

previous efforts in characterizing and developing metadata models for describing microbiome metadata. Due to the heterogeneity in microbiome and exposome data, we aligned them along a conceptual representation of different data used in translational research; microbiomes being biospecimen-derived, and exposomes being a combination of sensor measurements, surveys and computationally modelled data. We performed a review of literature describing microbiome data, metadata, and semantics [4–15], along with existing datasets [16] and developed an initial metadata model. We reviewed the model with microbiome domain experts for its accuracy and completeness, and with translational researchers for its utility in different studies, and iteratively refined it. We then incorporated the logical model into OpenFurther's metadata repository MDR [17,18] for harmonization of different microbiome datasets, as well as integration and assimilation of microbiome-exposome events utilizing the UPIE. RESULTS/ANTICIPATED RESULTS: Our model for describing the microbiome currently includes three domains (1) the specimen collected for analysis, (2) the microbial genomics pipelines, and (3) details of the microbiome genomics. For (1), we utilized biospecimen data model that harmonizes the data structures of caTissue, OpenSpecimen and other commonly available specimen management platform. (3) includes details about the organisms, isolate, host specifics, sequencing methodology, genomic sequences and annotations, microbiome phenotype, genomic data and storage, genomic copies and associated times stamps. We then incorporated this logical model into the MDR as assets and associations that UPIE utilizes to harmonize different microbiome datasets, followed by integration and assimilation of microbiome-exposome events. Details of (2) are ongoing. DISCUSSION/SIGNIFICANCE OF IMPACT: The role of the microbiome and co-influences from environmental exposures in etio-pathology of various pulmonary conditions isn't well understood [19–24]. This metadata model for the microbiome provides a systematic approach for integrating microbial genomics with sensor-based environmental and physiological data, and clinical data that are present in varying spatial and temporal granularities and require complex methods for integration, assimilation and analysis. Incorporation of this microbiome model will advance the performance of sensor-based exposure studies of the (UPIE) to support novel research paradigms that will improve our understanding of the role of microbiome in promoting and preventing airway inflammation by performing a range of hypothesis-driven microbiome-exposome pediatric asthma studies across the translational spectrum.

## Clinical Epidemiology/Clinical Trial

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### Vitamin D assay utilization and outcomes in pregnant women in an urban safety net medical center: a retrospective cohort study

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OBJECTIVES/SPECIFIC AIMS: The goals of this retrospective cohort study is threefold: 1) to assess how many pregnant women at Boston Medical Center from 2012 to 2017 have had their vitamin D status checked prior to and during pregnancy, 2) determine associations between vitamin D levels, birth outcomes and demographics and 3)

assess how many of those found to have lower than satisfactory vitamin D levels (<30ng/mL) received interventions, including receiving vitamin D supplementation and/or being referred to an appropriate specialist such as an endocrinologist or a nutritionist. METHODS/STUDY POPULATION: Our study population is mothers over age 18 who received care at Boston Medical Center during their pregnancy from 2012 to 2017. Our primary outcomes are vitamin D utilization rates and associations between vitamin D levels with clinical outcomes during pregnancy and at birth. Secondary outcomes are demographic predictors of mothers who receive vitamin D testing and those who have complications associated with low vitamin D. We will conduct multiple linear regressions to check for associations between vitamin D levels, birth outcomes and demographic variables. We will adjust vitamin D levels with maternal BMI. De-identified clinical data was gathered from Boston University Medical Center's (BUMC) Clinical Data Warehouse. This retrospective study was approved with a HIPAA waiver by the BUMC Institutional Data Warehouse. All statistical analysis was completed using SAS version 9.4 and was primarily done by the student PI and reviewed by Dr. Hossein, the co-investigator who is trained as a statistician and geneticist. The team also utilized Boston University's Biostatistics, Epidemiology & Research Design (BERD) team to check the feasibility of the statistical methods. RESULTS/ANTICIPATED RESULTS: We anticipate that our descriptive demographic data will reflect the medical center's predominantly black/Hispanic and low-income profile. Based on previous literature, we expect low vitamin D levels to have positive associations with gestational diabetes, pre-eclampsia, and preterm birth. Analyses are currently actively in progress and we expect to have results before the ACTS conference date in March, 2019. DISCUSSION/SIGNIFICANCE OF IMPACT: Vitamin D is an essential part of the human body system. It is well documented in current literature that vitamin D is correlated with bone health, mental health and maternal health. Moreover, there is evidence that maternal vitamin D supplementation prevents vitamin D deficiency in newborns. Previous literature suggests that low vitamin D may be associated with gestational diabetes, pre-eclampsia, and pre-term births. Boston Medical Center is Massachusetts' largest urban medical center and acts as its only safety-net hospital, serving predominantly low-income and socially marginalized patient populations. There is limited existing research on assessment of maternal vitamin D in urban hospital settings. Pregnant women rarely receive vitamin D screenings as part of their prenatal checkups as current national and regional guidelines do not require pregnant women to be screened for vitamin D deficiency or insufficiency. The results will demonstrate the potential effects vitamin D supplementation, or lack thereof, in expectant mothers living in urban, safety net communities. We hope to inform prenatal care practices and attitudes of vitamin D supplementation in maternal health with the results of our study.

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### A comparison between the Rolling 6 and 3+3 dose escalation study designs for phase 1 clinical trials

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OBJECTIVES/SPECIFIC AIMS: The development of new anti-cancer agents for children requires an inherently longer timeline than in adults. The 3+3 study design for Phase 1 dose escalation trials is commonly used to estimate the maximum tolerated dose and assess safety. The Rolling 6 study design was developed to shorten

the study conduct timeline. **METHODS/STUDY POPULATION:** This study compares twenty Phase 1 COG Pilot and Phase 1 Consortium trials that employed the Rolling 6 design with hypothetical results under the assumption that a 3+3 design had been executed. The number of evaluable patients required to complete the study, number of DLTs, number of inevaluable patients, overall study duration, time suspended to enrollment (i.e., waiting for DLT evaluation), and DLT risk are compared between study designs using Wilcoxon's signed rank test. **RESULTS/ANTICIPATED RESULTS:** The Rolling 6 study design required less time to complete the studies compared with 3+3 design (median 273 vs. 297 days,  $P = 0.01$ ). In general, the Rolling 6 study design required more patients, had more inevaluable patients, and there were more dose limiting toxicity (DLT) events. However, there was no significant difference in DLT risk (median 0.15 vs. 0.17,  $P = 0.72$ ). **DISCUSSION/SIGNIFICANCE OF IMPACT:** The Rolling 6 study design effectively shortens the study conduct timeline compared with the traditional 3+3 design for Phase 1 COG Pilot and Phase 1 Consortium trials without increasing the risk of toxicity.

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### **A cross-sectional analysis of opioid prescribing patterns among gynecologic oncologists using Medicare fee-for service provider utilization & payment data**

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**OBJECTIVES/SPECIFIC AIMS:** Opioids are the first-line treatment for moderate to severe cancer-related pain. Increased awareness of opioid prescription misuse and adverse outcomes has prompted statements on their use from multiple national medical groups. In this study we characterize national-level opioid prescription patterns among gynecologic oncologists treating Medicare beneficiaries. **METHODS/STUDY POPULATION:** The Centers for Medicare and Medicaid Services (CMS) database was used to access Medicare Part D beneficiary data (2016). All available opioid claims prescribed by gynecologic oncologists were identified. Medication type, prescription length and other prescribing factors were recorded. Physician demographics were obtained from departmental websites and accrediting bodies. Physicians with <10 opioid claims are not included in the CMS database. Bivariate statistical analysis including chi-squared, Fisher's exact test and Wilcoxon rank-sum test were performed to compare variables with threshold for significance set at  $p < 0.05$ . Linear regression modeling was also performed to examine association of gender with number of opioids prescribed. **RESULTS/ANTICIPATED RESULTS:** A total of 494 board-certified gynecologic oncologists were included in this analysis. In 2016, gynecologic oncologists wrote 23,584 opioid prescriptions for 267,824 days of treatment (average of 9.24 prescribed days per claim). The most commonly prescribed opioid was oxycodone/acetaminophen (41%). Male physicians had significantly more opioid prescription claims than females ( $p < 0.01$ ) including after adjusting for differences in years of experience. The majority of physicians had 11-50 opioid prescription claims (68%). A minority were high prescribing physicians with >100 opioid claims (11%). Of these, the overwhelming majority were male (82%) and late career (46%, >15 years since board certification). Physicians in the South had the greatest number of opioid prescription claims and significantly more than physicians in the Northeast, who had the fewest ( $p < 0.01$ ). Mean number of opioid claims increased with increasing

years of experience ( $p < 0.05$ ). **DISCUSSION/SIGNIFICANCE OF IMPACT:** Among gynecologic oncologists, there were gender-based, regional and experience-related variations in opioid prescribing in the Medicare population in 2016. Further longitudinal studies are required to elucidate secular trends in opioid prescription practice.

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### **A Randomized Controlled Trial Comparing the Nonabsorbable Antibiotic Rifaximin vs. Dietary Intervention Low in Fermentable Sugars (FODMAP) in Irritable Bowel Syndrome**

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**OBJECTIVES/SPECIFIC AIMS:** Objectives and goals of this study are to (i) determine whether IBS-D patients randomized to either rifaximin or low FODMAP diet show improvement in IBS-related symptoms; and (2) identify using longitudinal analyses how SIBO status and fecal microbiota features associate with response to either rifaximin or low FODMAP dietary intervention. **METHODS/STUDY POPULATION:** 42 patients  $\geq 18$  years of age who meet Rome IV criteria for IBS-D will be randomized to receive either rifaximin or low FODMAP diet intervention. The primary outcome will be the proportion of responders to intervention which is defined as  $\geq 30\%$  reduction in mean daily abdominal pain or bloating by visual analog scale compared with baseline. Exclusion criteria will include: (a) history of microscopic colitis, inflammatory bowel disease, celiac disease, or other organic disease that could explain symptoms, (b) prior gastrointestinal surgery, other than appendectomy or cholecystectomy > 6 months prior to study initiation, (c) prior use of rifaximin or formal dietary interventions for IBS-D, (d) use of antibiotics within the past 3 months, or (e) use of probiotics within 1 month of study entry. Glucose hydrogen breath tests will be performed at the beginning and end of the trial to evaluate for SIBO. Fecal samples will be collected at 0, 2, and 6 weeks to determine changes in fecal microbial composition and structure. **RESULTS/ANTICIPATED RESULTS:** This study seeks to examine whether longitudinal analyses of small intestinal and colonic microbiota can subtype IBS-D subjects into clinically relevant phenotypes. A total of 18 subjects have been enrolled into the study. Clinical variables, hydrogen breath test results, and fecal microbiota data are being collected for ongoing analysis. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Results from this study may help move treatment of IBS from a purely symptom based approach to a more individualized approach by stratifying IBS-D patients into distinct clinical phenotypes which are amenable to targeted therapeutic approaches.

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### **A1BG and ITIH4 proteins are upregulated on HDL of youth with type 1 diabetes and correlate with glycemic control**

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**OBJECTIVES/SPECIFIC AIMS:** Our objective was to compare the proteomics of HDL between youth with T1DM and healthy controls