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

Data Analysis Plan
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Introduction to the EQUIPPED study

Older Veterans are a vulnerable population at high risk of medication adverse drug events (ADE) especially when they are discharged from the Emergency Department (ED). More than half of older adults discharged from the ED leave with a new prescription medication. Multiple studies show that between 5.6%-13% of prescriptions written for older adults at ED discharge represent a potentially inappropriate medication (PIM). Prescribing new medications for older Veterans outside the setting of primary care increases the opportunity for suboptimal prescribing as well as adverse drug events (ADEs), both major reasons for repeat ED visits, hospitalization or death. In order to inform a Veterans Affairs (VA) system-wide approach to improve prescribing safety for older Veterans, we propose 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.

EQUIPPED (*Enhancing Quality of Prescribing Practices for Older Veterans Discharged from the Emergency Department*) was initially established as an innovative quality improvement initiative designed to reduce PIM prescribing for adults aged 65 years and older. The EQUIPPED QI initiative provides preliminary data supporting this proposal written in response to the Learning Health System Provider Behavior Change RFA. Initially funded by the Office of Geriatrics and Extended Care, the EQUIPPED QI intervention has three components aimed at influencing provider prescribing behavior: a) provider education; b) electronic clinical decision support via specialized geriatric pharmacy order sets at the point of prescribing; and c) academic detailing including audit and feedback and peer benchmarking. EQUIPPED is informed by the Beers Criteria, which indicate drugs that should be avoided in older adults because of the increased risk of ADEs. The Beers Criteria are widely used by government agencies and supported by research in various settings as a marker of prescribing quality.

The EQUIPPED QI intervention has been implemented in 10 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, suggesting the possibility of culture change with regard to provider prescribing behavior. The EQUIPPED QI intervention typically involves in-person academic detailing 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 individual electronic reports via a clinical dashboard.

In a parallel cluster randomized trial, we will randomize 8 VA facilities to implement EQUIPPED with either passive provider feedback or active provider feedback. Specifically, 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 electronic provider feedback via individual prescribing reports using a novel clinical dashboard with audit, feedback and peer benchmarking, while active provider feedback sites will implement one-to-one (1:1) in-person academic detailing that includes in-person audit, feedback, and peer benchmarking and engagement with an on-site champion. 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. To assess the optimal implementation of EQUIPPED and overall program effectiveness, our specific aims are:

Specific Aim 1 (Primary Aim): To compare the effectiveness of EQUIPPED with in-person academic detailing including proactive feedback (*active feedback*) vs EQUIPPED with passive electronic audit and feedback (*passive feedback*) intervention by comparing 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.

Specific Aim 2: Using a formative evaluation approach, we will evaluate the effectiveness of EQUIPPED implementation with passive feedback compared to EQUIPPED implementation with active feedback using including semi-structured qualitative telephone interviews and quantitative survey data.

Specific Aim 3: Using micro-costing methods, we will calculate the difference in the detailed cost of the passive vs. active feedback versions of EQUIPPED.

1. Rationale for the study sample size

Aim 1 Data Analysis Plan: 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 (Table 1) 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.

Sample Size and Power Considerations

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 the data presented in table 1, 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 an absolute change in the risk of PIMs of 5% (i.e., 7.1% to 2.1%).

Table1. Characteristics of First Three Recruited Sites (FY16 data)

Site and Champion	Number of ED Visits	Number of ED Patients age 65+	Total number of discharge prescriptions for older Veterans (65+)	Number of Beers list PIMs	% PIMs at discharge
Boston Champion: J. Driver	32,565	15,594	7,756	461	**5.9%**
Denver Champion: L. Robbins	28,144	10,487	7,164	545	**7.13%**
Gainesville Champion: R. Beyth	44,686	23,972	18,868	1,345	**7.61%**

Additionally, table 2 demonstrates the proposed sample size per randomization group will permit an assessment of non-inferiority within a range of potential non-inferiority margins that correspond to outcome assessments in our previous EQUIPPED QI sites.

Table 2: Number of prescriptions per group to determine if passive EQUIPPED is non-inferior to active EQUIPPED with 85% power

Standard deviation	Margin of non-inferiority between groups at 12 months (assumes baseline rate of 7.2% PIMs per month with 40% reduction (< 5% after active EQUIPPED))			
	10%	**12.5%**	**15%**	**20%**
0.8	792	507	352	199
1.0	1237	792	550	310
1.5	2783	1782	1237	696
1.7	3574	2288	1589	894

Aim 2: Determination of Factors Affecting Individual and Organizational Adoption of EQUIPPED

Our provider feedback reports include several key elements that are supported by evidence in the recent Agency for Healthcare Research and Quality (AHRQ) report,[1] which aligns with Social Cognitive Theory (SCT).[2] One key advantage of SCT for provider behavior change interventions implemented in a health system is that SCT specifically recognizes that the attributes of the behavior and an individual's cognitions about the behavior occur within the larger environment (i.e., healthcare organization) and are impacted by that environment.[2] This is both a reason for examining the individual behavior change in a cluster randomized trial and the need to examine factors that may impact whether the intervention is implemented in such a way that it has the opportunity to impact the individual behavior change.

Interventions aimed at impacting provider behavior must be effectively implemented within the environment/ healthcare organization so that they can support the individual behavior change. However, SCT is limited in what it says about the needed process to ensure that the intervention can be implemented in the environment to support the desired change in behavior. As a result, implementation theory will underlie conduct of a formative evaluation of that process (Secondary Aim 2). 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 to 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 3 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.[3-6] The numbers in the table referring to data collection processes correspond to section 2 below. Data will be collected form all eight randomized sites about the site quality improvement process. As outlined in the grant application, the exact number of individuals involved in the formative evaluation at each site is dependent on the quality improvement implementation process used by each of the individual sties.

Table 3: 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 [7].	3,5
Innovation-Values Fit	Extent to which implementers and users perceive that innovation use will foster the fulfillment of their values [7-10]. 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 [11].	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 [7,8,12].	4,5
Innovation Effectiveness	Benefits an organization realizes from an innovation [7] (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. Specific description of how the data will be collected

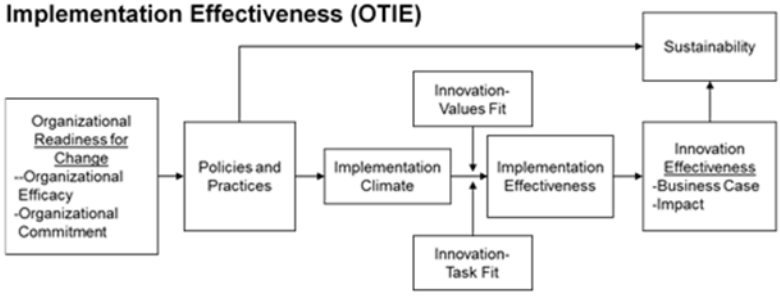
Aim 1: Monthly deidentified data related to PIMs and all prescriptions will be determined from the eight VAMCs 6 months before and 12 months after the EQUIPPED implementation period. These data are collected as part of the QI intervention for the EQUIPPED team and are not done solely for research purposes. 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 developed code (SQL) for the current 11 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).

Aim 2: Formative evaluation process: In summary, the formative evaluation will begin by identifying baseline characteristics 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 the 6-8 months following initial implementation of EQUIPPED; and 5) evaluation of program sustainability 1 year after the delivery of the delivery of the first EQUIPPED report.

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

We will ask prescribers 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,[13] provider implementation of motivational interviewing in primary care,[14] and provider intentions to prescribe preexposure prophylaxis[15]), survey questions will be developed specifically for this study and according to guidelines provided by Bandura (2006).[16] The environment (i.e. system level factors) will be assessed through a formative evaluation of the implementation process supported by the SCT and particularly guided by the Organizational Theory of Implementation Effectiveness (OTIE).

Figure 2. Components of the Organizational Theory of Implementation Effectiveness (OTIE)



Steps in the Formative Evaluation Process at the Facility Level

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 site-level survey per site/medical center sent to the site

champion to be completed on behalf of the facility) that will collect information on core implementation team members and processes and size and composition of the medical centers and impacted clinical services.

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,[17] 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).[6,18]

   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.[18] In addition, we will conduct semi-structured qualitative telephone interviews of the core implementation team and 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 apps). Semi-structured interviews will allow us to study implementation processes, which tend to be non-linear and context sensitive[19,20] and will permit us to compare patterns across cases.[21]
3. **Quarterly Monitoring of Process of Implementation**. At the start of the EQUIPPED implementation, the research team will interview the core implementation team during a conference call. Baseline information on the process of implementing the EQUIPPED intervention with active or passive feedback (depending on the study arm). Additionally, we will collect baseline information on the organization of ED services and the process for prescribing medications at patient check out (e.g., involvement of house staff in collaboration with attending providers and how the EQUIPPED tools may be integrated into that process). Components of the workflow process will be stored in an Excel spreadsheet to be sent to the sites for updates every three months. At 12 months into the implementation process, phone calls with the core implementation team will be repeated to ensure a full description of the final EQUIPPED workflow processes.
4. **Bi-monthly Monitoring of Implementation – Implementation Progress**. We will also measure the implementation process through bi-monthly reports from the eight sites. Implementation progress will be assessed utilizing the Stages of Implementation Completion (SIC).[22,23] 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 (1 site-level survey per site/medical center sent to the site champion to be completed on behalf of the facility).
5. **Evaluation of the Implementation Process – Qualitative Interviews.** At 6-8 months following the start of the implementation process at 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. Appendix 2 presents sample codes from OTIE components previously developed for another study.
6. **Assessment of Sustainability.** At one year, we will assess the sustainability of EQUIPPED. The Mancini & Marek Model of Community-based Program Sustainability will be used to conceptually guide the evaluation of sustainability.[24] 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) measures the 6 sustainability elements.[24] Each core implementation team member and ED provider will be surveyed. Using the semi-structured interview methods, we will interview the members of the core implementation team at each site. We have previously used the combination of PSI and qualitative interviews to evaluate the sustainability of a multi-facility VA program.[25]

Aim 3. Micro-Costing the Active and Passive Feedback Versions of the EQUIPPED Intervention
Specific costs will account for 1) labor costs; 2) equipment; 3) 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.[26] 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.

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. Method of randomization

Although the primary trial outcome is at the level of the individual prescription/provider decision, 8 participating sites will be randomized to either EQUIPPED with passive provider feedback or EQUIPPED with active provider feedback. Randomization is occurring at the facility level because the components of the decision support are made available to all ED providers at a given facility. It is not feasible to make them available to only a subset of providers or provider decisions at a given facility. To ensure relative balance of facility size across arms, randomization will be stratified based on the percentage of prescriptions written in the ED for patients age 65+ in the ED during the 6 full months prior to randomization. One stratum will include the 4 selected sites with the highest percentage with the 4 remaining facilities in the second stratum.

4. Plans for an specification of the purpose of any interim analysis

Aims 1 and 3: We do not have interim analyses planned for the prescribing data analysis or the health economics analysis.

Aim 2: Formative Data Analysis. Core to the concept of formative evaluation is continual analysis of results and feedback to stakeholders. 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 and 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) 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 investigators will conduct a preliminary test of codes by independently coding five transcripts. Based on the preliminary test, the investigators 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[27] and Miles and Huberman.[28] 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.[28]

5. Methods for handling missing data points and subject dropouts

Aim 1: We do not expect missing data to be a significant issue in this study. We will only enroll sites that have a minimum of 100 prescriptions for older Veterans discharged from the ED per month. All analyses will be performed on secondary data collected automatically via VA's CDW.

Aim 2: The formative analysis could be impacted by two types of dropouts: individual (provider) dropout and cluster (facility) dropout. Individual dropout could occur if providers fail to complete follow-up surveys. If this occurs, we will use the data we have collected to that point. All surveys will occur via email and will be brief (20 minutes or less). Providers will receive up to 5 email reminders to complete surveys. Facility dropouts could occur for various reasons, e.g. if the respective facility is not ready to implement EQUIPPED or leadership refuses to participate. We will minimize dropouts by working closely with the facility EQUIPPED champion to define the needed resources prior to the site's commitment to participate. During the implementation period, the team at the Atlanta site of the Birmingham/Atlanta GRECC will conduct bi-weekly conference calls for the site champions to discuss the team's local implementation strategy and identify strategies to address challenges. Separate calls will be held for sites randomized to passive feedback versus active feedback EQUIPPED to prevent influencing the provider feedback process at passive feedback sites. During calls, the site champions will have time to review cases, ask questions, and receive advice from the implementation team and other site leads. The EQUIPPED team has experience conducting similar calls nationally for the current VA sites since 2013.

Aim 3: The analysis will be based on data from available time logs from each facility. Our team has extensive experience using time logs with clinicians. While we will seek to collect time logs from each facility, the time for collected thought the logs will be averaged across logs/facilities, reducing the impact of any missing data from time logs. Other information is based on generally available national information on salaries by position type (not any information from individual people.

6. Definitions of covariates to be included in adjustment models

Aim 1: We will include stratum (high vs. low prescriber of PIMs at the facility level) and randomization group (active vs. passive feedback).

Aim 2: 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'); 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).[29] The mediators will be tested simultaneously in order to determine the unique influence of each potential mediator. Analyses will be conducted with structural equation modeling using Mplus (version 6.11)[30]

Aim 2: 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.

Aim 3: Not applicable for aim 3.

7. Methods for dealing with data transformations

Aim 1: Not applicable.

Aim 2: Generically not applicable. Individual scales will be calculated using published standards for each scale.

Aims 3: Not applicable.

8. Definitions of analytical sets

Aim 1: For the primary analysis related to the effectiveness of the EQUIPPED model to reduce the proportion of potentially inappropriate medications prescribed to older Veterans discharged from the ED, we will evaluate prescribing data according to intention to treat.

Aim 2: For the individual prescribing behavioral analyses, the prescribing data set from Aim 1 will be limited to prescriptions written by individual providers who volunteer to complete surveys regarding individual factors related to prescribing behavior. For facility level analyses, the prescribing data set from Aim 1 will be limited to a particular facility. Other data collected as part of the formative evaluation (qualitative and quantitative) will be stored and combined as described in this document and the IRB approved protocol.

Aim 3: Data from logs used to record time required to participate in the EQUIPPED activities will be combined with generally available information on VA salaries for individuals in different positions. Not individual salary data will be collected.

9. List of adverse and serious adverse events

Aim 1: Loss of control of prescribing data is the principal adverse event for Aim 1. 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. Monthly summary prescribing data by provider and facility will be stored in a research-secure project folder within VINCI. Data access requests to the VINCI folder will be coordinated through the Atlanta and Durham VAs with local IRB approvals.

Aim 2: There is a small risk of losing anonymity through the use of demographic information for Aim 2. This risk will be minimized by not reporting demographic information for individual VA facilities participating in the study when aggregate results are provided to any VA administrators, colleagues, affiliated university colleagues or affiliated university administrators. ED provider participant names and contact information will be stored in a secure database housed and maintained on the VA Atlanta research server. Information on individuals participating in the formative evaluation may be stored on the Durham VA and/or VA Atlanta research servers. Appropriately credentialed study staff members form the Atlanta and Durham, teams may access individually identifiable research information stored on the Atlanta or Durham VA research servers to the extent needed to conduct the study. Data for the formative evaluation and micro-costing aims do not include patient-level information. Final official study datasets containing all data collected throughout the study will be stored on the VA Atlanta research server.

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 the tracking database.

Audio recordings of interviews will also be housed on the same server. These recordings may initially be made on the remotely-located team member's VA-issued and maintained computer and will be moved to the Atlanta and/or Durham 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. As soon as practicable, final copies of all study interviews and verbatim transcripts will be stored on the VA Atlanta research services.

The EQUIPPED research team will have access to the survey dataset. These data may be stored on a secure VA research server maintained by the Atlanta VA and/or Durham VA. Any hard copy files will be kept in a locked file cabinet in a locked office space. As soon as practicable, final copies of all study interviews and verbatim transcripts will be stored on the VA Atlanta research services.

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. 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.

Confidentiality of participant data will be protected at all times. The following procedures will take place:

a) All study personnel will be thoroughly trained on how to maintain confidentiality.
b) EQUIPPED staff will be the only people with direct access to the online survey system and datasets with identifiers.
c) All data collected will be backed-up on a secure "Research" drive housed at the Atlanta VA Medical Center (or Durham VA Medical Center in the case of information related to Aims 2 and 3 of the study) and will only be accessible to staff on the study staff list submitted to the IRB..
d) Every effort will be made so that individual EDs cannot be identified in published reports, presentations, and manuscripts.

Participants will be identified from their job titles or roles in the ED at each facility as described above. Participation 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.

Aim 3: Data on individual salaries or other identifying information on time to complete EQUIPPED tasks will not be collected. We will track who returned information on time logs.

References

1. McNamara PS, D De La Mere, D, Ivers N. Confidential physician feedback reports: designing for optimal impact on performance. *Agency for Healthcare Research and Quality.* 2016;16-0017-EF(Rockville, MD).
2. Baranowski T, Perry CL, Parcel GS. How individuals, environments, and health behavior interact, social cognitive theory. In: Glanz K, Rimer BK, Lewis FM, eds. *Health Behavior and Health Education, Theory, Research and Practice*. 3rd ed. San Francisco, CA: Jossey-Bass; 2002:165-184.
3. Klein K, Sorra J. The challenge of innovation implementation. *Academy of. Management Review.* 1996;4:1055-1080.

4. Klein K, Conn A, Sorra J. Implementing computerized technology: A Organizational Analysis. . *Journal of Applied Psychology.*86(NO.5):811-824.
5. Weiner BJ, Lewis MA, Linnan LA. Using organization theory to understand the determinants of effective implementation of worksite health promotion programs. *Health Educ Res.* 2009;24(2):292-305.
6. Weiner BJ. A theory of organizational readiness for change. *Implement Sci.* 2009;4:67.
7. Klein KJ, Sorra JS. The Challenge of Implementation. *Academy of Management Review.* 1996;21(4):1055-1080.
8. 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.
9. Leonard-Barton D. Implementation as Mutual Adaptation of Technology and Organization. *Research Policy.* 1988;17:251-267.
10. Leonard-Barton D. Implementation Characteristics of Organizational Innovations. *Communication Research.* 1988;15:603-631.
11. 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.* 1990;58(5):878-891.
12. Klein KJ, Conn AB, Sorra JS. Implementing Computerized Technology. *Journal of Applied Psychology.* 2001;86(5):811-824.
13. 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.* 2015;5(1):68-76.
14. Midboe AM, Cucciare MA, Trafton JA, Ketroser N, Chardos JF. Implementing motivational interviewing in primary care: the role of provider characteristics. *Translational behavioral medicine.* 2011;1(4):588-594.
15. 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.
16. Bandura A. *Guide for constructing self-efficacy scales.* Vol 5. Greenwich, CT: Information Age Publishing; 2006.
17. 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.
18. 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.
19. Ferlie E. The nonspread of innovations: the mediating role of professionals. *Acad Manage J.* 2005;48:117-134.
20. Van De Ven A, Polley D. The Innovation Journey. *New York: Oxford University Press.* 1999.
21. Polit D, Beck C. *Nursing research: principles and methods.* Philadelphia: Lippincott Williams & Wilkins; 2004.
22. 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.
23. Saldana L, Chamberlain P, Wang W, Hendricks Brown C. Predicting program start-up using the stages of implementation measure. *Adm Policy Ment Health.* 2012;39(6):419-425.
24. Mancini JA, Marek LI. Sustaining community-based programs for families: conceptualization and measurement. *Family Relations.* 2004;53:339-347.
25. Fortune-Britt AG, Nieuwsma JA, Gierisch JM, et al. Evaluating the implementation and sustainability of a program for enhancing veterans' intimate relationships. *Mil Med.* 2015;180(6):676-683.
26. 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.
27. Trochim WMK. *The Research Methods Knowledge Base, First Edition.* Cincinnati, OH: Atomic Dog Publishing; 2001.
28. Miles MB, Huberman AM. *Qualitative Data Analysis: An Expanded Sourcebook, Second Edition.* Thousand Oaks, CA: Sage Publications; 1994.

29. 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.
30. Muthen LK, Muthen BO. *Mplus User's Guide.* 6th ed. Los Angeles, CA: Author; 2011.