

(32% and 25%, respectively) and hookah users (44% and 36%, respectively). Tobacco flavor was the most common among regular users of traditional cigars (80%), cigarillos/filtered cigars (55%), and smokeless tobacco (79%). Polytabacco users of ENDS and traditional cigars had the largest discrepancy, where about 68-76% used different flavor categories when switching products. Conversely, polytabacco users of traditional cigars and cigarillos/filtered cigars had the lowest discrepancy (23-25%). **DISCUSSION/SIGNIFICANCE OF IMPACT:** Many consumers of multiple tobacco products had different flavor preferences when switching between products. In the event of a partial or full flavor ban for ENDS, these findings raise questions about consumer loyalty to a particular tobacco product or a particular flavor category. **Conflict of Interest Description:** MLG serves as a paid consultant for Johnson & Johnson and has received research grant from Pfizer, manufacturers of smoking cessation medications. The other authors have no conflicts to declare. **CONFLICT OF INTEREST DESCRIPTION:** MLG serves as a paid consultant for Johnson & Johnson and has received research grant from Pfizer, manufacturers of smoking cessation medications. The other authors have no conflicts to declare.

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### Effects of Injectable, Erythropoietin and Glucocorticoids Combinational Therapy on Erythrocyte Sedimentation Rate Following Spinal Cord Injury

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**OBJECTIVES/GOALS:** Inflammation following traumatic injury to the spinal cord persists long after the primary insult and is known to increase complication rates and prolong recovery time. We investigated the effects of Erythropoietin (EPO) in combination with Glucocorticoids on the levels of erythrocyte sedimentation rate (ESR), an overall measure of inflammation. **METHODS/STUDY POPULATION:** Electronic medical records from approximately 38 million patients in 27 Healthcare Organizations were analyzed using the TriNetX Analytics platform. Patients with spinal cord injuries (SCI) were defined with the ICD-10 code, G95 and two unique cohorts were defined for patients treated with injectable EPO in combination with injectable Glucocorticoids within 6 months of SCI or only injectable Glucocorticoids with no injectable EPO. ESR rates were queried from patient cohorts to evaluate the potential effects of the two treatment pathways on the ESR. Most recent lab results within 6 months before initiating treatment and 1-year post-treatment were defined as "before" and "after" treatment, respectively. Changes in ESR lab results were evaluated using unpaired t-test with Welch's Correction. **RESULTS/ANTICIPATED RESULTS:** A total of 14,370 patients satisfied the inclusion criteria. 89 patients were treated with injectable EPO in combination with Glucocorticoids within 6 months of SCI. The ESR lab results were available for 33 patients before treatment with a mean of 63±33 mm/h. The ESR lab results were available for 22 patients after treatment with a mean of 51.7±34.1 mm/h. 14,281 patients were treated with Glucocorticoids (no injectable EPO) within 6 months of SCI. The ESR lab results were available for 2,042 patients before treatment with a mean of 29.2±30.5 mm/h. The ESR lab results were available for 2,184 patients after treatment with a mean of 32.6±30 mm/h. Patients treated with combinational therapy showed a reduction in ESR of 11.3 mm/h, while those treated with only Glucocorticoids showed an increase in ESR of 3.4 mm/h. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The present results demonstrated that combinational therapy with injectable, EPO and glucocorticoids exhibited a significant reduction in ESR level. The study suggests that EPO

and glucocorticoid might have a synergistic effect on reducing the inflammation following SCI. This approach might help reduce the therapeutic dose of glucocorticoids. **Conflict of Interest Description:** The authors declare that they have no competing interests. **CONFLICT OF INTEREST DESCRIPTION:** The authors declare that they have no competing interests.

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### Estimates of Dose Response using the Dixon Up-and-Down Method and BOIN study designs

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**OBJECTIVES/GOALS:** The Dixon up-and-down method (U/D), originally developed for testing explosives, is especially common in anesthesia research studies. The objective of this research is to compare the performance of the U/D method for obtaining and analyzing sensitivity data with that of the Bayesian Optimal Interval (BOIN) method. **METHODS/STUDY POPULATION:** A simulation study will compare the performance of the U/D method with the BOIN design. The two study designs offer alternative decision-making algorithms with respect to the dose at which the next experimental unit is treated. These alternative decisions may impact the precision of point estimates of the mean and standard deviation of the effective dose to elicit a response. Transition probability matrices are developed, and maximum likelihood estimates of the unknown parameters assessed for accuracy. For simulation, the effective dose is assumed to be randomly distributed with a known mean and standard deviation. Fixed dose levels are defined, and decisions for what level the next experimental unit should be treated at are defined by the Dixon up-and-down method and the BOIN design. For the U/D method, the stimulus is increased by one level in the absence of a response or decreased if a response occurs from an initial stimulus. A target toxicity probability of 0.50 is used to define the dose escalation or de-escalation rules for the application of the BOIN design. **RESULTS/ANTICIPATED RESULTS:** A feature of both methods is that the consecutive observations are concentrated about the mean value of the effective dose. However, the BOIN design tends to be more concentrated between these two dose levels. In the presence of severe adverse events, the BOIN design can choose to eliminate doses that are too toxic whereas the U/D design cannot eliminate any dose levels. Transition probability matrices are defined and parameters for the distribution of the effective dose are estimated using maximum likelihood estimation. Mean squared errors for the estimated mean and standard deviations compare the two study designs. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The BOIN design offers an alternative method for decision-making compared with the U/D method. The BOIN design tends to concentrate dose levels about the mean more than the U/D. This may provide better estimates of the mean and standard deviation of the effective dose for eliciting a response in some circumstances.

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### Harnessing the Power of the Electronic Medical Record in Interstitial Lung Disease

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**OBJECTIVES/GOALS:** Harnessing the EHR to support clinical research is critical for the study of rare diseases such as interstitial lung disease (ILD). However no studies have compared EHR and

research-quality data in the ILD population. Our objectives were to (1) identify ILD patients and extract clinical data from an EHR system and (2) assess the performance of ILD data capture. **METHODS/STUDY POPULATION:** Case validated algorithms were implemented to identify patients from the University of California San Francisco EHR and extract key ILD clinical information including, demographic variables, process measures and patient outcomes. Key clinical information were defined based on consensus statements and ILD clinical trials. A subset of ILD patients, had variables recorded in both the EHR and a separate ILD longitudinal research database. The completeness of EHR data capture and level of agreement were compared between three data collection methods: (1) data manually and systematically collected for an ILD research database (gold standard), (2) data automatically extracted from structured fields in the EHR, and (3) data extracted from unstructured data sources. **RESULTS/ANTICIPATED RESULTS:** We identified 5857 ILD patients in the EHR, of which 2100 patients had data available in the both the EHR and research database. Baseline demographic variables, co-morbidities, use of diagnostic testing, pharmacotherapy were accurately extracted from structured fields. Outcome measures, including lung physiology, radiographic patterns, pathology results, and health related quality of life (HRQoL) were unevenly extracted from structured fields alone. With the exception of HRQoL, these measures were accurately captured in unstructured EHR sources. Notably, certain metrics were better defined in the EHR, including health care resource utilization metrics, acute exacerbations, medication side effects, supplemental oxygen use and specialty care referrals (rheumatology, lung transplant, palliative care, etc). **DISCUSSION/SIGNIFICANCE OF IMPACT:** A large real-world ILD cohort can be algorithmically extracted from the EHR along with key clinical variables with accuracy comparable to protocol-driven research databases. Rigorous assessment of the types of disease-specific variables that are present in EHR-derived data will inform future interventions to improve the fidelity, accessibility and use of the EHR in clinical research.

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### Interactions of the Infant Nasopharyngeal Microbiota and Subjects' Clinical Traits in Development of Viral Upper Respiratory Tract Infections and Acute Otitis Media

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**OBJECTIVES/GOALS:** Identify the interactions between nasopharyngeal bacterial pathogens, commensals, and patient clinical characteristics in relation to the development of viral upper respiratory tract infections (URI) and acute otitis media (AOM) in infants. **METHODS/STUDY POPULATION:** The subjects were part of a prospective, longitudinal study (2008–2014) of infants to evaluate the prevalence and risks for the development of URI and AOM. Healthy infants (n = 362) were enrolled from near birth and followed to the first episode of AOM up to 12 months of age. Nasopharyngeal specimens and clinical traits were collected at monthly intervals between 1–6 months, month 9, and during viral URI episodes. Subjects were closely followed for AOM development. 16S rRNA sequencing was performed on the nasopharyngeal swabs to identify their bacterial composition. Multidimensional (2, 3, and 4 dimensional) co-presence, co-exclusion, and one-way relation patterns were identified between the microbiome compositions, health status,

and other collected clinical traits. **RESULTS/ANTICIPATED RESULTS:** We analyzed 971 specimens collected monthly and during URI and AOM episodes from 139 infants. Of the 139 enrolled subjects, 96% had 2 or more healthy samples, 77% contracted URI/AOM during the study period, and 60% had at least 1 healthy sample before URI/AOM onset. Otopathogens (Moraxella, Haemophilus, and Streptococcus), Staphylococcus, and Pseudomonas were the most common pathogenic genera. Corynebacterium, Dolosigranulum, and Acinetobacter were 3 most abundant commensal bacterial genera. Samples from infants with AOM in the first year had a significantly higher relative abundance of Haemophilus, Enterobacter, and Yersinia, and lower relative abundance of Corynebacterium, and Pseudomonas compared to samples from infants who did not develop AOM. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Identification of complex multidimensional interaction patterns within microbial communities and environmental factors is vital to understanding disease onset risk and prevention. Prophylactic microbiome and environmental factor modulation between enterotypes could be used to reduce URI/AOM onset in infants.

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### Longitudinal Assessment of Metabolic Syndrome as a Modifiable Risk factor of World Trade Center Particulate Matter Exposure Associated Lung Disease

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**OBJECTIVES/GOALS:** Metabolic syndrome (MetSyn) is a risk for World Trade Center-Lung Injury (WTC-LI; defined as developing FEV<sub>1</sub> < lower limit of normal [LLN]). Metabolic health is a modifiable disease risk factor. We propose to characterize how time-dependent covariates of MetSyn are longitudinally associated with WTC-LI. **METHODS/STUDY POPULATION:** WTC-particulate exposed firefighters, consented, with pre-9/11 FEV<sub>1</sub> LLN (N = 5,746). Data assessed from last pre-9/11 till August 1, 2017. Longitudinal MetSyn characteristics were assessed using 3 models: *i.* A linear mixed effect model to assess the effect size of longitudinal MetSyn and its components on longitudinal FEV<sub>1</sub>% predicted as an outcome; *ii.* a time-dependent Cox regression to assess the associations of MetSyn to time of onset of WTC-LI; *iii.* a novel, partially linear single index regression model with repeatedly measured MetSyn to assess their joint effects and delineate their relative contribution on the longitudinal lung function in the WTC-FDNY cohort. **RESULTS/ANTICIPATED RESULTS:** In **Model I**, BMI 30 kg/m<sup>2</sup> had the largest effect size compared to ever-smoking, with −2.524 (95% CI: −2.708, −2.340) compared to −1.681 (−2.325, −1.038) respectively. Having MetSyn, defined as 3/5 risk factors, had an effect size of −2.319 (−2.526, −2.112). In **Model II**, hazards of triglycerides 150mg/dL were highest at 1.497(1.336, 1.677), followed by BMI 30 kg/m<sup>2</sup> at 1.406(1.256, 1.575), and HDL < 40mg/dL 1.355(1.176–1.561), compared to ever-smoking (1.201, p = 0.002). Having high exposure to PM by being present in the morning of 9/11 was a significant covariate only in Model II investigating HDL < 40mg/dL or triglycerides 150mg/dL. **Model III** The proposed methods will be applied to our cohort study. **DISCUSSION/SIGNIFICANCE OF IMPACT:** MetSyn is both a predictor and concurrent marker of WTC-LI. The single index model can not only reduce dimensionality of the covariates, but also provides efficient estimates of the joint MetSyn effects, allowing linear or nonlinear effects. Future studies