Version 5/5/2015

Implementing Technology-Assisted Drug Treatment and Relapse Prevention in FQHCs.

PRINCIPAL INVESTIGATOR: **David H. Gustafson, PhD.**
University of WI - Madison
Department: Industrial Engineering
1513 University Avenue, ME Bldg. Suite 4109
Madison, WI 53706
Phone 608.263.4882
Fax:608.265.3281 or 608.890.1438
Email: Dhgustaf@wisc.edu

CO-INVESTIGATORS: **Lisa Marsch, PhD.**
Dartmouth College
Dartmouth Psychiatric Research Center
Rivermill Commercial Center, Suite B4-1
Lebanon, NH 03766
Phone: 603-448-0263
E-mail: Lisa.A.Marsch@Dartmouth.edu

Randall Brown, M.D.
Department: Family Medicine
1100 Delaplaine Ct Room 3832
Madison, WI 53715
Phone: 608.263.6558, 608.263.3111
E-mail: randy.brown@fammed.wisc.edu

BIOSTATISTICIAN: **Amy Atwood, PhD.**
Department: Industrial Engineering
1513 University Avenue, ME Bldg. Suite 4155C
Madison, WI 53706
Phone 608.265.6277
Fax:608.265.3281 or 608.890.1438
Email: amy.atwood@chess.wisc.edu

PROJECT DIRECTOR: **Fiona McTavish, M.S.**
Department: Industrial Engineering
1513 University Avenue, ME Bldg. Suite 4111
Madison, WI 53706
Phone 608.262.7852
Fax:608.265.3281 or 608.890.1438
Email: fiona.mctavish@chess.wisc.edu

Version 5/5/2015

SPONSOR: **National Institutes of Health: NIDA**

PARTICIPATING INSTITUTIONS:

Access Community Health Center in Madison, WI.,

.

The Institute for Family Health, Bronx, NY
Partnership Health Center Missoula, MT

TABLE OF CONTENTS

Abstract

Primary care providers at Federally Qualified Health Care facilities (FQHCs) are being asked to integrate substance use disorder (SUD) treatment and HIV care into their practices which are already overburdened. We will implement a wireless smart phone based delivery system called Seva (the Sanskrit word for selfless caring). Seva integrates HIV risk behaviors, status, and services into both the patient interface and provider registry components. Seva will combine: Therapeutic Education System (TES addiction treatment), Addiction Comprehensive Health Enhancement Support System (A-CHESS relapse prevention), and a symptom reporting system called the Clinician Report (CR). The CR facilitates patient- clinician communication and assists clinicians in better managing patient symptoms and treatment. Each component of Seva has proven to be effective, but each has its own interface and operates independently making it difficult to take advantage of their synergistic potential. While Seva has great potential, success relies not only on technology, but on creating a welcoming environment and effective processes to implement and sustain. We propose to overcome key barriers to integrating substance abuse treatment and HIV care into primary care by using a blending of three proven quality improvement strategies to implement Seva. We hypothesize that our implementation strategy will create a welcoming environment, and enhance implementation success and sustainability by removing barriers and building on facilitators, allowing Seva to flourish. We will use quantitative and qualitative methods to determine how much our implementation improves: Reach, Effectiveness, Adoption, Implementation and Maintenance. We will implement Seva in 3 FQHCs. ACCESS community health center in Madison will test and refine the implementation strategy and adapt Seva to meet FQHC needs & ensure ease of use. Two other FQHCs will receive Seva at six-month intervals in a stepped wedge design. A coach will be assigned to each FQHC to help implement, operate and sustain Seva. We will measure impact on the FQHC over a three-year period.

1.0 INTRODUCTION

This proposal combines evidence-based computerized intervention strategies designed to provide treatment and recovery support for Substance use Disorder (SUD) and tests a strategy for implementing them to make more efficient and effective use of limited healthcare and addiction treatment resources. The integrated intervention delivery system we propose, called Seva will be available to patients anytime and anywhere. If successfully implemented, it may be an important "clinician-extender" because much of ongoing therapeutic support can be delivered using Seva, allowing clinicians to focus on providing the primary care they are uniquely trained to deliver. The development period will be dedicated to the technical integration of these systems.

While Seva has great potential, success relies not only on technology, but on creating a welcoming environment and effective processes to implement and sustain. We propose to overcome key barriers to integrating substance abuse treatment and HIV care into primary care by using a blending of three proven quality improvement strategies to implement Seva. We hypothesize that our implementation strategy will create a welcoming environment, and enhance implementation success and sustainability by removing barriers and building on facilitators, allowing Seva to flourish. We will use quantitative and qualitative methods to determine how much our implementation improves: Reach, Effectiveness, Adoption, Implementation and Maintenance. We will implement Seva in 3 FQHCs. Access Community Health Center in Madison will test and refine the implementation strategy and adapt Seva to meet FQHC needs & ensure ease of use. Two other FQHCs will receive Seva at six-month intervals in a stepped wedge design. A coach will be assigned to each FQHC to help implement, operate and sustain Seva. We will measure impact on the FQHC over a three-year period. Below are the details of the integrated system:

Seva is a computer system that functions on smart phones and tablets with one easy-to-use interface. Seva combines three evidence-based computer systems--one for SUD treatment (TES), one for recovery support (A-CHESS) and one that allows patients to communicate healthcare concerns to their clinical team (Clinician Report) allowing these data to be used to improve patient care, reduce side effects and improve patient quality of life. Seva is much more than the sum of its parts because the programs will be integrated to make the resources unique to TES, A-CHESS, and Clinician Report (CR) available throughout treatment and recovery support. Seva will:

- support individual and population-based care (by tracking, reminding, and reporting on health status, visit attendance, and treatment adherence for addiction.
- speed up and make more predictable transitions between FQHCs and addiction specialists. Transitions (or handoffs, e.g. between a FQHC and specialty treatment) often produce dropouts, inefficiencies, and errors.
- allow patients to securely communicate health symptoms and concerns with their clinical team to facilitate clinician integration and patient care management.

Seva components include:

TES is a computer program built on the evidence-based Community Reinforcement Approach. TES has 65 interactive, multimedia modules, beginning with basic cognitive behavioral recovery support skills (refusing drugs, managing thoughts about drug use, etc.). TES also includes modules to prevent HIV, hepatitis, and sexually transmitted infections (STIs). Additional modules teach skills to improve psychosocial functioning (family/social relations, managing negative moods, etc). TES is a self-directed program that includes a module teaching patients how to use the system and a "customization program" to build an individualized treatment plan for patients. TES uses "fluency-based" computer-assisted instruction to assess a patient's grasp of material and adjust it to promote the mastery of skills and information. Its experiential learning environments (via interactive videos) help patients learn modeled behaviors (e.g., progressive muscle relaxation). Further, TES allows therapists to view (on their computers) summaries of their patients' TES activity and progress, and integrates patients' use of TES into counseling sessions so that TES can function as a clinician-extender. Randomized trials have found that 1) TES is as efficacious as behavioral therapy delivered by therapists and superior to standard substance abuse treatment , 2) TES modules for HIV, hepatitis, and STI risk increased HIV/disease prevention knowledge and self-reported risk for HIV and were perceived as more useful than a standard intervention , and 3) adding TES to methadone

treatment improved objectively measured opioid abstinence rates. TES is being converted to operate on wireless systems.

A-CHESS, or Addiction- CHESS, is a smart phone recovery support system. CHESS is the umbrella name for eHealth systems developed and tested for the past 25 years at the University of Wisconsin Center for Health Enhancement Systems Studies [chess.wisc.edu]. CHESS is also an NCI-designated Center of Excellence in Cancer Communication Research and an AHRQ-designated Center of Excellence in using technology to promote active aging. CHESS is built upon evidence-based principles of recovery support: long duration, assertive outreach, monitoring, prompts, action planning, peer and family support, and case management. Recovery support can improve health and reduce healthcare use, but is rarely used in addiction because of the lack of resources. Compared to the unrestricted Internet, CHESS offers a closed, guided universe of tailored information and support with efficient navigation, eliminating the need for complicated search and discovery. In randomized trials, CHESS significantly improved: 1) quality of life and costs of care in people with HIV, 2) quality of life and self-efficacy for women with breast cancer vs. control and Internet groups , 3) asthma control for young children, and 4) quality of dying and length of survival for lung cancer patients. Smart phone forms of CHESS are in randomized trials on colon cancer, urban teenagers with asthma, and alcohol-dependent patients. Four-month tests with 192 alcohol-dependent subjects found that A-CHESS reduced heavy drinking days by 46% vs. a control group and that long-term use of A-CHESS is higher than other CHESS applications. For more detail on A-CHESS, please see http://www.innovationsforrecovery.com

Clinician Report (CR) is a patient monitoring, clinical decision making and communication tool that allows patients to answer questions about their symptom status, current physical and emotional needs and concerns to be addressed by the clinicians at the next clinic visit. The CR summarizes the data provided by patients and makes it available online to their clinicians and patients. The CR also provides a graphical summary of the patient's longitudinal data so both the patient and the clinician can view status changes over time. Additionally by summarizing the needs conveyed by patients, the CR provides clinical staff with immediate patient health and behavioral issues as well as an understanding of other important life concerns. The CR is intended to facilitate coordination of care and assist clinicians in treatment follow-up to improve patient adherence and improved health outcomes.

2.0 OBJECTIVES

Clinician Subject: Approximately 45 (15 from each site) clinician subjects will be recruited. Participating clinicians will be asked to participate in three (30-45 minute) focus groups where they will be asked about their impressions and experience using Seva, whether the system helped or did not help their clinical practice and any suggestions to improve the Seva system. No personal health information will be collected during the focus groups, but we will audio record the focus groups so that we can transcribe responses after the groups are complete. Participants, however, will not be identified on the recording or transcription. Clinicians will also be asked to refer appropriate patients to the research study team for possible study recruitment and accept receipt of the Clinician Report and respond accordingly. Additionally they will be asked to complete 7 surveys about their work environment and how their clinic is using/implementing the Seva recovery support system. Clinicians will also be asked to keep track of the time they spend on project related activities.

Patient subjects: Approximately 300 (100 from each site) patient subjects will be recruited. A sample of 15-20 participating patients will be asked to participate in three (30-45 minute) focus groups where they will be asked about their opinion and experience using the Seva system and if the system helped or did not help them abstain from drug use and any suggestions to improve the system. No personal health information will be collected during the focus groups, but we will record the focus groups so that we can transcribe responses after the groups are complete. Participants, however, will not be identified on the recording or transcription.

Patient subjects will also be asked to complete 4 surveys. The first survey will be filled out in person at the clinic and the other two surveys will be completed at 6 and 12 and 18 months after they have received the phone and Seva system. Patients can complete these surveys either on the phone or on paper, whichever they prefer. These surveys will take about 20 minutes to complete and will ask information about drug and alcohol use and potentially risky behavior (i.e., sharing needles, unprotected sex). When patients use Seva they will also be asked how they are doing and about their recent alcohol and drug use. As part of the Clinician Report, these questions will be sent weekly on the Seva system and will take about 2-4 minutes to complete. All questions are voluntary. Patients are free to refuse to answer any survey questions they are uncomfortable with. However, by answering the weekly questions about their recent alcohol and drug use the Seva system can send the patient information to help them stay clean and sober. In addition, the information will be sent to his/her clinical team so the clinic team can provide him/her with the support they need

We propose that pre-post differences will reveal improvements in the following:

- Organization readiness for implementation and sustainability of the SUD system called Seva
- SUD care coordination between primary and specialty care systems
- Reduction in urgent and emergent care visits
- Patient satisfaction
- Patient perceived social support

By tracking both frequency and duration of Seva use (hours, minutes, and seconds) this research will also determine how much Seva is used in a real world healthcare context: The data will be relevant to decisions about implementation, sustainability and dissemination of SUD technologies, especially via FHQCs where the intervention might be integrated with other aspects of routine patient care. The Seva system will also use the phone's GPS to monitor location to help support their recovery. Patients are not required to use this feature. They can turn it off at any time.

The information being provided by patients is sensitive health information. Patients are free to refuse to answer any survey questions they are uncomfortable with. The objective of the study is to provide technology that will help the clinicians treat patients with SUDs better. Without collecting this sensitive information a study like this could not be conducted as the very nature of the intervention is to allow clinicians to be better informed and provide treatment more responsively to 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 effected by their participation in this study.

3.0 SELECTION OF PATIENTS

The UW CHESS Research team will not have access to medical records. Staff members from the Federally Qualified Health Centers (FHQC) as well as patients from those sites will be recruited as human subjects for this protocol.

Recruitment will be conducted at three 3 FHQCs; Access Community Health Center in Madison, WI., Partnership Health Center Missoula, MT and The Institute for Family Health Bronx, NY.

Clinician Subjects: **45 clinicians** among the 3 FQHCs **(**15 at each site**)**. Staff members include MDs, behavioral health providers, RNs and management staff from the clinics' primary care and behavioral health departments. Clinician must have an interest in the research objectives. Clinician participation will be voluntary.

Patient Subjects: **300 patients** among the 3 FQHCs (100 at each site). . Patients must be 1) age 18 or older 2) 3) meet criteria for Substance Use Disorder (SUD) according to the Severity of Dependence Scale. Clinician subjects referring patients (Drs. Randall Brown, , Chantelle Thomas, Jonas Lee and Mischa Ronick at Access) will ensure that patients: 4) have no current psychotic disorder severe enough to prevent participation, 5) have no acute medical

problem requiring immediate inpatient treatment, 6) are willing to use Seva, and 7) can understand and sign a consent form in English. If a patient is incarcerated during the study their participation will be stopped. If they are still interested in participating in the study when released from jail they will be able to rejoin the study. Patient participation will be voluntary.

4.0 REGISTRATION PROCEDURES

Clinician Subject Identification and Recruitment
Prior to the start of the study, Dr Randall Brown and the UW research team will either meet with potential clinician subjects either 1:1 and/or present the study at an Access Clinic provider staff meeting to gauge the clinicians' interest in participating in the study. UW researchers will explain the study objectives and subject participation expectations during this meeting. UW Researchers will assure the providers that there is no obligation to participate in the study. That their decision is voluntary and that their clinical practice will in no way be effected by their choice to participate or not. The clinicians will be told they do not have to decide about participation during this meeting. They can take their time to think about it and either contact Dr Brown or the UW Research team at a later time. They will also be told they can drop from study participation at any time. Dr Brown and the UW Researchers will be available at anytime to answer questions about the study. This will ensure the Access clinicians do not feel pressured or coerced in any way. UW Researchers will provide clinician subjects training on the Seva system prior to patient subject enrollment.

Patient Subject Identification and Recruitment
Drs. Randall Brown, Chantelle Thomas, Mischa Ronick, and Jonas Lee are clinicians at Access and also participating researchers (part of the research team). They will review medical records to identify potentially eligible patient subjects. These clinicians have valid access to the EMR as part of their clinical role. As part of routine care (at Access clinic) all patients will complete the Severity of Dependence Scale survey. This data will be used to assure the patient meets eligibility criteria. When potentially eligible patient subjects have been identified the clinician will inform the UW research team recruitment coordinator that there are potentially eligible patients coming into clinic. The UW research team recruitment coordinator will arrange to be in clinic to talk to any potentially interested patients. No protected health information will be shared with the UW research team recruitment coordinator prior to the patient giving permission.

During the clinic appointment, the clinician will ask the patient if they are interested in hearing about the study. If they are interested and give permission, the clinician will tell the UW research team recruitment coordinator there is a patient who is interested in hearing about the project. The clinician will not give the patient's name to the UW research team recruitment coordinator. In the privacy of a clinic exam room or private office the UW research team recruitment coordinator will explain the study, its benefits and potential risks of participation. The UW research team recruitment coordinator will also answer any questions the patient subject may have. If the patient is interested in participating they will be asked to complete informed consent and the first online survey in the clinic during this first meeting. After the informed consent is complete the UW research team recruitment coordinator will schedule a training meeting between the subject and the recruiter. The training will involve instructions on how to use the smart phone, complete survey questions to acquaint the patient with online surveys ecological momentary assessment and setting up the patient's profile and preferences (including if the patient allows the clinical team to assess the answers to their ecological momentary assessments and navigate the information and resources in Seva. This meeting will be scheduled at a time and place most convenient for the patient subject.

No additional clinic visits will be required of patient subjects. The UW research team recruitment coordinator will have a private space in the clinic for meeting with patients to confirm eligibility, obtain consent, and conduct training. This private space will be either a regular exam room or private office in the clinic. Patients will have access to Seva for 12 months. Patients must agree to allow monitoring of their Seva usage. Patients are not required to use the GPS monitoring system. They can turn it off at any time.

Intervention:
The study will be conducted over a 12 month period. All patient subjects will have access to the Seva system for 12 months and clinician subjects will have access for the duration of the study. There will be no cost to subjects for participating in this research study. There will also be an 800 number available for technical support. Clinician and Patients subjects will also have access to the internet and will be able to use email if they choose to do so. Use of the internet and email will not be tracked by the UW Research team.

Clinician Subjects will be asked to participate in three (30-45 minute) focus groups where they will be asked about their impressions and experience using Seva, whether the system helped or did not help their clinical practice and any suggestions to improve the Seva system. Clinicians will also be asked to refer appropriate patients to the research study team for possible study recruitment. Additionally they will be asked to complete 7 surveys about their work environment and how their clinic is using/implementing the Seva recovery support system.
Use of Seva: Clinician Subjects may use any or all of the elements of the Seva system, which combines the A-CHESS application that provides information and support to patients to help them maintain sobriety, the TES application which provides cognitive behavioral therapy based tutorials to improve decision making and help patients maintain sobriety and the Clinician Report which is a patient monitoring, clinical decision making and communication tool that allows patients to answer questions about their symptom status, current physical and emotional needs and concerns to be addressed by the clinicians at the next clinic visit. The CR summarizes the data provided by patients and makes it available online to their clinicians and patients. The CR also provides a graphical summary of the patient's longitudinal data so both the patient and the clinician can view status changes over time. Clinicians will receive a report from their patients participating in the study who elect to complete and send the information to their clinician. To accommodate the 'real word' processes of busy clinical practice, Clinicians can designate one of their team, registered nurse (RN), nurse practitioner (NP) or physician assistant (PA) to receive the report for them. Patients will be told if the report goes to a designee. This designee will be consented as a clinician subject for this protocol and have access to the Seva system. The designee RN, NP or PA will receive the report and provide the information to the clinician for follow-up. The clinical team can access the CR in three ways. First, the clinician (or designee) can log into Seva and then access a summary report of their patients. Second, for participating patients, the Seva system will generate an alert that is immediately sent to clinician (or designee) whenever the patient's BAM responses exceed a threshold score patient's BAM responses exceed a threshold score of 6 on a 0–7 scale or 1 on a reversed 0–7 scale for at least one symptom item. Finally, clinicians (or designee) can also receive a CR notification two days before a scheduled clinic visit. The Clinician can then review the report and respond to the patient information accordingly. These reports are private communication between the patient and their healthcare team.

Patient Subjects: A random sample of 15-20 participating patients will be asked to participate in three (30-45 minute) focus groups where they will be asked about their opinion and experience using the Seva system and if the system helped or did not help them abstain from drug use and any suggestions to improve the system. No personal health information will be collected during the focus groups. All patient subjects will also be asked to complete 4 surveys. The first survey will be completed in person at the clinic and the other two surveys at 6, 12, and 18 months after you have received the phone and Seva system. Patients can complete these surveys either on the phone or on paper, whichever they prefer. These surveys will take about 20 minutes to complete and will ask information about drug and alcohol use and potentially risky behavior (i.e., sharing needles, unprotected sex).
Use of Seva: When patient subjects use Seva they will also be prompted to complete the CR. They will be asked how they are doing and about their recent alcohol and drug use. These questions will be sent weekly on the Seva system and will take about 2-4 minutes to complete. All questions are voluntary. Patients are free to refuse to answer any survey questions they are uncomfortable with. However, by answering the weekly questions about their recent alcohol and drug use the Seva system can send the patient information to help them stay clean and sober. The information will be sent to his/her clinical team so the clinic team can provide him/her with the support they need. If their responses exceed a threshold score of 6 on a 0–7 scale or 1 on a reversed 0–7 scale for at least one BAM symptom item the Seva system will generate an alert that is immediately sent to the clinician (or designee). The patient decides whether to answer the questions. These reports are private communication between

the patient and their healthcare team. Using a self-selected username and password patient subjects will be able to access a discussion group within Seva to connect with other patient subjects. This discussion group will be monitored daily by UW research staff.

The Seva recovery support system will automatically collect data on how often and for how long subjects use each of the various parts of the system. This data will be used to determine which parts of the system are the most useful and valuable. This data will be kept in a secure, limited access, password-protected file service the UW Madison Center for Health Enhancement Systems Studies, 4th Floor Mechanical Engineering Building, 1513 University Avenue, Madison, WI 53706.

Privacy and Confidentiality:

Clinician Subjects: Clinician surveys will be distributed to clinic staff members by the UW recruitment coordinator and sent directly to the research team by respondents using self-addressed stamped envelopes. In survey responses, a code will be self-assigned by the respondent corresponding to the first two letters of their first name and the first two letters of their last name and the last number of their birth year (e.g., for a person whose name is Jan Donovan born 1967 would assign the code JA DO 7). This approach to coding for staff de-identification has been reviewed and approved by the University of Wisconsin IRB in our previous organizational research studies. Staff members will not have access to one another's responses in any form. Respondent identification will not be linked to survey responses. De-identified survey responses will be kept in a locked file in the CHESS office. Staff could also feel coerced into participation. To minimize this risk, the option to return a blank survey will be clearly stated.

Data collected during focus groups will be identifiable for the researcher collecting the data. Focus groups will be conducted by members the UW research team trained in qualitative research and in protecting patient confidentiality. Data collected during the focus groups will not be identifiable to anyone other than the group facilitators. The focus groups will be audio recorded and all responses transcribed after the groups are complete. Participants, however, will not be identified on the audio recording or transcription. Clinician subject survey date will be coded as described above. Research staff members that have access to the data for analysis purposes will not have access to subject names.

Patient Subjects: To mitigate the risk of patient breaches of confidentiality, all subjects will be assigned a code number. A list of subject code numbers will be maintained by the project director and stored in a password-protected spreadsheet. This data will be kept in a secure, limited access, password-protected file service on CHESS servers which are located in the Mechanical Engineering building on the 4th floor. Other identifiable data entered on the subjects' smartphones will be removed by the UW recruitment coordinator before it can be access by the research team. The UW Research Coordinator will assist patient subjects in choosing codenames and passwords to use to login to the Seva system. Patients 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).

There is a risk that information and resources provided in Seva will be used to the detriment of the subjects. Some potential risks include:

- The Seva recovery support program could give patient subjects wrong information. However, a panel of experts in the field of addiction looks at all information before it is put on the smart phone.
- Learning about sensitive issues (such as drug and alcohol use, mental health) while using the Seva recovery support program may cause anxiety, distress, embarrassment, or feelings of sadness. However, patient subjects do not have to answer any questions that they don't want to answer.
- Patient subjects could receive wrong information from the Internet and/or discussion group. However, we will provide simple tips to help them figure out whether they can trust the information they receive from these sources.
- We will be collecting information on how the smart phone is used and may discover behavior that raises concern about harm to self or others. If we see anything that suggests that patient subjects or others face

imminent risk of harm, we will contact appropriate others to intervene (e.g., your community mental health center, and/or police)
- The service to the smart phone is stopped after 12 months. Patient subjects may feel some loss when they no longer have that service.
- If patient subjects smart phone is lost or stolen, we will not be able to replace it. They may feel some loss if this occurs. Also, any personal information that they've put on the phone could be seen by unknown others.
- If patient subjects are incarcerated or enter inpatient treatment during the study their participation will be stopped. If they are still interested in participating in the study when released from jail or inpatient treatment they will be able to rejoin the study.
- Patient subjects might use the phone for unintended harmful purposes such as procuring drugs or alcohol.
- Patient subjects will also be able to upload images of themselves onto the Seva system. Subjects will be informed of the risks involved in using identifying services as part of the informed consent process. This is not required for participation in this study.

To further protect subject confidentiality the Principal Investigator has received a Certificate of Confidentiality through the National Institutes of Health, which grants immunity from legal process to identifiable subject information.

5.0 TREATMENT PLAN

There will be no randomization involved in this study. It is anticipated that 45 clinician subjects and 300 patient subjects will be recruited at the 3 participating Federally Qualified Health Centers. Clinician subjects will have access to Seva for the duration of this implementation study at their respective FQHC. All patient subjects will have access to Seva for 12 months.

6.0 MEASUREMENT OF EFFECT

The evaluation of our implementation strategy is built upon Glasgow's RE-AIM model.[1] RE-AIM has been used to plan and evaluate many disease management interventions. Gaglio and Glasgow[2] found over 140 published studies that claim to have used the RE-AIM model, though few adopted the model with fidelity.[3] Our evaluation uses the criteria Glasgow et al have set for "fully developed" use of RE-AIM. The labeling of outcomes as primary and secondary is challenging in the RE-AIM framework. On the one hand, organization-wide impact on patients (effectiveness measures) are central and we have labeled them primary. But this is primarily a study of Seva's impact on the organizations, where issues such as coordination of care, job satisfaction, and the cost of adopting and operating Seva are critical. Having said that, the **primary** outcomes attached to each dimension of the RE-AIM[4] framework are listed in ***italicized bold***. Other outcomes are listed in standard font.

- Adoption**:** The # and type of clinicians using Seva will be representative of the FQHCs' clinicians. The RIS scores and provider attitudes toward SUD treatment will increase after Seva implementation
- Effectiveness: The following outcomes will improve: # identified with SUD**,** # identified with HIV risk behaviors**, % treated for SUD, *Treatment attendance*,** Care coordination **% reducing HIV risk behaviors**, % reducing substance use, *Time to treatment, # treated for HIV.*
- Maintenance: Seva ***Cost effectiveness,*** *costs of operation***,** Sustainability score*,* long-term effectiveness (see above), , will increase during the posttest period.
- Reach: the # and type of patients served by Seva are representative of SUD patients served by the FQHC
- Implementation: *We describe* Seva services used & when, by what patients and providers

All quantitative analyses will be supplemented by qualitative research to help us understand the findings. All outcomes will be assessed with as much sensitivity-fidelity in the baseline as in post-intervention periods, thus

permitting unbiased assessment of performance from pre to post. Exceptions include: (except Seva adoption and use, HIV risk behavior and substance use). The specific surveys to be used are referenced next to the outcome. All surveys are validated. Other data come from EMRs and Seva.
As stated earlier, 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 effected by their participation in this study.

7.0 STUDY PARAMETERS

There will be no randomization involved in this study. It is anticipated that 45 staff subjects and 300 patient subjects will be recruited at the 3 participating Federally Qualified Health Centers. Clinician subjects will have access to Seva for the duration of this implementation study at their respective FQHC. All patient subjects will have access to Seva for 12 months.

8.0 DRUG FORMULATION AND PROCUREMENT (if applicable)

Not applicable.

9.0 STATISTICAL CONSIDERATIONS

Research Design**:** We propose to examine the quality, speed, and impact of implementing Seva in primary care at 3 FQHCs, using a stepped-wedge (or multiple-baseline) design.[5] [6] Using the clinic as the unit of analysis, this single-subject approach[7] will closely track the timing of intervention elements and repeatedly measure outcomes at the organizational level, including aggregated effects on clinicians, patients, and practices.
The design includes a pilot-testing phase during which Seva will be introduced at Access Community Health Center in Madison, WI. After pilot testing and improving Seva and the overall implementation strategy, we will standardize the implementation process and Seva so that the elements of the intervention are held constant from one site to another. Then we will sequentially introduce Seva at 2 other FQHCs (The Institute for Family Health, Bronx, NY, and Partnership Health Care in Missoula, MT). In this single-subject, stepped-wedge design, each FQHC acts as its own pretest control, with 12 months of baseline data collection. The 6-month gap creating the stepped-wedge design will give us insight into seasonal variation in substance abuse. During the data collection period, core organizational indicators will be assessed every 2 months, many aggregated from EMRs. During the 24 months of Seva deployment at each site, log-file analysis will also produce daily metrics about patterns of system use. Our FQHCs are typical of other FQHCs and similar to one another on core criteria. Responding to NIDA's call for innovative research methods, this stepped-wedge design offers advantages compared to RCTs. This design costs less than randomizing the large sample of organizations required to run the inferential statistics associated with RCTs. It makes it easier to understand the dynamics of change processes (such as implementation) than RCTs do. It avoids the ethical problem in RCTs of withholding interventions from a proportion of participants who might benefit[8].

The single-subject approach[9] [10]emphasizes recurrently tracking behaviors and practices in a "repeated time series" that permits the study of change patterns. The stepped-wedge designs that often accompany single-subject studies provide the intervention to all participants, but isolate the independent variable by introducing the intervention at specified points[11]. As Horner et al[12] note, "to document experimental control, *independent variables in single-subject research are actively, rather than passively, manipulated. ".*

While this design may not provide as strong a basis for causal inference as a large-scale experiment, this design is highly appropriate for the initial evaluation of a new innovative intervention strategy that targets patients, health

care systems, and methods for adoption, implementation, and maintenance. It would be inappropriate to launch a major randomized trial without the preliminary evidence that will be produced in the proposed work and that will lay the groundwork for more expensive, and extensive, analysis.

Cost measures: The sustainability of Seva will depend not just on its results but its cost. To be widely disseminated, Seva and its implementation must be cost effective. During the project, we will keep track of the following: 1) Development costs (time and effort spent by software developers for ongoing upgrades based on user feedback from the implementation process). 2) Setup costs (hardware and equipment such as smart phones issued to patients and tablet PCs used by clinicians to screen and access the registry). 3) Implementation costs (estimated allocations of clinician salaries for time spent recruiting and training new patients; setting up Seva and offering feedback; and attending required coaching and project management sessions). Any volunteer or other services provided free of charge during implementation will be documented. 4) Implementation costs (salaries for clinicians on the research team). Salary estimates for clinic and research clinician time include fringe benefits. Operating costs of the system consist mainly of the monthly phone/data charges for the patient smart phones and IT and clinician time required for data management and maintenance of the system. Any costs incurred by patients are expected to be minimal and are outside the scope of the evaluation. We will clearly separate research and clinical costs.

Data sources: Data will be collected using: EMR (for patient subject identification only), staff surveys, Seva use data, administrative records, and qualitative focus groups. FQHC clinicians will be asked to complete 7 surveys to collect readiness for implementation scores (RIS), and sustainability propensity scores (SI) (all validated instruments). Seva automatically records data on patient use of each service (e.g., times when the discussion group is entered and left) and movement from one service to another (e.g., a patient left a discussion group and went to relaxation exercises for 15 minutes). Seva also records test scores for each skills training module and sensor data (e.g., when a patient nears a high-risk location). Seva will also contain patient responses to Seva surveys on self-report substance use, HIV risk behavior, depression, and healthcare utilization outside the clinic (e.g., specialty addiction treatment appointments, trips to the emergency room, etc.). Qualitative data will come from focus groups with clinical staff and patients. To collect cost data, we will conduct a simple time study tracking project staff and clinician subjects' time spent on study implementation related activities.

Quantitative Analysis: Because this is a study of organizational impact of Seva, there will be no single patient analyses; all will be aggregated across patients. As listed above, the primary outcome measures are: **% at risk who enter treatment for SUD, % reducing HIV risk behavior, average treatment attendance, RIS, and Sustainability Index.** Analysis of these outcomes will proceed on 2 fronts: 1) Interrupted time series analysis will compare outcomes within a clinic before and after implementation using our primary outcome measures. Research questions will be tested using linear regression models, with each analysis having 2 time-series segments representing means and slopes before and after implementation. Given the limited degrees of freedom, no covariates will be included in the models. A test of the regression coefficient for *implementation* (a dichotomous variable indicating whether the time point occurred pre or post implementation) will allow us to examine differences in the mean change at implementation. Differences in slope from pre- to post-implementation will be tested using the coefficient for the *implementation* x *month* interaction, where *month* is a continuous variable indicating the month of measurement. Weighted least squares analysis will be used to account for potential differences in the number of patients or staff reporting outcomes within each clinic across time. Power. Observations from the NIATx 200 study provide estimates of baseline values and variability for the RIS, and Sustainability measures (5.05, 5, and 55, respectively). We assume no increase during time before implementation (i.e., pre-implementation slope of 0), while non-zero slopes are assumed post-implementation, due to both improved use of the system by clinic staff and additional patients entering the system over time. With a minimum of 6 time points measured before and after implementation, we will have adequate power ($1\text{-}\beta \geq .8$, $\alpha = .05$) to detect a 20% total increase in our primary outcomes of interest within each clinic. Using estimates based on clinic reported outcomes from 2010, we will also have adequate power to detect a 20% increase in the average percent of patients entering treatment for SUD. 2) Drawing from conventional approaches to single-subject analysis, we will

also compare within and across the clinics using visualization of the data[13] to determine whether the shift from baseline to intervention phases of the study generated shifts in the level, trend, and variability of performance.[12] This will allow us to evaluate the immediacy, consistency, and magnitude of the observed effects.[13] The visual analysis will be strengthened by including non-equivalent control time series.

Qualitative Analysis: We will use an integrative, mixed quantitative and qualitative method approach to determine the extent to which implementation and sustainability of Seva improve RE-AIM framework goals: reach, effectiveness, adoption, implementation, and maintenance. Our mixed-methods research is influenced by "Best Practices for Mixed Methods Research in the Health Sciences" (Office of Behavioral and Social Sciences Research). Because facilitators and barriers associated with RE-AIM rely on the intervention (i.e., Seva), the organization (e.g., staff, infrastructure), and implementation process (i.e., PPM, NIATx, and Rogers), we will use qualitative research methods to understand how they affect RE-AIM outcomes. Specifically, we will: 1) Tailor Seva to each FQHC and document and evaluate processes used in the tailoring. Focus groups data will help us understand these processes (months 6-12). 2) Provide insights into the quantitative results by using the mixed-method research model we employed to evaluate the VA's mental health systems redesign. We will interview key stakeholders following each wave of surveys. As within- and across-site findings emerge from RIS, and Sustainability data, we will interview people who can help inform the findings. 3) Understand the barriers to and facilitators of implementing and sustaining Seva and how they relate to outcomes. Key stakeholders will be asked to reflect on reach, outcomes, adoption at the setting level, staff participation, implementation, and long-term effects. 4) Ask informants to reflect upon how they might advise a similar FQHC in integrating Seva. Qualitative analysis is labor-intensive. Hence we will carefully select people who can best inform our questions, while limiting the number of interviews. We will collect, transcribe, and analyze (via NVIVO-9), researcher, counselor, and FQHC staff field notes and interviews collected during RE-AIM phases. The qualitative analysis will follow grounded theory to build a conceptual model of Seva's implementation.[14] Two researchers will independently and then together analyze 6 interviews that represent different organization-level stakeholders. Because RIS, OCM, and Sustainability factors as well as RE-AIM components are associated with adoption and sustainability, we will include them as a priori themes, while seeking new insights from the interviews. Researchers will then code the remaining interviews, comparing themes to distinguish different types of organizations and conditions. To assure coding consistency, every fourth interview will be double-coded. Significant inconsistencies will be discussed and recoded. Finally, we will categorize the themes into a working model.

Cost-effectiveness analysis: Conventional cost effectiveness analysis compares the costs and effects of different interventions assigned in parallel. In contrast, the stepped-wedge design allows each clinic to serve as its own control,[6] an approach similar to one used in a study of screening for abdominal aortic aneurysm.[15] When FQHCs use Seva to screen for drug use and identify potential subjects, patients who report drug use will be asked to report any hospitalizations or emergency department (ED) visits in the previous 6 months. Patient self-report has been validated as a means of assessing healthcare utilization in homeless and injection-drug-using populations.[16] [17] The validity of self-report improves with shorter recall periods and less frequent utilizations.[18] Provided other inclusion criteria are met, a patient screening positive for drug use is eligible for the study and will be invited to participate. The same measures of healthcare utilization (hospitalizations and ED visits) will be monitored in bi-monthly surveys of patients during the 12-month period they use Seva. Changes in the rate of healthcare utilization between the 6-month period before and the 12-month period after invitation are coupled with implementation and operating costs to generate 2 primary cost-effectiveness measures: cost per avoided hospitalization and cost per avoided ED visit. These cost-effectiveness measures will be aggregated to the clinic level. It is hypothesized that patient and clinician use of Seva will produce cost savings by reducing utilization of high-cost services among the drug-using population.

10.0 PATHOLOGY REVIEW

Not applicable.

11.0 RECORDS TO BE KEPT

- Subject Intake
- Subject Demographics
- Subject Consent Forms
- HIPAA Authorization Form
- Baseline and follow up survey data
- De-identified Seva Use data

12.0 PATIENT CONSENT AND PEER JUDGMENT

Potential subjects will be informed of: (1) the nature and purpose of the study, (2) the types of data which will be collected, (3) what will be given to study participants, (4) the measures taken to ensure confidentiality of data collected and HIPAA regulations privacy protection, (5) and the timeline of the study. Signed consent forms will be obtained from each subject and kept securely at UW Center for Health Systems Studies (CHESS). Potential subjects will be clearly informed that their treatments will be in no way affected by their decision to join, or not to join the study.

It is anticipated that recruitment for this study will begin in June 2013 upon receipt of IRB approval and completion of the technical development. Subject consent forms are included with this submission.

Appendix A
Revised 2/2010

Center for Health Enhancement Systems Studies
Data Security and Monitoring Plan

In accordance with the Health Insurance Portability and Accountability Act (HIPAA) the following Data Security and Monitoring Plan has been instituted at the Center.

The following policies have been adopted by the Center:

I. Appointment of Center Data Security Officers.

A. Susan Dinauer and Matt Wright are the security officers for the Center.
B. Responsibilities of the security officers include:
- Developing information technology (IT) security policies
- Increasing security awareness for all Center faculty and Team Members
- Providing virus protection for IT resources
- Maintaining security patches on computing equipment
- Developing and implementing back up procedures
- Performing periodic vulnerability scanning on computers
- Reviewing and updating firewall strategies and policies
- Enhancing the physical security of IT resources

II. Policy for Orientation and Training

A. All Center students, faculty and staff are required to complete the UW-Madison Human Subjects training on-line. https://my.gradsch.wisc.edu/citi/index.php (You register with your WiscID. Select the training program for Biomedical Researchers, social & Behavioral Researchers, or both. Team members who work on projects that are reviewed by the health Sciences IRB should complete the combined (both) training; otherwise the social and Behavioral training would be fine. Please contact me if you are not sure about which one to complete. You will also need to complete one elective.)
B. Successful completion of this training is required before any Team Member is allowed access to Center data. Certificate of completion must be given to a Center Data Security Officer.
C. All Center Team Members are required to complete an on-line training course on the HIPAA Privacy Rule training http://ptehipaa.doit.wisc.edu/moodle/login/index.php Certificate of completion must be given to the Center Data Security Officer. (Note: You will be asked a series of questions when you register. Sign-up as HIPAA Shared. We are not a member of the HCC, but we do work with the HCC; PHI is used in our research but not for teaching. You will be completing HIPAA 101 and Use & Disclosure sections of the training.)
D. All Center Team Members are required to complete training on Center security procedures and policies.
E. Sign the "Center Data Security Policy Certification" upon completion of this training.

III. Workstation Policy

A. All workstations will require login with a unique user name and password.
B. All workstations are required to be joined to the ENGR domain under the control of the College of Engineering.
C. All workstations are required to use anti-virus software that can be remotely administered from the College of Engineering domain.
D. Users will log-out from or lock workstations when leaving them unattended.

E. Screen savers will be configured to require a password and to activate after ten minutes of workstation inactivity.
F. Users requiring remote access to the Center network will only do so with computers specifically certified by a Center Data Security Officer.

IV. Password Policy

A. Users will require a password to access any computer connecting to the Center network.
B. Passwords must meet the requirements of the Computer Aided Engineering department (CAE). CAE password construction help can be found here: http://www.cae.wisc.edu/passwrdhlp.
C. Passwords may not be stored in proximity to the workstation and may not be shared by others.

V. Policy for the Use of Email

A. Patient Identifiable, Confidential or Personnel Data may only be included in an encrypted attachment and should never be sent in the body or subject line of an email message.
B. Team Members who need to send encrypted attachments should contact a Center Data Security Officer to schedule a training session.

VI. Policy for Storage, Retrieval, and Disposal of Protected Information

A. Any Patient Identifiable, Confidential or Personnel Data in electronic form 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 the R: Drive.
B. All paper-based files will be stored in locked rooms inside locked file cabinets with limited access.
C. Servers containing Patient Identifiable, Confidential or Personnel Data must be located within the Mechanical Engineering Server Room which can only be accessed via security card.
D. The Center Data Security Officers will be responsible for assigning and restricting access to shared resources on the Center servers.
E. Patient Identifiable, Confidential, and Personnel Data as a general rule may not be copied to or stored on the Center's publicly accessible servers at any time (currently CHESS1, CHESS2, and CHESS4). However, in some studies, patient's name, disease state, and physician are stored within the Center program. This information is only accessible via a codename/password.
F. Remote access to files on the secure Center servers will be provided in a very limited case only through a Remote Desktop connection from a certified Center Workstation (See Center Workstation policy above for details).
G. Storage media containing Patient Identifiable, Confidential or Personnel Data will be rendered unusable before disposal.
H. All back up media will be stored in locked rooms with limited access.

VII. Policy for the use of portable and home equipment and the transport of data media containing Patient Identifiable, Confidential, and Personnel Data

A. All computers being used from outside the Center to access the Center network must be certified by the Center Data Security Officer.
B. All computers being used from outside the Center to access the Center network must have Firewall software (such as Windows Firewall) installed and activated.
C. All computers being used from home to access the Center network must have all wireless connections ***disabled***.
D. All home and portable computers and PDAs on which Patient Identifiable, Confidential, and Personnel Data files are used, on which user account information is temporarily stored, or that access the Center network must comply with the policies for workstations listed above.
E. Use of Patient Identifiable, Confidential, and Personnel Data files offsite must comply with security policies and procedures developed for data use within the Center.

F. Patient Identifiable, Confidential, and Personnel Data files may not be transported from the Center unless the device/medium is monitored for physical security at all times.
G. Team members who place files on portable* and home computers must delete these files as soon as they are finished using them. Quarterly reminders will be sent to the team to facilitate compliance with this requirement. (*thumb drives, laptops, anywhere a file is placed with confidential information)

VIII. Policy governing the storage and use of audiovisual materials

A. Audiovisual media containing Patient Identifiable, Confidential, and Personnel Data are governed by the same policies and procedures that apply to handling and use of computerized data, including disposal, storage and access to media.
B. Such audiovisual media may not be transported from the Center unless the material is monitored for physical security at all times.

IX. Policy governing the transmission of information via fax

A. All outgoing correspondence via fax must be stripped of confidential information.
B. Before confidential information is transmitted to the Center via fax, the sender must notify the appropriate Center Team Member to ensure that the recipient is available to pick up the fax document.

X. Field hardware policy

A. Upon their return, all Center study computers, smartphones, or other devices that have been used in the field will have all data wiped from the hard drive in compliance with DOD standards.
B. Field computers will be stored at the Center in a wiped state.

XI. Study participant information.

A. Center Team Members will not share or talk about confidential information regarding the CHESS study participant with anyone who is not directly involved in the management of the CHESS Project.
B. Confidential or other sensitive information regarding the study participant cannot be left in an unsecured place where others may see it.
C. Copies of written correspondence about the study participants with anyone other than CHESS management cannot be provided, unless specifically authorized to do so by the Project Director.

XII. User Responsibilities

A. All Center Team Members are responsible for adhering to the Center Data Security Policies at all times.
B. All Center Team Members will be given a comprehensive briefing session upon hire.
C. Usernames and passwords are not to be shared with others.
D. No equipment may be connected to the Center network without specific prior certification by a Center Security Officer.
E. Specifically, no wireless access points may be deployed or connected to the network under any circumstances.
F. The Center Data Security Officers will maintain records to insure that all Center Team Members have been briefed.
G. The Center Data Security Officers will provide periodic refresher sessions to all Center Team Members.

References

[1] Glasgow, R. E., Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *American Journal of Public Health, 89*(9), 1322-1327.

[2] Gaglio, B., & Glasgow, R. E. (in press). Evaluation approaches for dissemination and implementation research. In R. C. Brownson, G. A. Colditz, & E. K. Proctor (Eds)*, Dissemination and Implementation Research in Health: Translating Science to Practice.* New York: Oxford University Press.

[3] Glasgow, R. Personal communication. September 18, 2011.

[4] Glasgow, R. E., Klesges, L. M., Dzewaltowski, D. A., Bull, S. S., & Estabrooks, P. (2004). The future of health behavior change research: What is needed to improve translation of research into health promotion practice? *Annals of Behavioral Medicine, 27*(1), 3-12.

[5] Cook, T. D., & Campbell, D. T. (1979). *Quasi-experimentation: Design & analysis issues for field settings*. Boston: Houghton Mifflin.

[6] Brown, C. A., & Lilford, R. J. (2006). The stepped wedge trial design: A systematic review. *BMC Medical Research Methodology, 6*, 54.

[7] Kazdin, A. E. (1982). *Single-case research designs: Methods for clinical and applied settings*. New York: Oxford University Press.

[8] Biglan, A., Ary, D., & Wagenaar, A. C. (2000). The value of interrupted time-series experiments for community intervention research. *Prevention Science, 1*(1), 31-49.

[9] Morgan, D. L., & Morgan, R. K. (2001). Single-participant research design: Bringing science to managed care. *American Psychologist, 56*(2), 119-127.

[10] Kearns, K. P. (1986). Flexibility of single-subject experimental designs. Part II: Design selection and arrangement of experimental phases. *Journal of Speech and Hearing Disorders, 51*, 204–214.

[11] Barlow, D. H., & Hersen, M. (1984). *Single case experimental designs: Strategies for studying behavior change.* 2nd Ed. New York: Pergamon.

[12] Horner, R. H., Carr, E. G., Halle, J., McGee, G., Odom, S., & Wolery, M. (2005).The use of single-subject research to identify evidence-based practice in special education. *Exceptional Children, 71*(2), 165-179.

[13] Bobrovitz, C. D., & Ottenbacher, K. J. (1998). Comparison of visual inspection and statistical analysis of single-subject data in rehabilitation research. *American Journal of Physical Medicine & Rehabilitation, 77*(2), 94-102.

[14] Strauss, A. (1987). Qualitative analysis for social scientists. Cambridge, England: Cambridge University Press

[15] Wilmink, A. B. M., Quick, C. R. G., Hubbard, C. Sff., & Day, N. E. (2003). Effectiveness and cost of screening for abdominal aortic aneurysm: Results of a population screening program. *Journal of Vascular Surgery, 38*(1), 72-77.

[16] Gelberg, L., & Siecke, N. (1997). Accuracy of homeless adults' self-reports. *Medical Care, 35*(3), 287-290.

[17] Palepu, A., Strathdee, S. A., Hogg, R. S., Anis, A. H., Rae, S., Cornelisse, P. G. A., Patrick, D. M., O'Shaughnessy, M. V., & Schechter, M. T. (1999). The social determinants of emergency department and hospital use by injection drug users in Canada. *Journal of Urban Health, 76*(4), 409-418.

[18] Bhandari, A., & Wagner, T. (2006). Self-reported utilization of health care services: Improving measurement and accuracy. *Medical Care Research and Review, 63*(2), 217-235.