

utilize the Internet as a health resource. Providers can refer patients to educational materials produced by major medical associations available on their websites. However, patient educational materials (PEMs) published by professional organizations from other surgical specialties have been shown to be difficult to read for the average American. The NIH and AMA recommend that PEMs be written between a sixth and eighth grade reading level. In this study, we assess the readability of online PEMs on gynecologic cancer published by major medical associations. **METHODS/STUDY POPULATION:** Seven national medical association websites with PEMs on gynecologic malignancy were surveyed: American College of Obstetricians and Gynecologists, Center for Disease Control, Foundation for Women's Cancer, National Cancer Institute, National Cervical Cancer Coalition, National Ovarian Cancer Coalition, and Society of Gynecologic Oncology. Online PEMs were identified and analyzed using five validated readability indices. One-way ANOVA and Tukey's test were performed to detect differences in readability between publishers. **RESULTS/ANTICIPATED RESULTS:** Two hundred and thirty PEMs were included in this analysis. Mean readability grade levels with standard deviation were: 11.3 (2.8) for Coleman-Liau index; 11.8 (3.2) for Flesch-Kincaid; 11.1 (1.2) for FORCAST formula; 12.5 (2.7) for Gunning FOG formula; 12.1 (2.6) for New Dale-Chall formula; and 13.5 (2.5) for SMOG formula. Overall, PEMs were written at a mean 12<sup>th</sup> grade reading level. Only 4.3% of articles were written at an 8<sup>th</sup> grade reading level or below. ANOVA demonstrated a significant difference in readability between publishing associations ( $p < 0.01$ ). PEMs from the Center for Disease Control had a mean 10<sup>th</sup> grade reading level and were significantly lower than all other organizations. PEMs from The Foundation for Women's Cancer had a mean 13<sup>th</sup> grade reading level and were significantly higher than most other organizations. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Gynecologic oncology PEMs available from major medical association are written well above the recommended sixth to eight grade reading level. Simplifying PEMs may improve patient understanding of their disease and facilitate physician-patient communication.

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### Reducing Reintubation Risk in High-Risk Cardiac Surgery Patients with High Flow Nasal Cannula

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**OBJECTIVES/SPECIFIC AIMS:** More than half a million adult patients nationally undergo cardiac surgery each year. Reintubation following cardiac surgery is common and associated with higher short- and long-term mortality, increased cost, and longer lengths of stay. The reintubation incidence is estimated at 5-10%. Patients undergoing cardiac surgery are increasing in age and comorbidity burden, and receive increasingly complex cardiac surgical procedures, complicating decision making around when to extubate post-operative patients. Compounding this complexity are financial pressures to maintain high throughput and maximize ICU bed availability. Providers are often compelled to extubate high-risk patients earlier, despite the potential for an increased risk of reintubation. Understanding the risk factors for reintubation after cardiac surgery and identifying effective interventions to reduce these reintubations is of critical importance to optimize patient outcomes. High-flow nasal cannula (HFNC) provides up to 60 liters per minute of 100% oxygen, dead space washout, and humidification to improve secretion clearance, and has shown some benefits in improving

hypoxia and reducing reintubation in select populations. However, its benefit in high-risk patients undergoing cardiac surgical procedures is not known and therefore clinicians may still be reluctant to extubate these patients early and introduce HFNC, despite the known risks of prolonged intubation. To address this important issue, we aim to develop and validate a model to predict post-operative reintubation after cardiac surgery using data readily available from the electronic health record (EHR) and use this data to complete a pilot randomized controlled trial (RCT) of post-extubation HFNC to prevent reintubation in cardiac surgery patients identified as at high risk for reintubation. **METHODS/STUDY POPULATION:** Based on retrospective data demonstrating a 4.7% reintubation incidence within 48 hours in our CVICU, we estimate that there will be 340 reintubations available for analysis of the risk factors for reintubation to develop our predictive model from November 2, 2017 (our EHR go-live). We require 15 events per predictive variable to avoid overfitting the model, giving us at least 22 variables for analysis and inclusion in the model. Model validation and calibration will be performed using a bootstrapped validation cohort. Next, we will prospectively study 120 patients with a greater than 10% predicted risk of reintubation (double the baseline risk of the overall population) and randomly assign them to either HFNC or usual care, to test the hypothesis that HFNC decreases the rate of reintubation in high-risk patients. **RESULTS/ANTICIPATED RESULTS:** In addition to developing a predictive model, refining it, and validating its ability to predict the primary outcome of reintubation within 48 hours, I will further assess whether HFNC reduces total duration of mechanical ventilation, hospital length of stay, and ICU length of stay in this high-risk population. I will use these data to establish the feasibility of EHR-integrated predictive modeling and randomization, as well as to guide a future multicenter clinical trial that will pragmatically leverage the EHR for patient selection, enrollment, randomization, and data collection. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Assuming HFNC decreases reintubation rates by 50%, at a 1:1 ratio of cases to controls, we will require 435 patients in each group (970 total), to have an 80% power and alpha of 0.05 to detect a difference. As this will require a multicenter study, we will instead focus on using data from this pilot study to: 1) refine our sample size estimates. 2) demonstrate the feasibility of our novel EHR-integrated pragmatic trial design. 3) identify and screen collaborators at other institutions, including obtaining important regulatory and legal approval. 4) establish a data safety monitoring board for the trial. 5) refine the data collection infrastructure, leveraging commercially available resources in one of the largest enterprise EHR systems (Epic) and associated resource-sharing products, such as Epic's App Orchard.

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### Systematically Integrating Microbiomes and Exposomes for Translational Research

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**OBJECTIVES/SPECIFIC AIMS:** Characterize microbiome metadata describing specimens collected, genomic pipelines and microbiome results, and incorporate them into a data integration platform for enabling harmonization, integration and assimilation of microbial genomics with exposures as spatiotemporal events. **METHODS/STUDY POPULATION:** We followed similar methods utilized in

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