an HLA-matched donor. This will be the largest study of haploidentical HCT in children. The data gathered will allow us to identify important donor characteristics to help guide physician decision-making when choosing a haploidentical donor.

**237**

**Studies of epilepsy surgery outcomes are statistically underpowered.**

Adam Dickey¹, Robert T. Krafty² and Nigel P. Pedersen³

¹Emory University, ²Department of Biostatistics and Bioinformatics, Emory University and ³Division of Epilepsy, Emory Brain Health Center

OBJECTIVES/GOALS: Low statistical power is a problem in many fields. We performed a systematic review to determine the median statistical power of studies of epilepsy surgery outcomes.

METHODS/STUDY POPULATION: We performed a PubMed search for studies reporting epilepsy surgery outcomes for the years 1980-2020, focusing on studies using stereo-electroencephalography (SEEG). We extracted patient count data for comparisons of surgical outcome between groups, based on a prognostic factor. We defined a clinically meaningful difference the surgical outcome for MRI positive (66.9%) compared to MRI negative (45.5%) in the largest study in the series. The statistical power of a Chi-square test was computed as the percentage of simulated runs (10,000 repetitions) assuming this difference with a p-value less than 0.05. RESULTS/ANTICIPATED RESULTS: Based on 69 studies, the median sample size was 38 patients, and the median statistical power was 24%. This implies at least a 17% (0.5/(0.24+0.05)) chance a study with a significant result in false, assuming 1:1 pre-test odds. A typical SEEG study with 33 patients and 2:1 allocation had a median significant odds ratio of 6.5, which over-estimates the true odds ratio of 2.4.

DISCUSSION/SIGNIFICANCE: Studies of epilepsy surgery outcomes using SEEG are statistically underpowered. This means true effects will be missed, the chance a study with a significant result is false will be inflated, and significant effects found will be over-estimated. Studies of surgery outcome need better statistical rigor if they are to reliably guide treatment.

**238**

**The association between quitting electronic cigarette use in pregnancy and the risk of preterm birth and low birth weight¹**

Lin Ammar¹, Hilary A. Tindle², Hui Nian², Chang Yu², Brittney M Snyder², Angela M. Miller², Kelli Ryckman², Tina V. Hartert² and Pingsheng Wu²

¹vanderbilt University, ²Vanderbilt University Medical Center, ³Tennessee Department Of Health and ⁴University of IOWA

OBJECTIVES/GOALS: Nearly half of mothers who report electronic (e)-cigarette use during pregnancy believe e-cigarettes are less harmful than traditional cigarettes. We aim to determine the association of quitting e-cigarette use in pregnancy with the risk of preterm birth and low birth weight.

METHODS/STUDY POPULATION: We conducted a cross-sectional study of women participating in the Pregnancy Risk Assessment Monitoring System and with live singleton birth during 2016-2019. Women were classified based on their e-cigarette use: before pregnancy only (quitters), last three months of pregnancy only (initiators), at both times (sustained users), and neither time (non-users). We used a modified Poisson regression to determine the association between quitting e-cigarette use and preterm birth (<37 weeks) and low birth weight (<2,500 grams) adjusting for demographic, social-economic, and behavior-related risk factors. Analyses were weighted to account for the survey design and non-response. RESULTS/ANTICIPATED RESULTS: Based on 150,950 women who responded to the survey, there were estimated 2.9% quitters, 0.2% initiators, 1.0% sustained users, and 95.9% non-users in the U.S. Compared to sustained e-cigarette users, quitters had a similar risk in preterm birth (adjusted risk ratio [ARR]: 0.84, 95% confidence interval [CI]: 0.65, 1.08) and a significantly reduced risk in low birth weight (ARR: 0.77, 95%CI: 0.61, 0.97) adjusting for traditional cigarette use, age, race/ethnicity, education, marital status, family income, prior preterm birth, prior live births, BMI prior to pregnancy, pregnancy weight gain, kotelchuk index, multivitamin use, drinking prior to pregnancy, year of birth, and residential state.

DISCUSSION/SIGNIFICANCE: As FDA authorizes sales of certain e-cigarettes, women smokers may switch to e-cigarettes, believing they are reducing harm. Our study shows that quitting e-cigarette use is associated with a reduction of low birth weight. Clear messaging is needed to help women cease e-cigarette use in pregnancy.

**240**

**Neurologic complications in children with seizures and respiratory illness: A comparison between SARS-CoV-2 and other respiratory viruses**

Grace Gombolay¹, Monique Anderson¹, Yijin Xiang¹, Shasha Bai¹, Christina A. Rostad³ and William Tyor¹

¹Emory University School of Medicine

OBJECTIVES/GOALS: To compare rates and types of neurological symptoms in children hospitalized with seizures and respiratory infections, including SARS-CoV-2, influenza, and endemic coronaviruses.

METHODS/STUDY POPULATION: Retrospective cohort study of children between 0-21 years of age admitted to a single pediatric free-standing quaternary referral center from January 1, 2014 to June 1, 2021 for seizures who had positive respiratory infection PCR for SARS-CoV-2, other coronaviruses (Coronavirus NL63 and Coronavirus OC34), influenza (A and B), adenovirus, Mycoplasma pneumoniae, and parainfluenza 3 or 4 infections. Patient characteristics including age, race, sex, ethnicity, hospital length of stay, intensive care unit admission, intubation, chest x-ray, and MRI results were included. The primary outcomes were rates of neurological diagnoses and mortality.

RESULTS/ANTICIPATED RESULTS: A total of 883 children were included: 68 SARS-CoV-2, 232 influenza, and 187 with other infections, including SARS-CoV-2, other coronaviruses (Coronavirus OC34), influenza (A and B), adenovirus, Mycoplasma pneumoniae, and parainfluenza 3 or 4 infections. Patient characteristics including age, race, sex, ethnicity, hospital length of stay, intensive care unit admission, intubation, chest x-ray, and MRI results were included. The primary outcomes were rates of neurological diagnoses and mortality. RESULTS/ANTICIPATED RESULTS: A total of 883 children were included: 68 SARS-CoV-2, 232 influenza, and 187 with other infections, including SARS-CoV-2, other coronaviruses (OC), 214 adenovirus, 20 M. pneumoniae, 121 parainfluenza 3, and 41 parainfluenza 4. Mortality rates were 0% M pneumoniae to 4.9% in parainfluenza 4, with 2.9% in SARS-CoV-2. Encephalopathy was noted in 5-15.6% and strokes were seen in all infections except for coronavirus OC43 and M. pneumoniae, with 4.9% in parainfluenza 4 and 5.9% in SARS-CoV-2. The most common brain MRI abnormality was diffusion restriction. Differences between SARS-CoV-2 and OC were observed in stroke (5.9% vs. 0.5%, p-value=0.019), ICU admission (50% vs. 69%, p-value=0.008), and intubation (19.1% vs. 34.8%, p-value=0.021, respectively). However, the rates of neurological symptoms were similar between SARS-CoV-2 and influenza.

DISCUSSION/SIGNIFICANCE: We found higher rates of stroke, but lower rates of ICU admission and intubation in SARS-CoV-2 versus OC. Strokes were observed in many infections. Rates of neurological
Utilizing real-world evidence to increase efficiency of randomized controlled trials with application to repurposed therapeutics for COVID-19

Lillian M F Haine1, Thomas A Murray1 and Joseph S Koopmeiners1
1University of Minnesota

OBJECTIVES/GOALS: We aim to extend a novel statistical method called the Semi-Supervised Mixture Multisource Exchangeability Model (SS-MIX-MEM) and to implement the SS-MIX-MEM approach to supplement ALPS-COVID data with N3C data to achieve analyses with greater precision and actionable conclusions.

METHODS/STUDY POPULATION: We will apply the SS-MIX-MEM to supplement the Angiotensin receptor blocker-based Lung Protective Strategy for COVID-19 (ALPS-COVID) RCTs with the National COVID Cohort Collaborative (N3C) database. ALPS-COVID includes both an inpatient and outpatient trial, which investigates losartan as a treatment for COVID-19. The outpatient trial sought to randomize 580 individuals but only enrolled 117, whereas the inpatient trial met its enrollment target and randomized 205 individuals. The N3C database has 3,237,344 COVID-19 cases alongside demographics, lab values, and more.

RESULTS/ANTICIPATED RESULTS: In simulation studies, the proposed SS-MIX-MEM approach effectively leveraged a subgroup of supplemental real world data for RCT analyses, improving trial efficiency by increasing precision of treatment effect estimates, decreasing necessary sample size, and introducing minimal bias. In an influenza trial real world data application, the SS-MIX-MEM approach was able to effectively provide insight into treatment effect heterogeneity found in an RCT analogous to incorporating around 80 individuals into a subgroup analysis. We anticipate that leveraging external real world data in a re-analysis of the ALPS-COVID RCTs could provide new insights into losartan, a readily available, potentially beneficial therapeutic for COVID-19.

DISCUSSION/SIGNIFICANCE: The high blood pressure drug, losartan, is readily available, has an established safety profile, and might be effective as a treatment for COVID-19. The outpatient trial real world data application, the SS-MIX-MEM approach was able to effectively provide insight into treatment effect heterogeneity found in an RCT analogous to incorporating around 80 individuals into a subgroup analysis. We anticipate that leveraging external real world data in a re-analysis of the ALPS-COVID RCTs could provide new insights into losartan, a readily available, potentially beneficial therapeutic for COVID-19. DISCUSSION/SIGNIFICANCE: We identify three unique domains of maternal psychosocial stress that are differentially related to sociodemographic, perinatal, and lifestyle characteristics. Correlates of stress domains shed light on upstream determinants and biological and psychosocial mechanisms through which experiences of stress manifest.

Characterization of Maternal Stress During Pregnancy

Satvinder K. Dhaliwal1, Greta Wilkening2, Angela Lee-Winn3, Deborah Glueck3, Dana Dabelea1 and Wei Perrig1
1University of Colorado, Denver and 2Colorado Children’s Hospital

OBJECTIVES/GOALS: 1. To characterize domains of maternal psychosocial stress from the Edinburgh Postnatal Depression Scale (EPDS) and Cohens Perceived Stress Scale (PSS) administered during pregnancy using principal components analysis (PCA). 2. To identify sociodemographic, perinatal, and lifestyle correlates of maternal psychosocial stress domains.

METHODS/STUDY POPULATION: Using data from 1,079 pregnant women in the Healthy Start Study who completed both the EPDS and PSS in early pregnancy, we ran PCA and retained factors representative of uncorrelated domains of maternal psychosocial stress based on the Scree plot and Eigenvalues >1. We then used linear regression to identify sociodemographic, perinatal, and lifestyle correlates of each maternal stress domain, followed by multivariable models that mutually adjusted for all characteristics that were statistically significant at alpha = 0.10.

RESULTS/ANTICIPATED RESULTS: We identified three domains of maternal psychosocial stress based on PCA results: Feeling Overwhelmed (Domain 1), Anhedonia (Domain 2), and Lack of Control (Domain 3). In unadjusted analyses, lower household income and poor diet quality were associated with higher scores for all three domains. In adjusted analyses, lower household income, being multiparous, inadequate or excessive GWG, and poor diet quality were associated with Feeling Overwhelmed. Older age, Hispanic ethnicity, and poor diet quality were associated with Anhedonia. Non-Hispanic, Black race/ethnicity, lower educational attainment, having a partner born outside the US, larger household size, receiving public assistance, and smoking during pregnancy were associated with Lack of Control.

DISCUSSION/SIGNIFICANCE: We identify three unique domains of maternal psychosocial stress that are differentially related to sociodemographic, perinatal, and lifestyle characteristics. Correlates of stress domains shed light on upstream determinants and biological and psychosocial mechanisms through which experiences of stress manifest.