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Presenting Author:	Michael Tocco	Sunovion Pharmaceuticals

1. A Collaborative Multimodal Mental Health Program for Young Adults Living with Cystic Fibrosis		
Presenting Author:	Rachel Conrad	Brigham & Women's Hospital

A Collaborative Multimodal Mental Health Program for Young Adults Living with Cystic Fibrosis

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Background:

Many young adults living with cystic fibrosis (CF) suffer from depression, anxiety, executive dysfunction, social isolation, and limited coping skills (Quittner 2016). Anxiety and depressive symptoms among individuals with CF are associated with decreased lung function, quality of life, and treatment adherence (Besier 2008, Haverman 2008). Evidence suggests that medical trauma associated with cystic fibrosis, cognitive effects of anticholinergic medications, loss of psychosocial developmental milestones, and limited educational and employment opportunities may contribute to adverse mental health outcomes. Both psychopharmacological and psychotherapeutic interventions may improve these outcomes. Acceptance and Commitment Therapy for Cystic Fibrosis is a unique psychotherapeutic curriculum developed specifically for patients living with cystic fibrosis, which takes a values-based approach to living with a chronic illness (O'Hayer 2021). Other potentially useful treatment modalities may include behavioral therapy, mindfulness, and peer-support (Goldbeck 2014, Jeffery 2020).

Methods:

IRB permission was obtained from the hospital. Young adults living with cystic fibrosis were recruited from within a collaborative clinical program across departments, disciplines and specialties spanning adjacent pediatric and adult hospitals. Appropriate patients over the age of 18 years old with cystic fibrosis and psychiatric symptoms were identified by the clinical psychologist and pulmonologist within the pediatric hospital. Patients with acute safety risk such as severe substance use disorder and recent suicide attempts were excluded as other evidence-based treatments were deemed more appropriate for their clinical needs. Clinicians from the pediatric hospital initially obtained consent from each patient, and a psychiatrist from the adult hospital subsequently contacted each patient to discuss the new clinical program. The psychiatrist from the adult hospital offered each patient both psychopharmacological treatment and group psychotherapy within the adult hospital department of psychiatry. Patients continued individual psychotherapy with the existing clinical psychologist within the children's hospital department of pulmonology. Patients were encouraged but not required to participate in both psychopharmacological care and group psychotherapy at the adult hospital. The tenants of the interventions were (1) promoting resilience (2) building coping skills (3) mindfulness (4) post-traumatic growth and (5) grit.

Inclusion criteria:

23 patients were initially deemed appropriate for transfer of psychiatric treatment from the pediatric hospital to the novel program within the adult hospital's department of psychiatry. 18 patients agreed to transition care to the adult hospital for psychopharmacological care, and 17 agreed to transition care to the adult hospital for psychopharmacological care and group psychotherapy and 1 agreed to group psychotherapy only. X number of patients were on Trikafta at the time of transfer, a new pharmacological agent which demonstrates significant efficacy in increasing the life expectancy for patients living with cystic fibrosis. x percent of patients had a prior diagnosis of depression, ADHD, anxiety, SUD, etc… X percent of patients had prior treatment with an SSRI, stimuland, antipsychotic, mood stabilizer, etc

Conclusions:

Young adults living with cystic fibrosis face mental health challenges due to unique stressors and potentially traumatic medical experiences. Peer support, psychopharmacology, and skills-based psychotherapeutic interventions may improve their quality of life, mental health and functioning. This study demonstrated the feasibility of a collaborative mental health treatment program that spanned institutions, departments, and disciplines to provide multi-modal coordinated mental health treatment for this vulnerable population.

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2. Using Cultural Awareness to Treat Depression in a 19 Year-Old Nepalese Immigrant

Presenting Author: Akanksha Dadlani Northeast Ohio Medical University (NEOMED)

Using Cultural Awareness to Treat Depression in a 19 Year-Old Nepalese Immigrant

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Background:

Since 2009, there have been at least 16 suicides among the Nepali refugee population in the U.S.(1). Per the World Health Organization, the global annual mortality rate is 11.4 per 100,000. The rate of suicides among US-resettled Nepali-Bhutanese refugee communities was 21.5 per 100,000 (2). In their native country, Nepali suicide rate is 8.8 per 100,000 while American suicide rates are 15.3 per 100,000 (3) . With the suicide rate almost two times as high in this population, it is essential to provide appropriate mental health aid. It is important to take cultural awareness into account, and treat the patient accordingly.

Methods:

A 19-year-old Nepalese Immigrant was admitted to the inpatient psychiatric unit for. This poster reviews, at a general level, his case, and offers stepwise solutions to foreseen problems in immigrant healthcare. These foreseen problems were determined by an in-depth literature review in which we found role of culture, family involvement, disease recognition, and language barrier to all be issues. A method developed by the authors was standardized and used to create recommendations.

Results:

This patient was successfully treated in the inpatient setting and the recommended guideline is as follows: understand contributing factors (family & community values, religious beliefs, and age/gender), ensuring access to a translator, formalizing disease diagnosis and recognition, and accommodating culture as part of the patient care plan.

In this patient's case, and in patients with similar cases to this one, we recommend serial PHQ-9s at outpatient Primary Care Physician follow-ups.

Conclusions:

Cultural considerations must be a baseline aspect of healthcare provision, especially in immigrant populations. Creating a standardized checklist or using the tools included in this poster should address many of the frequently experienced problem for immigrant healthcare. Not only will this augment individual patient level of care, it will also augment care at a community level. Considerations such as language interpreters, religious services, and cultural understanding all stand to significantly improve care provision for immigrant communities.
The goal of this poster is to highlight care discrepancies that many immigrant populations experience, and to provide potential solutions to commonly experienced problems.

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3. Estimating the Contribution of Symptom Clusters to Risk of Suicidal Ideation or Behavior in Bipolar Disorder		
Presenting Author:	Jess Fiedorowicz	University of Iowa, University of Ottawa

Estimating the Contribution of Symptom Clusters to Risk of Suicidal Ideation or Behavior in Bipolar Disorder

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Background: Bipolar disorder is typified by episodes of manic/hypomanic and depressive symptoms, which may occur either distinctly or concurrently as mixed symptoms. While depressive symptoms are the major driver of risk, it has yet to be examined whether specific combinations of manic and anxiety symptoms contribute differentially to suicidal ideation and behavior in bipolar depression.

Methods: This study uses a quantitative application of Rothman's theoretical framework of causation, or 'causal pies' model. Data were obtained from the National Network of Depression Centers Mood Outcomes Program for 1028 visits from 626 individuals with bipolar disorder with depressive symptoms, operationalized as a Patient Health Questionnaire-8 (PHQ-8) score ≥10. Individual symptoms of mania were captured using the Altman Self-Rating Mania scale (ASRM) and anxiety symptoms were captured using the Generalized Anxiety Disorder-7 scale (GAD-7). To mitigate low cell counts, latent class analysis was employed for variable reduction. The outcome of suicidal ideation or behavior was captured using the Columbia Suicide Severity Rating Scale (C-SSRS).

Results: We found no increased risk of suicidal ideation or behavior attributable to manic or anxiety symptoms, as represented by latent clusters of items from the ASRM and the GAD-7. We found a small (4%) proportion of the risk of suicidal ideation or behavior to be attributable to greater severity category of depressive symptoms (severe vs. moderate depressive symptoms), as captured by PHQ-8 score (PHQ-8 ≥20 vs. PHQ-8 10-19).

Discussion: This study did not identify any increased risk individually attributable to symptoms of mania and anxiety, using two commonly used self-reported rating scales, in individuals with bipolar disorder during depressive state. A small amount of risk was attributable to having severe depressive symptoms. These findings, however, may be influenced by limitations in sample size and measurement instruments. Future studies would benefit from larger samples and more rigorous assessments, including clinician-rated measures.

4. Association between Marijuana Laws in the United States and Mortality Risk During Adolescence and Young Adulthood

Presenting Author: Cynthia A Fontanella The Ohio State University Wexner Medical Center

Association between Marijuana Laws in the United States and Mortality Risk During Adolescence and Young Adulthood

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Background: Changes in marijuana laws (ML) over the past 20 years have resulted in dramatic shifts in societal perception of harm and increased availability and use throughout the United States (U.S.).[1] These policy shifts may result in unintended consequences for American youth[1], a population vulnerable to negative health outcomes related to cannabis use (CU).[1-3] The influence of ML on mortality risk for young people is poorly understood[1,2,4] **Objective**: To examine associations between changes in recreational ML (RML), medical ML (MML), and mortality risk in adolescents and young adults residing in the United States between 2000 and 2019. **Methods**: Data on all-cause mortality (ACM) and underlying causes of death among U.S. adolescents (ages 12-17 years) and young adults (ages 18-24 years) between 2000 and 2019 were obtained from the CDC's National Center for Health Statistics mortality datafiles and combined with U.S. census and state resource data. Difference-in-difference analyses were conducted to compare changes in mortality outcomes following RML and MML passage controlling for individual- and state-level covariates. **Results**: Twenty-five states passed MML and ten states passed RML during the study time period. Preliminary analyses examining mortality outcomes (reported as rates [95% CI] per 100,000) showed that mortality rates decreased from 79.9 [79.0-80.0] in 2000 to 69.7 [68.9-70.5] in 2019 in 15-to-24-year-olds. Focusing on the 10 leading causes of death: deaths per year related to neoplasms, infections, congenital malformations, and cardiovascular disease showed minor decreases or no change between 2000 and 2019. In contrast, deaths related to psychological functioning, interpersonal violence, and health-risk behaviors (e.g., suicides, homicides, and accidents/unintentional injuries) showed greater temporal variability. Deaths attributed to accidents decreased significantly from 36.0 [35.4-36.6] in 2000 to 27.5 [27.0-28.0] in 2019, and was the major driver of the decline in ACM in the sample. Deaths attributed to suicide increased from 10.2 [9.9-10.5] in 2000 to 13.9 [13.6-14.3] in 2019. In year-by-year analyses: Deaths attributed to accidents were stable from 2000-2005 and then deceased significantly from 2005-2013 followed by relative increases from 2013-2017 and decreases from 2018-2019. Deaths attributed to suicide were stable from 2000-2010 before increasing significantly from 2010-2017 and stabilizing from 2017-2019. **Conclusions**: These preliminary findings indicate that ACM and deaths related to accidents/unintentional injuries decreased whereas deaths related to suicide increased among American youth between 2000 and 2019, a time period of major cannabis policy change. As youth CU is associated with poor impulse control and increased risk for mood disorders,

aggression, and victimization, additional research is warranted to assess the impact of changing ML on risk for death related to these factors (e.g., from suicide, homicide, and accidents) in young people.

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5. Quantifying Illness Trajectories in Bipolar Disorder and Schizophrenia through the Rochester Epidemiology Project (REP).

Presenting Author: Manuel Gardea Resendez Mayo Clinic

Title: Quantifying Illness Trajectories in Bipolar Disorder and Schizophrenia through the Rochester Epidemiology Project (REP).

Authors: Gardea Resendez, Manuel; Ortiz Orendain, Javier; Nunez, Nicolas; Gruhlke, Peggy; Bostwick, J Michael; Singh, Balwinder; McKean, Alastair J; Ozerdem, Aysegul; Frye, Mark A

Background: Evidence suggests that many patients with bipolar disorder (BD) and schizophrenia (SCZ) experience a diagnostic confirmation delay as early symptoms are often unrecognized or are non- specific. The controversy is ascertaining whether BD and SCZ prodromes [i.e. early sign(s) or symptom(s) indicative of disease onset preceding more diagnostically specific signs and symptoms] exist, and if so, delineating time-frame from prodrome to diagnosis. The concept of prodrome is highly variable but, in cohorts who progress to meet diagnostic criteria for BD or SCZ, it can clarify the trajectory of illness and future potential targets for early interventions. We aim to review and analyze patient demographics and longitudinal patterns of symptom endorsement, healthcare utilization, and psychiatric diagnoses of people in Olmsted County who are diagnosed with BD or SCZ. We hypothesize that patients with BD with history of psychotic mania and patients with SCZ will have similar illness trajectory as quantified by symptoms of general anxiety, ADHD, insomnia, depression, and psychosis, but will have significantly different illness trajectory as quantified by time from first symptoms to incident case (BDI/BDII vs. SCZ), neurodevelopmental delays, patterns of drug and alcohol use, healthcare utilization and psychotropic drug use. **Methods:** Medical records of 2770 subjects with a diagnosis of BD or SCZ were identified from the Rochester Epidemiology Project (REP), a comprehensive medical records linkage system that indexes medical records, medications, procedures, and other health-related information of persons seeking medical care in Olmsted County, Minnesota. Records are currently under screening for identification of a first episode of mania/hypomania or psychosis. Subjects with a recorded incident case are then selected for abstraction of medical data preceding the first episode. The conceptualization of domains identified in the qualitative data through thematic analysis resulted in the following categories: demographics, perinatal data, previous psychiatric diagnoses, family history, identified risk factors and history of social and functional decline. We included the characteristics of diagnostic entities of clinical high risk for psychosis and cyclothymia, which evidence suggest may be diathesis for SCZ and BD, respectively. ***Results:*** We present preliminary findings of the first 1313 screened records and of the first 69 cases with a recorded incident case. From the screening phase, 241 patients (58.5% female) met full criteria for BD and 166 (24.1% female) for SCZ. On average, subjects with SCZ diagnosis had more comorbid psychiatric diagnoses (5.76±2.55 vs. 6.93±3.05; $p < 0.0001$) and history of neurodevelopmental disorders (16.3% vs. 7.9%; $p = 0.009$) than subjects with BD. Likewise, history of substance use (78.3% vs. 68%; $p = 0.02$) and suicidal ideation/attempts (56.6% vs. 48.1%; $p = 0.09$) were more common in SCZ. On the opposite. Borderline personality disorder was more frequent in BD subjects (19.1% vs. 9.6%; $p = 0.009$). Among patients with an identified incident case, first episode of psychosis occurred at a younger age (18.8±3.6) than first manic/hypomanic episodes in BD (20.6±3.9), however differences were not statistically significant. **Conclusion:** Results from this study will provide critical information on social and clinical features that precede a first psychotic or manic/hypomanic episode that help early illness detection and identification of individuals at high risk of BD and SCZ.

6. Perceived Barriers to Using Psychiatric Electroceutical Interventions: A National Survey of Psychiatrists, Patients, Caregivers, and the General Public

Presenting Author: Maryssa Gilbert, M — Michigan State University & Pine Rest Christian Mental Health Services

Perceived Barriers to Using Psychiatric Electroceutical Interventions: A National Survey of Psychiatrists, Patients, Caregivers, and the General Public

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Background: Along the care continuum, mental health providers, patients, and caregivers encounter barriers to providing or receiving timely and effective care for major depressive disorder (MDD). Psychiatric electroceutical interventions (PEIs)—treatments that use electrical or magnetic stimuli to treat psychiatric conditions—often face heightened barriers. Better understanding the barriers to using PEIs is important for planning mental health services, setting resource allocation priorities, reducing the burden of mental illness, [1,2] and addressing misconceptions. Toward this aim, we examined how psychiatrists, patients with depression, caregivers, and members of the general public perceive potential barriers to using PEIs. Methods: We administered national surveys with an embedded experiment to 4 nationwide samples of psychiatrists (n=505), people diagnosed with depression (n=1050), caregivers of people with depression (n=1026), and members of the general public with no major psychiatric condition (n=1022). We randomly assigned respondents to one of 8 conditions using a full factorial experimental design: 4 PEI modalities [electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), deep brain stimulation (DBS), or adaptive brain implants (ABIs)] by 2 depression severity levels [moderate or severe]. We asked participants to rank what they perceived as the top 3 barriers to using their assigned PEI from a list of 8 factors we provided. We analyzed the data with ANOVA and logistic regression, using the top barrier selected. Results: Respondents across all stakeholder groups and each PEI modality most frequently reported “limited evidence of the treatment’s effectiveness” and “lack of understanding of PEIs” as the top 2 most important practical barrier to using PEIs, respectively. Stakeholders assigned to DBS or ABIs were more likely than those assigned to ECT to perceive limited evidence of effectiveness as the most important barrier to PEI use. Compared to the general public, psychiatrists were

less likely to identify “low trust in mental health system” as one of the most important barriers. However, they were almost three times more likely than the general public to identify “lack of availability” and “stigma” about treatment as important practical barriers. Compared to participants assigned to ECT, those assigned to TMS, DBS, or ABIs were less likely to report stigma as the most important barrier to treatment, but were more likely to cite “lack of insurance coverage” as the most important barrier.

Conclusion: Overall, psychiatrists’ perceptions of the most important barriers to using PEIs were significantly different than those of non-clinicians, especially the public. Perceived barriers were significantly different for implantable (DBS and ABIs) versus non-implantable (rTMS and ECT) PEIs. Better understanding of how these barriers vary by PEI and stakeholder group could help us address structural and attitudinal barriers to effective use of these interventions.

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7. Associations between circadian rhythms and daily, self-reported mood states in bipolar I disorder

Presenting Author: Robert Gonzalez Penn State Milton S. Hershey Medical Center

Associations between circadian rhythms and daily, self-reported mood states in bipolar I disorder

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Background: Chronobiological disturbances are a hallmark of bipolar disorder [1]. We previously conducted a variable cluster analysis to ascertain how mood states are associated with seventeen chronobiological traits in bipolar I disorder (BDI) [2]. The findings demonstrated that Young Mania Rating Scales (YMRS) scores were negatively correlated with interdaily stability (IS), relative amplitude (RA), goodness-of-fit (GOF), circadian quotient (CQ), 24-hour correlation, and the 5-Item Social Rhythm Metric (SRM-5) and positively correlated with Pittsburgh Sleep Quality Index (PSQI). The 30-Item Inventory of Depressive Symptomatology (IDS-30-C) was positively associated with PSQI. After correcting for possible false discovery rate, YMRS remained significantly associated with IS, RA, CQ with a trend toward significance with PSQI. IDS-30-C remained associated with PSQI. In this study we sought to determine how well self-reported mood state assessments correlated with clinician-rated assessments of mood state correlated and to attempt to replicate the findings of our previous study using participant self-reported mood state. **Methods:** The protocol was a 1-week, naturalistic, ambulatory study designed to determine the relationships between chronobiological characteristics and mood state in BDI. The study included 83 BDI participants. The diagnosis of BDI was confirmed using either the Structured Clinical Interview for DSM-IV Axis I Disorders or Mini International Neuropsychiatric Interview. Participants were excluded if they presented with uncontrolled medical conditions or lifestyle factors that could impact chronobiology, current use of hypnotic agents for sleep, or a history of substance abuse or dependence one month prior to study participation. Subjects completed daily mood life charts to assess the severity of mania and depression based on a 4-point system (0 = no symptoms; 1 = mild symptoms; 2 = moderate symptoms; 3 = severe symptoms) over the course of the observational period. Actigraphy was used to calculate IS, RA, GOF, CQ, and 24-hour correlation. The PSQI was used to estimate subjective sleep quality. The SRM-5 was used to assess for the degree of lifestyle regularity. Spearman's correlation was conducted to determine the correlations between the weekly-averaged, self-reported ratings of mania and depression and YMRS and IDS-30-C scores, respectively. Spearman's correlations were also used to determine the relationships between weekly-averaged, self-reported ratings of mania and depression and chronobiological characteristics. Benjamini-Hochberg Procedure was used to correct for false positive probability. **Results:** There was a significant positive correlation between the weekly-averaged, self-reported ratings of mania and YMRS scores ($r = 0.291$, $p = 0.008$) and between the weekly-averaged, self-reported ratings of depression and IDS-30-C scores ($r = 0.451$, $p < 0.001$). The weekly-averaged, self-reported ratings of mania was significantly negatively correlated with IS ($r = -0.252$, $p = 0.022$), RA ($r = -0.296$, $p = 0.009$), CQ ($r = -0.368$, $p = 0.001$), GOF ($r = -.293$, $p = .008$), 24-hour correlation ($r = -0.292$, $p = 0.008$) and SRM-5 ($r = -0.315$, $p = 0.005$) and positively correlated with the PSQI ($r = 0.244$, $p = 0.027$). The weekly-averaged, self-reported ratings of depression was positively associated with PSQI ($r = 0.289$, $p = 0.010$). All results remained statistically significant after correcting for the false discovery rate. **Conclusions:** The results of our study demonstrate that BDI participants were able to accurately assess their mood state as demonstrated by the significant correlations between averaged, weekly, averaged, self-reported mood state and clinician-rated mood scales. In addition, we were able to replicate the findings from our previous study showing correlations between mood state and specific chronobiological characteristics. The present study supports the use of self-reported mood states for future longitudinal chronobiology studies in BDI.

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8.Combinatorial pharmacogenomic testing for patients with MDD has greatest potential utility for individuals taking medications with significant gene-drug Interactions

Presenting Author: John Greden, MD University of Michigan

Combinatorial pharmacogenomic testing for patients with MDD has greatest potential utility for individuals taking medications with significant gene-drug interactions

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Background: Trial-and-error prescribing is a widely employed treatment approach for major depressive disorder (MDD), despite a reduced likelihood of achieving remission following subsequent antidepressant trials. The Genomics Used to Improve DEpression Decisions (GUIDED) trial was a large, randomized controlled trial that evaluated the impact of combinatorial pharmacogenomic testing on outcomes for patients with MDD and an inadequate response to ≥1 psychotropic medication.[1] The present post hoc analysis assessed the relationship between number of medication failures at baseline and outcomes in GUIDED.

Methods: Patients were randomized into treatment as usual (TAU) or combinatorial pharmacogenomic-informed (guided-care) arms. All patients received testing, though results were only available for those entering guided-care. All patients and raters were blinded until after week 8. Medications on the test report were categorized based on the predicted gene-drug interactions (GDI): 'use as directed' (no GDI), 'use with caution' (moderate GDI)', 'use with increased caution and with more frequent monitoring' (significant GDI). Week 8 outcomes were assessed using the HAM-D17 rating scale [symptom improvement (% change from baseline), response (≥50% reduction), remission (score of ≤7)]. Analyses were conducted for the subgroup of patients who took ≥1 incongruent (significant GDI) medication at baseline and by their number of medication failures at baseline.

Results: Patients who were taking ≥1 incongruent medications at baseline had significantly improved outcomes when they changed to congruent medications at week 8 compared to those who remained on incongruent medications. In addition, patients who had <5 medication failures tended to have better outcomes compared to those with ≥5 medication failures. In TAU, there was a 2-fold decrease in congruency with subsequent medication failures. In contrast, the proportion of patients taking congruent medications in the guided-care arm was consistent regardless of the number of prior medication failures.

Conclusions: These data support the finding that combinatorial pharmacogenomic testing has the greatest potential utility for individuals taking medications with significant GDI,[1,2] and suggest that individuals may benefit more from testing earlier in their treatment journey, whereas treatment resistance among those with multiple (>5) medication trials may be due to non-genetic factors.

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9. Marijuana and cannabidiol related attitudes, perceptions, and behaviors among adolescents receiving mood disorder treatment in the United States and their parents

Presenting Author: Christopher Hammond Johns Hopkins University

Marijuana and cannabidiol related attitudes, perceptions, and behaviors among adolescents receiving mood disorder treatment in the United States and their parents

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Background: Dramatic shifts in marijuana laws over the past 20 years along with federal deregulation of hemp with the 2018 Farm Bill have resulted in increased availability and use of cannabinoid-based products (CBP) including medical marijuana and cannabidiol (CBD) supplements, throughout the United States. The widespread advertising and multimedia promotion of CBP that have accompanied these legislative changes carry unknown implications for American youth.[1-3] Furthermore, adolescents with mood disorders may be more vulnerable to adverse health outcomes related to cannabinoid exposure. In the present study, we examine attitudes, perceptions, and behaviors related to marijuana and CBD use among youth receiving mood disorder treatment in the U.S. and their parents. **Methods**: Data are from the Marijuana and Cannabidiol Attitudes, Beliefs, and Behaviors Survey (MABS) study, a multisite study recruiting youth (ages 12-25 years) receiving mood disorder treatment, along with their parents, from NNDC-affiliated child mood disorder clinics across the U.S. All participants completed an anonymous survey querying marijuana- and CBD related attitudes, perceptions, and behaviors, including acceptability, perception of harmfulness and medical benefit, beliefs and expectancies about marijuana's and CBD's effects on different mental health symptoms. Preliminary data presented here are from N=47 youth and N=45 parent participants from 3 NNDC sites. **Results**: Among youth: (a) 20% reported having a household member use medical marijuana and/or CBD treat a mental health condition in the past year; (b) 87% and 68% agreed with the statements that "medical marijuana and CBD products are safe and effective treatments for certain mental health conditions", with 57% and 51% believing that mental health providers should be recommending or prescribing medical marijuana and/or CBD to their patients; (c) 66%, 72%, and 45% of youth reported believing that marijuana, when used regularly, improves depression, anxiety, and suicidal thoughts and behaviors (STB), while 63%, 73%, and 38% reported believing that CBD product use improves those respective symptoms/behaviors. Among parents/caregivers: 5% and 23% reported giving medical marijuana and/or CBD to their youth for treatment of their mental health condition in the past year. Parent attitudes and perceptions while slightly less enthusiastic largely paralleled youth reports. **Conclusions**: Our preliminary results

show that CBP are commonly used by household members of youth receiving mood disorder treatment in the U.S., and that these youth and their parents widely perceive marijuana and CBD products to be safe and effective treatments for mental health problems, including depression, anxiety, and STB. These findings suggest a mismatch between youth and parent perception[1-3] and the current evidence related to safety and efficacy of CBP for mood disorders and STB.[4,5] Mental health clinicians and public health campaigns should provide targeted, evidence-based education to youth and parents and encourage fact-driven discussions about cannabinoids and mood disorders with their providers.

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10. Improving the Value of a Hospital-Based Consultation-Liaison Psychiatry Service During the COVID-19 Pandemic through Interprofessional Work: A Qualitative Analysis and Framework for Collaboration

Presenting Author: Patrick Ho The Ohio State University

Improving the Value of a Hospital-Based Consultation-Liaison Psychiatry Service During the COVID-19 Pandemic through Interprofessional Work: A Qualitative Analysis and Framework for Collaboration

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Background: Consultation-liaison (CL) psychiatry is an emerging field of psychiatry that has undergone a great deal of growth in recent years.[1] While patients with primary psychiatric illnesses and co-occurring medical problems are achieving longer lives through advances in medical care, prolonged inpatient general hospital care is often necessary when inpatient psychiatric settings are unable to safely manage complex co-occurring medical problems during periods of behavioral health crisis. The COVID-19 global pandemic has underscored the need for robust integrated behavioral health care to patients across inpatient medical settings, especially when patients in behavioral health crisis are COVID-19 positive and are unable to receive care elsewhere. CL psychiatry's ability to sustain growth in this context will depend in large part on our ability to provide and demonstrate value within healthcare systems and the larger healthcare apparatus, which includes fostering critical connections with other professional groups.[2,3] Innovating care through collaborative approaches can help to maximize continuity, care outcomes, and increase the value of our services. Our inpatient consultation-liaison psychiatry team (covering ~1400 hospital beds, ~11 new consults/day, >9500 bedside visits/year) regularly collaborates across professions with other healthcare professionals to provide full spectrum mental health care that assists with needs that cannot be met by primary medical or surgical teams.

Methods: Our CL psychiatry service interfaces with nursing (a behavioral emergency response team), social work, health psychology, speech and language pathology (SLP), occupational therapy (OT), and physical therapy (PT) to provide full spectrum mental health care to patients admitted to inpatient medical/surgical hospital services. A daily multidisciplinary review of patients on whom we have been consulted occurs with the input of nursing and social work, facilitated by secure virtual conferencing technology, with an emphasis on proactive intervention opportunities. Care coordination through targeted therapy referrals to inpatient health psychologists, as well as functional assessment referrals to SLP/OT/PT have become critical in developing multdimentional assessments and safe, comprehensive discharge plans. Our team continuously analyzes trends in interprofessional collaborations on focused consultations to identify opportunities for quality improvement and collaborative efficiency.

Results: Integrated daily case reviews with behavioral emergency response nurses, social workers, and health psychologists have been critical in synthesizing and anticipating the functional and biopsychosocial needs of patients with complex behavioral and medical illnesses, especially when these patients are otherwise unable to be safely cared for in traditional inpatient behavioral health hospitals. By expanding our interprofessional team in the general hospital setting, we have been able to more efficiently address care coordination and aftercare planning, effectively engage providers and staff attached to hospital medical teams, teach medical learners, and develop treatment plans (medications, therapy that address all aspects of behavioral health recovery when complex medical problems preclude access to inpatient and ambulatory psychiatric providers. In the past year, we have found four areas to be the most representative of our interprofessional collaboration: (1) crisis care of agitated medical inpatients, (2) general hospital care of COVID-19 positive patients unable to receive care in traditional psychiatric hospitals, (3) long

stay patients with dispositional capacity and complex discharge issues, and (4) increasing clinical stakeholder engagement through secure messaging platforms, handoffs, and care continuity.

Conclusion: As our inpatient hospital CL psychiatry service grows, it has been important to streamline the mechanisms by which we collaborate with our colleagues from other healthcare professions. Although COVID-19 has created unique challenges for healthcare systems, it has also created new opportunities and modalities to collaborate.[4] Rapidly evolving electronic medical record communication tools and secure virtual platforms (implemented during the global pandemic to facilitate social distancing) have increased our ability to dynamically engage a broader interprofessional team, engage in real-time treatment planning, and increase the sophistication of care coordination across a large medical-surgical hospital setting. Opportunities to increase understanding of professional cultures and streamline workflows remain as we continue to dismantle traditional siloed approaches for the benefit of our patients with complex, integrated medical and behavioral needs.

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11. The Gut Microbiome of Youth Who Have Affective Problems: A Scoping Review

Presenting Author: Cherry Leung University of California San Francisco

The Gut Microbiome of Youth Who Have Affective Problems: A Scoping Review

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Background: The microbiome includes the collective genomes of the microbes living in an organism. A robust body of research indicates the existence of a bidirectional communication system between the gut microbiome and the brain that is mediated by neuroendocrine, neuroimmune, and sensory pathways. There is growing evidence for the importance of this gut-brain axis to mental health, including a link between characteristics of the gut microbiome and affective problems. While a number of recent reviews have synthesized research linking the microbiome to depression, anxiety and mood of adults, no review has examined this literature for youth. Affective problems of children and young adults, such as anxiety and depression, have increased substantially over the past several decades, with little understanding of the pathophysiology involved. Greater insight into the role of the microbiome may inform novel assessment and treatment approaches for youth. This scoping review examined existing research on the relationship of the gut microbiome to affective problems for children and youth, comparing findings across these younger age groups. Our goals were to identify: 1) commonly reported alterations in specific microbiota species that are associated with affective problems, and 2) differences in diversity of microbial communities that may distinguish youth with affective disorders from those with no known problems. **Methods:** A literature search using PubMed, PsycINFO, and CINAHL was performed, and bibliographies were manually searched. Studies were eligible if they involved youth between the ages of 2 and 25 and described outcomes associated with affective disorders, including their diagnosis and symptomology. Nine articles met eligibility for our scoping review. A table was developed to extract the characteristics of each study: author and year of publication, study design, sample size, age of participants, sample characteristics, assessments utilized, approach to sequencing of stool samples, and results. Findings from each study were evaluated, focusing on bacterial composition and diversity among children/adolescents and young adults. **Results:** There were no studies specifically on the adolescent age group, so data was synthesized comparing the child/adolescent (2 to <18 years of age) and young adult (18-25 years of age) groups. Studies utilized several different methods for gut microbiome analysis, with most employing 16s rRNA or shotgun metagenomic sequencing. Anxiety and depression were the primary diagnoses/symptoms examined. Findings for both age groups were mixed, reporting perturbations in varied microbiota species. Some studies did not examine diversity of microbial communities. However, 2 key findings did emerge. The abundance of *Bifidobacteria* was decreased for both children/adolescents and young adults with symptoms of depression compared to those not depressed. Alpha diversity was higher for young adults with Major Depressive Disorder. **Conclusions:** Results of this review are congruent with reviews of the adult literature in some ways but not others. Reduced levels of *Bifidobacteria* have also been associated with adult depression. However, studies with middle age to older adults suggest decreased alpha diversity (measuring the total number of behavioral taxa in a microbial community) as a characteristic gut dysbiosis in depression or no differences in diversity between depressed individuals and healthy controls. Further research is needed to clarify the nature of microbial composition associated with depression and other affective problems across the life span versus characteristics of the gut microbiome unique to specific age groups. Inconsistencies of findings across studies in this review are likely due to inclusion of research based on both measures of symptom severity and diagnostic groups, diverse age ranges within studies, and varied research designs or measurements used. Future research should replicate studies to confirm findings, examine lower taxonomic levels, consider longitudinal designs to assess for directionality, and conduct clinical trials to examine the effects of probiotics with the same strains in managing depression and other affective problems.

12. Gender Disparity in Bipolar Disorder Diagnosis in the United States: A Retrospective Analysis of the 2005-2017 MarketScan Commercial Claims Database

Presenting Author: Guodong Liu Penn State Milton S. Hershey Medical Center

Gender Disparity in Bipolar Disorder Diagnosis in the United States: A Retrospective Analysis of the 2005-2017 MarketScan Commercial Claims Database

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Background: Gender bias in opinions towards seeking medical help may be especially strong for mental health illnesses, including severe mood disorders such as bipolar disorder (BD).[1] However, little is known about gender disparity in diagnosis and seeking treatment for BDs while most previous studies have shown a similar prevalence of BDs between genders.[2,3] This study examined gender disparities in the diagnosis of BDs within a privately insured population in the United States. We hypothesized that males with BDs were less likely to be diagnosed than females in the general US population. In this study, we compared the likelihood of being diagnosed with BDs between genders, and examined potential factors that may contribute to the gender disparity in BD diagnosis.

Methods: This retrospective cohort study utilized 2005-2017 claims data from the IBM® MarketScan® Commercial Claims and Encounters database. The study cohort included subjects, aged 10-64, who had a minimum of one-year continuous insurance coverage and no record of a BD diagnosis before cohort entry. We examined the gender difference in BD diagnosis rate, overall and by subgroups. We then used Cox regression models to evaluate the gender effect on time to first BD diagnosis, and the potential moderators of gender effect.

Results: The study cohort consisted of 97,193,443 subjects; 0.45% of subjects were diagnosed with BDs after cohort entry with males having a lower diagnosis rate than females (0.36% vs. 0.54%). Gender disparity was consistently strong among most age groups, but varied in other demographic subgroups. The Cox regression analysis further confirmed our hypothesis that males were less likely to be diagnosed with BDs (unadjusted Hazard Ratio, HR [95%CI]: 0.69 [0.68-0.69]). Gender difference remained significant but markedly reduced after adjusting for demographics, comorbidity and healthcare utilizations (adjusted HR [95%CI]: 0.77 [0.76-0.77]). Our results suggested that while gender disparity in BD diagnosis may be partially explained by gender difference in accessing healthcare services, there is still a direct and unexplained effect of gender on BD diagnosis.

Conclusions: This study found significant gender disparity in BD diagnosis in a privately insured population in the United States. Males, especially adult men between 25 and 54 years old, were less likely to be diagnosed with BDs despite the consensus of an equal prevalence between genders. This pattern was consistently observed in all age groups and across different subpopulations. Our findings are not consistent with those reported from the population-based national survey studies of prevalence of disease. Future studies aimed at identifying and understanding the barriers to diagnosis of BDs in men are warranted in order to facilitate the development of effective interventions to address this critical issue.

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13. Transcranial Electrical Stimulation as a Potential Intervention for Internalizing Psychopathologies: Does Current Type or Sham Ordering Matter?

Presenting Author: Jessica McAleer University of Illinois at Chicago

Transcranial Electrical Stimulation as a Potential Intervention for Internalizing Psychopathologies: Does Current Type or Sham Ordering Matter?

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Background: Internalizing psychopathologies involving depression and anxiety are characterized by negative bias and a disruption in the ability to successfully regulate emotions. Potential biomarkers to target this disruption include the dorsolateral prefrontal cortex (DLPFC), an integral region to successful emotion regulation shown to be disturbed in internalizing psychopathologies, and the theta frequency band which becomes more synchronized during conflict and anxiety. Transcranial electrical stimulation (tES) is an exciting up and coming technique that allows researchers to target underlying neural network activity either by increasing/decreasing membrane potentials in the targeted regions (transcranial direct current stimulation, tDCS) or by increasing/decreasing synchrony in a targeted frequency band (transcranial alternating current stimulation, tACS). In the present pilot study we utilized multiple sessions of tACS or tDCS to alter the related potential biomarkers in emotion regulation dysfunction, which we hypothesized would increase participants' emotion regulation capabilities and thus improve their clinical measures of depression and anxiety. Further, we took a deeper look at the effect of sham (placebo) stimulation and compared the results of participants receiving verum stimulation initially to those receiving sham stimulation initially. **Methods:** Participants were split into two groups, one receiving ACS and one receiving DCS. DCS participants' stimulation electrodes were placed over the DLPFC and contralateral supraorbital region. ACS participants' electrode placement was determined by the electrodes between which theta synchrony was highest during a baseline recording. Each group underwent 4 sessions of stimulation, 2 verum and 2 sham, either during or immediately preceding an emotion regulation task (ERT). Half of the participants in each group received sham stimulation first and half received verum stimulation first. Participants completed the Beck Depression Index (BDI) immediately before and after the study and the Spielberger State and Trait Anxiety Index (STAI) immediately before the study and after each set of stimulation plus ERT. **Results:** Initial analyses of each current type showed that ACS participants displayed a significant decrease in BDI ($F(1,14)=8.914$, $p=.010$), and DCS participants displayed a significant main effect of stimulation type on STAI over their five completions of the questionnaire ($F(1,16)=7.128$, $p=.017$) and a significant decrease in STAI from start to finish ($t(16)=2.945$, $p=.009$). Once the data was stratified by the order of stimulation, however, analyses revealed an interesting effect of stimulation. Neither ACS nor DCS participants receiving sham stimulation first showed any significant difference in BDI or STAI from before to after the study, though sham-first DCS participants displayed a main effect of stimulation type on STAI over the course of the study ($F(1,9)=11.929$, $p=.014$). ACS participants receiving verum first displayed a marked significant decrease in BDI scores ($F(1,7)=21.862$, $p=.002$), a main effect of stimulation type on STAI ($F(1,7)=7.589$, $p=.028$), and a significant decrease in STAI from before to after the study ($t(7)=2.592$, $p=.036$). DCS participants receiving verum first displayed a slight but significant decrease in BDI scores ($F(1,9)=6.183$, $p=.035$), no main effect of stimulation type on STAI, and only a slight but insignificant decrease in STAI from before to after the study ($p=.078$). **Conclusions:** tACS is a promising technique for connectivity-driven, frequency-based interventions, but there appears to be a strong negating effect of placebo stimulation which should be considered when designing future tES studies.

14. Short-term and long-term depression outcomes following ECT are predicted by distinct social and clinical features

Presenting Author: Brian J. Mickey University of Utah

Short-term and long-term depression outcomes following ECT are predicted by distinct social and clinical features

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Background. Patients and clinicians considering electroconvulsive therapy (ECT) for treatment-resistant depression are faced with limited prognostic information about their likely short- and long-term outcomes. Furthermore, the individual characteristics that predict those outcomes are not well established. This study aimed to identify baseline sociodemographic and clinical features that predict acute ECT response and subsequent long-term depression outcomes.

Methods. This prospective longitudinal study followed 114 adult patients at a single ECT referral center. Dozens of subject characteristics were measured through a comprehensive clinical assessment at baseline, prior to ECT. One-hundred-five participants completed an index ECT series. The Clinical Global Impression (CGI) scale was the primary short-term outcome measure, and the Montgomery Asberg Depression Rating Scale (MADRS) was the secondary short-term outcome measure. Eighty-two subjects provided data on long-term depression severity (Patient Health Questionnaire; PHQ-9) during a 2-year period following ECT. Logistic, linear, and linear mixed models were used to evaluate predictors of depression outcomes.

Results. Seventy of 105 participants (67%) were classified as acute ECT responders on the CGI Improvement scale. MADRS total score decreased by 19 points (54%) on average from baseline to post-treatment ($p<10^{-15}$). Better acute ECT response was predicted by less medication resistance, shorter index episode, and psychotic features ($p<0.05$). PHQ-9 scores during the two-year follow-up period improved from baseline at all time points ($p<10^{-6}$) but individual scores varied widely. Long-term PHQ-9 scores were predicted by acute therapeutic response to ECT ($p=0.004$) but not by ECT adverse effects. Shorter index episode, psychotic features, and catatonic features at baseline predicted better long-term PHQ-9 scores ($p<0.05$). Married status and higher baseline MADRS score predicted lower PHQ-9 scores longitudinally ($p<0.001$), independent of other baseline features, initial ECT response, or intensity of ongoing treatment.

Conclusions. These findings confirm previously identified predictors of acute ECT response and demonstrate that a distinct set of individual characteristics predict long-term depression outcomes. An individual's social context appears to strongly influence long-term but not short-term outcomes, suggesting that social support may protect against post-ECT relapse.

15. Predictors of Functional Impairment in Bipolar Disorder: Results from 13 Cohorts from Seven Countries by The Global Bipolar Cohort Collaborative

Presenting Author: Caitlin E Millett Brigham & Women's Hospital

Predictors of Functional Impairment in Bipolar Disorder: Results from 13 Cohorts from Seven Countries by The Global Bipolar Cohort Collaborative

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Background: Persistent functional impairment is common in bipolar disorder (BD) and is influenced by a number of demographic, clinical, and cognitive features. The goal of this project was to estimate and compare the influence of key factors on community function in multiple cohorts of well-characterized samples of individuals with BD. Methods: Thirteen cohorts from 7 countries included n=5,882 individuals with BD across multiple sites. The approach was planned as purposefully simplistic with a focus on one question via systematic uniform application of analyses across sites. First, each site was asked to empirically identify how they defined "good versus poor functioning" in their BD cohort. Sites were required to dichotomize whatever measure was chosen for defining function in their study, such that individuals with BD were described as having either good or poor functional status. The way in which the variable was dichotomized was also up to the investigator, based upon the measure used at each site (e.g., some scales have recognized cutoffs, some used median splits, etc.). Each site was then asked to provide detailed characteristics on their cohort(s), including demographics, diagnostic, clinical, cognitive, and functional features. The listing of the variables available at each site were reviewed by the first and second authors (KEB; CEM) and recommendations were made as to which variables should be included in the regression model at each site. This decision was based upon considerations of statistical power (e.g., the sample size at each site) and the validity of the data collected for each variable. After a consensus was achieved, sites were instructed to conduct a logistic regression with functional outcome as the dependent variable (dichotomized as good versus poor global functioning) using the entry method while model-level and predictor-level results were collated. Example analysis scripts and instructions were provided to each participating site for consistency and checked upon completion. The results of each site's logistic regression were then compared descriptively side-by-side, i.e., the results were not directly combined as each site had different predictors/definitions of outcome. The goal herein was to find consistencies across samples and to identify where differences exist by individual site. Thus, meta-analyses were not conducted, rather a multiple cohort replication and expansion approach was used. Results: Akin to prior work, we found high rates of functional impairment, ranging from 41-75%. Poor community functioning was associated with depressive symptoms in 10 of 12 of the cohorts that included this variable in the analysis. Lower levels of education, a greater number of prior acute episodes, presence of a comorbid substance use disorder, and a greater total number of psychotropic medications were also associated with poor functioning. Conclusions: This study provided an opportunity to survey the global landscape of current data, identify the challenges inherent to conducting global collaborative research in this area, and highlight the overt need for future collaborative work that will identify specific contributors to continued functional impairment in BD to prioritize targets of intervention. The bipolar clinical research community is poised to work together to characterize the multi-dimensional contributors to impairment and address the barriers that impede patients' complete recovery. Likewise, we must also identify the core features which enable many to thrive and live successfully with BD. A large-scale, worldwide, prospective longitudinal study focused squarely on BD and its heterogeneous presentations will serve as a platform for discovery and promote major advances toward optimizing outcomes for every individual with this illness.

16. Daily Affective Dynamics in Major Depressive Disorder

Presenting Author: Dahlia Mukherjee Penn State Milton S. Hershey Medical Center

ABSTRACT

Objective: Affective responses to daily stressors and positive events have long-term implications for mental health, yet research has focused primarily on means levels of negative and positive affect rather than variability in affect within individuals. The application of a daily diary design study in community settings provides a powerful opportunity to obtain measures of affective dynamics in real time including assessment of affect, affective variability and reactivity to daily life events. In the current study, we examined differences in affective variability and magnitude of affective changes in response to daily stressors and positive events between individuals with major depressive disorder (MDD) and non-MDD individuals in a large community-based sample. We hypothesized that individuals with MDD will experience higher variability of daily negative and positive affect and greater affective reactivity to daily stressors and positive events. Methodology: Participants were from the second wave of National Study of Daily Experiences (NSDE II), a sub-project of the Midlife in the United States (MIDUS) study.1 Participants in the NSDE II completed structured clinical interviews on mental health in the past year and telephone interviews about their daily experiences over the course of eight consecutive evenings. Total number of participants was 2,022 with 14,912 phone interviews (average response = 7.4/8 days). The final study sample (n = 1,970) after excluding participants with missing data included 202 individuals with MDD and 1,768 non-MDD individuals. We tested multilevel models with heterogeneous within-person variance, and then tested multilevel models with interaction terms of daily events and MDD. Models controlled previous-day affect levels, percent of positive event days and stressor day events in addition to age, gender, marital status. Results: Individuals with MDD tended to experience lower positive affect ($b = -0.598$, $p < .001$) and greater fluctuations (variance = 0.244 vs. 0.133) in daily positive affect than non-MDD. MDD experienced a greater decrease in daily positive affect on stressor vs. non-stressor days ($b = -0.200$, $p < .001$). MDD individuals also experienced a greater increase in daily positive affect ($b = 0.256$, $p < .001$) on positive event vs. non-positive event days than non-MDD ($b = 0.071$, $p < .001$). Similarly, we found higher negative affect ($b = 0.228$, $p < .001$) and greater fluctuations (variance = 0.131 vs. 0.037) in daily negative affect in MDD individuals. MDD experienced a greater increase in daily negative affect on stressor vs. non-stressor days ($b = 0.247$, $p < .001$). Individuals with MDD experienced a great decrease in daily negative affect ($b = -0.097$, $p < .001$) on positive event vs. non-positive event days compared to non-MDD ($b = -0.000$, n.s.). Conclusion: Affective variability and affective reactivity to daily events, both stressors and positive events, may be indicators of depressive symptomatology and potential targets for intervention. Targeting these areas for improvement and observing clinically significant changes in these variables may lead to more sustained improvement and remission rates. 1. Almeida DM, Wethington E, Kessler RC. The daily inventory of stressful events: an interviewbased approach for measuring daily stressors. Assessment. 2002;9(1):41-55.

17. Concomitant Deep Brain Stimulation and Vagus Nerve Stimulation for Treatment-Resistant depression: a case report

Presenting Author: Flavio Nascimento e Silva University of Texas Health Science Center at Houston

Concomitant Deep Brain Stimulation and Vagus Nerve Stimulation for Treatment-Resistant depression: a case report

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Background: Treatment-resistant depression (TRD) has a substantial individual impact on psychosocial functioning, morbidity, and mortality. This report presents a case in which Deep Brain Stimulation (DBS) and Vagus Nerve Stimulation (VNS) were co-administered in a patient with TRD. **Methods:** The patient is a 58 year-old male with major depressive disorder onset at age 13. During his life, the patient underwent several pharmacological trials, electroconvulsive therapy sessions and hospitalizations due to suicide attempts. In 2010, the patient underwent a VNS device implant with good response to VNS therapy. In 2014, after four years of good response to VNS therapy, benefits from VNS therapy stopped and the participant started his current depressive episode. In 2018, the patient decided to join a clinical trial of medial forebrain bundle DBS treatment. VNS device was turned off about 6 weeks before DBS device implant. At some point during DBS treatment, participant concomitantly used ketamine with no symptoms remission. After 27 months under DBS therapy, in December 2020, the participant was still experiencing significant symptoms, and a decision was made to reactivate his VNS device. From that point, DBS and VNS were concomitantly administered. The patient's Montgomery-Asberg Depression Rating Scale (MADRS) scores were obtained starting 67 weeks before VNS device reactivation and until 30 weeks after DBS-VNS therapy begun, totalizing seven assessments (six assessments before and one assessment after the DBS-VNS therapy has started). **Results:** MADRS scores at 67 weeks, 65 weeks, 60 weeks, 51 weeks, 38 weeks and 12 weeks before the VNS reactivation were 18, 16, 29, 36, 27 and 13 respectively. After 30 weeks of joint stimulation with DBS and VNS, MADRS scores was 7. There were no severe side effects reported that could be attributed to the DBS-VNS treatment. **Conclusion:** In this case report, the lowest level of depressive symptoms (MADRS score = 7) was reported during the concomitant use of two modalities of invasive neurostimulation, with no severe side effects. Further follow-up is necessary to investigate if the remission of the depressive symptoms and safety remain sustained.

18. Religiosity and suicidality among patients with bipolar disorder

Presenting Author: Carolina Olmos University of Texas Health Science Center at Houston

Religiosity and suicidality among patients with bipolar disorder

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Background: The relationship between religiosity and suicide risk has been regarded as an area of great interest, not only from an academic perspective but also due to its potential clinical implications. While several studies indicate that religiosity is a protective factor against suicidal behaviors, it is not clear if that protective effect is consistent across specific diagnostic categories. We carried out a study to assess the impact of religiosity on suicidal behavior among inpatients with bipolar disorder (BD). **Methods**: the sample consisted of 346 inpatients (174 males, 172 females; mean age = 32.71 +-10.70 years) who met DSM-IV criteria for BD. All patients completed the Duke University Religion Index questionnaire (DUREL) upon admission. Patients with and without a history of suicidal attempts were compared with regards to the different dimensions of the DUREL: organizational religiosity (ORA), non-organizational religiosity (NORA), and intrinsic religiosity (IR). The statistical analysis was performed using the Student "t" test, and a 0.05 significance level was adopted. **Results**: 55.2% (191) of the patients had no history of suicide attempts, while 44.8 % (155) reported one or more past suicide attempts. The statistical analysis revealed significantly higher religiosity scores among patients without a history of suicide attempts compared to the ones with a positive past history of suicidal attempts, according to the ORA (3.92 vs. 3.28, respectively; $p<0.001$), NORA (3.85 vs. 3.24, respectively; $p<0.002$), and IR (11.95 vs. 10.90, respectively; $p<0.006$) scores. **Conclusions**: Our results are in agreement with previous findings supporting the role of religiosity as a protective factor against suicidal behavior, and indicate that this protective role is specifically present among inpatients with BD.

Key words: Bipolar Disorder, Religiosity, Suicide, Suicide attempts

19. Cardiovascular Comorbidity in Women with Bipolar Disorder

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Cardiovascular Comorbidity in Women with Bipolar Disorder

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Background: Bipolar Disorder (BD) is a chronic psychiatric disorder with almost equal sex distribution for BD-I and female predominance for BD-II.[1] Patients with BD have a high medical comorbidity burden (30-60%). Cardiovascular diseases (CVD) have been reported as the most common medical comorbidity in BD with rates reaching 30%.[2,3] Despite well documented sex differences in CVD in general population, data on sex differences in BD patients with comorbid CVD is scarce. In this systematic review, we aimed to study the CVD comorbidity in women versus men in BD and in comparison, to women in general population. **Methods:** A comprehensive search of electronic databases including PubMed, PsycINFO, Embase, and SCOPUS was conducted. The eligibility criteria included (1) Case-control/ Cohort/ Cross-sectional/ Retrospective/ Prospective/ Observational study design; (2) Medical comorbidities in BD together with gender data; and (3) English language only. **Results: A** total of 10 studies met our inclusion criteria, out which five large sample population studies have reported higher risk for CVD and mortality in the BD group as compared to the general population. Women with BD were reported to be at higher risk of developing MI at early age, other CVD like hypertension, and higher mortality due to cardiovascular events as compared to the women in the general population. However, the risk of CV events and mortality was comparable among women and men with BD in majority of the studies. A small retrospective study underscored twice the prevalence of CVD risk factors in BD females in comparison to general population. A higher risk of MI at an early age for women with BD has been reported in comparison to women in general population. Also, a correlation among obesity, metabolic syndrome, and CVD has been underscored in women with BD. **Conclusion**: In the BD population, the risk of CVD in women is comparable to men, whereas the risk is much higher in BD women in comparison to women in general population. There is also a younger age of onset of CVD/MI in BD, and more so in premenopausal women with BD in comparison to general population. The findings can be pointing at attenuated estrogen protective mechanism in women with BD, thus predisposing them to an early onset of CVD.

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20. Moderation role of family history of suicidal behavior in the relationship between childhood trauma and lifetime suicide attempts among children and adolescents with bipolar disorders

Presenting Author: Alexandre Paim Diaz University of Texas Health Science Center at Houston

Moderation role of family history of suicidal behavior in the relationship between childhood trauma and lifetime suicide attempts among children and adolescents with bipolar disorders

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Background: Suicidal behavior is probably the result of a complex interaction between biological and environmental factors. This study aims to investigate if a family history of suicidal behavior in first degree relatives of children and adolescents with bipolar disorders (BD) moderates the association between childhood trauma and lifetime suicide attempts.

Methods: The psychiatric diagnosis was assessed using the MINI International Neuropsychiatric Interview for children and adolescents, English version (MINI KID). The Children's Depression Rating Scale (CDRS) was used to evaluate depressive symptoms and the Childhood Trauma Questionnaire (CTQ) to assess the history of childhood trauma. During the interview, the investigator questioned about "Family History of Suicidal Behavior (attempts, self-mutilation, and/or completed suicide) in first degree relatives" (FHSB). We conducted moderation analysis using SPSS PROCESS v3.5.3, controlling for age, sex, and depressive symptoms to investigate the potential moderation role of FHSB on the association between different types of childhood trauma and a history of lifetime suicide attempts.

Results: Among the 53 children and adolescents with BD, 16 (30.2%) reported a lifetime history of suicide attempts, which was associated with significantly higher scores of emotional abuse (p=0.03), physical abuse (p=0.03), and emotional neglect (p=0.001). Moderation analyses showed that the association between emotional abuse, physical abuse, emotional neglect, and history of lifetime suicide attempt was significant only in the presence of a family history of suicidal behavior (p=0.02, p=0.049, and p=0.008, respectively).

Conclusions: In children and adolescents with BD, the risk of suicide attempts associated with childhood trauma may be moderated by a family history of suicidal behavior in first degree relatives.

21. Transdiagnostic and Functional Predictors of Course of Depression in the Penn State Psychiatry Clinical Assessment and Rating Evaluation System (PCARES) Registry

Presenting Author: Erika Saunders Penn State Milton S. Hershey Medical Center

Transdiagnostic and Functional Predictors of Course of Depression in the Penn State Psychiatry Clinical Assessment and Rating Evaluation System (PCARES) Registry

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Background: As a leading cause of disability worldwide, depressive disorders affect 4.4% of the global population and have devastating individual and societal socioeconomic consequences. Timely, accurate diagnosis and subsequent identification of risk factors for depression that is difficult to treat can allow for the alignment of pursuit of effective treatment strategies with decreasing the burden of illness and probability of future disability. Several studies of large research cohorts including STAR*D, the Collaborative Depression Study (CDS) and the Veterans Affairs (VA) Augmentation and Switching Treatments for Improving Depression Outcomes (VAST-D) study have investigated the predictive factors of the course of illness of depression. We sought to study the course of depression in a real-world, naturalistic, transdiagnostic clinical sample through analysis of sociodemographic, transdiagnostic clinical, and functional factors. **Methods:** The Penn State Psychiatry Clinical Assessment and Rating System (PCARES) is a dynamic cohort that systematically enrolled patients seeking mental health care at a mid-Atlantic clinic. Self-report transdiagnostic measures, functional measures were obtained, and sociodemographic features and clinical diagnoses were extracted from the Electronic Medical Record from 1,766 patients receiving care. The Patient Health Questionnaire 9 (PHQ-9) depression scale was obtained at each visit. Depression Severity groups were classified based on PHQ-9 scores during one year. Multinomial logistic regression models were estimated to evaluate associations between characteristics and the likelihood of depression severity group membership. Predictors of the slope of the PHQ-9 trajectory were examined for patients with moderate depression. **Results:** The strongest predictors of high depression severity over one year were poor functioning, high transdiagnostic DSM-5 Level 1 crosscutting symptom score, diagnosis of co-morbid Post-Traumatic Stress Disorder (PTSD), public/self-pay insurance, female gender, and non-White race. Among patients with moderate depression, the strongest predictor of improvement was commercial insurance; the strongest predictors of worsening were high functional impairment, high transdiagnostic Level 1 symptom score, diagnosis of PTSD, diagnosis of bipolar disorder, and marital status of single or formerly married; depression-specific symptom measures were not predictive. Limitations include: education and income status are inferred from zip code level-data, non-random missingness of data and electronic medical record diagnosis used in analysis due to collection from a clinical sample. **Conclusion:** Functional impairment, transdiagnostic measures of symptom burden, and insurance status are strong predictors of depression severity and poor outcomes. By identifying and monitoring trans-diagnostic measures of health, functioning and socioeconomic burden, clinicians can identify individuals at risk.

22. Feasibility of Multimodal Outpatient Treatment and Group Psychotherapy Interventions for Young Adults with Recent First-Episode Mania

Presenting Author: Arya Shah Brigham & Women's Hospital

Feasibility of Multimodal Outpatient Treatment and Group Psychotherapy Interventions for Young Adults with Recent First-Episode Mania

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Background: Coordinated Specialty Care (CSC) is a well-established model for treatment in first episode psychosis; CSC, which includes both individual and group-based therapeutic interventions, has been shown to improve treatment adherence and illness outcomes and reduce rates of hospitalization in young individuals experiencing first episode psychosis [1,2]. Group-based interventions in early psychosis may provide benefits in terms of overall functioning and self-esteem and are an important aspect of CSC [3,4]. However, similar programs or evidence-based wrap-around services have not been widely studied or implemented for first episode mania, reflecting significant disparity in both research and access pertaining to early intervention for bipolar disorder as compared to schizophrenia. Group interventions are one aspect of early intervention that may be especially important for young adults with first episode mania, given the complex identity and social dynamics influenced by a new diagnosis of a mental illness. Further, the stigma of mental illness may have a distinct psychological impact on young adults who are forming their identity and sense of self [5]. Group interventions among young adults, including college students, with a variety of psychiatric disorders have proven beneficial [6,7]. Preliminary studies have shown that group-based therapy interventions may benefit individuals with bipolar affective disorder [8,9,10]. Promising results were found in a pilot study of interventions targeting problem-solving, sleep-wake cycle regulation, and skills to reduce rumination among patients at risk of developing a bipolar disorder [11].

Methods: This feasibility study of a group-based intervention for young adults with first episode mania will involve chart review and survey-based data collection on BAD-specific symptom metrics, treatment outcomes, and developmental/psychological metrics that may be uniquely related to the young adult experience of new BAD diagnosis. The group will utilize evidence-based protocols for group interventions for young adults with recent diagnosis of chronic mental illness to address disparities in access to multidisciplinary interventions among young adults with first episode mania (compared to access to CCC among young adults with first episode psychosis. Data collection will include retrospective EHR data such as visit attendance, medication adherence, and monitoring adherence. We will measure symptoms and outcomes using standardized clinician report tools (Hamilton Depression Rating Scale, Montgomery-Asberg Depression Rating Scale, Young Mania Rating Scale) and patient report tools (Beck's Depression Inventory, Internal State Scale, Altman Self-Rating Mania Scale, Inventory of Attitudes Toward Seeking Mental Health Services, 36-Item Short Form Survey Instrument,

Connor-Davidson Resilience Scale, and Three-Item Loneliness Scale.

Results and Conclusions: We have applied for an NNDC Momentum Grant to facilitate data collection and analysis for this feasibility study.

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23. DEVELOPMENT OF THE NATIONAL NETWORK OF DEPRESSION CENTERS MOOD OUTCOMES PROGRAM: A Multi-site Platform for Measurement-based Care

Presenting Author: Michael Van Wert Johns Hopkins University

Poster Title: DEVELOPMENT OF THE NATIONAL NETWORK OF DEPRESSION CENTERS MOOD OUTCOMES PROGRAM: A Multi-site Platform for Measurement-based Care

Poster Category: Clinical (other categories are Basic Science & Covid-19)

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ABSTRACT

Background: Mood disorders are among the most burdensome public health concerns. The National Network of Depression Centers (NNDC) is a non-profit consortium of 28 leading clinical and academic member centers around the U.S. providing care for patients with mood disorders, including depression and bipolar disorder. The NNDC has established a measurement-based care program called the Mood Outcomes Program whereby participating sites follow a standard protocol to electronically collect

patient reported outcome assessments on depression, anxiety and suicidality in routine clinical care. The purpose of this poster is to provide an update on the Mood Outcomes program development, recruitment, and initial observations.

Methods: To date, 14 centers have collected assessments from more than 16,000 unique patients. Standard assessments included the 9-item Patient Health Questionnaire, the 7-item Generalized Anxiety Disorder Questionnaire, and the Columbia Suicide Severity Rating Scale plus basic demographic and diagnosis information.

Results: By collecting this data as a part of the standard of care, researchers have access to longitudinal patient records from real world settings that forms the basis of a Learning Health System, providing insights into patient outcomes over time. Updated longitudinal data will be presented.

Conclusion: The Mood Outcomes program demonstrates that large scale standard collection of patient-reported outcomes is possible with current health information technology. It also demonstrated the need for a more robust set of data to better characterize the patient experience. Based on these findings, a new version of Mood Outcomes that captures additional patient information from the electronic health record based on the PCORnet data model has been developed and is currently being piloted. It is expected to be made available to all NNDC sites in 2022.

24. Repurposing an Over-the-Counter Formulation of Dextromethorphan (DXM) as the first Oral, Ketamine-like Psychedelic Antidepressant: Preliminary Results

Presenting Author: Michael Wang Johns Hopkins University

Repurposing an Over-the-Counter Formulation of Dextromethorphan (DXM) as the first Oral, Ketamine-like Psychedelic Antidepressant: Preliminary Results and Implications

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Background: Ketamine and its enantiomers are rapid acting antidepressants of the NMDA receptor (NMDAR) antagonist class known for inducing a rapid antidepressant response among patients with severe and/or treatment resistant depression. The highly regulated nature of the drug and specialized programs necessary for ketamine treatment for TRD have greatly limited its widespread use. Thus, exploring other readily accessible NMDA receptor antagonists is warranted for curtailing the mounting rates of depression and suicide. DXM, the active ingredient in over-the-counter antitussives, demonstrates high similarity to ketamine in pharmacology and subjective effects. In our ongoing open-label unblinded feasibility and safety study, subjects with an incomplete response to their current antidepressant were randomized to one of three DXM adjunct treatment regimens for 28 days, during which depressive symptoms and adverse events were intensively tracked. **Methods:** Subjects (n=4, mean age=27.4yrs, 2M/2F) with an incomplete response to their current stable antidepressant regimen (as determined by a Montgomery Asberg Depression Rating Scale [MADRS] score of >20 after >6 weeks stable dose of current antidepressant) were randomized to one of two regimens (300mg every 2 weeks, 300mg once + 60mg daily) for 28 days with a washout and follow-up period up to 90 days. The primary outcome measure was time-to-all-cause-discontinuation. Adverse events were tabulated for 90 days. Kruskal-Wallis tests, including a variable Time (t0, t4h, t24, t7d, t14d, t21d, t28d) were used to assess the treatment effects on MADRS scores. Symptoms of dissociation were tracked using the Clinician Administered Dissociative States Scale (CADSS). **Results:** All subjects completed the treatment and follow up phases with no premature trial discontinuation. Baseline MADRS was 30.5 +/- 4.1 and t24h MADRS was 8.3 +/- 3.9 In this preliminary report, all subjects met criteria for response (>50% reduction from baseline) at 24 hours. Treatment effects were not significantly different between the two treatment arms ($p = 0.56$). No severe adverse events were reported in the dosing or washout period. Most common acute side effects included dissociation (n=4), dizziness (n=3), and nausea (n=2). The most common side effect during follow-up was change in appetite (n=2 increased, n=2 decreased) with no accompanied weight loss or gain (defined as > +/- 5% baseline body weight). Transient hypertension reported in ketamine administration was not observed during DXM dosing. Despite recommendations that DXM be contraindicated for those utilizing monoamine-elevating drugs, no symptoms of serotonin toxicity were observed among all subjects. No subjects were prematurely discontinued due to significant adverse events. **Conclusions:** Preliminary results indicate that oral high-dose DXM is well tolerated while exhibiting rapid antidepressant effects and dissociative sensoria comparable to ketamine. Up to 15 subjects will be ultimately recruited by DEC 2022, after which significance of treatment effects and interaction variables will be reported. We felt compelled to present these preliminary data to discuss the medical, social, and policy implications associated with the observation that DXM, an unregulated molecule found at drugs stores worldwide, might be a ketamine-like antidepressant.

25. Late Life Mood Disorders: A Multi-Site Registry Project

Presenting Author: Sara Weisenbach University of Michigan

Late Life Mood Disorders: A Multi-Site Registry Project

Authors: Geriatric Mood Disorders Task Group

Background: Most studies of late-life depression (LLD) and bipolar disorder (BD) are limited by small, demographically homogenous sample sizes, reducing the ability to generalize findings to a broader population of older adults experiencing mood disorders. Multi-site studies can overcome some of the limitations inherent in single-site designs by including larger sample sizes and increased participant diversity. Methods: The Geriatric Mood Disorders Task Group has been developing a multi-site data registry that capitalizes on existing data collected by members of the Task Group at different institutions. This project combines clinical, neuropsychological, and fMRI data collected among older adults with depression, bipolar disorder, and no history of mental illness. Results: To date, we have data from five different institutions, including 206 with depression, 238 with bipolar disorder, and 243 healthy controls. One project underway investigates the frequency of apathy and its relation with cognitive functioning in subjects across mood disorders. Preliminary results involving a sample of 108 subjects (M/F, 50/58; mean ± SD age, 68.82±7.88) show that apathy is present in approximately 40% of patients (43.75% in LLD, 38.8% in BD) and associated with worse cognitive performance. Conclusions: We anticipate using these data to apply for a multi-site study that investigates neuropsychiatric symptoms and behaviors and their underlying neurobiology from a trans-diagnostic perspective within the context of late life mood disorders.

26. Predominant Polarity and Associated Posttraumatic Stress Disorder in Patients with Comorbid Bipolar Disorder and Borderline Personality Disorder: A Cross-Sectional Study

Presenting Author: Taylor Wolfenberger University of Texas Health Science Center at Houston

Predominant Polarity and Associated Posttraumatic Stress Disorder in Patients with Comorbid Bipolar Disorder and Borderline Personality Disorder: A Cross-Sectional Study

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Background: Psychosocial morbidity is significant in patients with comorbid bipolar disorder (BD) and borderline personality disorder (BPD). Several studies indicate an increased number of depressive episodes, earlier age of onset, and higher frequency of traumatic experiences in childhood in patients with BD comorbid with BPD compared to BD patients without comorbid BPD[1]. Early identification and proper treatment of clinical presentation is crucial to minimizing the detriment to the quality of life in these patients. However, the effect of the comorbidity of BD and BPD on predominant polarity patterns has not been fully investigated. We conducted a study to investigate possible differences in predominant polarity patterns and possible clinical and psychopathological implications among patients with BD with and without comorbid BPD.

Methods: This study consisted of a cross-sectional analysis, utilizing data previously collected by the UT Center of Excellence on Mood Disorders (UTCEMD). A sample of 38 patients with BD and comorbid BPD was compared with 38 patients with BD without comorbid BPD; groups were matched according to age, sex, and subtype of BD. The diagnoses of BD and BPD were confirmed through the Structured Clinical Interview (SCID) for DSM-IV disorders. Predominant polarity was defined by a proportion equal or higher than 2:1 lifetime depressive vs. manic + hypomanic episodes or vice-versa. Non-parametric tests were run to compare the predominant polarities exhibited by both groups; several other measures were also compared. The statistical analysis was performed with the IBM-Statistical Package for Social Sciences (SPSS) version 26.0.

Results: There was no statistically significant difference in predominant polarity between individuals with BD with and without comorbid BPD (p=0.75). However, the groups differed significantly in the frequency of Post-Traumatic Stress Disorder (PTSD) (p=0.04), with 39.5% of patients with the comorbidity and 17.1% of patients without the comorbidity meeting criteria for PTSD diagnosis. There was a trend among several of the anxiety disorders, specifically Generalized Anxiety Disorder (GAD) (p=0.08) and social phobia (p=0.09), with higher frequencies in the comorbidity group. Mean Functional Assessment Short Test (FAST) scores were also higher (albeit not statistically significant) in the comorbidity group (38.0 vs 30.1; p=0.07).

Conclusions: The predominant polarities did not differ significantly between individuals with BD with and without comorbid BPD. However, preliminary data suggests that patients in the comorbidity group are further impaired, as indicated by an increase in the frequency of anxiety disorders, PTSD, and lower self-reported levels of functioning. Further studies in larger clinical sample are warranted to fully evaluate the degree to which comorbid BPD impacts patients with BD.

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27. Dissemination of Computer-assisted Cognitive-behavior Therapy for Depression in Primary Care: A Cost-effectiveness Analysis

Presenting Author: Jesse Wright University of Louisville

Dissemination of Computer-assisted Cognitive-behavior Therapy for Depression in Primary Care: A Cost-effectiveness Analysis

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Background: The goals of computer-assisted cognitive-behavior therapy (CCBT) for depression are to improve the efficiency, convenience, availability, and cost of effective psychotherapy[1,2,3]. While the effectiveness of CCBT for depression has largely been established [REF], the present study examined the cost-effectiveness of CCBT vs. treatment as usual (TAU) in a sample of primary care patients with depression symptoms. Cost-effectiveness analyses examined quality of life from the physical health and mental health perspectives, assessing them relative to intervention cost.

Methods: Cost-effectiveness analyses from the health care payer perspective were conducted from baseline to 6-month post-intervention. Quality of life was measured using the Short-Form 12 (SF-12 v2)[4,5,6], yielding a physical component score (PCS) and mental component score (MCS) ranging from 0-100, with higher scores reflecting better health[6]. For the economic analysis, SF-12 scores were converted into quality-of-life values ranging from 0 to 1 (1 implying perfect health and 0 implying death)[4], which were then used to calculate quality-adjusted life years (QALYs) over the study period.

Intervention cost was calculated by multiplying the number of sessions attended by each participant receiving CCBT by the Medicare reimbursement rate for a 16–30 minute session delivered by a licensed clinical social worker. Additionally, 17 of 95 CCBT participants elected to borrow a laptop, including MiFi device and 3-month data plan. These costs were calculated, including the cost of 9 laptops that were not returned. Finally, incremental costs and incremental QALYs were estimated by taking the difference between the CCBT and TAU arms in costs and outcomes. Baseline differences between the two groups were adjusted in a linear regression model that included baseline quality-of-life level[7] and participant age. The incremental cost-effectiveness ratio (ICER) was calculated as the ratio of incremental costs and QALYs. Estimates from the bootstrap samples were plotted on a cost-effectiveness plane and used to estimate the probability of CCBT being cost-effective at willingness-to-pay thresholds of $50,000 and $100,000/QALY[8]

Results: At baseline, participants were comparable and low on the SF-12 mental (MCS) and physical (PCS) component scores in both groups, the former scores indicating the participants' mental health problems. At 12 weeks and again at 6-months, CCBT participants had higher mean MCS scores compared to TAU, a statistically significant difference. PCS scores remained stable during the follow-up periods across both groups. The quality-of-life values were higher in the CCBT group at 12-weeks and 6-months. The overall incremental cost of CCBT, compared to TAU, was $689.8 (95% CI: $642.1 to $737.6). The incremental QALYs for CCBT, compared to TAU, was 0.016 (95% CI: -0.004 to 0.037). The incremental cost-effectiveness ratio for CCBT, compared to TAU, was $41,932 – this is the incremental cost

per one QALY gained due to CCBT. For the commonly used willingness-to-pay range of $50,000/QALY to $100,000/QALY in the US, the probability of CCBT being cost-effective was 60% and 82%, respectively.

Conclusions: CCBT has a high probability of being cost-effective at the commonly used willingness-to-pay thresholds for health gains.

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28. Summary of Early (Day 2/3) Primary (Day 15) Clinical Efficacy Outcomes from the Ongoing Clinical Development Program for Zuranolone in the Treatment of Major Depressive Disorder and Postpartum Depression

Presenting Author: Anita Clayton University of Virginia

Summary of Early (Day 2/3) and Primary (Day 15) Clinical Efficacy Outcomes from the Ongoing Clinical Development Program for Zuranolone in the Treatment of Major Depressive Disorder and Postpartum Depression

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Background: There is a significant unmet need for alternative, innovative treatments for depression that offer a rapid effect without the need for chronic treatment. Zuranolone (ZRN) is an investigational, oral neuroactive steroid and γ-aminobutyric acid type A ($GABA_A$) receptor positive allosteric modulator in clinical development for once-daily, 2-week treatment of major depressive disorder (MDD) as part of the LANDSCAPE program and for postpartum depression (PPD) as part of the NEST program. Treatment with ZRN has shown early onset of improvement in depressive symptoms with a generally well-tolerated safety profile, which has the potential to differentiate ZRN from standard of care antidepressants. Here, we present a summary of early and primary clinical efficacy data from placebo-controlled trials in these clinical development programs. **Methods:** All studies assessed improvements in depressive symptoms by analyzing the least squares mean (LSM) change from baseline (CFB) in 17-item Hamilton Rating Scale for Depression total score (HAMD-17) after a once-daily, 14-day treatment course of ZRN. The 3 completed studies in the LANDSCAPE program summarized here include MDD-201 (NCT03000530; Phase 2; ZRN 30 mg [ZRN30] vs placebo; baseline HAMD-17 ≥22; N=89), MOUNTAIN (NCT03672175; Phase 3; ZRN 20 mg [ZRN20] or ZRN30 vs placebo; baseline HAMD-17 ≥22; N=581), and WATERFALL (NCT04442490; Phase 3; ZRN 50 mg [ZRN50] vs placebo; baseline HAMD-17 ≥24; N=543). The completed study in the NEST program summarized here is ROBIN (NCT02978326; Phase 3; ZRN30 vs placebo; baseline HAMD-17 ≥26; N=153). **Results:** Zuranolone treatment led to rapid improvements in depressive symptoms compared with placebo across clinical trials, with significant improvements (LSM [SE] treatment difference in CFB in HAMD-17 total score) observed as early as the first, post-baseline time-point: Day 2 MDD-201 (ZRN30−placebo: −2.3 [0.99], p=0.0223), Day 3 MOUNTAIN (ZRN20−placebo: −0.4 [0.65], p=0.5725; ZRN30−placebo: −1.5 [0.64], p=0.0160), Day 3 WATERFALL (ZRN50−placebo: −3.0 [0.52], p<0.0001), and Day 3 ROBIN (ZRN30−placebo: −2.7 [1.19], p=0.025). At Day 15 (primary endpoint for all trials), significant improvement compared with placebo was observed across 3 of the 4 trials: MDD-201 (ZRN30−placebo: −7.0 [1.6], p<0.001), MOUNTAIN (ZRN20−placebo: −0.4 [0.85], p=0.6638; ZRN30−placebo: −1.4 [0.89], p=0.1158), WATERFALL (ZRN50−placebo: −1.7 [0.70], p=0.0141), and ROBIN (ZRN30−placebo: −4.2 [1.37], p=0.003). Treatment emergent adverse events with an incidence of ≥5% in ZRN treatment arms (range across trials) included headache (6.3% to 18.0%), somnolence (5.9% to 15.3%), dizziness (5.7% to 13.8%), nausea (3.6% to 11.0%), sedation (4.7% to 7.5%), diarrhea (5.9% to 6.3%), upper respiratory tract infection (8.0%), and fatigue (1.6% to 6.8%). No incidences of loss of consciousness or excessive sedation were observed in any of the trials to date. **Conclusions:** Clinical trials of the LANDSCAPE and NEST programs have consistently reported that patients receiving ZRN have shown significant improvement in depressive symptoms (as assessed by the CFB in HAMD-17 total score compared with placebo) as early as Day 2/3. Across trials and doses to-date, treatment with ZRN has been generally well-tolerated with a consistent safety and tolerability profile.

29. Long-term Efficacy of Lurasidone in Pediatric Bipolar Depression: Post-hoc Analysis of Response, Remission and Recovery

Presenting Author: Michael Tocco Sunovion Pharmaceuticals

Long-term Efficacy of Lurasidone in Pediatric Bipolar Depression: Post-hoc Analysis of Response, Remission and Recovery

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**Presenting Author*

Background: The aim of this analysis was to evaluate the long-term efficacy of lurasidone in achieving response and remission in children and adolescents with bipolar depression.

Methods: Patients 10-17 years with bipolar I depression who completed a 6-week double-blind (DB) study of lurasidone vs. placebo enrolled in a 2-year, open-label (OL) study of lurasidone (20-80 mg/d). Efficacy measures included the Children's Depression Rating Scale, Revised (CDRS-R) and the Clinical Global Impression, Bipolar Depression Severity scale (CGI-BP-S). Functioning was evaluated utilizing the Clinician-rated Children's Global Assessment Scale (CGAS) score (score ≥70: no functional impairment). Response criteria: ≥50% reduction from DB baseline in the CDRS-R score; remission criteria: CDRS-R Score ≤28, YMRS score ≤8, and CGI-BP-S score ≤3; and recovery criteria: in remission with a CGAS score ≥70.

Results: A total of 305 patients completed the 6-week DB study and entered the extension study; 195 and 93 completed 52 and 104 weeks of treatment, respectively. Responder rates at OL baseline, and weeks 52 and 104 were 51.0%, 88.4% and 91.1%, respectively; remission rates were 24.3%, 61.3%, and 75.6%, respectively; and recovery rates were 17.7%, 53.8%, and 73.8%. On a Pearson correlation analysis, there was a strong inverse relationship (r = -0.71) between CDRS-R total score, and global functioning as measured by the CGAS.

Conclusions: In children and adolescents with bipolar depression, up to 2 years of treatment with lurasidone was associated with continued improvement in depressive symptoms, resulting in progressively higher rates of remission, recovery, and sustained remission.

Clinicaltrials.gov identifier: NCT01914393.

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