

Collision of Public Health Crises

Substance Use Disorders Research and COVID-19

Adapting Designs, Interventions, Data Collection

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- Virus spreading rapidly in Europe (Italy), reaching U.S.
- Mode of transmission?
 - Surface? Droplet ? Airborne?
- Should “non-essential” research be halted?
- How to keep research participants safe?
- How to keep patients safe?

COVID-19 and Research Participants

- Social-physical distancing
 - Interviews, clinical research visits
 - Neuropsych testing
 - Procedures, e.g. blood draws, MRI
- Risks of travel to research visits
- COVID-19 as risk of research participation
- Essential vs non-essential personnel



Adaptations to Research Methods

- Remote or virtual procedures
 - Remote consent with e-signature
 - Remote assessment via “Zoom” or web-based data collection
 - Remote neuropsychological testing
 - Remote behavioral intervention, via “Zoom” or digital interventions
 - Delivery of medications to participants’ homes
 - Home delivery/pickup of sample collection materials and biological samples

Adaptations to Research Methods

- In person procedures
 - Reduced participant, patient “traffic”—25%, 50%
 - Reduced staff on site
 - Volunteers, students, research assistants
 - Staff not directly needed for on-site procedures
 - How to conduct long procedures safely, e.g. MRI
 - Cleaning surfaces
 - Ventilation
 - Distancing participants from staff
 - PPE

Adaptations to Research: Outcomes and Lessons Learned

- Speed of initiation and conduct of clinical trials for COVID-19 medications and vaccines (*Tuttle, Nat Rev Nephrol 2020*)
 - Expedited protocol preparation, review, approval
 - Accelerated contracting/budgeting
 - “First participant enrolled <1 week from protocol receipt”
 - “A study for every patient”
- Adaptations for COVID-19 related trials (remote consent, remote monitoring, telehealth, remote delivery of meds, etc) well accepted by research staff (*Gerber et al., J Natl Compr Canc Netw 2020*)

COVID-19 Impact on HEAL and Substance Use Disorder Research

- Dozens of commentaries, anecdotal reports
 - Limited hard data on impact on research
- Research slowed at least temporarily
 - Recruitment more difficult
 - Impact on engagement and retention?
- Can the COVID-19 research adaptations be harnessed across the board for HEAL and other research?
 - More flexible, nimble, speedy research process

COVID-19 Related Adaptations to SUD Clinical Practice

- March 2020: DEA, SAMHSA, State agencies swiftly relaxed rules governing treatment for substance use disorders
 - Telehealth facilitation; initiation of buprenorphine by telehealth without an in-person visit; expanded methadone take-homes for stable patients
 - Potential to make medication treatments more convenient, attractive
- Anecdotally these changes have been well-accepted by patients and providers
 - Survey of 227 administrators or clinicians at outpatient treatment or harm reduction programs in NY State found the majority supported continuing these practice adaptations (*Mandavia et al., submitted*)

Outcomes of Practice Adaptations

- Clinical research underway, examples:
 - CTN-0102: Rural Expansion of Medication Treatment for OUD
 - Telemedicine vs usual in-person care for buprenorphine treatment of opioid use disorder
 - CTN-0100: Retention, Duration, Discontinuation
 - Commercially available smartphone-based apps, reSET, ACHES (ACCESS), for behavioral treatment of OUD along with buprenorphine or XR-naltrexone
 - Healing Communities Study
 - Comprehensive community-level intervention to reduce opioid overdose deaths and opioid morbidity: OEND, MOUD, safe prescribing
 - CTN-0112 (OPTIMMAL)
 - Chart review on outcomes of methadone maintenance before vs after COVID-related liberalization of methadone takehomes, testing, counseling

COVID-19 and Substance Use Disorders

Disruption and Opportunities



- Innovative adaptations to research methods
 - Remote procedures
 - Make research participation more attractive, convenient?
 - How does this work? Lack the human touch of in-person attention?
- Example of swift conduct of COVID-19 clinical trials
- More flexible rules governing treatment, medications for opioid use disorder, telemedicine, technology-based treatments
 - Potential to make treatment more convenient, more attractive
 - Need evidence on effectiveness