new clinical research staff (CRS) and leadership were hired that included a Sr. Dir. of CR Operations, clinical research nurses (CRNs) and coordinators (CRCs), Regulatory/Data/Fiscal/Project/Compliance/Coverage Analysis Coordinators between the CTSU/CTSO and the CTO of the EFCC. The CTSU was built with 10 FTE CRS [CRNs = 5, CRCs = 2, administrative staff = 2, Sr. Lab. Tech. = 1, and a manager]; the CTSO was re-built with 9 FTE CRS [Fiscal (n = 3), Project (n = 2), Compliance (n = 2), Coverage Analysis (n = 1) and Recruitment (n = 1) coordinators]. The EFCC CTO was re-built with 8 FTE CRS [CRNs = 4, Fiscal (n = 1), Data (n = 1) & Regulatory (n = 2) coordinators]. The implementation of the OnCore CTMS tracking function was also completed. DISCUSSION/SIGNIFICANCE OF IMPACT: Overall, the development and establishment of the CTR infrastructure has led to a significant increase and enhancement (e.g., capacity) to conduct clinical trials at the MU SOM. For example, this has led to a significant increase in the average annual enrollment to interventional oncology clinical trials [n = 82 (2021–2023) vs. n = 42 (2016–2020), p = 0.004].

Science Policy and Advocacy

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A catalyst for change: Elevating mental health considerations in Ontario using a mental health in all policies approach

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OBJECTIVES/GOALS: Our goal for this project is to develop a metric that integrates the intersectional social and structural determinants of health and well-being into the existing policy development framework to impact the integration of such considerations on population mental health. METHODS/STUDY POPULATION: This project was developed from a case study module offered by the Translational Research Program at the University of Toronto. This course was designed to sharpen contextual inquiry skills and further develop a case through employing strategies, including outreach engagement with stakeholders, conducting informational interviews and formulating potential pathways forward based on the integration of insights from interdisciplinary perspectives. RESULTS/ANTICIPATED RESULTS: The anticipated outcome would be improved mental health outcomes as measured by the Mental Health Commission of Canada's Mental Health Indicators (Mental Health Commission of Canada, 2015) DISCUSSION/SIGNIFICANCE OF IMPACT: Although there are established mental health indicators and policy development framework the two operate independently of each other. Our proposal bridge the gap between the sectors so that one may inform the other, and they can collectively formulate reflective and representative policies.

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Evaluating pediatric pain assessment tools in practice

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OBJECTIVES/GOALS: This project will focus on identifying the barriers that result in low adherence to quality care indicators that establish effective and efficient pediatric emergency care. The overall objective is to understand motivations behind adherence (or lack thereof) and find solutions to facilitate compliance. METHODS/STUDY POPULATION: This study will use a mixed-methods design to investigate the barriers. Quantitative data will be collected through a survey provided to healthcare providers involved in pediatric emergency care, including physicians, nurses, and administrative staff in both pediatric and general hospitals. Qualitative data will be collected through semi-structured interviews with a group of respondents to gain insight on their experience regarding compliance. Quantitative data will be analyzed using statistical analyses while qualitative data will undergo a thorough thematic analysis. Both sets of data will be reviewed to identify themes and differences in barriers across hospital types and healthcare roles. RESULTS/ANTICIPATED RESULTS: We will have gathered insights and perspectives from key stakeholders that are relevant to our study to ensure a comprehensive understanding of any potential implications that may arise from our study. We anticipate that the specific results will highlight key differences in adherence between pediatric and general hospitals. The study is expected to identify specific barriers hindering compliance with established guidelines in both settings. The results may be used to increase adherence to critical quality indicators and improve patient care. DISCUSSION/SIGNIFICANCE OF IMPACT: Pediatric injury care prioritizes the immediacy of care for children with acute illness and injury. With certain hospital protocols not being adhered to, there is a risk of wasting crucial time and resources that can affect patient care outcomes. The results would provide recommendations to improve and increase efficiency in pediatric injury care.

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Effects of policy on enrollment of populations facing multimorbid conditions: A systematic analysis

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OBJECTIVES/GOALS: To identify gaps in policy that influence enrollment trends of patients with multimorbidity in Phase III

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clinical trials. We aim to propose policy recommendations for increasing use of real-world evidence (RWE) that increases safety and efficacy information for patients with multimorbidities. METHODS/STUDY POPULATION: Conduct a systematic policy analysis on the current regulatory landscape of RWE, referencing the 2020 FDA Guidance "Enhancing the Diversity of Clinical Trial Populations." Evaluate guidelines using the Department of Health and Human Services' (HHS) 2016 Regulatory Impact Assessment (RIA) Framework. Utilize the Center for Drug Evaluation and Research's New Molecular Entity Database to identify novel hypertensive drugs approved after 2006, and assess clinical studies' alignment with the 2020 Guidance. Review additional policies, FDA guidelines, and ICH documents to establish baseline compliance. Two case studies will evaluate past policy impacts on drug development. Assess costs and benefits of increasing multimorbid patient enrollment to inform a policy framework. RESULTS/ANTICIPATED RESULTS: Anticipated results include all components of the HHS's RIA and a policy framework informed by the assessment. To identify problems, an analysis of clinical trial exclusion criteria in novel hypertensive drugs will be conducted to show diversity and enrollment gaps in regulatory policy, referencing the FDA's 2020 Guidance. The RIA's cost–benefit analysis will highlight costs faced for utilizing RWE and expanding enrollment criteria in Phase III studies. The cost–benefit analysis, RIA, and case studies will inform a policy framework that explains dynamics between stakeholders and outline policies that increase clinical trial representation in ways that are less burdensome to sponsors and patients. DISCUSSION/SIGNIFICANCE OF IMPACT: By understanding the barriers to enrolling participants with multimorbid conditions, we can outline incentives to increase diverse trial populations, helping healthcare providers choose more treatments for complex conditions. This research supports policy recommendations to make drugs more representative of conditions the population faces.

Team Science

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Team science training needs and preferences for clinical research professionals: A focus group analysis

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OBJECTIVES/GOALS: To present findings from a focus group study that evaluate clinical research professionals' (CRPs) team science learning preferences. The study aims to better understand CRPs' experiential perceptions of team science skills, training gaps, team cohesion, conflict, and contributions for their preferred team science training. METHODS/STUDY POPULATION: This study targeted CRPs across various roles in Academic Health Centers via focus groups. The focus groups will assess current skills, identify training gaps, and share experiences on team cohesion, team conflict, team contribution, and their thoughts and perceptions about clinical research professional team science training. The focus groups will be held via Zoom in the Autumn of 2024 with volunteer participants from an initial survey that was conducted earlier in 2024. We will report on combined data from multiple 90-minute focus groups, with approximately 6 participants per session. RESULTS/ANTICIPATED RESULTS: The focus group facilitator's guide includes questions informed by the CRP team science learning needs assessment results and other questions on team issues that would benefit from focused training. Focus group methods and demographic characteristics of the participants by role and experience level will also be presented. Qualitative analyses of recorded focus-group discussions will present key themes by demographic groups, and as a whole, these data will contribute to the development of CRP team science educational programs and toolkits. DISCUSSION/SIGNIFICANCE OF IMPACT: CRPs are vital members of clinical translational science teams. Overlooking CRP team science training can negatively affect the efficiency and effectiveness of the clinical translational science enterprise. CRP team science skills will foster a more collaborative and productive research environment.

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A CTS team approach to leveraging EHR data for predicting necrotizing enterocolitis in NICU

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OBJECTIVES/GOALS: This research aims to harness electronic health records (EHR) combined with machine learning (ML) to predict necrotizing enterocolitis (NEC) in preterm infants using data up to their first 14 days of life. We aim to provide interpretable results for clinical decisions that can reduce infant mortality rates and complications from NEC. METHODS/STUDY POPULATION: Through a retrospective cohort study using data from the University of Florida Integrated Data Repository and One Florida, we will develop machine learning models suitable for sequential data to predict NEC. Our inclusion criteria include very low birth weight (VLBW; < 1500g) infants born < 32 weeks gestation and EHR data availability from the first 14 days of life. We will include infants with NEC and infants without NEC to train our ML model. Exclusion criteria include infants diagnosed with spontaneous intestinal perforation and severe congenital anomalies/defects requiring surgery. RESULTS/ANTICIPATED RESULTS: We anticipate that our model will provide an accurate and dynamic prediction for the risk of NEC in neonates using data up to the first 14 days of life. Our model will be interpretable to identify key risk factors and can integrate real-world clinical insights to increase early detection and improve patient outcomes. DISCUSSION/SIGNIFICANCE OF IMPACT: The development of a model to predict NEC could be used in neonatal intensive care guidelines and protocols and could ultimately decrease mortality, reduce complications, improve the overall quality of care, and lower healthcare costs associated with NEC.

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