Testing of a patient-centered e-health implementation model in addiction treatment

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Study Summary

Patient-centered e-health has failed to achieve its promise despite considerable consumer interest in technology and research supporting its potential. E-health adoption rates in healthcare are poor, with specialty substance use disorder (SUD) treatment having the lowest technology adoption rate of any sector.[1] Implementation science can address this emerging gap in the e-health field by augmenting existing models, that explain organizational and individual ehealth behaviors retrospectively, with prospective models that can guide implementation. The organizational planning discipline, with its decades of research, could provide a cross-disciplinary "jump start" to developing an e-health implementation model for health organizations.[2, 3] Henry Mintzberg, a respected pioneer in this field, describes 2 beneficial approaches to planning: the *deliberate approach,* which is grounded in pre-implementation planning, and the *emergent approach* that is grounded in adapting to the environment as the plan is implemented.[4] The proposed e-health implementation model, called the Network for the Improvement of Addiction Treatment–Technology Implementation *(NIATx-TI) Framework,* incorporates both approaches.

NIATx-TI was piloted in the Iowa Rural Health Information Technology Initiative (IRHIT) with 14 of Iowa's 105 SUD treatment sites and resulted in a 2-fold increase in patients receiving distance treatment. The framework's *deliberate* component includes using an organizational technology assessment[5] and patient simulation.[6] These tools identify and address assets and barriers to incorporate into the technology's implementation protocol. The framework's *emergent* component includes using a project team to uncover and prioritize implementation barriers as they arise, develop changes to address identified barriers, and monitor selected adoption measures, while receiving monthly coaching.

This project, based in Iowa, will compare a control condition (using a typical product training approach to software implementation that includes user tutorials and instruction on administrative and clinical protocols, followed by access to on-line support) to the typical product training combined with NIATx-TI. While e-health spans many modalities and health disciplines, this project will focus on the implementing Addiction Comprehensive Health Enhancement Support System (A-CHESS), an evidence-based SUD treatment recovery app developed by our Center for a disease that affects 21.5 million and kills 136,000 Americans annually: substance use disorder.[7] A mobile app was selected, as opposed to another e-health technology, because of the near ubiquitous daily use of mobile technology and because mobile e-health adoption requires supportive participation of both health centers and patients.

In response to the COVID-19 pandemic, we have added a study component focused on describing how patients are responding to receiving remote treatment (e.g., telehealth). We will also seek to understand how using A-CHESS mitigates COVID-19 associated anxiety and loneliness among those with substance use disorders.

1. BACKGROUND AND SIGNIFICANCE

This project addresses an issue of substantial public health significance: enhancing the uptake of the growing list of patient-centered evidence-based addiction treatment e-health technologies.

Substance Use Disorders (SUDs) Impact on Society and Health. Every day on average, 96 Americans die due to opioid overdoses and another 6 die due to alcohol poisoning, making SUDs the third-leading cause of preventable death in the United States.[8] Many injuries and

diseases (e.g., cancer, diabetes, cardiovascular problems, cirrhosis, and HIV/AIDS) are caused or exacerbated by alcohol abuse.[9] Despite the health and societal consequences of SUDs, just 9.2% of those who need treatment receive it[7] and, for those treated, 75% fail to achieve longterm sobriety.[10] **The gap between the need for and the effectiveness of SUD treatment services calls for implementing fundamentally different treatment modalities to improve SUD.**

Patient-centered Mobile E-health: A Potential Answer? Patient-centered mobile e-health technologies offer innovative ways to improve treatment and recovery supports for SUDs.[11] Seventy-seven percent of the adult population in United States currently have a smartphone,[12] as do 74% of adults accessing Iowa SUD treatment clinics. By 2020, over 95% of the US population is expected to have smartphone access.[12] Meta-analyses of mobile behavioral ehealth interventions have found superior treatment outcomes when compared to treatment as usual.[13,14] The combination of consumer interest, research evidence, and the number of research dollars being dedicated to evaluating these technologies will continue to place positive pressure on the use of e-health. **Despite the promise of e-health, its potential benefits are far from being realized**.[15-17] A prominent example of this is in SUD care. Despite the availability of evidence-based e-health tools such as the Drinker's Check-up,[18,19] Therapeutic Education System (TES),[20] CBT4CBT,[21] and A-CHESS, none of these technologies are used by >1% of SUD treatment providers.[22] **This proposal tests the premise that an evidence-based technology implementation framework can reduce the gap between patient-centered ehealth evidence and practice.**

Technology Adoption Models: Strengths and Needs. Extensive research supports building models to speed diffusion and sustainability of technology adoption.[23] Technology adoption research began with models, grounded in behavioral change,[24] explaining why individual users abandon traditional practices in favor of new technologies.[25] Over time, these individual-focused models have had to expand because of the necessary role organizational practices and climate play in individual decisions to adopt and continue to use a technology.[26,27] Explanatory models emerged based on 2 prominent frameworks: the diffusion of innovation and the technology, organization, and environment framework.[24] These frameworks include the key organizational factors of management support, clinician satisfaction, clinical workflow, and financial resources for technology purchase, implementation, and use.[28,29] Financial resources such as start-up grants and reimbursement supporting technology use are important factors in technology adoption. However, reviews by Brooks[28] and Jeyaraj[29] demonstrate that reimbursement cannot be the only issue considered. Two health technology implementation projects conducted by our Center in 7 different states during 2012–2015 confirmed that patient, clinician, and organizational as well as financial barriers can limit technology adoption. In seeking approaches to address these multi-faceted barriers, we were surprised to find that most models described the barriers,[30,31] but not how to address them. **In seeking technology implementation models, we realized the organizational planning field could provide the frameworks needed to address the competencies and processes that remained unexplored in previous technology implementation research.**

Planning Model Theory as a Conceptual Foundation for Network for the Improvement of Addiction Treatment (NIATx)- Technology Implementation (TI): Two important evolutions have created a planning field that has remained relatively stable in theory and approach for the past 2 decades.[32] The first was Porter's (1979)[33] 5 competitive forces framework, which created a foundation for deliberate planning. This "look before you leap" planning approach relies on a centralized planning function and development of "the plan." Concerns with this methodology led Mintzberg and Waters (1985)[4] to assert that Porter's *deliberate (*sometimes called

prescriptive) planning for organizational strategy and change was necessary, but not sufficient. Simply too much occurred once a plan was hatched. Their *emergent (*sometimes called *descriptive) planning* approach used data that emerged from the implementation process to improve the plan. This moved planning from a purely centralized (top-down) process to include a more emergent (staff engaged) approach.[34-36] Using these concepts, our Center, The Center for Health Enhancement Systems Studies (CHESS), searched through our field experiences[37-40] and the literature, for pre-implementation (*deliberate*) as well a post-implementation (*emergent*) strategies capable of quickly adjusting to environmental feedback to construct the NIATx-TI ehealth implementation framework.

Mobile Technology as a Focus was selected because of its pervasive use, the evidence base for the CHESS platform that supports A-CHESS, and our familiarity with A-CHESS**.** A-CHESS is based on the CHESS platform, which has been studied in 16 randomized control trials (RCTs) over 16 years, using several technology media.[41-43] These RCTs, each involved hundreds of people, found that the CHESS platform improved key dimensions of quality of life,[41,
44] health behavior adherence (e.g., smoking cessation and risky drinking),[45-47] and outcomes (e.g., lung cancer death rates and sobriety). A-CHESS is consistent with respected health behavior change models such as self-determination theory (SDT)[48] and Marlatt's Cognitive Behavior model[49] of relapse prevention. In a randomized trial (N=349), patients using A-CHESS, compared to those in the control group, reported 51% fewer risky drinking days in the prior 30 days at the 4-, 8-, and 12-month follow-ups (mean of 1.39 days in A-CHESS vs. 2.75 days per month in TAU, p = .003). Rates of alcohol abstinence were significantly higher among A-CHESS patients at 8 months (78% vs. 67%) and 12 months (79% vs. 66%).[50] The A-CHESS app includes educational materials, discussion groups, links to SUD resources and weekly self-monitoring for patients. The CHESS platform has also been an effective method for clinicians to interact with their patients.[51] A-CHESS provides a report for clinicians that delivers to the clinician team information about worrisome changes in symptoms collected from the patient during self-monitoring of risk-related items (i.e., sleeping problems, depression, urge, risky situation and relationship troubles).[52] A-CHESS contacts the clinical team by email, phone, or fax (according to clinician preference) whenever a threshold symptom is reported. The alert was intended to quickly bring clinician attention to emerging symptoms.

Technology like A-CHESS is a potential game changer: it can provide recovery supports 24 hours a day, 7 days a week and can be customized to individual needs. **This research will test a technology adoption framework to increase use of the A-CHESS smartphone app.** A supplemental study will help understand how A-CHESS may help patients manage increased levels of anxiety and loneliness during the COVID-19 pandemic.

2. STUDY OBJECTIVES

The specific aim of this study is to compare the effectiveness of NIATx-TI (Arm 2) and Product Training (Arm1) in implementing an evidence-based innovation (A-CHESS). Impact will be measured using the RE-AIM framework:[53]

- Reach or Participation (Primary Outcome): a) percent and representativeness, based on age, gender, and ethnicity by organizational site, and b) A-CHESS use per each counselor, by days of use;
- Effectiveness: retention rates of eligible patients overall

- Adoption: percent and representativeness, based on age, gender, race, ethnicity, and education level of counselors referring and not referring patients to A-CHESS;
- Implementation: a) organizational readiness for, and b) fidelity of A-CHESS implementation; and c) qualitative and d) cost effectiveness analyses to develop a better understanding of the implementation processes for delivering NIATx-TI compared to product training alone; and
- Maintenance: A-CHESS use (e.g., A-CHESS downloads and days of A-CHESS use) during the post-test phase.

The specific aims of the COVID-19 supplemental study are 1) to understand whether using A-CHESS may help patients manage anxiety and loneliness associated with social isolation, physical distancing, and other changes to daily life during the COVID-19 pandemic, and 2) to understand how patients have adapted to changes in treatment modality during the COVID-19 pandemic. Impact will be measured by offering all patients who have ever signed up for an A-CHESS account the chance to complete an online survey (administered through REDCap) as well as the opportunity for a qualitative interview with a member of our research team using a standardized interview guide.

Study Coordination

The UW-Madison Center for Health Enhancement Systems Studies (CHESS) is the coordinating site for this study. The UW study coordinator will oversee all recruitment activities which includes:

- developing organizational site-specific recruitment and data collection processes that meet study objectives;
- training staff on protocol procedures prior to start of recruitment and continuous monitoring to assure compliance with the protocol and human subjects regulation;
- communicating with clinic site staff as needed via conference calls to monitor progress, inform of protocol changes/distribute new version of protocol, and address unanticipated issues or challenges;
- and manage all study data.

3. SELECTION OF SUBJECTS

This study will engage SUD organizations, counseling and peer recovery support specialist staff at those organizations, and patients of those organizations.

Organizations: Sixteen SUD organizations in Iowa, with a total of forty sites, have agreed to participate in the project.

Counselors: The site coordinator will invite all outpatient counselors serving adult patients employed by the 16 SUD organizations to be part of the study as part of their role in the participating organizations. Any counselor may formally decline to participate during the training or any time thereafter.

Peer Recovery Support Specialists: Peer Recovery Support Specialists associated with the organization will be invited to be part of the study. Any Peer Recovery Support Specialists may formally decline to participate during training or any time thereafter.

Patients: We will aim to enroll 1,800 outpatients from the 16 enrolled organizations. Each organization is expected to have about 516 A-CHESS-eligible patients on average. We estimate that we will recruit a conservative 30% (or approximately 43 per organizational site) for a total n=1,800 patients in the study. We will recruit patients for the 18-month intervention period plus 6 months into the maintenance period. Patients are eligible for the study if they:

- Are 18+ years old
- Understand English
- Have a SUD diagnosis
- Have access to a smartphone

All patients will be offered the opportunity to complete a survey through REDCap. To date, n=520 patients have created an A-CHESS account. We will also conduct in-depth interviews with 40 patients who have created an A-CHESS account.

4. REGISTRATION PROCEDURES

Recruitment and Consent Procedures

Counselor and Peer Recovery Support Specialists Recruitment:

Initially, Counselors and Peer Recovery Support Staff will be provided with the Counselor and Peer Recovery Support Specialists consent (092518 Version 2.0) when they go to log onto the App (in a similar fashion to how the patient consent is occurring in the study). This will occur prior to the A-CHESS product training. In addition, during the A-CHESS product training, that will occur in both arms of the study, the ACHESS trainer will explain the Counselor Training consent form (10.1 Version 2.0) to the counselors as well as Peer Recovery Support Staff and give them the opportunity to sign the consent form should they want to participate in the study. The trainer will remind counselors and Peer Recovery Support Staff that are not required to participate in the study and can leave the study at any time. For those counselors and Peer Recovery Support Staff involved with the study that are unable to attend the product training, or are hired after the training, those counselors and Peer Recovery Support Staff will be sent an e-mail with the consent form and will be given the opportunity to check the consent form (after reading it) and return it to the research team should they want to participate in the study.

Patient Recruitment:

Patients meeting the criteria outlined in section 3.0 will be introduced to A-CHESS during their first 3 group or individual treatment sessions at the participating clinic. Counselors in both arms of the study that choose to introduce patients to A-CHESS will follow a standard protocol that makes clear that clients should be offered the opportunity to download A-CHESS, but clients are not required to download the app. For group participants, A-CHESS will be offered during every group and anyone who is interested can pick up the A-CHESS URL information sheet, with login instructions, following the group session. A-CHESS will be available as an Internet download to patients in the study. The consent form will be part of the initial sign-on to the A-CHESS application. The consent form will clearly state that use of ACHESS is voluntary and not a condition of receiving treatment services. Once patients download A-CHESS and agree to the consent form via checkbox, they are enrolled in the study.

Organizational and Staff Recruitment:

The organizational survey will be completed by a member of the management team. The staff surveys will be completed by staff that are invited to complete the survey by the site coordinator. (The site coordinator's role in the clinic may be an administrative support position in the quality or staff training departments, a member of clinical supervision, or management.) The site coordinator will inform the staff person that survey completion is optional, and the consent form that precedes the survey in REDCap will also state that survey participation is optional. The site coordinator does not have access to the survey data nor will they receive any data feedback or summaries from the surveys. The consent form will describe that completing the staff or organizational survey infers their consent. For those who do not complete the survey, the survey will not be recorded and no record of the person not wanting to participate will be made.

Patient COVID-19 Supplemental Redcap Survey and Interview Recruitment:

All patients who have signed up for an A-CHESS account will be contacted via email and invited to complete a supplemental survey about their experiences during the COVID-19 pandemic. It will be necessary to collect patient's names and email addresses in order to link their survey responses to passively collected app usage data. Patients will then complete an approximately 30-minute online survey through REDCap. Participants will be remunerated $25 for their time. At the end of the survey, participants will be asked whether they are interested in being contacted by a member of the research team to participate in a follow-up, in-depth interview. A research assistant will contact interested participants and set up a time to conduct an approximately 30-minute interview. Research assistants will go over an informed consent document, and participants will need to consent to interviews being recorded. Participants will be remunerated an additional $25 for their time.

5. TREATMENT PLAN

Treatment as Usual (TAU)/Control: *Product Training/On-line Support* – SUD organizational sites in the TAU or Control arm will participate in 1. day product implementation (or training) period sessions during Ms 11 - 15. On-line technical support will occur for the 18 months following product training.

Product training consists of two components: A-CHESS Demo and A-CHESS Product Training. During the A-CHESS Demo with the organization's IT, clinical leadership, and the A-CHESS site coordinator, the A-CHESS Product Trainer will:

a) describe the features of A-CHESS (Tutorial)
b) provide an A-CHESS organizational case example on how A-CHESS is implemented (including clinical protocols)
c) provide examples of how to recruit and prepare clinicians and patients for A-CHESS

During the 1-hour A-CHESS Product Training, the organization's A-CHESS Site Coordinator and the A-CHESS Product Trainer will train the counselors and Peer Recovery Support Specialists at each site. Prior to the training, the site coordinator will present the Counselor and Peer Recovery Consent Form to each counselor as well as Peer Recovery Support Specialists and give them the opportunity to consent or decline to participate.

For those counselors that agree to participate, the training will include:

a) demonstrating A-CHESS features and how A-CHESS allows patients to self-manage their recovery in conjunction with their counselor.
b) role-playing (or patient simulation) live A-CHESS enrollment with counselors, where they can use the A-CHESS patient description sheet to guide conversations with patients
c) demonstrating how to use the A-CHESS counselor dashboard.

Following the product training session, on-line technical support will be available. Patients and counselors can call or e-mail questions using the A-CHESS portal.

Counselor and Peer Recovery Support Specialist's role (same for Control and Intervention) – The counselors will learn about A-CHESS during the A-CHESS Product training. Counselors and Peer Recovery Support Specialists may use A-CHESS to view comments in discussion groups. Counselors and Peer Recovery Support Specialists will also have access to the counselor dashboard which contains data from his/her patients' weekly reports. The counselor may access the dashboard at any time and can use the information from the dashboard in counseling sessions. Following the demo and training, counselors will identify potentially eligible patients and ask them if they are interested in the study. If yes, the counselor will provide a study overview at a regularly scheduled appointment.

Patients will learn:

- the benefits and potential risks of participation
- how their privacy will be protected.

The counselor will provide a brief introduction to A-CHESS and provide the client with the information necessary to enroll in A-CHESS. If the patient is interested in participating, informed consent will be documented via an IRB-approved consent form on the A-CHESS app, containing the above information regarding benefits, risks and privacy protections. Record of their consent will be stored on a DoIT server at UW Madison. Patients declining participation will receive treatment as usual.

. Staff at the clinic site are responsible for:

- Identifying potential subjects
- Providing patients with the information on how to sign-up for ACHESS

Some (5 or fewer), but not all, counselors and Peer Recovery Support Specialists at each site will be asked to voluntarily participate in the study's annual staff survey. Also, a few counselors and Peer Recovery Support Specialists in the sites who are invited to participate in the quantitative analysis may also be invited to participate in qualitative interviews.

Patient use of A-CHESS app (same for Control and Intervention) – At the first use of the A-CHESS app, the patient will use an automated A-CHESS set up. The set-up tool will train patients to use A-CHESS and customize it (e.g. by sources of support [e.g. family], and contacts who detract from recovery [e.g. friends who use illegal drugs]). A-CHESS will be updated monthly with activities for the healthy event calendar, changes to therapeutic goals and recovery plan (e.g., self-help groups, medication, home-work-education responsibilities), and high-risk locations to avoid. Patients can use video tutorials to practice A-CHESS services and experience how A-CHESS can help them

With subsequent use of the A-CHESS app patients will be asked how they are doing and about their recent alcohol and drug use. These questions will be sent weekly on the A-CHESS system and will take about 2-4 minutes to complete. All questions are voluntary. Patients are free to refuse to answer any questions they are uncomfortable with. However, by answering the weekly questions about their recent alcohol and drug use A-CHESS can send the patient information to help them in their recovery. In addition, data based on their responses will be accessible to his/her clinical team via the *Counselor Dashboard* so the clinic team can provide needed support. This sensitive health information is being collected and shared via the *Counselor Dashboard* to allow clinicians to be better informed and provide treatment more responsively based on their patients' needs as they deal with addiction and other serious health issues. All patients will be reminded that they are under no obligation to participate in this study, can withdraw from the study at any time, and in no way will their health care be affected by their participation in this study.

Intervention: *NIATx-TI with Product Training/On-line Support* – For SUD organizational sites in the Intervention arm, the NIATx TI framework includes the product training as well as a pre-implementation (planning) phase and a post-implementation (problem-solving) phase. A NIATxTI coach (who is also an A-CHESS product trainer) will provide the training for this arm. The coach will also assist the organizations with applying the NIATx-TI framework. **Figure 1** presents the steps in the NIATx-TI Framework.

Pre-implementation (Planning) Phase

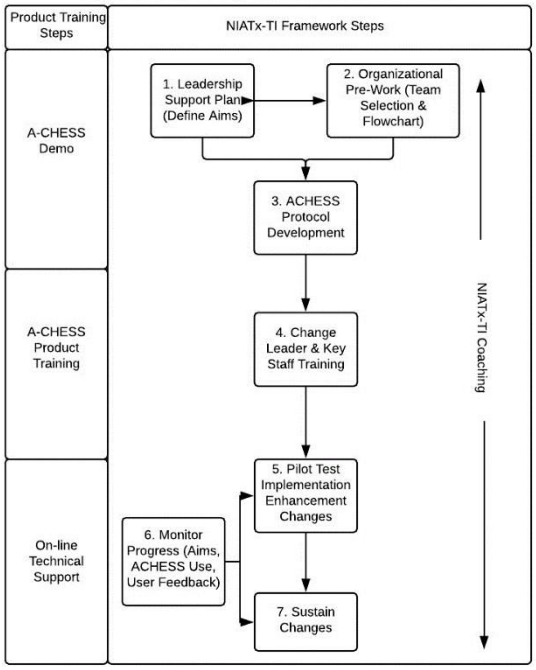
Step1. Define Aims: The NIATx-TI coach will provide an executive briefing on project setup and developing strategic and implementation A-CHESS aims for the organization. (This occurs before Product Training.)

Step 2. Organizational Pre-work & Assessments of assets and barriers, organizational readiness (using OCM).

Step 3. Protocol Development: Develop clinical and administrative protocols that integrate assessment findings. Steps 3 – 5 are part of two partial day NIATx-TI Implementation/Product Training meetings.

Post-implementation (Problem-solving) Phase

Figure 1: Product Training & NIATx -TI Framework Overview



Step 4. Change Leader & Change Team Training/Planning on how to modify organizational processes to address barriers to A-CHESS implementation. This is combined with the Product Training visit/Implementation meeting.

Step 5: Pilot test A-CHESS implementation enhancement changes. During implementation meetings, via a series of Plan Do Study Act (PDSA) cycles as staff and patients are being recruited and trained, unstructured feedback on the progression of A-CHESS implementation will be collected. Step 5 begins at the Implementation meeting and is also part of the iterative PDSA change cycle process with steps 6 and 7.

Step 6. Monitor A-CHESS Implementation by reviewing progress on Aims and gaining real-time user feedback. The A-CHESS app will provide monthly de-identified enrollment reports to the site coordinator or his/her designee on the number of patients enrolled in A-CHESS for the month.

May return to Step 5 again - *Change Cycles or pilot tests* to overcome barriers to implementing A-CHESS. Monthly calls from the NIATx coach support the organization through the change cycles that occur as part of steps 5 – 7.

Step 7. Sustain Changes: Implement plans to institutionalize gains and incorporate use of ACHESS in organizational processes.

Data collection

Surveys: See table 1 for a complete list of Measures, Sources, and Tool/Frequency. Contacts at organizational sites will complete two main surveys: organizational and staff. Clinic staff participants will be sent links to complete the survey via REDCap (Research Electronic Data Capture managed by ICTR).

Organizational Surveys: Will be completed by a member of the management team two times during the project (organizational baseline and end of the intervention.) To increase survey completion rates for the organizational surveys, we conduct follow-up phone calls and e-mails with the change leaders at Week 1 of post-survey distribution to assure the survey receipt, then at Weeks 4 and 12-post survey distribution if surveys are not complete.

Staff Surveys: The full organizational and staff surveys (A-CHESS Implementation Fidelity, Organizational Change Manager, and Financial Resource Availability) will be administered two times during the project organizational baseline and end of the intervention). A 'generic' version of the Organizational Change Manager (OCM) will be administered prior to training. This

version of the survey will include questions that focus on prior change projects or innovations in the organization. During the second administration the OCM (as part of the full Staff Survey, the OCM questions will focus on the planned implementation of the e-health app. Each survey (A-CHESS Implementation Fidelity, Organizational Change Manager and Financial Resource Availability) is expected to take approximately 15 minutes or less to complete. Up to seven staff including a clinical supervisor, an administrative staff person, and up to 5 randomly selected counselors and Peer Recovery Support Specialists will complete the staff surveys. Staff completing surveys will receive consent documents when they are sent the survey link.

Each organizational site will receive a $1000 stipend once all organizational and staff surveys, have been completed.

The trial will use 4 cohorts that will have staggered starts in order to have sufficient training resources for the trial (Figure 2). Each cohort will have 2 matched pairs with a control and treatment site in each pair, resulting in 4 organizations per cohort and n=16 organizations total.

Figure 2

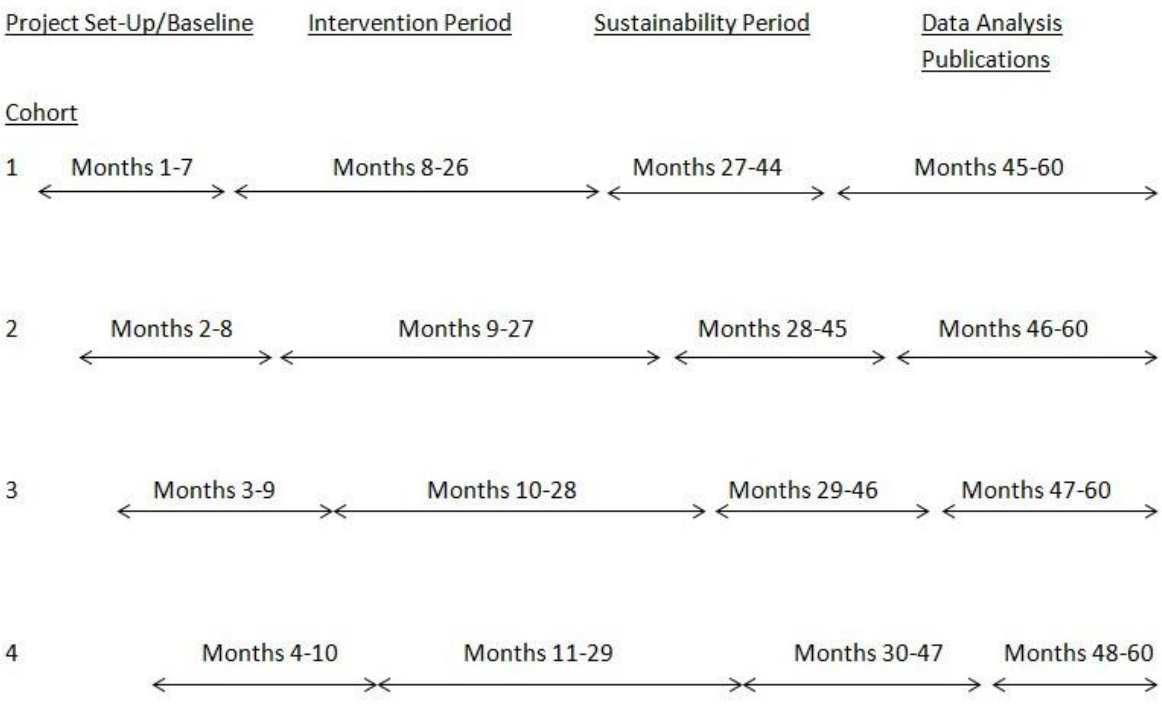


Table 1 - Measures, Sources, and Tool/Frequency

Measurement	**Measure Source**	**Data Source/Frequency (for Cohort 1)**
Descriptive Statistics		
Organizational traits: Admissions, Rural v. Urban *Patient traits*: Age, Gender, Ethnicity, and Poverty Level	N-SSATS[55] TEDS[56]	IDPH – Ms 11, 22,34, 46IDPH – Ms 11, 22,34, 46
Counselor traits: Age, Gender, Ethnicity, Race, Certification or education level		Organizational Survey – Ms 12, 30
Reach		
% who download A-CHESS app and frequency of A-CHESS use in days	Gustafson et al.[50]	A-CHESS Server - Monthly (Ms 11 - 47) IDPH – Monthly (Ms11 - 47)
Adoption		
% Counselor Using A-CHESS	Knight et al.[59]	Organizational Survey & A-CHESS Logs
Effectiveness		
Retention (Length of Stay)	Simpson et al.[61]	IDPH- Ms 11 - 50
Maintenance		
Finance Resource Availability	Klein[62]	Organizational Survey – Ms 12, 30

Measurement	Measure Source	Data Source/Frequency (for Cohort 1)
A-CHESS Implementation Fidelity	Developed for this trial	Staff Survey – Ms 12, 30
Organizational Change Manager (OCM)	Gustafson et al.[63]	Staff Survey – Ms 11, 12, 30
Patient COVID-19 Survey		
Patient socio-demographic and descriptive characteristics: age, race/ethnicity, sex, gender, sexual orientation, education, marital status, income, housing, family size, employment status, health insurance	PhenX repository	Patient COVID-19 Survey – once during March 2021
Criminal justice history	Justice Community Opioid Involvement Network	
Alcohol Use Disorder Severity	Saunders et al.; Babor et al.	
Substance Use Disorder Severity	Skinner	
Loneliness	Hays & DiMatteo	
Anxiety	Cella et al.	
Substance use disorder recovery strengths	Vilsant et al.	
COVID-19 risk and protective behaviors and impact on daily living	Adapted from several COVID-19 surveys	

Qualitative Interviews: Qualitative data will be gathered from organizational staff at four points. Qualitative interviews with clinicians and peer recovery support staff will occur during the intervention phase. The goal of the interviews is to gain a better understanding of patterns with app adoption and use. Phone interviews of up to 30 minutes will be conducted with approximately 15 people at various sites. The interviews will be audiotaped (with participant permission), but the staff person's identity will be protected and in no way be linked to results.

Additionally, the study, interviews with staff from a randomly selected site in all organizations will occur at the end of intervention phase and again at the same site at the end of sustainability phase. The intent of the surveys is to gain a retrospective understanding of what occurred during implementation. Phone interviews of up to 30 minutes will be conducted with up to four people in at each site. The interviews will be audiotaped (with staff participant permission), but the staff person's identity will be protected and in no way be linked to results.

Use data: A-CHESS use data will be collected monthly to assess the percentage of eligible patients who download the A-CHESS app per month per site and the frequency of use by app user. For the percentage who download A-CHESS, data will be collected during the 18-month intervention period and 6 months of post-intervention period for that organization. Frequency of use data for an individual user will be collected during the 12-month period following initial use of A-CHESS. The app automatically collects use data by placing "cookies' on patients' smartphones (with patients' consent) when they enroll in the study. Data are stored on a central server at CHESS. Electronic data, such as A-CHESS use data, will be stored on a secure DoIT server which is backed up according to a standard protocol. Access to this data will be limited by granting individuals access via their UW user log-in.

The Iowa Department of Public Health (IDPH) will also provide data available through existing IDPH administrative databases. A preliminary analysis of *organizational* data will compare baseline characteristics between the NIATx-TI and Product Training alone organizations, as well as organizations enrolled in the project and eligible organizations not participating (Admissions, Rural v. Urban, and Gender/Age/Ethnicity, and Poverty Level), using the National Survey of Substance Abuse Treatment Services (N-SSATS)[55] and Treatment Episode Data Set (TEDS)[56] data definitions.

During the study, IDPH will provide *patient* demographic data (gender, age, and ethnicity, using TEDS definitions) for all patients by organizational site. As part of the organizational survey, we will include questions about *counselors'* gender, ethnicity, and race.

Retention data will be collected by IDPH and provided monthly using existing data.

We will use UW Box to store data received from IDPH.

Supplemental COVID-19 Study – Patient Surveys and In-Depth Interviews

All patients who have signed up for an A-CHESS account will be invited to complete an online, standardized survey through REDCap. Protected Health Information will be collected only as necessary; patients who consent to participate will provide their name (on the informed consent) and their email address, phone number, and zipcode (on the survey). All participants will be assigned a unique study ID number that will be stored with their survey data (names will not be collected on the survey) and the informed consent document will provide the only link between the patient's name and study ID number. Informed consents and survey data will

be stored securely and separately to minimize any risk of compromising patient privacy. Patients will be asked to report their socio-demographic information, level of loneliness and anxiety, criminal justice system involvement history, substance use disorder and treatment history, and COVID-19 risk and protective behaviors. On the informed consent, patients will be informed that they can skip or stop the survey at any time. A total of $25 remuneration will be provided.

At the end of the survey, patients will be asked if they would like to be contacted about the possibility of completing an in-depth interview about their treatment and A-CHESS experience during COVID-19. If they are interested, a research study team member will reach out to them by email and/or phone, explain the study and informed consent document, and conduct an in-depth interview. Again, a unique study ID number will be used instead of the patient's name. During transcription of interview recording, any remaining identifying information stated by the patient will be removed prior to analysis. Recordings and transcriptions will be stored securely and separately from informed consent documents.

Unanticipated events

Should any unanticipated problems arise, they will be reported to the IRB reviewing the site and the UW-IRB per the appropriate IRB's guidance on unanticipated problems and reportable events.

Privacy and Confidentiality

Since substance use disorder (SUD) treatment sites will play a role in the testing of the NIATx Technology Implementation (TI) and Product Training implementation strategies, we view both consumers (patients) and staff members as human subjects. For the project's evaluation plan, we will address human subjects' protection from both the staff and consumer levels. CHESS (The Center) has addressed human subjects' protection during the development and testing of A-CHESS, the technology, the NIATx-TI Framework and product training approaches we will attempt to implement. The Center has successfully handled sensitive personal health information in numerous studies of CHESS modules, including cancer, asthma, and the A-CHESS app.

The data to be collected in the evaluation will come from existing consumer data collected in state administrative databases, user data automatically collected by the A-CHESS App server (based on the activities of the unique users), organizational and staff surveys, and staff interviews. Table 2 (below) briefly describes the individuals referred to in the protection plan who will have access to the project data and their level of access.

Table 2 Research participant overview

Title	**Affiliation**	**Access**
Clinic A-CHESS Site Coordinator	Participating Clinics	Consumer A-CHESS App server data only. They will not receive or view any administrative, survey, or interview data

Clinic staff member(s) - clinicians only	Participating Clinics	Consumer A-CHESS App server data for his/her patients only. They will not receive or view any administrative, survey, or interview data
State database administrator	Iowa Dept. of Public Health	Consumer administrative data only. They will not receive any A-CHESS App server, survey, or interview data
Scientific Director (PI)	UW-Madison	Limited Data Set consumer administrative data, A-CHESS App server, survey, and interview data
UW project team (researchers/students)	UW-Madison	Limited Data Set consumer administrative data, A-CHESS App server, survey, and interview data

Study Design

Staff level: The A-CHESS Site Coordinator within each treatment site will handle recruitment for employees to complete interviews and surveys. Information on the implementation process will be gathered from clinic staff members during surveys and interviews. Staff participation will be voluntary. The PIs (Dr. Molfenter and Dr. Gustafson) are formally trained on human subjects' protection.

The Organizational Change Manager (OCM), and ACHESS Implementation Fidelity will be assessed by staff survey at months 11 – 14 and 30 – 33 for the four cohorts. Each survey cycle, at months listed above , ill include 280 people per cycle. The 280 staff will include up to 7 participants from the 40 sites and will likely include a supervisor, a member of administrative staff, and up to 5 counselors and Peer Recovery Support Specialists. Since many of the same staff will likely complete surveys in successive cycles, 350 unique staff are expected for survey completion across all cycles. The total is not 560 unique people (e.g., 280 x 2 rounds of surveys) because many of the same people are expected to complete the survey in successive rounds. The 350 unique people projected assumes 25% or 70 new people per round during rounds that occur post-intervention. Hence, there will be 280 unique people in the early intervention – and 70 new or unique people in the subsequent round (post-intervention), for a total of 350.

During the intervention as well as at the end of the intervention phase and at the end of the sustainability phase we will conduct qualitative interviews. We will conduct an interview with staff at an organizational site from each of the 16 organizations in the study. During the intervention we will interview approximately 15 clinicians or peer recovery support staff regarding success with getting patients on the app. We will assess the implementation process in both the product training alone (Arm 1) and NIATx-TI sites (Arm 2).

Staff participation will be voluntary. Jacobson, Horst, and a staff person from the Iowa Consortium for Substance Abuse Research and Evaluation will conduct telephone interviews

with up to 4 staff members (the organization's Executive Director, the site's clinical director, the A-CHESS site coordinator at each clinic, and a randomly selected counselor) at 16 sites. This will result in 64 interviews per period for a total of 80 interviews (assuming 25% turnover for between the rounds of interviews). During the interviews, participants will reflect on their participation, issues that arose in using NIATx-TI and A-CHESS, factors that influenced acceptance, and perceptions of short- and long-term effects, as well as unintended consequences.

The grand total of staff surveys for the main study, at n=350, and staff interviews, at n=80 participants, is 430.

We will create and distribute an information sheet for staff giving them the option to decline to participate in the trial or A-CHESS distribution.

Organizational Data: We will assess Financial Resource Availability Inventory, A-CHESS Implementation Fidelity, and List of Counselors (for counselor A-CHESS participation rates) at two points during the study - at organizational baseline (M 11 - 14) and end of the intervention period (M30 - 33) (M=months are in a range due to the 4 study periods) The Iowa Department of Public Health (IDPH) will provide, by site, aggregate data on Admissions, and Rural v. Urban. This data will be collected from IDPH databases at months 11, 22, 34, and 42

Consumer level: Eligible consumers will be identified in real time during their first three outpatient appointments with a participating SUD treatment site. Site counselors will provide information about the study. If the patient is interested in the study, the counselor will provide a brief introduction to A-CHESS and provide information to the client with the URL to download A-CHESS. If the patient chooses to participate, informed consent will be documented via an IRB-approved consent form on the A-CHESS app.

To be eligible for A-CHESS, SUD consumers must: 1) be >18 years old; 2) understand and agree to an English language consent form via the A-CHESS app; 3) have access to a mobile smartphone, and 4) have an SUD diagnosis.

We anticipate enrolling consumers to use A-CHESS (approximately 43 per organizational per site, for a n=1,800 for the study). The state (IDPH) will provide de-identified data including gender, age, ethnicity, poverty level, and units of service for each site.

During approximately March 2021, all patients who have signed up for an A-CHESS account (to-date n=520) will be invited to participate in a one-time, online, self-report survey through REDCap.

Sources of Materials

All data will be coded before reaching evaluation staff. These include data collected by A-CHESS App server on A-CHESS use as well as organization and staff interview and qualitative survey data. Coding of consumer and counselor/staff data will take place, where necessary, by replacing identifying information (such as consumer and staff names) with code numbers prior to data analysis. A unique study ID number will be assigned to all patient surveys and in-depth interviews. Names collected through the informed consent process will be stored separately.

Site-level aggregate data will be received from the Iowa Department of Public Health (IDPH). The individual de-identified consumer data from the state database will be transmitted to the University of Wisconsin database administrator (Wright). The evaluation team will monitor overall use and effectiveness of A-CHESS through consumer data directly from the A-CHESS App server.

Consumer level:

A-CHESS usage based on A-CHESS App server tracking of consumer use of their smartphones (for initial log-in, duration and frequency of use).

Surveys and in-depth interviews about COVID-19 associated anxiety and loneliness.

Staff level:

The OCM Survey will collect data on the organizational philosophy. The A-CHESS Implementation Fidelity will document the fidelity to the NIATx TI implementation process.

Counselor level:

The organizational survey will be used to document all active counselors per site. The following information will be gathered about each counselor: title or certification, age, gender, ethnicity, and race. The Iowa Consortium for Substance Abuse Research and Evaluation will check for any changes in counselor employment during quarterly check-ins. This will be used to create and maintain a counselor list to be compared to the counselors listed during A-CHESS log-ins to develop the % of Counselors Using A-CHESS Measure. This same data will not be collected for the Peer Recovery Support Specialist.

Organization level:

IDPH database will provide program characteristics and organizational descriptive characteristics and will collect data on the nature and scope of the individual SUD treatment sites. Site-level aggregate data on adults with SUD diagnosis by organization by site, including gender, age, and ethnicity. Retention data will also be obtained from IDPH.

The organizational survey will also collect the names and demographics of all counselors and Finance Resource Availability assessment. The Finance Resource Availability assessment assesses the resources the organization dedicates to adoption of the targeted technology.

6. POTENTIAL RISKS

Staff level:

Staff members could feel pressure to participate in the study. It will be made clear, through written materials and oral instruction, that staff participation in the project's evaluation is completely voluntary. The cost and implementation analyses and their purpose in understanding the feasibility of implementing A-CHESS will be explained. Staff responses to interviews will be

coded and responses will be accessible only by evaluation team members (survey and interview data will not be accessible to other clinic staff members, including the A-CHESS Site Coordinator). If staff members are asked to complete the interview or survey, but refuse, the A-CHESS Site Coordinator will attempt to identify replacement staff respondents. In addition, members of management and clinical supervision will be notified of the importance of staff not feeling coerced to participate the study, A-CHESS recruitment, or survey completion.

The potential risk for staff is that the information they provide could be offensive to members of management or their peers. Hence, protecting staff confidentiality is an important element of our protection plan. Researchers (Jacobson, Horst) trained in protecting consumer confidentiality will conduct interviews. Data collected in the interviews and surveys will have a code number assigned (as previously defined) attached prior to storing in the project dataset. In this way, we can ensure that the interviewer (in the case of interviews) and the University of Wisconsin database administrator (in the case of surveys) will be the only person who can identify the interviewee's responses. Also, managers or other members of the organization will not see transcripts of interviews.

Consumer level:

There is a risk that patient subjects may feel uncomfortable sharing personal information or answering weekly survey questions through A-CHESS or questions about COVID-19 on the supplemental survey and in-depth interviews, especially about sensitive topics. Participants will be asked personal questions related to past behaviors and experiences, such as illicit drug use, that could produce psychological stress.

The on-line consent process will inform consumers of the need to provide the A-CHESS app with information on an ongoing basis to determine whether treatment goals are being met. Consumers must agree to allow monitoring of their A-CHESS usage. We will ask consumers to consent to share information with their SUD provider. Consent to share information will also be provided through the consent form and will comply with 42CFR regulations, specifying what information will be shared with the SUD provider and how long the information will be shared. The consumer will be given the right not to share specific information with specific people and retain the right to revoke the permission granted at any point. Informed consent and assurance of confidentiality, with a description of privacy protection measures, should assist with lowering participant anxiety.

An additional and similar consent process will be used for the COVID-19 supplemental patient survey and in-depth interviews. Individual survey and in-depth interview results will not be shared with anyone outside the research team, including with counselors or others at the treatment organization.

Consumers can turn on must consent GPS monitoring of their location via A-CHESS, which could pose a privacy risk. GPS monitoring is included in A-CHESS to trigger a system response when consumers approach high-risk locations. These locations are identified and entered by the consumer. GPS monitoring will be used for no other purpose than avoidance of high-risk locations. The GPS data is strictly a feature of the A-CHESS app and will not be used for any type of analysis as part of this study. Users are able to turn the GPS monitoring on or off (and similarly can choose whether or not to participate in other aspects of A-CHESS such as the

discussion group). The COVID-19 surveys do not involve GPS monitoring, but the patient survey will ask about patients' zipcode to help understand their COVID-19 risk and community spread. All protected health information will be stored securely and only with a unique study ID number (not the patient's name).

There is also a risk of breach of confidentiality. Dissemination of some of the more sensitive information could result in risk to reputation. To mitigate the risk of consumer breaches of confidentiality, all subjects will be assigned a code number. A list of subject code numbers will be maintained by the project director (Horst) and stored in a password-protected spreadsheet.

There is a risk that information and resources consumers may divulge in A-CHESS will be used to the detriment of the subjects. Particular sources of risk include A-CHESS communications written within the discussion groups or personal profiles. Consumers will be instructed not to use their real names as a code name and will be warned of the potential dangers of divulging confidential information (e.g., real names or telephone numbers). An explicit statement regarding security and lack of confidentiality will be provided each time users enter discussion groups. These data will be collected by subjects' codename and will not be attached to real names or identities.

Additionally, numerous methods are taken to assure the security of ACHESS data, COVID-19 survey data, and patient in-depth interview recordings and transcriptions. The data from various components of A-CHESS will be housed on the secure CHESS servers at the University of Wisconsin. A database administrator (Wright) will be the only member of the evaluation team who will have direct access to this database. The CHESS Center, Dr. Molfenter, and Wright have extensive experience with HIPAA and IRB compliant practices for accessing, storing, and using personal health information. Furthermore, the A-CHESS registry is equipped with a log that records who accessed what data, at what time, and for how long as an added layer of security. Consumer data will be identified using a unique A-CHESS ID number (based on the A-CHESS log-in). Similarly, survey and in-depth interview data will be stored securely as indicated above.

In summary, during the on-line consent, potential subjects will be informed of (1) the nature and purpose of the study, (2) the types of data that will be collected from smart phone use tracking, (3) measures taken to insure the confidentiality of data collected (4) their right to leave the study at any time, and (5) the timeline of the study. Consent will be documented by obtaining online IRB-approved consent forms containing all of the above information. Consent forms will be digitally based. The A-CHESS system will store the consent form at the University Wisconsin – Madison on a secure server. The consumer can download a PDF of the consent form. Upon signing the consent forms, the A-CHESS Site will provide a unique login name for the system, a mandatory requirement of HIPAA. A similar online consent will be provided to participants invited to complete the COVID-19 patient survey. Verbal consent with a trained research assistant will be used for in-depth interviews related to COVID-19. Copies of all consents will be provided to participants and stored securely.

A Certificate of Confidentiality has automatically been granted by virtue of this study being funded through the National Institutes of Health. This provides an additional level of protection for participant data.

There is a risk that inaccurate or harmful information could be provided to consumers; to

mitigate this risk, all A-CHESS content has been screened by experts from our A-CHESS Consumer Advisory Committee, which has existed at the Center for 7 years. Despite the rigorous review process that occurs with all CHESS content, we will encourage study participants during training to contact their counselor or A-CHESS Site Coordinator if they are uncomfortable with the information provided by A-CHESS.

Features such as a "panic button" could produce over-reliance on a system such as A-CHESS to provide support during periods of intense craving and when the perceived risk for relapse is high. We don't expect that such incidences would be frequent. It is possible that a counselor and peers may not be immediately available to answer a call for help from an A-CHESS user. Study participants will be told that every effort will be made for their pre-designated support team to follow-up on their call for help. Additionally, if nobody in their immediate support network is able to respond, the individual calling for help will be forwarded to the central desk of their treatment agency and referred to other support people as needed. Study participants will be told during training that the panic button is for the most serious situations where relapse is imminent, and not to be used when other modes of communication (e.g., phone call, text message) will suffice.

Study data collected at both the staff and consumer levels will be input to a SQL Server database housed at CHESS for analysis purposes. The University of Wisconsin database administrator will manage access to appropriate levels of study data for the evaluation team via password-protected accounts.

7. MEASUREMENT OF EFFECT

All scales used in this study have good psychometric properties with similar populations. Listed below are the factors to be measured and measurement instruments with references to validation studies.

Descriptive Statistics - Organizational traits such as admission and rural v. urban will be obtained via IDPH data at four points during the study (N-SSATS[55]). Patient traits such as age, gender, ethnicity, and poverty level will also be obtained at four points during the study via IDPH data (TEDS[56]). Counselor traits such as gender, ethnicity, race, and certification or education level will be obtained via the organizational survey.

REACH - The percentage of patients that download the A-CHESS app and frequency of use in days will be obtained monthly during the study via the A-CHESS server and IDPH data.[50]
Adoption - The percentage of counselors using A-CHESS will be assessed via the organizational survey and A-CHESS logs.[59]

Effectiveness - Retention (length of stay) will be assessed using IDPH data.[61]

Maintenance - The organizational survey, which will be administered at two points during the study, will assess Financial Resource Availability.[62] The staff survey will assess A-CHESS Implementation Fidelity (developed for trial) and Organizational Change Manager (OCM)[63].The OCM and A-CHESS Implementation Fidelity will be administered at two points during the study.

Patient COVID-19 Surveys – Surveys will assess how A-CHESS use may have lessened the impact of COVID-19 on anxiety and loneliness. We will collect several patient socio-

demographic traits as recommended by NIH, including age, race, self-identified gender, sex at birth, approximate income level, educational attainment, sexual orientation, marital status, housing type, family size, health insurance. We will use several validated measures to assess patients' substance use severity, loneliness, anxiety, and substance use disorder recovery strengths. Where validated measures are not available due to the rapidly emerging COVID-19 situation, we have drawn measures from existing population-based studies recommended by the National Insititutes of Health.

8. STUDY PARAMETERS

The 16 participating Iowa SUD organizations will be assigned to the

- Control arm (typical Product Training/On-line Support alone, n=8 organizations, n=20 sites) or
- Treatment arm (NIATx-TI framework plus Product Training/On-line Support, n=8 organizations, n=20 sites)

We will use a stratified randomization (or blocking with matched pairs). The matching criteria, using organizational characteristics and technology adoption traits, are:

a) Innovation score per organization

b) # of rural sites (due to the digital divide in these areas)

c) # of outpatient sites per organization.

The innovation score per organization will be calculated based on the level of "success " (i.e. volume of patient enrollment) the organization had with implementing an online gambling portal in 2014. The implementation of the online gambling portal was in partnership with the Iowa Department of Public Health, who will provide gambling project enrollment numbers. This is an objective and relevant measure for innovativeness of the organizations as we will be implementing a mobile technology that will require the organizations to disperse the technology to their patients.

We will apply urn randomization to achieve arm balance, using these 3 traits (e.g., # above/below mean for each trait or # of outpatient sites). An organization from each matched pair will be assigned to a study arm. Organizations (and their staff and patients) will have access to A-CHESS for the duration of the study regardless of which arm they are randomized to. Organizations and staff in the treatment arm will have access to NIATx-TI for 36 months.

9. STATISTICAL CONSIDERATIONS

Sample Size, Power & Data Analysis Plan: We will fit a mixed-effects model with the appropriate link function (e.g., linear, log) to the monthly results for the performance measures, % of eligible A-CHESS users and frequency of A-CHESS use, for each of the participating organizational sites, clustered by organization, and estimate the NIATx-TI framework and

product training effects. A mixed-effect model offers 2 advantages over conventional regression models: 1) The mean outcomes for a given treatment organization are expected to be correlated from month to month. A mixed-effect model allows for auto-correlated error terms. 2) Many unobservable treatment organizational site characteristics are likely to influence the key measures. Random effects at the treatment organization site level can be employed within the mixed-effect model to capture the correlation introduced by such characteristics. Proper reflection of auto-correlation and random effects allows for more reliable estimates of the fixed effects, starting at baseline, then again during the 18-month test and post-test periods. The power of the study design is determined by the anticipated standardized effect size based on effects experienced in the IRHIT project. The standardized effect size is calculated following Cohen's definition of mean effect size divided by effect size standard error.[65] The higher the standardized effect size, the more powerful the study design. Historically, cluster-randomized trials portray the standardized effect sizes of 0.2, 0.5 and 0.8 as small, medium, and large respectively. The IRHIT pilot data found that NIATx-TI increased client technology use rates by 12.4% (increase of intervention success), which can be transformed into Cohen's d = 0.352.[66] Intraclass correlation (ICC) among sites affects the power of cluster-randomized trials.[67] An estimate of ICC is around 0.10.[50] With a total of 8 organizations, with 20 organizational sites in each arm, where each site has an average 62 eligible patients, the study will achieve a power of .90 with a type I error rate of 0.05.

Mediational (and Maintenance) analysis: We will examine the mediating effects of organizational factors of: % of counselors using A-CHESS, organizational readiness (via OCM), financial resource availability (via Klein's inventory), and A-CHESS implementation readiness on A-CHESS use through a causal mediational analysis, using data from end of intervention periods. These factors will be analyzed using mixed-effects models. Through a mediation analysis,[68,69] we can estimate the direct (A-CHESS use with NIATx TI and Product Training) and indirect effects (Adoption and Implementation factors) of each implementation arm on A-CHESS use. We will test the mediation effect of each potential mediator at each time point as well as across time. The R package 'mediation,' will estimate the causal mediation effects, examine moderated mediation effects, and conduct sensitivity analysis.[70]

Effectiveness analysis: We will compare a retention rates in the 2 different arms using hierarchical linear models, where arm membership is used as the treatment assignment. We will examine the distribution of this outcome measure and will implement an appropriate transformation or nonlinear link function when appropriate (e.g., logistic, Poisson, exponential). Monthly data collection of the Effectiveness as well as Reach (A-CHESS Use) measures, allows for analysis after each stage of NIATx-TI.

Qualitative Analysis: The qualitative portion of the study will support the specific aims by exploring how NIATx-TI and product training are implemented, how implementation affects ACHESS use, and how staff users react to NIATx-TI, product training, and A-CHESS. *During the study*, interviews with a randomly selected site in all organizations n=16 will occur at Ms 26-30 (at the end of intervention phase) and 44-48 (at the end of sustainability phase), with the same sites in each phase, to gain a retrospective understanding of what occurred during implementation. The interviews will include closed and open-ended questions designed to explore participants' experiences within each arm and the perceived effectiveness of each approach in assisting with implementing A-CHESS. The closed-ended questions will be based on elements of CFIR, developed by Damschroder et al. (2013),[71] that will address: 1) intervention characteristics; 2) outer setting; 3) inner setting; and 4) process. The additional open-ended questions will allow for discovery of other factors affecting NIATx-TI, product training, and A-CHESS implementation. The information collected will inform our understanding

of implementation assets, barriers, and potential revisions for each approach. Interviews of up to 30 minutes will be conducted with the organization's Executive Director, the site's clinical director, the A-CHESS site coordinator, and a randomly selected full-time site counselor. Four interviews/organization will result in n=64 interviews per phase and up to n=80 interviews overall (assuming 25% turnover between phases).

The qualitative analysis will be conducted by a team consisting of a qualitative methodologist (Jacobson), an outreach specialist from the Iowa Consortium for Substance Abuse Research and Evaluation, and Project Director from NIATx/CHESS. Jacobson will train the research team to assure that proper and consistent interviewing and analysis techniques are used. All interviews will be audio recorded and transcribed verbatim. Using a coding scheme derived from CFIR concepts, project staff will conduct a directed content analysis[71] of these data. To assure coding consistency, every fourth interview will be double-coded. Significant inconsistencies will be discussed within the team and recoded. In addition, an inductive approach based on grounded theory and dimensional analysis[72-74] will be used to identify and explore additional contextual and process factors that affect NIATx-TI and product training, as well as A-CHESS use. The inductive analysis will emphasize open and axial coding; coding divergences will provide opportunities for further reflection and exploration during team analysis meetings. Both directed and inductive analyses will include within-site, cross-site, and cross organization comparisons. Qualitative analysis will begin with the first interview and will continue in tandem with data collection, allowing the investigators to use later interviews to delve into factors that are identified in early interviews.

The qualitative analysis will produce a description of the technology implementation process. It will encompass grounded explications of the theoretical concepts that influenced development of the NIATx-TI framework. This description will enhance our understanding of how the NIATxTI framework works, promoting valuable insights that can be applied to future dissemination of mobile e-health applications.

Analysis of Supplemental COVID-19 Patient Survey and In-Depth Interview Data: Patient survey data will be matched with longitudinal app usage data. We anticipate using linear regression models to quantify the association between app usage (modeled continuously and binary as an indicator of meaningful use of A-CHESS) and several continuous outcomes based on validated measure – anxiety (PROMIS 29) and loneliness (UCLA Loneliness Scale-8). We will adjust for potentially confounding variables, including socio-demographic characteristics, recovery capital, criminal justice involvement, and substance use disorder severity. Further, we will use logistic or log-binomial regression models to assess how app usage is associated with substance use disorder treatment participation (e.g., AA/NA/self-help group participation, attendance at group therapy).

10. RECORDS TO BE KEPT

- Organizational traits
- Patient/counselor traits
- Survey results (Organizational and staff surveys, COVID-19 surveys)
- A-CHESS Server data specific to project

- IDPH data

Appendix A: CHESS DATA SECURITY PLAN

In accordance with the Health Insurance Portability and Accountability Act (HIPAA), CHESS has adopted the following Data Security and Monitoring Plan:

Data Security Officer. Matthew Wright is the primary security officer for CHESS. Responsibilities of the security officer includes: developing information technology (IT) security policies, increasing security awareness for all CHESS staff, providing virus protection for IT resources, maintaining security patches on computing equipment, developing and implementing back-up procedures, performing periodic vulnerability scanning on IT equipment, reviewing and updating firewall strategies and policies, and enhancing the physical security of IT resources.

Training. Before gaining access to our data, all of our students, faculty and staff must provide our Data Security Officer a copy of their certificates of completion of the UW-Madison Human Subjects online training (http://info.gradsch.wisc.edu/research/compliance/humansubjects/tutorial/) and the online HIPAA Privacy Rule training: http://www.wisc.edu/hipaa/ResearchGuide/index.html. Furthermore, they are required to complete training on CHESS security procedures and policies and sign a "CHESS Data Security Policy Certification" upon completion of this training.

Workstation. All workstations will require login with a unique user name and password. Users will log-out from or lock workstations when leaving them unattended. Screen savers will be configured to require a password to activate after 10 minutes of workstation inactivity. Users requiring virtual private network (VPN) access to the CHESS network will only do so with computers specifically certified by a CHESS Data Security Officer.

Passwords. Users require a password to access any computer connecting to the CHESS network. Passwords may not contain all or part of the user's account name and must be at least 7 characters long. Passwords may contain characters from 3 of the following four categories: English uppercase characters (A through Z); English lowercase characters (a through z); base 10 digits (0 through 9); non-alphanumeric characters (e.g., !, $, #, %). User accounts will be locked after 5 failed login attempts and will reactivate automatically after 30 minutes of no failed attempts. Passwords may not be stored in proximity to the workstation and may not be shared by others.

Data created by subjects as they use ACHESS. Data are not stored on smartphones, so there is no danger if a subject's phone is stolen. Hackers could obtain data from the server, but useridentifying data are not stored on servers. We do not ask for identifying information (e.g. addresses, phone numbers) on ACHESS. Users receive code names and passwords. Users could walk away from their phone and not log out, leaving sensitive information on screen. We warn users (on enrollment, during training, and when they use the services) to not share personal data in the on-line discussions or ask-an-expert service and to close the browser if they leave ACHESS. All dynamic pages are configured so the browser stores a local copy only when they appear on screen. Cookies last only for the duration of the session. We use encryption software on our system so the website will be secure.

Storage, Retrieval, and Disposal of Protected Information. Any computer-based Consumer Identifiable, Confidential, or Personnel Data will be stored on secure servers only and may not be stored on individual workstations. Currently, the only place such information can be stored is a secured section of the CHESS Intranet. Servers within CHESS will be located in locked rooms with limited access. The CHESS Data Security Officer will be responsible for assigning and restricting access to shared resources on the CHESS servers. Consumer Identifiable,

Confidential, and Personnel Data may not be copied to or stored on CHESS publicly accessible servers at any time. Remote access to files on secure CHESS servers may be provided only through a virtual private network (VPN) on a certified CHESS Workstation (See CHESS Workstation policy above for details). Storage media will be rendered unusable before disposal. All back-up media will be stored in locked rooms with limited access.

Sending data by fax. All correspondence via fax must be stripped of consumer identifiers. The sender must call the receiver to ensure the receiver is available to receive the fax.

10. ACRONYM LIST

ACHESS	Addiction Comprehensive Health Enhancement Support System
CBT4CBT	Computer Based Training for Cognitive Behavioral Therapy
CFIR	Consolidated Framework for Implementation Research
CHESS	Center for Health Enhancement System Studies
ICC	Intraclass correlation
IDPH	Iowa Department of Public Health
IRHIT	Iowa Rural health Information technology Initiative
NIATx-TI	Network for the Improvement of Addiction Treatment-Technology Implementation
N-SSATS	National Survey of Substance Abuse Treatment Services
OCM	Organizational Change Manager
PDSA	Plan-Do-Study-Act
RCT	Randomized Control Trials
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
RIS	Readiness for Implementation (of Technology)
SDT	Self-Determination Theory
SUD	Substance Use Disorder
TAM	Technology Acceptance Model
TAU	Treatment as Usual
TEDS	Treatment Episode Data Set
TES	Therapeutic Education System

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