Implementation Intervention to Improve Care for Unhealthy Alcohol Use

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VA Ann Arbor Healthcare System – (506)

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Abstract

Please Note, Dr. Bachrach transferred from the Pittsburgh VA to the Ann Arbor VA, HSR&D Center for Clinical Management Research (CCMR) in August 2023. All research activities for AIM 1, AIM 2 and the recruitment, enrollment, and intervention activities of AIM 3 were completed at the Pittsburgh VA before her station transfer to the Ann Arbor VA. We are requesting regulatory approval for the remaining research activities for AIM 3 only. These activities are limited to completing the extraction, cleaning, and analysis of AIM 3 outcome data from the VA's electronic health record (via the Corporate Data Warehouse). Additionally, the study team may pull data from CAPRI/Joint Legacy Viewer (JLV) to examine notes, charts, dates of AUDIT-C administration and other details to validate the accuracy of our AIM 3 dataset.

Objectives: Unhealthy alcohol use is common among Veterans and a significant risk factor for numerous negative health consequences, including chronic disease, injury, mortality, and suicide. It is also linked to increased financial and societal costs (e.g., higher healthcare utilization, criminal justice expenses). Due to these burdens, effective, evidence-based care for Veterans with unhealthy alcohol use was implemented in VA primary care (PC) settings. However, significant gaps in this care have been identified, indicating that a substantial proportion of Veterans in need of help are not receiving it. This study used an evidence-based implementation strategy called practice facilitation, at the VA Pittsburgh, to pilot test whether practice facilitation has the potential to improve the quality of PC-based alcohol-related care.

Research Plan: We are requesting IRB approval for the remaining research activities for AIM 3 only. These activities are limited to completing the extraction, cleaning, and analysis of AIM 3 outcome data from the VA's electronic health record (via the Corporate Data Warehouse). All research activities for AIM 1, AIM 2 and the recruitment, enrollment, and intervention activities of AIM 3 were completed at the Pittsburgh VA.

Methods: **Aim 1**(completed at the Pittsburgh VA) utilized qualitative methods to assess Veteran and PC stakeholders to understand barriers and facilitators to high-quality alcohol care, which was then used to help refine and hone the practice facilitation intervention. **Aim 2** (completed at the Pittsburgh VA) included focus groups with a sample of PC providers to assess the acceptability and feasibility of the refined practice facilitation intervention. **Aim 3** pilot tested the finalized practice facilitation intervention in the full PC clinic (this pilot implementation intervention was completed at the Pittsburgh VA) to understand whether practice facilitation improves the quality of PC-based alcohol-related care. The AIM 3 outcome data analysis will take place at the Ann Arbor VA utilizing the VA electronic health record (via the Corporate Data Warehouse).

(Please double click the correct box below):

☒ This Study **WILL** use the VA electronic health record (EHR) or EHR Data on or after Jan. 2019 (for example: entering notes; entering consults; ordering labs, medications, procedures, imaging, etc.; eligibility screening with EHR chart review or CDW; using CDW data; etc.).

☐ This Study will **NOT** use the VA electronic health record (EHR) or EHR Data on or after March 2022 (for example: entering notes; entering consults; ordering labs, medications, procedures, imaging, etc.; eligibility screening with EHR chart review or CDW; using CDW data; etc.).

List of Abbreviations

Provide a list of all abbreviations used in the protocol and their associated meanings.

AUD: Alcohol use disorder

AUDIT-C: Alcohol use disorders identification test- Consumption survey

BI: Brief intervention

CCMR: VA Center for Clinical Management Research

CDW: VA Corporate Data Warehouse

DART: VA Informatics and Computing Infrastructure Data Access Request Tracker

DoD: Department of Defense

HIPAA: Health Insurance Portability and Accountability Act

HSR&D: VA Health Services Research and Development Service

IRB: Institutional Review Board

PACT: Patient Aligned Care Teams

PC: VA primary care

PHI/PII: Protected Health Information/Personally Identifiable Information

PTSD: Post-traumatic stress disorder

OI&T: VA Office of Information and Technology

SSN: Social Security Number

VA: Veterans Affairs

VHA: Veterans Health Administration

VINCI: VA Informatics and Computing Infrastructure

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Protocol Title:

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1.0 Study Personnel

Personnel	**Project Role**		**Affiliation/employee status**
Principal Investigator	Rachel Bachrach, PhD		Ann Arbor VA employee
Co- Investigator/CDA Primary Mentor	Mark Ilgen, Phd		Ann Arbor VA employee
Co- Investigator/CDA Secondary Mentor	Paul Pfeiffer, MD, MS		Ann Arbor VA employee
Co- Investigator/CDA Secondary Mentor	Kara Zivin, PhD		Ann Arbor VA employee
Research support staff			
Project Manager	Barbara Stanislawski, MSW, MPH		Ann Arbor VA employee
Data Analyst	Brittany Porath, MPH		Ann Arbor VA employee

2.0 Introduction

Unhealthy alcohol use is common among Veterans and a significant risk factor for numerous negative health consequences, including chronic disease, injury, mortality, and suicide. It is also linked to increased financial and societal costs (e.g., higher healthcare utilization, criminal justice expenses). Due to these burdens, effective, evidence-based care for Veterans with unhealthy alcohol use was implemented in VA

primary care (PC) settings. However, significant gaps in this care have been identified, indicating that a substantial proportion of Veterans in need of help are not receiving it.

3.0 Objectives

Previous work on this study conducted at the Pittsburgh VA included utilizing qualitative interviews with Veteran and PC stakeholders to understand barriers and facilitators to high-quality alcohol care and to help refine and hone a practice facilitation intervention (**AIM 1**), conducting focus groups with a sample of PC providers to examine the acceptability and feasibility of the practice facilitation intervention (**AIM 2**), and conducting a pilot test of the finalized intervention in the full PC clinic (**AIM 3**). Research activities at the Ann Arbor VA that Dr. Bachrach will be conducting are limited to completing the extraction, cleaning, and analysis of AIM 3 outcome data from the VA's electronic health record (via the Corporate Data Warehouse). Additionally, the study team may pull data from CAPRI/Joint Legacy Viewer (JLV) to examine notes, charts, dates of AUDIT-C administration and other details to validate the accuracy of our AIM 3 dataset.

4.0 Resources and Personnel

Project Team

Rachel Bachrach, PhD, Principal Investigator
Dr. Bachrach is a Research Scientist and Clinical Psychologist at the VA Ann Arbor Health Services Research & Development (HSR&D) Center for Clinical Management Research (CCMR), and an Assistant Professor in the Psychiatry Department at the University of Michigan. As the PI, Dr. Bachrach will be responsible for all aspects of the project, which include managing and supervising research staff, implementation of the research plan, quality control checking, analysis of data, and contribute to report and manuscript preparation. She will have access to PHI.

Mark Ilgen, PhD, Co-Investigator/Primary Mentor
Dr. Ilgen is a VA Research Career Scientist and Core Investigator at the VA Ann Arbor HSR&D Center for Clinical Management Research (CCMR), Professor in the Psychiatry Department at the University of Michigan, and Director of the University of Michigan Addiction Treatment Services (UMATS). As primary mentor in Ann Arbor, Dr. Ilgen will advise on CDA-related research and training goals. Dr. Ilgen will also help Dr. Bachrach with staffing needs and provide guidance in managing research projects at CCMR, including onboarding research staff, study management, and troubleshooting research-related issues as they arise. He will also contribute to report and manuscript preparation. He will have access to PHI.

Paul Pfeiffer, MD, MS, Co-Investigator/Secondary Mentor
Dr. Pfeiffer is a Research Scientist at CCMR, the Susan Crumpacker Brown Research Professor of Depression, and Associate Professor in the Psychiatry Department at the University of Michigan. He also directs the Mental Health Innovation, Services, and Outcomes (MHISO) program and supervises a team of investigators who are interested in mental health

services research at the VA Ann Arbor. As a secondary mentor in Ann Arbor, Dr. Pfeiffer will advise Dr. Bachrach on using her CDA findings as pilot data for a multi-site implementation science trial. He will also contribute to report and manuscript preparation. He will not have access to PHI.

Kara Zivin PhD, Co-Investigator/Secondary Mentor
Dr. Zivin is a Research Career Scientist at the Center for Clinical Management Research (CCMR) in the VA Ann Arbor Health System and a Professor of Psychiatry at the University of Michigan. As a secondary mentor in Ann Arbor, Dr. Zivin will advise Dr. Bachrach on using electronic health record data to evaluate her implementation intervention and career development issues as they arise. They will meet regularly to determine data analysis needs for AIM 3 of the project. She will also contribute to data interpretation and manuscript preparation. She will have access to PHI.

Barbara Stanislawski, MSW, MPH, Project Manager
Ms. Stanislawski is a Project Manager at the VA Ann Arbor HSR&D CCMR. For this study, Ms. Stanislawski will have day-to-day responsibility for the oversight of administrative activities throughout the remainder of the project. She will be responsible for the preparation and maintenance of all regulatory applications and approvals. She will have access to PHI.

Brittany Porath, Data Analyst
Under the supervision of Drs. Bachrach and Zivin, Ms. Porath will conduct data analyses for AIM 3 and assist with manuscript preparation. She will have access to PHI.

5.0 Study Procedures

5.1 Study Design

AIM 1: *Ann Arbor regulatory approval is not requested for this AIM. All study activities were completed at the Pittsburgh VA.* Aim 1 was conducted to further understand barriers and facilitators to high-quality alcohol care, and to use the findings to develop and hone the practice facilitation intervention. Recruited from a single primary care clinic at the Pittsburgh VA, remote-based, semi-structured and open-ended, 1-on-1, interviews with key clinical stakeholders and Veteran patients with unhealthy alcohol use were conducted. Clinical stakeholder interviews focused on clinicians' prior experiences working with Veterans with unhealthy alcohol use, elicit perceptions and attitudes towards alcohol-related care, and elicit feedback on using practice facilitation to improve alcohol-related care. Interviews with Veterans asked about preferences and needs related to alcohol use and to explore how primary care can best support Veterans in achieving goals related to cutting back or abstaining from drinking. Feedback on the practice facilitation helped to ensure that providers, staff, and Veterans were receptive to the practice facilitation content.

AIM 2: *Ann Arbor regulatory approval is not requested for this AIM. All study activities were completed at the Pittsburgh VA.* Aim 2 delivered the refined practice facilitation to a group of primary care providers and staff, recruited to assess its feasibility and

acceptability. Based on participant feedback, the practice facilitation was revised again in preparation for the pilot implementation intervention in Aim 3. The facilitator conducted the focus groups with recruited PC staff and providers as a way to practice delivering the material, refining the material, and to assess whether material was acceptable and feasible in the primary care setting.

AIM 3: *Ann Arbor regulatory approval is being requested for only the data analysis portion of AIM 3 (extraction, cleaning, and analysis of AIM 3 outcome data from the VA's electronic health record (via the Corporate Data Warehouse). All AIM 3 recruitment, enrollment, intervention, and survey activities were completed at the Pittsburgh VA.* AIM 3 recruited providers and staff in the primary care clinic at the Pittsburgh VA. The facilitator met with primary care staff/providers as a group to introduce the final version of the practice facilitation. During the early months of the intervention, the facilitator, observed clinicians as they cared for patients with unhealthy alcohol use. It was essential for better understanding clinic workflow and where gaps in knowledge occur. While the facilitator observed clinic workflow, she excused herself when providers or patients requested it. She observed providers use of the electronic health record and typical workflow as providers triaged and treated patients with unhealthy alcohol use. Additionally, the facilitator conducted ongoing monthly meetings with a small subset of primary care participants interested in championing this care and communicated regularly via email with the clinic champions for ongoing support. Ongoing meetings discussed ways to improve alcohol-related care, based on "Plan Do Study Act" or "PDSA" cycles, to help providers identify gaps in alcohol care and test solutions to optimize care quality.[1] Educational handouts for providers and patients were developed and distributed and training sessions regarding evidence-based alcohol care (e.g., medications for alcohol use disorder, motivational interviewing overview to improve brief interventions) was offered when providers expressed a desire for more training and education on this topic. Any trainings that occurred were based on VA/DoD clinical guidelines for treating substance use disorders, thus part of routine clinical activity.

Evaluation of the Practice Facilitation Intervention: Implementation and Clinical Outcomes.

Aim 3 implementation and clinical-specific outcomes were derived guided by the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) evaluative framework, often used to guide implementation evaluations.[2] RE-AIM will be assessed using EHR data pulled from VA's Corporate Data Warehouse (CDW). The data pull will include data from January 1, 2019 – December 31, 2023, to evaluate these outcomes, which includes the pre-intervention period, the active facilitation intervention period, and the post-facilitation intervention period (i.e., 3-, 6-, and 12-months after active implementation). RE-AIM constructs are defined as follows:

Reach of alcohol-related care will be assessed at the patient level using EHR data, pulled from VA's CDW. Reach outcomes will be expressed as a rate, with the

denominator (for all outcomes) defined as all Veterans with a visit to the Pittsburgh VA primary care clinic during the practice facilitation intervention. The numerator for each Reach outcome is as follows: the number of Veterans who screened positive for unhealthy alcohol use (AUDIT-C ≥ 5) AND had any documented brief intervention, encounters with primary care-mental health integration (PC-MHI), encounters with PACT/ Whole Health clinical pharmacists, specialty addictions treatment (inpatient and outpatient clinic visits for substance use disorder treatment encounters with an accompanying AUD diagnosis), or pharmacotherapy for AUD (any filled prescription for FDA-approved medications: acamprosate, disulfiram, or oral/injectable naltrexone or non-FDA approved effective medications: gabapentin, baclofen, or topiramate) in the 30 days following a positive screen. Denominators will also be derived to represent specific subpopulations (e.g., women, Black and Hispanic Veterans). Rates at the start of the practice facilitation intervention and at 3- and 6-months post intervention will be calculated to examine change in Reach outcomes over time.

Adoption is identified as the percentage of providers from the PC clinic who deliver alcohol-related care when a Veteran screens positive for unhealthy alcohol use. Specifically, we will use data available in the EHR to examine delivery of brief interventions, consults placed to PC-MHI/clinical pharmacists or specialty addictions treatment and providing pharmacotherapy for AUDs at the provider and clinic level. Rates of alcohol-related care pre-intervention (2019-2022), during the course of the practice facilitation intervention (July 2022-December 2022), after the intervention (e.g., 3- and 6-months post intervention (Jan 1, 2023-March 31, 2023, and Jan 1, 2023-June 30, 2023 respectively) will be used to measure whether adoption rates of alcohol-related care increased over time.

Maintenance is defined as the extent to which evidence-based alcohol care becomes routine and part of the PC culture (care sustained over time). Reach and Adoption outcomes using EHR data will be assessed at 12-months post intervention (Jan 1, 2023-Dec. 31, 2023) to examine whether high-quality alcohol care was sustained.

Effectiveness is defined as the prevalence of unhealthy alcohol use at 12-months post-intervention (Jan 1, 2023-Dec. 31, 2023) as measured by AUDIT-C scores pulled from the EHR. This variable will also be expressed as a rate with the denominator defined as all Veterans with a visit to PC during the practice facilitation intervention (same as for Reach outcomes). The numerator will be the number of Veterans with an encounter in PC who screened positive for unhealthy alcohol use (AUDIT-C ≥ 5) at 12-months post facilitation intervention. While it is unlikely that a pilot study will have a measurable

impact on clinical outcomes, measuring effectiveness will serve as pilot data for a larger trial.

5.2 Recruitment Methods

Ann Arbor regulatory approval is being requested only for the data analysis portion of AIM 3 (extraction, cleaning, and analysis of AIM 3 outcome data from the VA's electronic health record via the Corporate Data Warehouse). All recruitment, enrollment and intervention activities were completed at the Pittsburgh VA.

Approximately 10,000 Veterans' data will be pulled from the CDW to examine implementation and clinical outcomes. Data to evaluate implementation and clinical effectiveness outcomes will be obtained electronically and securely from already collected administrative databases, using scrambled SSN or Patient ICN to link data together. Data sources will include the CDW, Health Factors (AUDIT-C and Brief Intervention information), Vital Status File to obtain DOB for calculating age of Veterans, and Prescription/Pharmacy information (for data on whether medications for alcohol use disorder were prescribed). Other specific records include: sociodemographics (e.g., sex, gender identity, marital status, indicator of socioeconomic status, race/ethnicity, sexual orientation), past-year diagnoses (Alcohol use disorder diagnosis, Substance use disorder diagnoses, Tobacco use disorder diagnosis, Mental Health disorder diagnosis (Depression, anxiety, PTSD, Bipolar, Psychotic-spectrum)), index of medical complexity (e.g., Charlson index, VA CAN score) utilization of primary care services pre-implementation (2019-2022), during (July 2022 - Dec. 2022) and post-implementation intervention (Jan 2023 - Dec. 2023), referral and utilization of substance use services in the past year (yes/no), and referral and utilization of past-year mental health services (yes/no). Data may also be reviewed within CAPRI/Joint Legacy Viewer (JLV) to allow study team members to look into potential data anomalies from our dataset. In addition, members of the study team may review notes, charts, dates of AUDIT-C administration, etc. to verify the accuracy of our Aim 3 dataset.

5.3 Process of Obtaining Informed Consent and Protecting Patient Privacy

We are requesting a Waiver of Informed Consent and a HIPAA waiver for full access to PHI to complete this work. There will be no participant contact. All data will be stored in VINCI (VA Informatics and Computing Infrastructure) or in a restricted access study folder located on the Ann Arbor VA secure server. All study team members are current on their human subjects protection, HIPAA privacy, and data security training.

In accordance with HIPAA, only approved Study Team Members will have access to protected health information (PHI). Computerized data will be stored in an electronic folder maintained on the VA Server or behind the VA Firewall.

5.4 Inclusion/Exclusion Criteria

We will include all Veterans with a visit to the Pittsburgh VA primary care during the practice facilitation intervention.

5.5 Risk/Benefit Assessment

The risk of accessing identifiable data on VINCI (VA Informatics and Computing Infrastructure) or in a restricted access study folder located on the Ann Arbor VA secure server is minimal, while the benefit is potentially great. Veterans who are included in secondary data analysis may benefit indirectly by improvements in their alcohol-related care. In addition, the potential to contribute to scientific knowledge outweighs the minimal risks. Unhealthy alcohol use is common and leads to adverse consequences, including suicide risk and early mortality. VA has invested in alcohol-related care in primary care, however, past implementation gaps have been identified and hypothesized to contribute to lower quality and access. The study is aligned with VA and HSR&D research priorities focused on access to care, suicide prevention, and implementation science and with VA's commitment to providing patient-centered care for unhealthy alcohol use. If effective, the implementation intervention could be scaled throughout VA primary care settings, which may optimize return on VA's large investment in this care.

5.6 Study Evaluations

Not applicable.

5.7 Data Analysis

Implementation Outcomes: Reach outcomes will be reported descriptively (e.g., percentage of patients with an AUDIT-C≥ 5 who were offered a BI or pharmacotherapy for AUD) and compared pre- (2019-2022) and post-implementation (at 3- and 6-months) to see whether Reach of alcohol care increased over time. Adoption outcomes via EHR will be descriptive, and include percentages, frequencies, and means (SD) of alcohol-related care by provider and clinic to understand whether Adoption of high-quality alcohol-related care increased over time. Descriptives will be examined and compared at the start of Active Implementation and at 3- and 6-months post Active Implementation. Reach and Adoption rates will again be examined at 12-months post Active Implementation and compared to rates at 3- and 6-months to see if high-quality alcohol-related care was sustained (Maintenance). **Effectiveness outcomes:** Effectiveness will be assessed via a time-series analysis, where the intervention site will serve as its own control, and we will investigate whether Veterans' with an encounter in Pittsburgh VA Primary Care during the implementation intervention reduced their drinking 12-months post intervention using AUDIT-C scores in the EHR. Time-series analysis was chosen because historical trend is accounted for in the analytic model, results can be displayed graphically, and the size of the effect can be estimated at different times post

intervention. The outcome (AUDIT-C scores) will be modeled using a regression model with an indicator for practice facilitation (pre- vs. post-), a continuous term for time (days since practice facilitation dissemination) and the interaction between the two. The indicator variable will assess immediate changes in AUDIT-C scores post implementation intervention, while the interaction term will assess if there is a change in the slope of AUDIT-C scores pre- and intervention at 12-months. While there is controversy over whether pilot studies should assess clinical efficacy or effectiveness,[3,4] we decided to examine it here as a training opportunity and as preparation for a possible hybrid effectiveness-implementation Merit trial investigating practice facilitation as a way to improve alcohol-related care on a larger scale.

Personal identifiers will be required to pull the dataset from VA databases and link data across databases. However, once the data are extracted, merged, and cleaned for analyses, the identifiers (such as scrambled Social Security number, or patient ICN) will be removed from the dataset and replaced with a unique study ID. We will however maintain the linkage between study IDs and scrambled Social Security number or patient ICN in the form of a separate crosswalk file stored in VINCI (VA Informatics and Computing Infrastructure) or in a restricted access study folder located on the Ann Arbor VA secure server until the study is complete. All study team members are current on their human subjects protection, HIPAA privacy, and data security training. Only approved Study Team Members will have access to the data.

5.8 Withdrawal of Subjects

Not applicable.

6.0 Reporting

In the unlikely event that a data breach occurs, the study team will notify the Ann Arbor VA IRB, Privacy Officers, and Information System Security Officers as soon as the breach is identified.

7.0 Privacy and Confidentiality

All study staff accessing the data is approved for VA research and are up-to-date on all mandatory annual trainings in data security and human subjects protections and are educated in the use of all data security procedures necessary to ensure patient privacy and data security. All information will be maintained in accordance with the security requirements of 38 CFR section 1.466 or more stringent requirements. The data analyst will be responsible for creating analytic datasets for investigators; these datasets will be de-identified per HIPAA guidelines. All resulting research data will be presented in aggregate only and will not identify any individual patient in any report of the research, or otherwise disclose patient identities. No data will be disclosed outside the VA.

7.1 Records Control and Disposition

Data will be destroyed by the data manager 6 years following the end of the fiscal year after completion of the research in accordance with VA policy as described in VHA Records Control Schedule 10-1.

8.0 Communication Plan (if applicable)

Not applicable.

9.0 References

1. Glass JE, Bobb JF, Lee AK, et al. Study protocol: A cluster-randomized trial implementing Sustained Patient-centered Alcohol-related Care (SPARC trial). Implement Sci. 2018;13(1):108-120.

2. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. Am J Public Health. 1999;89:1322-1327.

3. Leon A, Davis L, Kraemer H. The role & interpretation of pilot studies in clinical research. PsyRes 2011;45.

4. Moore CG, Carter RE, Nietert PJ, et al. Recommendations for Planning Pilot Studies in Clinical and Translational Research. Clin Transl Sci. 2011;4(5):332-337.