Yale University NECN ODE McLean Hospital

News from the Principal Investigators

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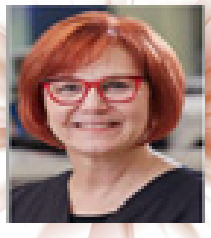

We are greatly saddened by Kathy's sudden, unexpected death. She has been a vital part of the NE Consortium Node since its inception. We are heartened by the fact that so many investigators have become part of our Node and that the number continues to grow. We are committed to expand upon Kathy's legacy and improve the care of patients with substance use disorders.

-Gail D'Onofrio MD, MS

-Roger Weiss MD

History of our Node

The New England Consortium Node (NECN) was formed in 2010 through a merger of 2 highly productive nodes; the New England Node, led by Kathleen Carroll, and the Northern New England Node, led by Roger Weiss. The New England Node entered the CTN in 1999 as part of the first wave of nodes, and Kathy Carroll and her team of collaborators immediately left their mark on the CTN. As one of 4 founding nodes in 1999, the NE Node, under Kathy's direction led two early protocols, "Motivational Enhancement Therapy to Improve Treatment Engagement" and "Motivational Interviewing to Improve Treatment Engagement and Outcome" which set the standard for subsequent CTN behavioral trials: meeting recruitment and retention goals, and highly productive, generating over 30 peer-reviewed papers. The Node also conducted the first CTN trial for monolingual Spanish speakers. Kathy's contribution to the CTN was immeasurable; as arguably the leading addictions behavioral therapy researcher in the world, she set the standards for incorporating the highest-quality behavioral research standards into CTN trials.

The Northern NE Node, under Roger Weiss' direction, entered the CTN in the second wave, in 2002.When prescription opioid dependence emerged as a prevalent but little-studied problem, Roger and his colleagues at McLean Hospital led the Prescription Opioid Addiction Treatment Study (POATS). In 2010, Betty Tai, the director of the Center for the Clinical Trials Network, announced that the CTN would be reducing the number of nodes in the network, and she encouraged geographically proximate nodes to merge. The merger of the NE and the Northern NE nodes provided an ideal opportunity for integration, based on our geographical proximity, complementary scientific expertise, and history of successful collaboration. The merger occurred seamlessly, as the newly formed NECN was founded in 2010.

In 2015, the mission of the CTN expanded; there was now an increasing emphasis on conducting addiction treatment research in general medical settings. This change led to the incorporation of a new group of researchers in the node, including Gail D'Onofrio and David Fiellin from Yale, Richard Saitz and Jeffrey Samet from Boston University, Sharon Levy from Boston Children's Hospital, and Sarah Wakeman from Mass. General Hospital; all national leaders in addiction medicine research. NECN researchers are now leading multiple trials and demonstrating CTN leadership in other ways, e.g., Shelly Greenfield's leadership of the Gender Special Interest Group since 2002. As a result of Gail D'Onofrio's leadership of two major Emergency Department trials, she became a third PI in 2020, along with Kathy and Roger. With the devastating loss of Kathy, Gail has assumed the role of contact PI.

This Node was founded by a heart whose depth centered on genuine concern for the welfare of all individuals, a heart who opened to those in need, not only to those suffering from addiction, but those who needed a colleague, a mentor, a friend who would accept and love them. Kathy is light, both in life, and in death. She'll never extinguish.

New England Consortium Node Active Protocols

CTN0060-A1: Study Name

Lead Investigators: Sharon Levy MD, MPH
Description: Validating 3 Substance Use Screening Tools for Adolescents. Tests the psychometric properties of Brief Screener for Tobacco, Alcohol, and other Drugs (BSTAD), Screening to Brief Intervention (S2BI), and Tobacco, Alcohol, Prescription medications, and other Substance (TAPS), against a criterion standard of DSM-5 substance use disorder diagnoses in adolescents presenting for routine primary care. Status: Actively recruiting.

CTN0069: Opioid Use Disorder in the Emergency Department

Lead Investigators: Gail D'Onofrio MD, MS & David Fiellin MD
Description: Evaluate the impact of (1) Implementation Facilitation (IF) on rates of provision of ED-initiated buprenorphine/naloxone (BUP) with referral for ongoing MOUD and the (2) effectiveness of IF on patient engagement in formal addiction tx at 30 days. Status: 4 sites completed, N= 757 patients. Data is being analyzed.

CTN0069A

Leads: Andrew Herring MD & Gail D'Onofrio MD, MS
Description: Retrospective review cohort of patients receiving high-dose ED initiated bup defined as >12 mg of bup. Status: Paper out for review.

CTN0069 COVID Supplement

Lead: E. Jennifer Edelman MD, MHS
Description: Accessing the impact of COVID-19 on individuals with OUD who received ED care. A survey study of Project ED Health participants and medical leadership at four EDs. Data collection complete. Status: Analysis ongoing.

CTN0079A: Emergency Department Connection to Care with Buprenorphine for Opioid Use Disorder

Lead Investigators: Ryan McCormack MD, MS & Kathryn Hawk MD, MHS
Description of Study: Evaluate the diffusion and sustainability of ED-initiated BUP at the initial 3 clinical sites (0079) in furtherance of initial question: In settings with high need, limited resources, and differing staffing structures for managing OUD, what is the feasibility and impact of introducing a clinical protocol for OUD screening and BUP initiation in the ED with referral for treatment? Status: Ongoing.

CTN0080 MOMS: Medication Treatment for Opioid-dependent Expecting Mothers (MOMs): A Pragmatic Randomized Trial Comparing Two Buprenorphine Formulations

Lead Investigators: Theresa Winhusen PhD
Description: Primary objective to evaluate the impact of treating OUD in pregnant women with BUP-XR, compared to BUP-SL, on maternal-infant outcomes. Testing a conceptual model of the mechanisms by which BUP-XR may improve maternal-infant outcomes, relative to BUP-SL, is a secondary trial objective. Status: Nationally, 12 sites recruiting. Locally, Project RESPECT Clinic at Boston Medical Center and MGH HOPE Clinic.

CTN0081: Emergency Medicine Opioid Data Infrastructure: Key Venue to Address Opioid Morbidity and Mortality (Project CODE PRO)

Lead Investigators: Arjun Krishna Venkatesh MD, MBA, MHS
Description: Build clinical data research infrastructure to begin to enhance capacity to use EHR data and patient-reported outcomes measures to conduct pain and opioid related research in EDs. Status: Manuscripts in preparation.

CTN0098A/B: Exemplar Hospital Initiation Trial to Enhance Treatment Engagement (EXHIT ENTRE)

Lead Investigators: Gavin Bart MD, PhD, FACP, FASAM
Description: CTN0098A will examine whether in hospitals with addiction medicine consultation services, hospital-initiated XR-BUP, compared to TAU, results in increased OUD tx engagement following discharge; and CTN0098B will examine, in community hospitals that have not yet implemented hospital-based opioid tx (HBOT), whether a high-intensity strategy (training/education + practice facilitation) for implementing HBOT is associated with greater MOUD engagement post-discharge than a low-intensity (training/education only) strategy. Status 98A: Nationally 5 sites. Locally, Yale, Dept of EM, BU, and MGH. 98B: Nationally 4 sites. Locally, BU.

CTN0099/0099A: ED-INitiated bupreNOrphine and VAlidaTIOn Network Trial (ED-INNOVATION)

Lead Investigators 99: Gail D'Onofrio MD, MS & David Fiellin MD
& 99A: Andrew Taylor MD
Description: To evaluate implementation of ED-initiated BUP; compare XR-BUP with SL-BUP in RCT of ED patients with untreated OUD; determine safety of XR-BUP with minimal withdrawal (99A); and develop and validate EHR phenotypes of opioid-related illnesses to better characterize and identify pts with OUD. Status: 99: 26 sites, N=178 of 2000. 99A: 4 sites, N=56 of 75. Locally, Yale-NH Hospital ED.

CTN0099 Supplement:

Lead Investigator: Kathryn Hawk MD, MHS
Description: Better understand impact of COVID-19 on the care of ED patients with SUDs, using EMR data to from up to 30 EDs to evaluate changes in ED visits for substance use. Status: Data being prepared for analysis.

CTN0100 RDD: Optimizing Retention, Duration, & Discontinuation Strategies for OUD Pharmacotherapy

Lead Investigators: Edward Nunes, Jr. MD & John Rotrosen MD & Roger Weiss MD
Description: 2 linked studies. 1) test strategies to improve OUD pharmacotherapy treatment retention & to improve outcomes among patients who have been successfully stabilized on OUD medications & want to stop medication; 2) identify predictors of successful outcome and develop a stage model of relapse risk. Status: 18 sites. Projected launch, 3/21. Locally, Liberation Programs, Square Medical Group, SSTAR.