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Exploring Physician Investigator Clinical Trials Training and Quality Management Systems and its Implementation in Medical School Curriculums

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OBJECTIVES/GOALS: Although many physicians conduct clinical trials as Principle Investigators, a systematic training is often lacking. Instead, most receive on-site training, potentially compromising data quality and human subject safety. This research assesses the landscape for physician training through medical school curriculums. **METHODS/STUDY POPULATION:** This project explored training programs for physician researchers, specifically in the emerging field of quality management systems (QMS). To understand the scope of academic research available for QMS and Good Clinical Practice (GCP) training and lack of clinical trial training implemented in medical school curricula, a literature review was conducted. Available training for physicians was assessed through existing training programs from the FDA, NIH, DIAMOND, ACRP, and Google for accessibility in terms of costs, completion timelines and certification, format (online vs. in-person), and inclusion of GCP and QMS training in the curriculum. **RESULTS/ANTICIPATED RESULTS:** Literature review revealed that not much is known about physician researcher training beyond the institutional requirement for minimal GCP review. Examination of select medical school curriculum also discovered a lack of clinical trial training for students interested in clinical research. Furthermore, existing training programs and modules available for physicians are limited as their syllabi do not include QMS training. In addition, these programs commonly have inaccessible registration links, are expensive, and have significant time commitments for in-person courses. These findings support the need for more accessible and effective training and certification tools for physician researchers. **DISCUSSION/SIGNIFICANCE OF IMPACT:** QMS training is not included medical school curricula or programs for physician researchers, potentially compromising data integrity and subject protection. This research supports the development of essential QMS training concepts and practical approaches for physician researcher clinical trials.

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Glycemic control in a weight management-focused group medical visits (WM/GMV) intervention: examining the moderating effects of body mass index (BMI)

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OBJECTIVES/GOALS: The impact of baseline BMI on glycemic response to group medical visits (GMV) and weight management (WM)-based interventions is unclear. Our objective is to determine how baseline BMI class impacts patient responses to GMV and interventions that combine WM/GMV. **METHODS/STUDY POPULATION:** We will perform a secondary analysis of Jump Start, a randomized, controlled trial that compared the effectiveness of a GMV-based low

carbohydrate diet-focused WM program (WM/GMV) to traditional GMV-based medication management (GMV) on diabetes control. The primary and secondary outcomes will be change in hemoglobin A1c (HbA1c) and weight at 48 months, respectively. Study participants will be stratified into BMI categories defined by BMI 27-29.9kg/m², 30.0-34.9kg/m², 35.0-39.9kg/m², and ≥40.0kg/m². Hierarchical mixed models will be used to examine the differential impact of the WM/GMV intervention compared to GMV on changes in outcomes by BMI class category. **RESULTS/ANTICIPATED RESULTS:** Jump Start enrolled 263 overweight Veterans (BMI ≥ 27kg/m²) with type 2 diabetes. At baseline, mean BMI was 35.3 and mean HbA1c was 9.1. 14.5% were overweight (BMI 27-29.9) and 84.5% were obese (BMI ≥ 30). The proposed analyses are ongoing. We anticipate that patients in the higher BMI obesity classes will demonstrate greater reductions in HbA1c and weight with the WM/GMV intervention relative to traditional GMV. **DISCUSSION/SIGNIFICANCE OF IMPACT:** This work will advance the understanding of the relationship between BMI and glycemic response to targeted interventions, and may ultimately provide guidance for interventions for type 2 diabetes.

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Identification of the most salient risk factors of preterm birth in the US using geospatial mapping[†]

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OBJECTIVES/GOALS: Preterm birth is the most common birth complication in the United States. To date, there are no effective public health strategies to reduce the burden of prematurity. Using geospatial information system (GIS) mapping, we identified the most salient risk factors of preterm birth across US counties targetable for future interventions. **METHODS/STUDY POPULATION:** Risk factors of preterm birth were identified from the perinatal health nonprofit organization, March of Dimes, and included factors such as obesity, smoking, insurance coverage and poverty. US 2013 county-level data on sociodemographic characteristics, behavioral risk factors and preterm birth were extracted and combined from the American Census, Center for Disease Control, and US Health Resources and Services Administration. Spatial autocorrelation and multivariate spatial regression were used to determine the risk factors most strongly associated with preterm birth. These models were adjusted for race, given well-documented race disparities for preterm birth. As a case-study comparison, we mapped risk factors in the two states with the highest and lowest proportion of preterm births in 2013. **RESULTS/ANTICIPATED RESULTS:** In our preliminary analysis, obesity was the factor most strongly associated with preterm birth ($\beta = 7.32$, SE: 1.13, $p < 0.001$) at the US county-level. Surprisingly, smoking was not found to be significantly associated with preterm birth. In 2013, Vermont had the lowest prevalence of preterm birth at 7.6% and Mississippi had the highest prevalence of preterm birth at 13.1%. Health insurance coverage and obesity were the two risk factors that differed between Vermont and Mississippi. The median proportion of uninsured individuals in Mississippi counties was four times higher than that of Vermont counties (26.3% vs 10.9%, $p < 0.01$). Similarly, the median obesity prevalence in Mississippi counties was significantly higher than the median obesity prevalence in Vermont counties (38.8% vs. 25.2%). **DISCUSSION/SIGNIFICANCE OF IMPACT:** Public health efforts aimed at reducing obesity and increasing health insurance coverage may have the greatest impact at addressing the US burden of preterm birth. Further, geospatial mapping is a powerful