2018 Medical Toxicology Foundation Practice Awards

Study title: TeleSUDE: A Telemedicine-based Substance Use Disorder Evaluation to facilitate addiction treatment referrals after near-fatal opioid overdose

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A. HYPOTHESIS AND SPECIFIC AIMS:

Emergency departments (EDs), the primary sites of medical care after opioid overdose, are poorly equipped to provide adequate substance use treatment planning before discharge. This results in a "revolving door" phenomenon of iterative resuscitation and rapid discharge; patients may be successfully resuscitated multiple times for opioid overdose before their fatal overdose.[1,2]

To address the epidemic of opioid overdose and death, Massachusetts enacted legislation in 2016 mandating that individuals evaluated in the ED after suspected opioid overdose be offered a substance use disorder evaluation (SUDE).[3] This targeted, 20 minute intervention by a behavioral health or addiction medicine clinician is adapted from the evidence-based Screening, Brief Interview and Referral to Treatment (SBIRT), and identifies individual patterns of substance use, details appropriate level of addiction care, and motivates patients to seek treatment.[3] The ED-based SUDE represents a paradigm shift from prior "treat-and-release" strategies, providing structured substance use assessment and treatment following opioid overdose.

Since the SUDE legislation was enacted, we have observed that only 21% of eligible patients actually receive a SUDE prior to discharge. Individuals who received SUDE were less likely to have an ED visit for an opioid-related complaint in the next 3 months. Despite our initial success, EDs face several barriers to providing SUDE evaluation in an efficient manner, including lack of immediate access to trained clinicians, and a concurrent high volume of psychiatric assessments.[4]

To address the need for timely ED-based SUDE evaluations, we propose teleSUDE, an innovative, unobtrusive, and effective telemedicine platform to provide immediate bedside SUDE. This innovative proposal utilizes our prior experience in mobile telemedicine to provide immediate bedside access to diagnostic evaluations equivalent to a face-to-face encounter. We intend to evaluate the feasibility of providing a SUDE using a telemedicine platform similar to those we have demonstrated to be effective in previous investigations.[5,6]

Our longstanding collaborative research team, with extensive expertise in medical toxicology, addiction medicine, emergency medicine, novel technology deployment, is optimally positioned to complete this investigation. Our specific aims are:

Aim 1: Technology development. We will develop teleSUDE by optimizing the telemedicine platform for use with our hospital network, and training providers on the use of the technology.

Aim 2: **Technology evaluation.** We will perform a feasibility study of teleSUDE in a cohort of opioid overdose individuals (N=30) at a remote ED to assess its acceptability to patients and providers. *We hypothesize that patients and providers will be highly accepting of teleSUDE.*

Aim 2a: Technology impact. We will evaluate the impact of the teleSUDE pilot on selected ED performance metrics at our remote ED. *We hypothesize that our intervention will decrease time to SUDE initiation, time-to-discharge, and the number of patients who leave prior to SUDE initiation when compared to baseline performance metrics.*

Aim 2b: Practice and sustainability. We will evaluate various reimbursement models to evaluate the return on investment (ROI) of teleSUDE. *We hypothesize that teleSUDE will be a cost-effective means to facilitate addiction treatment referrals, including initiation of medication-assisted treatment (MAT)*.

This proposal contains considerable innovation, significance, and impact. Innovation: teleSUDE represents an innovative method to perform personalized substance use assessments in the ED. Significance: Death from opioid overdose is avoidable if behavioral intervention is completed in a timely manner. teleSUDE represents a novel method to offer efficient SUDE after overdose. Impact: teleSUDE is a scalable telemedicine initiative that can improve access to addiction treatment programs and facilitate initiation of MAT by medical toxicologists.

B. BACKGROUND AND SIGNIFICANCE:

B.1. The SUDE evaluation addresses the needs of opioid overdose individuals after ED discharge. The SUDE is an intervention adapted from the evidence-based Screening, Brief Intervention and Referral to Treatment (SBIRT), a behavioral health intervention which identifies problematic behavior that may result in worsening substance use. Adaptation of SBIRT to ED settings is effective in decreasing substance use, and improving referral to treatment.[7,8] SUDE evaluations are conducted by behavioral health or addiction medicine clinicians in real-time, focusing on 1) the patient's personal and family history of substance use; 2) responses to previous treatment for substance use; and 3) co-occurring psychological disorders.[3] The SUDE evaluator augments emergency care by providing concrete recommendations for treatment and assisting physicians in targeted referrals to support patients post discharge or as inpatients.

B.2. When immediate SUDE is available, evaluations take place. Our emergency medicine group provides care at two urban, university hospital campuses (University and Memorial) that are within two miles of each other. For the remainder of the application, these will be called the immediate bedside-access site (University) and remote site (Memorial). Both sites receive opioid overdoses from EMS, and as "drop-offs." The differences in local resources provide a natural setting for this study. Our experience with SUDE stems from our immediate bedside-access site, where SUDE providers are in-house and available 24/7. In the first 18 months since the SUDE legislation was enacted, our immediate bedside-access site has provided 585 SUDEs to patients presenting after opioid overdose.

B.3. Barriers exist to timely SUDE access at remote sites. Although providers are required to offer a SUDE under the new legislation, patients are not required to remain in the ED until a SUDE becomes available. Our remote site lacks access to in-hospital mental health or addiction medicine providers. Patients who require a SUDE may wait for extended periods of time for 1) transfer to the immediate bedside-access site, or 2) an on-call SUDE evaluator to arrive; often, patients decide to leave prior to assessment. The major barrier to obtaining a SUDE is the availability of a SUDE practitioner: at the remote site, the average time from medical clearance to SUDE availability is 90 minutes, and only 29 SUDEs have been completed in the first 18 months since the law was enacted.

B.4. Telemedicine can improve access to SUDE at remote sites. Video telemedicine effectively replicates bedside mental health treatment and evaluation.[9-11] We have previously demonstrated the feasibility of deploying mobile telemedicine platforms within the ED in coordination with remote providers to facilitate real-time subspecialty clinical decision support.[5,6,12,13] Moreover, we will pilot the teleSUDE evaluation and platform for SBIRT with a plan to move further into teledelivery of medication-assisted treatment by toxicologists for appropriately screened patients.

B.5. Impact. TeleSUDE increases access to SUDE following opioid overdose, improving the efficiency of existing SUDE while positioning toxicologists as leaders in addiction telemedicine.

B.5.1. Providing cost-effective SUDE evaluations. TeleSUDE represents a significant advance, eliminating the need for interfacility transfers for in-person SUDE, improving the response time of SUDE, and providing a virtual face-to-face evaluation through low-cost telemedicine.

B.5.2. Positioning toxicologists as leaders in addiction telemedicine. Classically, toxicologists are trained in the management of acute drug overdose, but the opioid epidemic has elevated the importance of our expertise in chronic drug use and addiction treatment, including pharmacologic therapy. This unique perspective on both acute and chronic drug exposure has been parlayed into a series of advances in the practice of ED telemedicine to assess poisoned patients.[14] TeleSUDE represents a significant advance for toxicologists; experiences piloting and evaluating a tailored intervention to provide SUDE in a busy ED can be adapted to improve long-term care in individuals who require continued treatment by toxicologists trained in addiction medicine.

C. PROJECT DESIGN:

C.1. General Approach. In this proposal, we will first develop teleSUDE by training SUDE clinicians in the operation of video telemedicine. This training will be validated through mock SUDE sessions with standardized patients. We will then test teleSUDE using a cohort of individuals who present to the remote ED after opioid overdose to determine the user and provider satisfaction with teleSUDE. Next, we will gauge the impact of teleSUDE on percent completion of SUDE and ED performance metrics during the pilot. Finally, we will evaluate various reimbursement models for teleSUDE.

C.2. Setting. Both the immediate bedside-access and remote ED sites are located in Worcester, MA, which is at the epicenter of an opioid epidemic. In 2015, Worcester county ranked third among Massachusetts counties in opioid overdose deaths, with 218 individuals dying from opioid-related deaths.[15]

C.3. Adequacy of the Study Site. The immediate bedside-access campus cares for an average of 42 individuals after opioid overdoses each month, while the remote campus cares for 7 to 10 opioid overdoses monthly.

C.4. Collaboration. Our multidisciplinary study team channels expertise in technology, substance abuse, and ED-based mental health. Dr. Lai, senior toxicology fellow, completed his residency at UMass and has worked closely with all his mentors for years. Dr. Babu will serve as primary mentor, overseeing all aspects of this work, and removing obstacles for study completion. Experts in novel technology development, SBIRT and ED-based drug abuse interventions, Drs. Chai and Boudreaux will mentor Dr. Lai regularly and provide a rigorous foundation for this investigation. Dr. Boudreaux is the director of research in the Department of Emergency Medicine at UMass, and will facilitate access to RAs.

C.5. Interventions/Measurements.

C.5.1. Specific Aim 1: Technology development. In this aim, we will train SUDE clinicians to conduct teleSUDE through a tablet computer-based video telemedicine platform using standardized patient (SP) interactions.

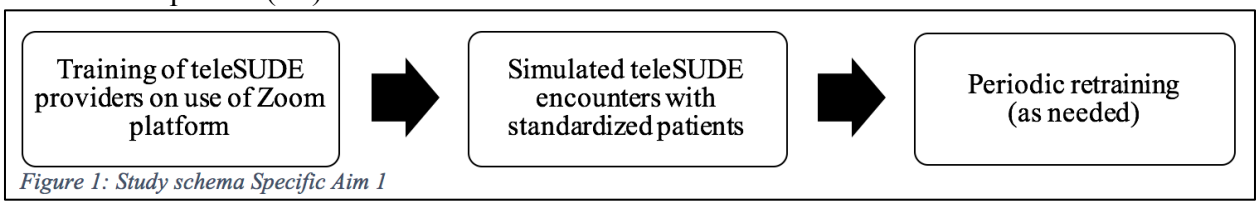

Figure 1: Study schema Specific Aim 1

C.5.1.1. Components of teleSUDE. TeleSUDE is comprised of matched tablet computers equipped with Zoom (San Jose, CA), a HIPAA-compliant software backbone. Zoom is a video conferencing software platform that is device and operating system agnostic. When a SUDE clinician activates Zoom, a secure video conference call similar to "FaceTime" is made to the paired tablet computer accessed by the patient. A split screen allows clinicians and patients to see each other, providing recorded evidence of a face-to-face evaluation to generate documentation required for a billable telemedicine encounter.[16]

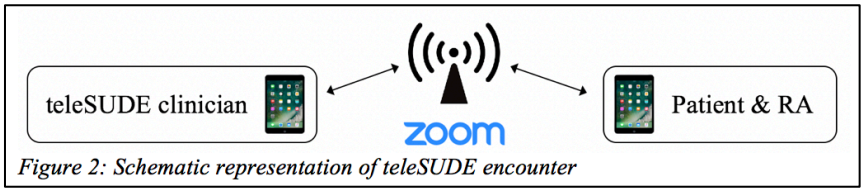

Figure 2: Schematic representation of teleSUDE encounter

C.5.1.2. Participant recruitment: Clinicians from our immediate bedside-access site who are previously trained in bedside SUDE will be recruited to participate in the development of

teleSUDE. We will hold periodic retraining sessions as needed during weekly staff meetings.
C.5.1.3. Training SUDE clinicians in the operation of teleSUDE. SUDE clinicians will undergo a two-step training program. First, they will learn to operate the Zoom-enabled tablet computer from our immediate bedside-access site. We will instruct SUDE clinicians on how to troubleshoot issues with connectivity, potential loss of video and voice streams, and techniques to re-establish the teleSUDE in the instance of lost connectivity. Second, we will test the competency of teleSUDE clinicians to operate teleSUDE in 30-minute standardized patient encounters. We will randomly insert errors in connectivity, loss of audio or video, and software failure during these encounters to ensure teleSUDE clinicians can appropriately troubleshoot common barriers in successful connection. Clinicians who are unable to operate teleSUDE will receive a second training by the study staff and a subsequent standardized patient teleSUDE encounter. We will conduct periodic retraining as necessary, and maintain a manual of procedures regarding teleSUDE operation. We have successfully utilized this approach in other technology based investigations.[6,12,17]

C.5.2. Specific Aim 2: Technology evaluation. In this aim, we will evaluate teleSUDE in a pilot descriptive trial of patients (N=30) who present to the remote site ED following opioid overdose.

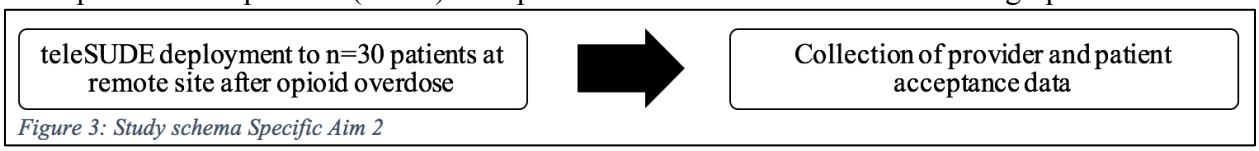

Figure 3: Study schema Specific Aim 2

C.5.2.1. Research assistant recruitment. Research assistants (RA) will be recruited from an existing pool of RAs maintained by Dr. Boudreaux, and will be trained in study protocols and inclusion criteria. We will also train RAs on the operation of teleSUDE so they are available to help troubleshoot potential technology issues. RAs will be tested on their knowledge of the study protocol, and will recruit their first participant with the study investigator.
C.5.2.2. Study participant recruitment. RAs will access the ED electronic medical record (EMR) to identify potential study participants. Potential participants that meet enrollment criteria and are medically cleared will be approached by the RA, and enrolled in teleSUDE.
C.5.2.3. Inclusion Criteria. We will include individuals at the remote site who 1) present after known or suspected opioid overdose, or 2) receive naloxone in the pre-hospital or ED setting for reversal of a suspected opioid overdose.
C.5.2.4. Exclusion Criteria include: 1) age less than 18; 2) unable to provide informed consent due to language barrier, psychosis, or critical illness; 3) prior study participation; 4) prisoners, or those in police custody. In our prior work, these exclusion criteria applied to less than 3% of patients who presented to our ED after overdose.
C.5.2.5. Performing teleSUDE. Patients at the remote site who consent to participation will be taken to a private consultation area in the ED, and given a brief introduction to the teleSUDE equipment. Providers trained in Aim 1 will complete the teleSUDE from the immediate bedside-access campus. At the completion of the teleSUDE encounter, the provider will transmit a written summary of the encounter and recommendations for treatment to the patient and the ED physician. Providers and study participants will then complete standardized surveys on their respective tablet computers that assess their attitudes and beliefs toward teleSUDE.
C.5.2.6. Measures.
C.5.2.6.1. Technology acceptance outcomes. We will evaluate the user feedback to teleSUDE from both SUDE providers and patients to gain formative data on the real-world utilization of telemedicine in ED-based substance use counseling. Under the guidance of my mentors, I will develop a questionnaire that addresses providers and participant willingness to use teleSUDE, usability of teleSUDE, and sustained teleSUDE use grounded in the Technology Acceptance

Model. We will conduct questionnaires among provider/participant dyads immediately after each teleSUDE session.[18]

C.5.2.6.2 Provider/patient surveys. Following the teleSUDE encounter, the SUDE provider and patient will each complete a survey regarding teleSUDE acceptance using SurveyMonkey (San Mateo, CA) software (Table 1).

Content Area	Intent	Probes
Acceptability of teleSUDE	Determine how SUDE providers and patients accepted the use of teleSUDE	• Prior experience with telemedicine? • Ease of operation
Fidelity of teleSUDE	Understand how teleSUDE reproduced the effect of a bedside SUDE	• Were clinicians and patients trusting of the telemedicine platform? • Fears of privacy violations? • Willingness to interact with teleSUDE?

Table 1. Themes for post-teleSUDE survey for Specific Aim 2

C.5.3. Specific Aim 2a: Technology impact. In this dependent aim, we will measure the impact of the teleSUDE pilot on selected ED performance metrics at our remote ED. Our primary measure in this aim will be time from determination of medical stability until initiation of SUDE. Other clinical measures include 1) time to discharge or admission; 2) whether patient elects to leave prior to substance use evaluation; and 3) type of disposition (home, outpatient drug treatment, inpatient drug treatment, inpatient psychiatric admission, inpatient medical admission). For comparison, we will use rigorously time-stamped historical data from the remote site.

C.5.4. Specific Aim 2b: Practice and sustainability. In this dependent aim, we will consult with a collaborator with extensive experience in telemedicine and toxicology billing and reimbursement to create a sustainable compensation framework for telemedicine addiction treatment evaluations. We will evaluate the feasibility of various models, including pay-per-use and subscription plans, with special attention to facilitating MAT initiation using teleSUDE.

C.6. Data Analysis Plan. All data analysis will be planned and conducted with statisticians employed in the Department of Emergency Medicine at UMass.

C.6.1. Acceptance of teleSUDE. In this pilot study of teleSUDE, the outcomes are for feasibility and efficacy. We are unable to determine an appropriate sample size as there is no data on the effectiveness of this new technology. For the feasibility outcome of the proportion of patients and providers who accept teleSUDE, we will use an exact Clopper-Pearson confidence interval to determine what proportion lower than 0.80 will still include 0.80 in the confidence interval. Proportions as low as 0.65 and 0.70 with a sample size of 30 and 40, respectively, will still include the proportion of 0.80 in the confidence interval. These are consistent with Cohen's d effect size indicated for the secondary efficacy outcome below.

C.6.2. Clinical impact of teleSUDE. We estimate that developing a reasonable confidence interval from the time of determination of medical stability until initiation of SUDE will require recruitment of 30-40 patients. Although we will use a complex modeling approach to these data as described below, we do not have the information to estimate the effect of teleSUDE over time. Thus, for simplicity, we will use a confidence interval approach for the sample size. This sample size will allow us to establish a confidence of ±0.51 s.d. units for 30 patients and ±0.45 s.d. units for 40 patients. The use of standard deviation units in reference to Cohen's d descriptors indicates that these represent "medium" effect sizes, a reasonable goal for a feasibility study. With the historical control at the remote site, we can treat this as an interrupted time series and use a generalized estimating equations (GEE) approach to the analysis. This approach adjusts for the correlation among the 6 months' measure both before and after. This model will yield estimates of

any slope (change over time) in the clinical outcomes before the introduction of teleSUDE, the immediate impact of the teleSUDE, and the slope of the primary outcome over the 6 months after the introduction of teleSUDE. The same model can be fit to the other clinical outcomes above.

C.7. Potential Scientific Problems.

C.7.1. How will we address lower than expected enrollment? Our previous investigations among injection drug users receiving care in the ED attained a 94% recruitment rate in an uncompensated cohort. The time commitment for this proposed study is comparable to our previous work and does not extend the duration of patient care. If we find that accrual lags, we will expand recruitment to other remote sites (e.g. community affiliate EDs). Considering our prior success and the experience of Drs. Babu and Chai in recruiting hidden populations in clinical environments, we believe that accrual is assured as long as our current pace of patient presentations after opioid overdose persists.

C.7.2. Are clinicians reluctant to utilize mobile technologies? Our previous investigations have demonstrated successful use of mobile videoconferencing devices to facilitate specialist consultations in the ED.[5,6] Because of our prior experience in utilizing these technologies in the ED, we believe that we will be able to successfully train SUDE clinicians and deploy the teleSUDE platform in the ED. In addition, we plan to incorporate feedback from users during the training phase to make iterative improvements to the technology platform.

C.7.3. Will opioid users be reluctant to utilize mobile technologies? Our previous work has shown that illicit substance users receiving care in the ED readily accept technology-based interventions.[17,19,20] To help allay potential patient concerns regarding any privacy issues, we will include a technology primer as part of the informed consent process. With our prior success in deploying mobile technologies in patients with active substance use, we do not believe we will encounter significant problems with acceptance of the teleSUDE in this population.

C.7.4. How will we solve connectivity issues? We will enlist UMass Information Technology to ensure optimal network connectivity prior to deploying teleSUDE for clinical use. Study staff will trial the technology platform at various locations within both the immediate bedside-access and remote sites to verify that the technology functions as intended, and to ensure fidelity of the audiovisual stream. In case of unanticipated technical issues, the circumstances of the event will be documented, and patients will receive the current standard of care (an in-person SUDE).

C.8. Practice and billing. To optimize potential remuneration for ongoing teleSUDE work, we will consult with Dr. Timothy Wiegand (University of Rochester). Our budget facilitates travel for Dr. Wiegand, and we will leverage his expertise in telehealth to create a sustainable and compensable model for teleSUDE that can be adopted by other toxicology services. Moreover, Dr. Wiegand will be essential to the next step – adapting our pilot teleSUDE intervention for the provision of MAT through standardized eligibility protocols for buprenorphine and naltrexone.

C.9. Dissemination of results. We have the capacity to distribute study results to researchers in emergency medicine, toxicology, emergency medical services, drug abuse, psychiatry, addiction medicine, and public health. The Medical Toxicology Foundation will be credited in any dissemination of our results.

C.10. Next steps. The data from this pilot will generate the evidence base for future funded work by Dr. Lai, including protocols for teledelivery of MAT (focused on buprenorphine and naltrexone). Additionally, Dr. Lai's career goals include applying for a mentored career development award (K23) in technology-based delivery of opioid use disorder behavioral interventions. His overarching work will focus on prevention of recurrent overdose and overdose deaths through delivery of addiction medicine interventions via telemedicine to underserved areas.

D. STUDY TIMELINE.

	Prior to funding period	Q1	Q2	Q3	Q4
IRB approval	X				
Recruit and train RA and SPs		X			
teleSUDE training for clinicians; SP simulations		X			
Participant recruitment for teleSUDE			X	X	X (PRN)
Analysis of ED metrics				X	X
Evaluation of teleSUDE billing and reimbursement models				X	X
Drafting of manuscripts and meeting presentations					X

E. BUDGET.

Line Item	**Cost**
Research assistant (Annual salary $35,000, 8.3% FTE) o Salary: $35,000 x 8.3% (1 calendar month effort) o Fringe: $2,905 x 37.63%	 $2,905 $1,093
Site visit by collaborator with billing and reimbursement expertise o Round-trip airfare o Hotel accommodation (3 nights @ $200/night)	 $402 $600
TOTAL	**$5,000**

We have previously acquired tablet computers with wireless internet capabilities that run commercially available telemedicine software, resulting in minimal technology startup costs. We will conduct technology maintenance ourselves in order to save costs associated with technology upkeep.

We have arranged for a site visit by an expert with extensive toxicology and telemedicine billing and reimbursement experience, with whom we have collaborated in the past.

We have a full-time statistician on staff within the department of emergency medicine who will assist with data cleanup and analysis. We will not be requesting funds from MTF to cover statistical analyses.

We anticipate 10% effort for Dr. Lai (PI), but will not be requesting funds from MTF to cover effort. Drs. Babu, Chai, and Boudreaux will serve as mentors, providing guidance as needed to facilitate completion of the project.

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