Reducing Potentially Inappropriate Medication Prescribing for Older Patients: Enhancing Quality of Provider Practices for Older Adults in the Emergency Department (EQUIPPED)

Protocol **NCT: 04004936**

JUNE 25, 2021

Enhancing Quality of Prescribing Practices for Older Adults Discharged from the Emergency Department (EQUIPPED)

VA HSR&D Grant Multiple Principal Investigators
E. Camille Vaughan, MD, MS (corresponding, Atlanta VAMC) and
George L. Jackson, PhD, MHA (Durham VAMC)
Funding agency: VA Health Services Research & Development (IIR HX00257-01A1)

Atlanta VA Health Care System Protocol – Version 1 Submission Date – August 6, 2018
-- Version 2 Submission Date- August 8, 2019
--Version 3 Submission Date – March 18, 2021
--Version 4 Submission Date – June 25, 2021

Atlanta VA Health Care System Principal Investigator
E. Camille Vaughan, MD, MS
Atlanta Site Director
Birmingham/Atlanta GRECC

Site Summary Roles

Sites Collecting and Analyzing Identifiable Data
Atlanta, Durham

Sites with access to CDW data:
Atlanta, Durham

Additional Sites Receiving Research Dollars
The Salt Lake City VA will adapt a currently available clinical dashboard for EQUIPPED using CDW data. The dashboard developed for operational purposes. Dr. Karen Jeans, PhD, CCRN, CCIP, and colleagues with the VA Office of Research and Development have indicated that this is part of the quality impartment aspects of the EQUIPPED program (please see letter submitted with version 1 of this protocol).

Statisticians at the Birmingham VA will analyze deidentified prescribing data (to be certified by the Atlanta VA as deidentified) to examine outcomes of the clinical trial. Additional Birmingham staff members will consult on study methods.

ORD Determination that Randomized Sties are Not Engaged in Research
Dr. Karen Jeans, PhD, CCRN, CCIP, and colleagues with the VA Office of Research and Development have indicated that the sites randomized as part of EQUIPPED are not engaged in research. The implementation of EQUIPPED, which was developed for quality improvement purposes, by these sites is part of clinical quality impartment. The sites engaged in research as described above are evaluation/studying the process of implement EQUIPPED and the resulting

impact on prescribing. Please see the please see letter from Dr. Karen Jeans submitted with version 1 of this protocol

Background, Purpose, and Significance

1.1 Background

Enhancing Quality of Prescribing Practices for Older Adults Discharged from the Emergency Department (EQUIPPED) is a multi-component program to reduce the prescribing of potentially inappropriate medications (PIMs) to older adults upon discharge from the Emergency Department (ED). It has three core components: 1) provider education, 2) Electronic Health Record (EHR)-based clinical decision support (CDS) including pharmacy quick order sets to facilitate provider order entry, and 3) provider audit and feedback with peer benchmarking. In order to inform a Veterans Affairs (VA) system-wide approach to improve prescribing safety for older Veterans, we will conduct a study to determine best practices for influencing provider prescribing behavior in order to decrease PIMs prescribed for older Veterans at the time of ED discharge. The overall goal of this project is to determine which EQUIPPED implementation strategy (active or passive feedback) is most effective to reduce prescribing of PIMs for older Veterans discharged from the ED.

1.2 Purpose/Specific Aims

This research is being conducted to learn which implementation strategy of EQUIPPED is most effective to improve prescribing practices of ED providers toward older Veterans and determine the factors influencing implementation of this program to reduce the prescribing of PIMs to older adults upon discharge from the ED. Key questions include:

- Which implementation strategy (passive or active feedback) is most effective to influence provider prescribing behavior?
- To what extent is each component of EQUIPPED implemented with fidelity within each site and across sites?
- In what way is each component adapted in each site?
- What steps are taken to implement EQUIPPED in each site and what are the similarities and differences across sites?
- What facilitates and inhibits implementation?
- How well are EQUIPPED components maintained over time?
- What steps are taken toward sustainability in each site?
- What resources are needed to maintain EQUIPPED over time?

1.3 Preliminary Studies & Significance

The EQUIPED QI intervention was developed and implemented with funding from the VA Office of Geriatrics and Extended Care and Office of Rural Health. The EQUIPPED QI intervention, which provides pilot/preliminary information for the proposed trial, has been implemented in 11 VA EDs. Results from 4 of the initial EQUIPPED sites with in-person academic detailing demonstrated sustained pre-post improvement (reduction) in PIM prescribing rates by nearly 50% at 6 months,[1-3] suggesting the possibility of culture change with regard to

provider prescribing behavior. The EQUIPPED QI intervention typically involves in-person academic detailing (defined as educational outreach visits to improve clinical decision making[4]) using audit and feedback with peer benchmarking, which is more resource intensive.

The VA already uses both passive feedback (i.e. dashboards to report psychotropic medication use in community living center residents) and active feedback (i.e. implementation of a national academic detailing pharmacy program); however, there is little guidance on which strategy is most effective in the ED. In order to inform the optimal EQUIPPED strategy for improving provider prescribing behavior toward older Veterans in ED, we propose a trial comparing EQUIPPED with active provider feedback including academic detailing to EQUIPPED with passive provider feedback using a dashboard to deliver individual electronic reports.

1.4 EQUIPPED Tools that will be implemented by randomized sites

While each site will be randomized to be with 1) Active Provider Feedback Sites or 2) Passive Provider Feedback Sites, the work of implementing the tools will be done as part of clinical care quality improvement. In other words, specific decisions about how to implement the tools and with Active Provider Feedback or Passive Provider Feedback versions of EQUIPPED will be made by managers, administration, and staff at the facilities. Likewise, local or VA-wide entities may make the decision to rename components of the EQUIPPED program. Research documents may be changed to reflect any related name changes. Researchers from sites other than the randomized sites will evaluate/study the implementation process and results of EQUIPPED at the eight randomized sties. However, the sites, not the researchers, will have quality impartment/operational control over the process. It is possible and expected that the exact process of implementing EQUIPPED will vary from site to site based on the clinical, organizational, and quality improvement realities of the specific sites.

Dr. Karen Jeans, PhD, CCRN, CCIP, and colleagues with the VA Office of Research and Development have indicated that the sites randomized as part of EQUIPPED are not engaged in research. The implementation of EQUIPPED, which was developed for quality improvement purposes, by these sites is part of clinical quality impartment. The sites engaged in research as described above are evaluation/studying the process of implement EQUIPPED and the resulting impact on prescribing. Please see the please see letter from Dr. Jeans submitted with version 1 of this protocol.

1.4.1 The EQUIPPED tools are described in the background of this protocol because the precise implementation is being done as QI to enhance usual clinical care at the randomized facilities. Information provided in this background section is for reference in reviewing the protocol. Information provided in the background section does not represent research procedures.

EQUIPPED with passive provider feedback includes the following components: 1) didactic education, 2) computer decision support tools, and 3) provider feedback via monthly individual prescribing reports with peer benchmarking provided to ED clinicians.

1) Didactic Education: The component addresses the social cognitive theory (SCT) component of behavioral capacity. The EQUIPPED team has developed a presentation which covers the

physiology of aging, the burden of polypharmacy, and PIMs in older adults as defined by the 2012 and updated for the 2015 American Geriatrics Society Update to the Beers Criteria.[5] This presentation can be adapted for shorter presentation times as well. The site champions will offer learning sessions to their emergency medicine journal clubs to review the 2015 update to the Beers Criteria as published in the *Journal of the American Geriatrics Society* (may be based on future versions if published).[5] All educational activities may be monitored for attendance.

2) EHR-based Clinical Decision Support: This component addresses the SCT concept of self-efficacy by offering providers alternative medications that may be prescribed. Based on previous feedback from ED providers, the EQUIPPED team developed templates for outpatient pharmacy order sets within CPRS targeting common ED discharge diagnoses among older adults. Embedded within the pharmacy quick order sets are dose adjustments for renal impairment, point-of-prescribing education regarding medications to avoid, and links to publicly-available, evidence-based geriatric content such as a screening tool for depression (Geriatric Depression Scale). Providers will be trained by the on-site champion to refer to the quick order sets. When providers prescribe medications using the pharmacy quick order sets, the order entry process is streamlined with pre-populated fields including: "day's supply", "number of pills," and "method for prescription pick-up." For our VA QI project, template logic was reviewed by clinical pharmacists, ED providers, and the local VA pharmacy and therapeutics committee prior to implementation. In addition to expediting the order entry process, the order sets encourage providers to choose safer medications.[1] The pharmacy order sets simultaneously offer point of prescribing education for geriatric conditions and alternatives to PIMs as defined by the Beers Criteria. The order sets can be designed to include links at the point of prescribing to additional online geriatric educational content. For instance, based on provider feedback, order sets adapted by one EQUIPPED site offered links to the World Health Organization analgesic ladder and narcotics equivalency tables to simplify pain management.

3) Provider Feedback: As stated above, a key component of EQUIPPED is the provider feedback (example in Figure 3) about his or her monthly rate of PIM prescriptions written for older adults discharged from the ED. Based upon our experience within the VA, the Beers PIM framework was highly useful in the context of the multicomponent EQUIPPED Intervention. The usefulness was examined qualitatively among providers participating in the EQUIPPED pilot, who indicated that "usefulness" of the order sets was based on both "safety" (i.e., reducing risk of adverse events) and increasing "efficiency" of the prescribing process.[59] These are indications of both enhancing the perceived value of the desired behavior (i.e. SCT concept of expectancies) and the ability of the provider to change behavior (i.e. SCT concept of self-efficacy). Data related to individual prescribing behavior involves data pulled from VA's CDW. The Atlanta site has successfully piloted pulling ED discharge prescriptions from CDW using a Beers lookup SQL tool (developed at the Durham VA), which includes a list of all medications considered potentially inappropriate according to the 2015 update to the Beers criteria. For provider feedback, we focus on Category 1 medications, which are considered potentially inappropriate in all older adults. For the purposes of the ED setting, chronic nonsteroidal anti-inflammatory drug prescriptions are defined as any dose for 30 days or more. The Beers lookup tool facilitates evaluation of prescribing data in order to easily generate monthly provider reports. The Atlanta site EQUIPPED team will include a project coordinator who will assist in generating the provider reports based on the CDW data pull. Aggregate de-identified prescribing data will

be provided to the statistician based at the Birmingham site of the Birmingham/Atlanta GRECC each month for outcome assessment of PIM prescribing. In addition to feedback of individual prescribing patterns, providers also receive anonymous peer benchmarking comparing his/her individual performance to other ED providers at the same site (i.e., a scorecard of PIM prescriptions).[6,7] This monthly feedback will come in the form of an emailed link to a clinical dashboard showing individual and site level prescribing data for each provider. No patient-identifiable health information will be included in the provider feedback form; however, site champions will have access to individual records if a provider would like to review specific cases to determine the appropriateness of a given prescription.

1.4.2 EQUIPPED with active provider feedback includes the same 3 components as those included previously with the addition of 1:1 in-person provider feedback using academic detailing.

1) The initial individual feedback session will be provided in-person to all staff providers (physician, APRN, PA). Clinical pharmacists or an ED provider may partner with the site champion to provide 1:1 feedback depending upon team composition at each site. In-person 1:1 provider feedback typically requires about 15 minutes and involves the following: a) an introduction of the provider's individual report structure and their baseline data as well as the current month's prescribing pattern; b) review the specific drug classes of PIMs that were prescribed during the reporting period; c) comparison of individual prescribing data to the cohort of peer providers within local ED; d) review of the top 5 PIM classes to avoid for the local ED; e) discussion of evidence-based alternative treatments appropriate for older adults; f) a brief demonstration of the EQUIPPED order set appropriate to that provider's needs based on prescribing of PIMs; and g) allowing time for provider question and discussion.
2) The onsite EQUIPPED champion will be an ongoing local expertise to provide consultation on clinical questions resulting from the 1:1 sessions such as consideration of appropriate medication alternatives.
3) To reinforce prescription decisions at the point of the prescription, enhanced medication safety alerts/messages will be placed on the screen for prescribing Beers list medications, reminding prescribers of potential impacts on older patients. These "blue line" messages were added as part of the EQUIPPED quality improvement work at two facilities, and were associated with reductions in PIM prescribing even outside the ED.[8]

1.4.3 As with many other quality impartment activities, facility leadership will indicate approval to implement the program as indicated. This process and documentation is part of a common quality improvement activities that occurs frequently outside of the research setting.

1.5.1 Process for Providing Tools to Sites that will Be Randomized.

The section below describes the assistance that will be provided to sites who are implementing the EQUIIPED intervention (Active or Passive) as part of their quality improvement efforts. While the processes outlined below will be provided by individuals who are on the research team, the process is part of the quality improvement implementation of EQUIPPED. Members of the team have provided similar assistances are part of previous QI development and implementation of EQUIPPED. **These processes were reviewed with the VA Office of Research and Development, which determent that they did not result in the eight sites**

being engaged in research (please see letter submitted with version 1 of this protocol). Names are mentioned as examples. Tasks described below may be done by members of the study team with appropriate credentials who are listed on staff study lists and have completed required research training. Additionally, the time lines outlined for the process of implementation support provided by the study team may need to be adjusted depending on the needs of given facilities.

Stage 1 - Pre-Implementation Preparation (Approximately 6 Months):

1) *Identify and Coach Site Champion.* It is critical that all sites have a clinical champion, typically an ED physician or geriatrician, who will lead the efforts to promote ongoing EQUIPPED education and use of the order set. The site champion will liaison with the Atlanta-based implementation team, negotiate time for clinical staff to participate in EQUIPPED activities, and help to interface with the local clinical applications coordinator and pharmacy service in order to facilitate implementation of the EQUIPPED discharge order sets.
2) *Adaptation of the EQUIPPED Order Set:* Each site champion will participate in conference calls approximately twice a month with the implementation team in Atlanta to guide the implementation of EQUIPPED components. The EQUIPPED discharge medication order sets are adaptable depending on local formulary alternatives or based on recommendations from the local implementation team. There are 25 EQUIPPED order sets originally developed through focus groups with ED providers at the Atlanta VA. These were updated in 2016 according to the most updated version of the Beers Criteria. Most EQUIPPED sites opt to include all of the order sets. Some sites opt to implement a select number of order sets targeting the most commonly prescribed PIMs at the local facility. This is an example of how the EQUIPPED program may be adapted.
3) *Obtain Baseline Data:* The Atlanta VA implementation team includes Chris Jasien, who is an experienced CDW data analyst. Ms. Jasien incorporated the Beers lookup tool developed the Durham VA to obtain monthly prescribing data from VA's Corporate Data Warehouse for all 11 VA EDs currently implementing EQUIPPED. Once the eight implementation sites for the HSR&D project are confirmed, Ms. Jasien will obtain baseline prescribing data for the 6 months prior to implementation to establish initial levels of performance.

Stage 2 – Launch Implementation Models (Approximately 1 Month Prior to Initial Measurement of Outcomes):

The Atlanta team, led by Dr. Vaughan, will finalize a training manual for champions to use to deliver provider prescribing education for older Veterans in the ED setting, specifically in their local VAMCs. The education materials include didactic information on geriatric prescribing, EQUIPPED order set education, AGS pocket cards on Beers drugs, reminder cards, alternative prescribing tables, and other tools and training materials needed to train staff at their own hospital. All clinical decision support tools will be accessible in CPRS. Baseline data will be available through a Research project folder within the VA's VINCI framework on a secure VA server. Baseline data from Stage 1 will be shared with all site champions to incorporate in the initial provider education session. Additionally, if a site is randomized to active provider feedback, the Atlanta team will coach the site champion (and clinical partner for 1:1 feedback, if applicable) in the use of the education materials to train providers in the rationale for using the EQUIPPED order sets within the VA EHR. An additional module for the training manual for

active provider feedback sites will review teaching concepts, techniques, and materials for providing academic detailing regarding prescribing practices toward older Veterans. Using a short 20-minute, PowerPoint presentation appropriate for in-service training, a teleconference training session will be conducted to provide a structure for the academic detailing approach outlined in section C.3.b. A certification checklist will be used to ensure all champions demonstrate competency.

Stage 3 – Continue Provider Feedback and Measurement of Outcomes for 1 Year:

1) ED providers will receive monthly electronic provider prescribing feedback reports for monthly PIM rates, including the number of older Veterans seen in the ED, number of prescriptions given, and the number of PIMs (including drug class).
2) *Active Provider Feedback:* In addition to the electronic feedback reports available for the remote intervention, the champion (or clinical partner) will provide 1:1 academic detailing that includes audit and feedback with peer benchmarking to ED providers and ongoing monthly 1:1 feedback to outlier PIM prescribers in the ED at the site.

Research Methods

2.0 Design

In a parallel cluster randomized trial, we will randomize 8 VA facilities to implement the EQUIPPED QI intervention with either passive provider feedback (4 sites) or active provider feedback (4 sites). Specifically, it is anticipated that all sites will implement EQUIPPED components including: didactic education concerning the Beers Criteria; decision support by order sets; and monthly provider prescribing feedback. However, *passive* provider feedback sites will implement monthly provider feedback via an electronic dashboard with audit, feedback and peer benchmarking, while *active* provider feedback sites will implement one-to-one (1:1) in-person academic detailing from a professional colleague that includes in-person audit, feedback, and peer benchmarking and provide on-site expertise. To compare the effectiveness of EQUIPPED with in-person academic detailing including proactive feedback (*active feedback*) versus EQUIPPED with passive electronic audit and feedback (*passive feedback*) intervention, we will evaluate the monthly proportion of PIM prescribing as % of individual prescriptions (primary outcome) in each arm. It is hypothesized that the decline in PIM rates will be greater in the presence of EQUIPPED with active feedback compared to EQUIPPED with passive feedback.

After the initial recruitment and randomization, one of the eight sites had to pause order set development due to COVID-19 and an off-site detail of one of the core implementation team members. After several months of stalled progress with EQUIPPED implementation, the site decided to pause EQUIPPED implementation until at least spring 2021. We have recruited an additional site to fill the open study spot. We will continue to collect prescribing data from both sites and collect implementation evaluation data from the newly recruited facility based on the timeline for the award. If the initial facility determines they can move forward in 2021, we propose collecting implementation evaluation data as originally planned (would increase number of sites to n=9). The data analysis plan for this change is reflected below in section 2. 1. 3.

As described in detail in the background section, researchers from sites other than the randomized sites will evaluate/study the implementation process and results of EQUIPPED at the eight randomized sties. However, the sites, not the researchers, will have quality impartment/operational control over the process. It is possible and expected that the exact process of implementing EQUIPPED will vary from site to site based on the clinical, organizational, and quality improvement realities of the specific sites. Further, local or VA-wide entities may make the decision to rename components of the EQUIPPED program. Research documents may be changed to reflect any related name changes.

In order to inform the eventual dissemination strategy, we will also include formative evaluation and micro-costing of the two methods of implementing provider feedback as part of EQUIPPED.

We will conduct an in-depth, theory-based formative evaluation of sites, with the goals of understanding: 1) factors that may impact organizational readiness to implement EQUIPPED (i.e., organizational readiness for change (ORC)) and implementation of the EQUIPPED as outlined in the Organizational Theory of Implementation Effectiveness (OTIE); 2) changes in these factors over the course of one year; and 3) association between ORC and factors suggested by the OTIE to both successful implementation and sustainability over time. We will use a mixed-methods approach to measure ORC and change in related components over time. The ultimate goal is to inform the process of implementing EQUIPPED and be able to interpret potential results of the behavior change intervention regardless of primary trial outcome.

The study has three research aims. The procedures for these research aims are described below.

- Aim 1 – Examining the Impact of Passive Provider Feedback vs. Active Provider Feedback Through a Randomized Trial
- Aim 2 – Determination of Factors Affecting Organizational Adoption of EQUIPPED
- Aim 3 – Micro-Costing the Active and Passive Feedback Versions of the EQUIPPED Intervention

2.1 Aim 1 – Examining the Impact of Passive Provider Feedback vs. Active Provider Feedback

2.1.2 Primary Implementation Science Trial Outcome – % of Prescriptions that Represent Potentially Inappropriate Medications (PIMs)

The primary aim of the study is to compare the effectiveness of the EQUIPPED intervention to reduce the proportion of PIM prescriptions using active vs. passive processes for provider feedback aimed at improving prescribing toward older Veterans in the ED setting. PIMs will be defined according to the Beers criteria, which list medications that should generally be avoided in older adults.[15,40,41] The Beers criteria have been used extensively in PIM research in the outpatient setting, along with data supporting the use of PIM measurement as an overall measure for better prescribing quality.[4-6] Data on PIMs and all prescriptions will be gathered from the CDW from the eight VAMCs 6 months before and 12 months after the intervention period. As detailed in the power calculation, the study requires a minimum of 100 prescriptions per month

for older Veterans at each site. It is likely that most EDs will have many more than the required 100 prescriptions per month during the sampling period. The limit is above 100 because it is likely some EDs will have lower overall patient volumes, especially for older Veterans. Using our previously developed code (SQL) for the current EQUIPPED QI sites, we will be able to collect data needed to determine monthly PIM rates, number of older Veterans (≥65 years of age) seen monthly, number of older Veterans who were discharged home, number of prescriptions for these discharged Veterans, and the number of PIMs, including specific drugs. For the sites, we will be able to describe the volume of ED visits overall and for older Veterans, the number of providers, and the number of overall prescriptions. We will ensure data validity by checking for inter-rater agreement on 10% of the data gathered by CDW and chart review at each site by the champions. **The primary endpoint will be the reduction in PIM risk from baseline to 12-months after the EQUIPPED Intervention, with a benchmark goal of <5% at each site.** We have data suggesting that PIM risks vary at sites from 7.4-11.8% at baseline (standard deviation of 0.8 to 1.9).

We are applying for waivers of informed consent and HIPAA authorization to allow for collecting prescription and related health data originating in the VA electronic health record for qualifying patients seen in randomized Emergency Departments.

2.1.3 Aim 1 Data Analysis Plan

The statistical analysis plan described below may be adjusted based on changes in statistical science methods and/or to fit the specific mathematical properties of collected data.

The primary efficacy outcome of interest is the % of prescriptions that are PIMS as defined according to the Beers criteria prescribed to adults aged 65 and older and discharged from the ED. Poisson regression will be used to evaluate the number of PIMs prescribed for 6 months prior to the first EQUIPPED intervention at each site compared to at least 12 months of prescribing data following the implementation of EQUIPPED provider feedback at the local site. The total number of prescriptions will be used as an offset term to account for differing volumes of prescriptions between sites as well as potentially over time. We will not have a single date of implementation as the implementation period will begin based on local scheduling. The implementation timeline will vary by site. Poisson regression will be used to evaluate the effect of the two methods of provider feedback on prescribing behavior of PIMs by including randomization group as a variable in the model. If the Poisson model demonstrates over (or under) dispersion other, related, models will be explored, e.g., negative binomial. Analyses will be conducted using SAS version 9.4 (SAS Institute, Cary, NC). Our primary aim, on which we will base sample size, is the evaluation of the EQUIPPED implementation. We will have 6 months of pre- and 12 months of post data including hospital site, provider ID, total prescriptions, and PIMs.

We will conduct three analyses for the primary outcome of monthly PIM prescribing to assess the impact of both the initially recruited, randomized sites and the newly recruited VA facility's inclusion. The analyses will be conducted as follows:

1) Intention to treat analysis: Include eight originally randomized sites

2) Per protocol analysis: Include seven originally randomized sites that implemented EQUIPPED
3) Per protocol analysis: Include seven originally randomized sites that implemented EQUIPPED + the non-randomized 8th site that was added to the Active Provider feedback EQUIPPED group

2.1.4 Sample Size and Power Considerations (power calculated prior to trial) and Selection/Recruitment of Sites/Subjects

Power estimates are based on Aim 1, hypothesis 1 (i.e., primary outcome of change). The primary outcome is at the level of the individual prescribing decision. We plan to engage a total of eight VA sites with at least 1,200 eligible prescriptions per year to patients ages 65+ per ED. This will provide a total of approximately 4,800 eligible prescriptions during the pre-implementation period and 9,600 eligible prescriptions during the post time period. It can be reasonably assumed that these eligible prescriptions will be equally distributed between the randomization groups. Based upon preliminary data, we estimate that approximately 7.1% of these total prescriptions at baseline will be Beers PIMS. Given this sample size, we have near 100% power to detect a change in the risk of PIMs of 5% (i.e., 7.1% to 2.1%).

2.1.5 Assess Impact of EQUIPPED on the Social Cognitive Factors Impact Individual Behavior Change

We will ask physicians at participating EDs to complete a brief survey at baseline, 6, and 12 months to assess key components of the SCT that we expect to be impacted by the intervention. This will allow us to determine if these components change and whether they are associated with the impact of the intervention on decisions made by individual providers. Measured components will include: 1) behavioral capability (knowledge of Beers List Medications); 2) expectations about the importance of addressing PIMs as defined by the Beers List; 3) self-control (believe that alternative medications are available); 4) reinforcement/information to monitor goals (use of EQUIPPED components at 6 and 12 months), and 5) self-efficacy for making changes. Similar to other studies on various provider behaviors and self-efficacy, for example, (e.g., provider panel management,[9] provider implementation of motivational interviewing in primary care,[10] and provider intentions to prescribe pre-exposure prophylaxis[11]), survey questions will be developed specifically for this study and according to guidelines provided by Bandura (2006).[12] The environment (i.e. system level factors) will assessed through a formative evaluation of the implementation process supported by the SCT and particularly guided by the Organizational Theory of Implementation Effectiveness (OTIE). This survey will be fielded after it is approved by the IRB.

We will conduct statistical mediation analyses to test whether EQUIPPED changed the targeted intermediate variables of behavioral capability, expectations/expectancies, self-control, reinforcements, and self-efficacy (an 'action test') that are obtained through the survey described above; if change in these targeted intermediate variables was associated with a change in the % of prescriptions that represent PIMS (a 'conceptual test'), and if EQUIPPED's effects on this outcome variable were attributable to its effects on the intermediate variables (an 'indirect effects' or mediation test).[13] The mediators will be tested simultaneously in order to determine the unique influence of each potential mediator. We plan for analyses will be conducted with

structural equation modeling using Mplus (version 6.11).[14] However, other appropriate software may be utilized to analyze data from this study.

2.2 Aim 2: Determination of Factors Affecting Organizational Adoption of EQUIPPED

We will conduct an in-depth, theory-based formative evaluation of sites, with the goals of understanding: 1) factors that may impact organizational readiness to implement EQUIPPED (i.e., organizational readiness for change (ORC)) and implementation of the EQUIPPED as outlined in the Organizational Theory of Implementation Effectiveness (OTIE); 2) changes in these factors over the course of one year; and 3) association between ORC and factors suggested by the OTIE to both successful implementation and sustainability over time. We will utilize a mixed-methods approach to measure ORC and change in related components over time. The ultimate goal is to inform the process of implementing EQUIPPED and be able to interpret potential results of the behavior change intervention regardless of primary trial outcome. Further, we will inform the implementation of future provider behavior change programs. Table 1 below details factors that will be examined using the OTIE through the formative evaluation. Definitions are those developed by Bryan Weiner based on his adaptations of work by Klein and Sorra.[15-18] The numbers in the table referring to data collection processes correspond to section 2.2.1 below. Other applicable theories, frameworks, or related concepts may be considered during data analysis.

Table 1: OTIE Factors Assessed through Formative EQUIPPED Evaluation

Factor	Definition	Data Collection Process
Pre-and Early Implementation of EQUIPPED – Factors Expected to Impact the Readiness of Sites to Implement EQUIPPED		
Change Valence	Value that organizational members ascribe to a proposed change (i.e., its perceived attractiveness).	2
Task Demands	Knowledge about the tasks that need to be performed, the resources (human, financial and material) that are needed, and the time and effort that are needed to implement the intervention.	2
Resource Availability	Accessibility of financial, material, or human assets that can be used to support initial and ongoing innovation use.	1,2
Situational Factors	Contextual elements that affect the confidence and commitment of organizational members to implement the intervention.	2
Organizational Readiness for Change/To Implement EQUIPPED		
Organizational Readiness for Change (ORC)	Extent to which targeted organizational members are prepared to make the changes in organizational policies and practices that are necessary to put an innovation into practice and support its use. This is based on 2 factors: 1) commitment to change and 2) change efficacy.	2
Process of EQUIPPED Implementation		

Implementation Policies and Practices (IPPs)	Plans, practices, structures, and strategies that an organization employs to put the innovation into place to support innovation use	3,5
Implementation Climate	Shared perceptions of implementation policies and practices in terms of their meaning and significance for innovation use [19].	3,5
Innovation-Values Fit	Extent to which implementers and users perceive that innovation use will foster the fulfillment of their values [19-22]. Values are concepts or beliefs that (a) pertain to desirable end-states or behaviors, (b) transcend specific situations, and (c) guide the selection and evaluation of behavior and events [23].	3,5
Innovation-Task Fit	Extent to which the innovation is compatible with task demands, work processes, and organizational capabilities.	3,5
EQUIPPED Effectiveness and Sustainability		
Implementation Effectiveness	Consistency, quality, and appropriateness of innovation use within an organization[19,20,24].	4,5
Innovation Effectiveness	Benefits an organization realizes from an innovation [19] (i.e., did EQUIPPED lead to a reduction in PIMs).	Trial outcome
Sustainability	Expected ability to continue to utilize EQUIPPED following the study.	6

2.2.1 Formative Evaluation Process:

In summary, the formative evaluation will begin by identifying baseline characteristics (i.e., before and/or during the early stages of implementation) of the organization and team that may impact implementation. This will be followed by: 1) assessment of readiness to implement EQUIPPED; 2) monitoring of the implementation process; 3) monitoring of implementation progress; 4) qualitative interviews addressing implementation factors suggested by approximately the 6-8 months following initial implementation of EQUIPPED; and 5) evaluation of program sustainability approximately 1 year after the delivery of the delivery of the first EQUIPPED report.

Steps in the Formative Evaluation Process

1. **Collection of Baseline Characteristics that may Impact Implementation**. The eight sites will be asked to identify all individuals directly involved in the planning and execution of implementing EQUIPPED (e.g. clinical champions, ED Chiefs, pharmacists CACs). This is termed the core implementation team. Additionally, the eight sites will be asked to identify ED providers and staff that may encounter changed clinical decision-making as a result of implementation of the applications. These sites will be asked to complete a baseline site information document (1 survey report per site/medical center filed via VA REDCap Survey software) that will collect information on core implementation team members and processes and size and composition of the medical centers and impacted clinical services, as well as

identify additional ED providers and staff potentially impacted by the implementation. The research team may update lists of names of individuals or information from the site information document as needed to conduct the study.

2. **Assessment of ORC.** Organizational readiness for change is the extent to which organizational members are prepared as a group to make changes in organizational policies/practices that are necessary to implement and support innovation use (change commitment) and their perceived ability to do so (change efficacy). As with individuals,[25] attributes impacting ORC include change valence (perceived value of the innovation) and information about perceived task demands, resources available, and situational context (e.g., competing demands).[18,26]

   ORC Survey: Core implementation team members and ED providers will receive the validated Organization Readiness for Implementing Change measure, a 12-item computer-based survey which examines perceptions of organizational-level change efficacy and commitment to newly implemented interventions. Survey responses will objectively examine ORC as a two-dimensional construct encompassing change commitment and change efficacy. This instrument was developed specifically to measure aspects of the Weiner Theory of ORC.[26] The survey may include additional context questions and will receive IRB approval prior to being fielded. The survey will be fielded via VA REDCap survey software.

   ORC Semi-Structured Qualitative Phone Interview: In addition, we will conduct semi-structured qualitative telephone interviews of the core implementation team and approximately 3-5 ED providers at each site to assess ORC and factors that are hypothesized to predict ORC (i.e. change valance/value place on the apps and assessment of what it will take to implement the EQUIPPED program). Semi-structured interviews will allow us to study implementation processes, which tend to be non-linear and context sensitive[27,28] and will permit us to compare patterns across cases.[29] The semi-structured interview guide will need to receive IRB approval interviews are conducted.

3. **Quarterly Documentation of Process/Workflow of Implementation**. As part of the quality improvement support (i.e., not research activity) for implementing EQUIPPED, the QI team will work with each site to establish and summarize the workflow used as part of equipped. Components of the workflow process will then be stored in a Microsoft Excel or Word spreadsheet or document to be sent to the sites for updates approximately every three months. The exact format of the summary, which may be updated and will be retained by the research team, will potentially vary based on the quality improvement needs and decisions of each participating site. .

4. **Bi-monthly Monitoring of Implementation – Implementation Progress**. We will also measure the degree of implementation and barriers and facilitators of implementation process through approximately bi-monthly facility-level reports from the eight sites collected through a computerized survey using the VA REDCap survey software. Site progress with implementation will be assessed using the Stages of Implementation Completion (SIC).[30,31] The SIC enumerates key pre-implementation, implementation and sustainability milestones. Dates by which specific implementation milestones were reached will be identified. We will then examine if the degree of ORC is associated with the rapidity with which sites go through implementation steps. Bi-monthly (every other month) reports will also include assessment of barriers and facilitators identified through the ORC measurement process.

5. **Evaluation of the Implementation Process – Qualitative Interviews.** At approximately 6-8 months following the start of the implementation process at each of the eight sites, we will

conduct semi-structured qualitative telephone interviews among the core implementation team at each site to assess OTIE factors suggestive of implementation success. The goal will be to interview the same individuals interviewed at baseline. The questions composing the qualitative interview guide will depend upon the formative evaluation. As such, the guide will be developed after the initial implementation of EQUIPPED and approved by the IRB prior to use.

6. **Assessment of Sustainability.** At approximately one-year post-implementation at each site, we will assess the sustainability of EQUIPPED.

   Sustainability (PSI) Survey: The Mancini & Marek Model of Community-based Program Sustainability will be used to conceptually guide the evaluation of sustainability.[32] Mancini & Marek propose that six elements are important to achieve long-term sustainability: Leadership competence, effective collaboration, demonstrating program results, strategic funding, staff involvement and integration, and program responsivity. The validated 23-item Program Sustainability Index (PSI) computer-based survey measures the 6 sustainability elements.[32]Sustainability Semi-Structured Qualitative Phone Interview: Each core implementation team member and ED provider may be surveyed. Additionally, using semi-structured interview methods, we will interview the members of the core implementation team at each site. Precise timing of the interviews may be impacted by individuals' schedules in relation to time of the intervention and previous interviews. We have previously used the combination of PSI and qualitative interviews to evaluate the sustainability of a multi-facility VA program.[33] The questions composing the qualitative interview guide will depend upon the formative evaluation. As such, the guide will be developed after the initial implementation and approved by the IRB prior to use.

7. **Consent Process for Formative Evaluation.** Staff participation in the formative evaluation is entirely voluntary. Some individuals may feel self-conscious or embarrassed if asked questions about something with which they are unfamiliar. Additionally, because research participants are VA employees, they may be concerned their responses will become known to colleagues or supervisors. To minimize this risk, we are requesting a waiver of documented consent, in part, to avoid providing a link between the research participant and the data collected.

   An introductory email may be sent from a known individual at each site informing each potentially eligible participant of the study. The introductory email need not be resent upon outreach for subsequent surveys or invitations to participate in interviews with the same participants.

   For the surveys, the potential introductory email described above will be followed by a scripted email (must be approved by the IRB) sent from study staff containing information about the study and informed consent. Clicking the link to start the survey implies informed consent.

   For the qualitative interviews, the potential introductory email described above will be followed by a scripted email sent from study staff containing information about the study and informed consent. Study staff will follow-up either by email or phone to schedule a phone interview with interested parties. At the start of the scheduled interview, the person conducting the interview will ask if there are any questions about the study and review the elements of informed consent. The study staff member will gather verbal informed consent from the participant(s) prior to proceeding with the interview. Consent documents must be approved by the IRB prior to beginning related study procedures.

2.2.2 Formative Data Analysis

The analysis plan described below may be adjusted based on changes in related scientific methods and/or to fit the specific properties of collected data.

Core to the concept of formative evaluation is continual analysis of results and feedback to stakeholders. Like with statistical analysis, the analysis plan laid out below may be adjusted based on the statue of the science related to such analysis and the specific features of collected data. Key data sources are qualitative interviews, surveys to assess organizational readiness for change, and collection of detail about organizational characteristics and implementation process and progress. All qualitative interviews will be transcribed in full. Rapid analysis approaches will generate preliminary findings to share among the research team. This effort will involve an initial review of factors identified as directly impacting the process of supporting implementation and impact on clinical workflow. Rapid analysis will be followed by in-depth content analysis. Content analysis to examine the telephone interviews will involve three phases: data coding, within-case analysis, and between-case analysis. In the data coding phase, we will use qualitative data analysis software (ATLAS.ti or other appropriate analysis software) to code the study data. The OTIE will provide a starting list of codes, which we will supplement with emergent codes as analysis proceeds. Using a common codebook, two research staff members will conduct a preliminary test of codes by independently coding approximately five transcripts (more may be independently reviewed if determined to be necessary). Based on the preliminary test, the research staff members will sharpen the coding manual's definitions, decision rules, and examples. Research assistants will code the remaining documents.

In the second phase, we will conduct a within-case analysis of each VA using ATLAS.ti to generate reports of all text segments for each code. We will assess the degree to which the construct emerges in the data (its "strength"), the degree to which the construct positively or negatively affects implementation (its "valence"), and the degree to which relationships among constructs are consistent with the hypothesized model. We will assess support for the hypothesized relationships by using three criteria proposed by Trochim[34] and Miles and Huberman.[35] First, we will look for the overall covariance of the constructs (e.g., whether VA clinics exhibiting strong implementation climate have supportive administration). Second, we will look for explicit attributions or the identification of plausible mechanisms to link the two constructs (e.g., participants attribute a strong implementation climate to the deployment of appropriate implementation policies and practices).

In the third phase, we will apply the same criteria across the cases to determine if cross-case variation in implementation is consistent with the hypothesized relationships in the model. Consistent with the organization-level focus of the model, we will aggregate and analyze quantitative data on implementation policies and practices (e.g. staffing levels) and other study constructs using simple statistics. In addition, we will create within-case and between-case data displays that cross-tabulate the quantitative and qualitative data in order to facilitate the use of pattern-matching logic.[35]

2.2.3 Linking Measures Within and Across Implementation Processes from Different Data Sources:

We will combine quantitative measures of the degree of ORC, factors outlined in the OTIE that may influence implementation process, completeness of implementation progress, and sustainability to both implementation and intervention effectiveness outcomes. These data will be supplemented with qualitative data sources such as semi-structured individual interviews and supplemental process information. Inclusion of the qualitative component will enhance understanding of the local context. Quantitative and qualitative findings will produce mixed method findings to inform our understanding of the process of implementing EQUIPPED.

2.3 Aim 3. Micro-Costing the Active and Passive Feedback Versions of the EQUIPPED Intervention

Because the earlier version of the EQUIPPED intervention was done as a quality improvement project, we do not have detailed information on how much the intervention costs. For example, while the 10 sites that have implemented a QI version of EQUIPPED received an average of $50,000 from the Office of Geriatrics and Extended Care, we have no way of knowing details of how that money was spent and whether costs were covered. By micro-costing the intervention we will be able to learn details of specific factors that may impact the cost of the intervention to the organization. Such costs will impact feasibility of wide and sustained implementation of EQUIPPED, if successful. Specific costs will account for 1) labor costs; 2) equipment; and 3) overhead costs such as utilities. The cost of the intervention will be considered from the VA health system perspective, hence, we will not consider individual patient-level direct or indirect costs.[36] Costs will consider both the cost of implementing the program and carrying it out. Because many of the tools have been developed for the intervention and will be provided to the medical centers, the incremental cost of the program will not include the cost of developing these tools.

The micro-costing analysis plan described in this section may be adjusted based on changes in related scientific methods and/or to fit the specific properties of collected data.

Micro-costing of the intervention involves direct measurement of the labor inputs required to both implement and conduct each intervention task. Labor cost includes the fixed costs of implementation planning (e.g., participation in meetings) and training staff of the intervention processes as well as the variable cost of delivering the intervention to each provider. We have developed a log sheet with instructions that can be used by a sample of providers to log their activity time for patients in a given project over the course of a one-week period. The training, implementation, and intervention-related time of each provider will be multiplied by his/her respective wage rate (including fringe benefits), aggregated, and then divided by the number of Veterans served at each ED to derive per-Veteran intervention labor cost for a site. We will account for equipment needed to deliver the interventions (e.g., computers, patient handouts). The VA healthcare system also incurs substantial indirect costs such as administrative costs, utilities, etc., that are not specific to a health service. We will calculate a cost multiplier using the total indirect and direct cost variables in the VA's Managerial Cost Accounting System

(formerly Decision Support System) extract file and apply it to the above direct cost estimates to derive total (direct + indirect) intervention cost.

3.0 Privacy, Confidentiality, and Information Security

3.1. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:

3.1.1 Patients: The Personal Health Information that will be obtained, used, and/or shared for VA patients in this study includes:

Identifier(s)	Source(s) of Health Information
☐ Names	☒ Medical history & physical exam information
☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: VA Facility, city	☐ Photographs, videotapes, audiotapes, or digital or other images
☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: ED visit dates, patient's DOB	☐ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe:
☐ Telephone numbers	☒ Progress notes
☐ Fax numbers	☒ Diagnostic / Laboratory test results
☐ Electronic mail addresses	☒ Operative reports
☒ Social Security Numbers	☐ Imaging (x-ray, CT, MRI, etc.)
☒ Medical record numbers	☒ Discharge summaries
☐ Health plan beneficiary numbers	☐ Survey / Questionnaire responses
☐ Account numbers	☒ Billing records
☐ Certificate and/or license numbers	☒ HIV testing or infection records
☐ Vehicle identifiers and serial numbers, including license plate numbers	☒ Sickle cell anemia information
☐ Device identifiers and serial numbers	☒ Alcoholism or alcohol use information
☐ Web Universal Resource Locators (URLs)	☒ Drug abuse information
☐ Internet Protocol (IP) address numbers	☐ Mental health (not psychotherapy) notes
☐ Biometric identifiers, including finger & voice prints	☐ Psychological test results
☐ Full-face photographic images and any comparable images	☐ Genetic testing
☐ Any other unique identifying number, linked study ID, characteristic, or code, describe:	☐ Other, describe:

3.1.2 VA Employees: We are NOT collecting Personal Health Information from VA employees in this study. However, this is the data that will be obtained, used, and/or shared for VA

employees: names, the employee's VA facility including city, survey/questionnaire responses, audiotaping of interviews, and a study ID created for the VA employee.

3.2 Data and/or Specimen Acquisition
Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Provide description of processes: The primary outcome related to provider prescribing will collect aggregate data relating to provider prescribing patterns for Veterans 65 years and older who are discharged from each of the eight EQUIPPED VA ED sites through the VA Corporate Data Warehouse (CDW). While some characteristics such as unique Veteran ID will be collected in order to develop the provider feedback reports, the research project has no direct or indirect patient contact or involvement. Data collected for the formative evaluation and micro-costing aims do not include patient-level information. Data for the formative evaluation will be obtained via electronic surveys and interviews of VA Employees. Regarding the data collection in support of Aim3, authorized study personnel will access the VA's Managerial Cost Accounting System (formerly Decision Support System) extract file and apply it to the direct cost estimates to derive total (direct + indirect) intervention cost.

☒ Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.): As noted previous in Section 1.5.1, Stage 1, subsection 3, the Atlanta implementation team will obtain from CDW baseline prescribing data for the 6 months prior to implementation to establish initial levels of performance.

☐ Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number: .

3.3 Level of Data
The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

☒ Identified (e.g., names, addresses or other identifiers included)
☒ Coded (direct and/or all identifiers removed, but study code/ID included)
☒ De-Identified (all HIPAA 18 and study ID/code removed):
- ☒ Verified Statistically
  OR
- ☐ Verified by Absence or Removal of HIPAA 18 and study ID

☐ Limited Data Set
☐ Other: Describe:

4.4 Location of Data and/or Specimens, and Data Retention Plan

4.4.1 Data and/or Specimen Location:

Electronic Data: ED provider participant names and contact information will be stored in a secure database housed and maintained on the VA Atlanta research server. Appropriately credentialed study staff members form the Atlanta and Durham VAMC teams may access identifiable research information stored on the Atlanta server to the extent needed to conduct the study. Further, a copy of data related to the formative evaluation and micro-costing aims of this study may be stored on secure servers at the Durham and Atlanta VAMC. All electronic data stored in Durham will be on VA servers behind the VA firewall on the HSR&D drive (p:\EQUIPPED). Identifiable data from the study may be analyzed on either the Atlanta or Durham VAMC research servers. As soon as practical, all official final datasets from all aims will be stored on research server at the Atlanta VAMC.

Prescribing data will be stored in a research-secure project folder within the VA Informatics and Computing Interface (VINCI at http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). VINCI is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

As described above, surveys and reports collected as part of the formative evaluation will be collected through VA REDCap (Research Electronic Data Capture) stored on the VINCI servers. These surveys will not contain individually identifiable patient information. Data from the REDCap surveys may be downloaded to secure research servers at the Atlanta and/or Durham VA Medical Centers. Interview data will be collected by recording phone conversations. While most study interviews will be recorded directly to researcher servers in Durham or Atlanta, study interview recordings may initially be made on the remotely-located team member's VA-issued and maintained computer and will be moved to the Atlanta server as soon thereafter as is practical.

Per standard VA-wide Health Services Research & Development operating procedures for transcribing VA research recordings, approved staff from the VA Salt Lake City (VASLC) will transcribe the EQUIPPED audio files. The VASLC has a Professional Transcription Service available to VA sites and monitored by their own IRB. The EQUIPPED audio recordings to be transcribed by VASLC staff will be labeled by the subject's unique alphanumeric code and saved behind the VA Firewall in EQUIPPED study's secure shared project folder on the Atlanta or Durham VAMC researcher servers. The VASLC transcription staff will be given access to a sub-folder within EQUIPPED study's secure project folder located on the Durham IRB server (study folder labeled EQUIPPED IIR) where audio files are located. While not anticipated, similar arrangements may be made to access data on the Atlanta researcher server if needed. Approved study staff will place a copy of the audio files in this folder for an approved VASLC transcriptionist to access for the purposes of transcription. The VASLC transcriptionist will transcribe each interview verbatim and save the completed transcript in the sub-folder using the same alphanumeric code. No data (audio files, in process transcripts, or completed transcripts) will leave the Durham or Atlanta secure research server. As completed transcripts become available, approved study staff will move these files from the transcription sub-folder into another sub-folder that is only accessible to study staff, where they will be stored and accessed for qualitative analyses.

Paper records of data: As referenced in Section 2.3, cost data will be calculated by using a log sheet with instructions that can be used by a sample of providers to log their activity time for patients in a given project over the course of a one-week period. This log sheet will be collected by the Site Champion and sent via encrypted email to study staff. Any hard copy files containing identifiable information will be kept in a locked file cabinet in a locked office space under the care of study research staff.

4.4.2 Data Retention Plan

Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently, destruction of research records (see DAA-0015-2015-0004, section 7.6 "Research Investigator Files" for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager.

5.0 Data Access and Data Recipients

Only study staff in Atlanta and Durham involved in recruitment, interviewing, sending surveys, and general participant contact as well as those supervising said activities and staff will have access to individually identifiable research data. As previously mentioned, a certified de-identified data set will be provided by our research team in Atlanta to study team at the Birmingham VA for their analysis work.

All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team.

6.0 Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:

The coded data containing identifiers will be transmitted between the Durham and Atlanta VA study sites using PKI encrypted email. The data set shared with the study team at the Birmingham VA will be de-identified and thus can be sent via unencrypted e-mail or

unencrypted disk (encryption is optional). Data will not be removed from the VA protected environment.

7.0 Risk Mitigation Strategies:

For the data collection involving gathering data from patient medical records using CDW, the risk of a privacy or data security incident is minimal as there is no subject contact and data is collected in aggregate. Only study staff have access to the research data. As described above in Section 1.4.1, subsection for "Provider Feedback", the Site Champion will have access to prescribing data for operational purposes. The Site Champion will be trained as to appropriate use of this information and patient privacy protections.

For the survey and qualitative interviews of VA employees, there is a small risk of losing anonymity with the use of demographic information. Additionally, some individuals may feel self-conscious or embarrassed if asked questions about something with which they are unfamiliar, and they may be concerned that their responses will become known to colleagues and supervisors. All research-related interaction with VA employees will be conducted by study staff located at a different VA facility. Survey responses and recordings/transcripts of interviews will be stored on secure servers to which only study staff have access.

All study staff, including the PI, will participate in the monitoring of participant data. The proposed protocol contains minimal risk so no adverse events are expected. Some participants may not complete scheduled interviews or surveys. This is expected and will not be considered an AE. However, should any adverse event occur, the study staff member who discovered the adverse event would immediately alert the Principal Investigator, who will have the responsibility of informing the IRB of record for the study.

8.0 Suspected Loss of VA Information

Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

9.0 Reporting of Results

Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.

10.0 Future Use of Data

No future use of data is currently planned.

11.0 Use of Mail Merge Technology

Not applicable.

12.0 Use of Non-Standard Software

We do NOT intend to use any new specialized software (i.e. software that's not already approved OR installed) in this study.

13.0 Use of Cloud Computing Services

Cloud computing services will NOT be used in this study.

References

1. Stevens MB, Hastings SN, Powers J, et al. Enhancing the Quality of Prescribing Practices for Older Veterans Discharged from the Emergency Department: preliminary results from EQUIPPED, a novel multicomponent interdisciplinary quality improvement initiative. *J Am Geriatr Soc.* May 2015;63:1025-1029.

2. Moss JM, Bryan 3rd WE, Wilkerson LM, et al. Impact of clinical pharmacy specialists on the design and implementation of a quality improvement initiative to decrease inappropriate medications in a Veterans Affairs emergency department. *J Manag Care Spec Pharm.* 2016;22:74-80.

3. Stevens M, Hastings SN, Markland AD, et al. Enhancing Quality of Provider Practices for Older Adults in the Emergency Department (EQUiPPED). *Journal of the American Geriatrics Society.* 2017;65(7):1609-1614.

4. O'Brien MA, Rogers S, Jamtvedt G, et al. Educational outreach visits: effects on professional practice and health care outcomes. *Cochrane Systemat Rev.* 2007;4.

5. By the American Geriatrics Society Beers Criteria Update Expert P. American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc.* 2015;63(11):2227-2246.

6. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev.* 2012;6:Cd000259.

7. Kiefe CI, Allison JJ, Williams OD, Person SD, Weaver MT, Weissman NW. Improving quality improvement using achievable benchmarks for physician feedback: a randomized controlled trial. *JAMA.* Jun 13 2001;285(22):2871-2879.

8. Vanderman AJ, Moss JM, Bryan WE, Sloane R, Jackson GL, Hastings SN. Evaluating the Impact of Medication Safety Alerts on Prescribing of Potentially Inappropriate Medications for Older Veterans in an Ambulatory Care Setting. *Journal of Pharmacy Practice.* December 23, 2015 2015.

9. Strauss SM, Jensen AE, Bennett K, Skursky N, Sherman SE, Schwartz MD. Clinicians' panel management self-efficacy to support their patients' smoking cessation and hypertension control needs. *Translational Behavioral Medicine.* 09/16 2015;5(1):68-76.

10. Midboe AM, Cucciare MA, Trafton JA, Ketroser N, Chardos JF. Implementing motivational interviewing in primary care: the role of provider characteristics. *Translational behavioral medicine.* 10/28 2011;1(4):588-594.

11. Sachdev DD, Stojanovski K, Liu AY, Buchbinder SP, Macalino GE. Intentions to Prescribe Preexposure Prophylaxis Are Associated With Self-efficacy and Normative Beliefs. *Clinical Infectious Diseases.* 2014;58(12):1786-1787.

12. Bandura A. *Guide for constructing self-efficacy scales.* Vol 5. Greenwich, CT: Information Age Publishing; 2006.

13. Cerin E, MacKinnon DP. A commentary on current practice in mediating variable analyses in behavioral nutrition and physical activity. *Public Health Nutr.* 2009;12(8):1182-1188.

14. Muthen LK, Muthen BO. *Mplus User's Guide.* 6th ed. Los Angeles, CA: Author; 2011.

15. Klein K, Sorra J. The challenge of innovation implementation. *Academy of. Management Review.* 1996;4:1055-1080.

16. Klein K, Conn A, Sorra J. Implementing computerized technology: A Organizational Analysis. . *Journal of Applied Psychology.* 86(NO.5):811-824.

17. Weiner BJ, Lewis MA, Linnan LA. Using organization theory to understand the determinants of effective implementation of worksite health promotion programs. *Health Educ Res.* Apr 2009;24(2):292-305.

18. Weiner BJ. A theory of organizational readiness for change. *Implement Sci.* 2009;4:67.

19. Klein KJ, Sorra JS. The Challenge of Implementation. *Academy of Management Review.* 1996;21(4):1055-1080.
20. Holahan PJ, Aronson ZH, Jurkat MP, Schoorman FD. Implementing Computer Technology: A Multi-Organizational Test of Klein and Sorra's Model. *Journal of Engineering and Technology Management.* 2004;21:31-50.
21. Leonard-Barton D. Implementation as Mutual Adaptation of Technology and Organization. *Research Policy.* 1988;17:251-267.
22. Leonard-Barton D. Implementation Characteristics of Organizational Innovations. *Communication Research.* 1988;15:603-631.
23. Schwartz SH, Bilsky W. Toward a Theory of the Universal Content and Structure of Values - Extensions and Cross-Cultural Replications. *Journal of Personality and Social Psychology.* May 1990;58(5):878-891.
24. Klein KJ, Conn AB, Sorra JS. Implementing Computerized Technology. *Journal of Applied Psychology.* 2001;86(5):811-824.
25. Prochaska JO, Redding CA, Evers KE. The Transtheoretical Model and Stages of Change. In: Glanz K, Rimer BK, Lewis FM, eds. *Health Behavior and Health Education, Theory, Research, and Practice*. 3rd ed. San Francisco, CA: Jossey-Bass; 2002:99-120.
26. Shea CM, Jacobs SR, Esserman DA, Bruce K, Weiner BJ. Organizational readiness for implementing change: a psychometric assessment of a new measure. *Implement Sci.* 2014;9:7.
27. Ferlie E. The nonspread of innovations: the mediating role of professionals. *Acad Manage J.* 2005;48:117-134.
28. Van De Ven A, Polley D. The Innovation Journey. *New York: Oxford University Press.* 1999.
29. Polit D, Beck C. *Nursing research: principles and methods.* Philadelphia: Lippincott Williams & Wilkins; 2004.
30. Chamberlain P, Brown CH, Saldana L. Observational measure of implementation progress in community based settings: the Stages of Implementation Completion (SIC). *Implement Sci.* 2011;6:116.
31. Saldana L, Chamberlain P, Wang W, Hendricks Brown C. Predicting program start-up using the stages of implementation measure. *Adm Policy Ment Health.* Nov 2012;39(6):419-425.
32. Mancini JA, Marek LI. Sustaining community-based programs for families: conceptualization and measurement. *Family Relations.* 2004;53:339-347.
33. Fortune-Britt AG, Nieuwsma JA, Gierisch JM, et al. Evaluating the implementation and sustainability of a program for enhancing veterans' intimate relationships. *Mil Med.* Jun 2015;180(6):676-683.
34. Trochim WMK. *The Research Methods Knowledge Base, First Edition.* Cincinnati, OH: Atomic Dog Publishing; 2001.
35. Miles MB, Huberman AM. *Qualitative Data Analysis: An Expanded Sourcebook, Second Edition.* Thousand Oaks, CA: Sage Publications; 1994.
36. Sanders GD, Neumann PJ, Basu A, et al. Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: Second panel on cost-effectiveness in health and medicine. *JAMA.* 2016;316(10):1093-1103.