

Preliminary Implementation of an
Informational Nudge to Improve Heart
Failure Prescribing

NCT05986695

October 11, 2023



SAVAHCS Research Protocol

Project Title:	Preliminary Implementation of an Informational Nudge to Improve Heart Failure Prescribing	
Sponsor:	HSRD	<input type="checkbox"/> N/A
Grant or Protocol No.:	IRBNet #1735462	<input type="checkbox"/> N/A

INVESTIGATOR INFORMATION

Principal Investigator Name,
Degree(s):

Sandesh Dev, MD

Service/Care Line:

Medicine

Contact Phone:

6028881257

Official VA Email:

sandesh.dev@va.gov

CO-PRINCIPAL INVESTIGATOR INFORMATION (if applicable)

☐ N/A

Name:

Name

CO-INVESTIGATOR/COLLABORATOR INFORMATION (if applicable)

☐ N/A

☒ Co-Investigator / ☐ Collaborator: Sherry Ball, Ph.D.

☒ Co-Investigator / ☐ Collaborator: Jenice Ria Guzman, Ph.D.

☐ Co-Investigator / ☒ Collaborator:

ALTERNATE/COORDINATOR CONTACT INFORMATION

☐ N/A

Name:

Rene Hearn

Contact Phone

216-386-5220

Official VA Email:

rene.hearns@va.gov

Abbreviations

CDS	Clinical decision support
CPRS	Computerized Patient Records System
GDMT	Guideline-directed medical therapy
HF	Heart failure
HF Dashboard	VA PBM web-based dashboard for facility HF patient management
HFrEF	Heart failure with reduced ejection fraction
HSRD	Health Services and Research Development
NP	Nurse Practitioners
PBM	VA Pharmacy Benefits Management
PRISM	Performance of Routine Information System Management
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
SGLT2	Sodium-glucose Cotransporter-2 Inhibitor
MRA	Mineralocorticoid Receptor Antagonists
SAIL	Strategic Analytics for Improvement and Learning
SAVAHCS	Southern Arizona VA Health Care System
VA	Department of Veterans Affairs
VANEOHS	VA Northeast Ohio Healthcare System

1.0 BACKGROUND

Cognitive biases (Cheng, et al., 2021) can lead to irrational decisions. Nudge theory exploits cognitive biases in rejecting the assumption that humans will make optimal choices when given access to the right information. Based on nudge theory, interventions have provided support for decision making on how to save for retirement and whether to donate an organ. **Nudge theory also offers novel solutions to improve decision making in health care** (Lamprell, Tran, Arnolda, & Braithwaite, 2021). Nudges present **subtle changes in the decision-making environment** that can influence behavior by exploiting cognitive biases without significantly restricting choice (Lamprell, Tran, Arnolda, & Braithwaite, 2021). Nudges can range from most restrictive (e.g., opt-out) to minimally restrictive (e.g., providing information). This project will test the use of nudges to influence providers' prescribing behavior.

Gaps in VA heart failure (HF) prescribing practices provide an opportunity to test the effectiveness of nudges to improve decision making for prescribing heart failure medications. Of VA patients with HF with reduced ejection fraction (HFrEF) only 22% of eligible patients are receiving SGLT2 inhibitors and only 39% are receiving MRAs (U.S. Department of Veterans Affairs, 2022); despite clinical effectiveness, clinical inertia and barriers have prevented greater adoption of these two foundational therapies. In this proposed study, we will evaluate two nudge interventions, **informational alerts (in CPRS) and peer comparison feedback emails**, to improve HF prescribing.

Prior experience: Our group has previously reported HF prescribing barriers for VA clinicians (Dev, et al., 2016), and we believe that the strategies in this proposal will overcome these barriers. Provider-based barriers to MRA prescribing include unclear provider roles/responsibilities, difficulties coordinating care, and lack of knowledge/experience with the drug (Dev, et al., 2016). Two small studies suggest that SGLT2 barriers are similar; cardiologists reported barriers to prescribing SGLT2s including potential adverse effects (hypoglycemia, urogenital infections), lack of knowledge/skills with drug, concerns about managing diabetes, and concerns of professional roles (perceived SGLT2 as outside their scope of responsibilities) (Cheng, et al., 2021) (Gao, Peterson, & Pagidipati, 2020).

Preliminary data: Informational alerts and peer comparison nudges have proven effective in other studies to change behavior. The PROMPT HF trial done in a university medical center demonstrated that informational alerts were associated with an increase in the number of GDMT medication classes prescribed (primary endpoint) from 19% to 26% ($p=.03$). One study compared individual audit feedback, peer comparison, and the combination, in a four-group design to influence clinician opioid prescribing in emergency care sites. They found a significant decrease in pills per prescription in the peer comparison arms.

We lack adequate knowledge about how to improve HF prescribing with nudges. Despite promising initial studies on the value of information alerts to improve HF prescribing, the improvements in prescribing were seen exclusively with beta-blockers, not in prescribing of SGLT2 inhibitors and MRAs – where the largest gaps exist in VA.

We need more information on whether combining nudges into multicomponent interventions is more effective.

A systematic review reported that only five of 48 nudge (10%) interventions in the literature were multicomponent; none of the studies were performed in the VA. For example, an evaluation active choice patient dashboard (delivered by email) with and without peer comparison to increase statin prescribing amongst PCPs found that only the active choice plus the peer comparison arm was associated with increased statin prescribing but not the active choice or the usual care arm alone. However, in these multicomponent trials, it is not clear which component is most impactful. Comparative effectiveness nudge trials are needed due to relative advantages and potential tradeoffs of each intervention. Further, research is needed to how nudges interact with one another and whether they may crowd each other out. In this proposal, we will evaluate whether informational alerts, peer comparison, or the combination of the two, is most effective.

This research will generate comparative evidence on which types and combinations of behavioral nudges work best. This study targets an HF treatment gap (SGLT2 and MRA) in which no prior nudge studies have demonstrated efficacy.

Our target population is clinicians in primary care and cardiology who are the main clinicians who treat HF. To incorporate the voice of the Veteran, we will meet with Veteran and Family Advisory Panel at SAVAHCS for feedback on the study design.

1.1 SIGNIFICANCE TO VETERANS AND/OR THE MISSION OF THE VA

Rates of HF GDMT have stagnated in the VA since 2013, and researchers have noted that 'new approaches to increase the uptake of evidence based HF treatment are urgently needed.' This proposal addresses several VA HSRD priority research areas including 'primary care practice and complex chronic disease management', 'quality and safety of care', and 'population health and whole health.' This application also addresses ORD-wide research priorities to 'increase substantial real-world impact of VA research' and 'putting VA data to work for Veterans.' **This proposed research will generate comparative evidence on which types and combinations of behavioral nudges work best.** Refinement of behavioral nudge interventions is likely to improve quality of VA HF management and effectiveness of HF care. This project leverages and enhances the existing VA PBM HF dashboard resource by testing new, user-centered implementation strategies. **By generating simple, scalable, and low-cost nudge strategies** directed at prescribing behavior, this proposal may extend the effectiveness of the VA PBM Academic Detailing program to improve medication prescribing across other therapeutic areas.

2.0 AIMS

Aim 1. Conduct a process evaluation ['PROCESS EVAL'] to develop two nudge strategies, an informational alert and peer comparison feedback, to encourage clinicians to prescribe MRA and SGLT2 inhibitors.

Aim 2. Evaluate preliminary outcomes ['NUDGE EFFECTIVENESS'] of the two nudge strategies to improve HF prescribing using the RE-AIM framework.

- a) Evaluate the preliminary Effectiveness of the alert and peer comparison strategies in a four-group design.
 - i) The four-groups to be compared are: control (no intervention), peer comparison email alone, information alert alone, and peer comparison/informational alert in combination. We will examine provider prescribing behavior and patient outcomes.
- b) Evaluate the implementation outcomes of the two nudge strategies.
 - i) We will report the following PRISM/RE-AIM outcomes: intervention, recipients, external environment, infrastructure, Reach, Adoption, and Implementation.

We hypothesize that an informational nudge and peer comparison will each increase prescribing compared to usual care (no nudge intervention). Further, we hypothesize that the combination of the two strategies will be more effective than either strategy alone.

3.0 SETTING & RESOURCES

Recruitment Clinic/areas	Primary care (all SAVAHCs sites at TUC and CBOCs) and Cardiology departments
Research location	SAVAHCS (Research Service [study coordinator], telework [PI, statistician, co-investigators, staff])
Study procedures location	SAVAHCS activities: <ol style="list-style-type: none"> 1. INTERVIEW/FOCUS GROUPS WITH CLINICIAN AND VETERAN ADVISORY PANEL: Virtually via TEAMS conferencing VA-Outlook, 2. NUDGE DELIVERY: Virtually via CPRS electronic record, VA Outlook, and VINCI/CDW (for patient outcomes data)

PERSONNEL RESOURCES	TOTAL
TUCSON	
Qualitative researcher (WOC)	2
Co-investigator, pharmacy (WOC)	1
Database manager, analyst (WOC)	1
Research coordinator/regulatory	1
PI	1
Co-investigator, nurse scientist	1
Consultant, behavioral economist	1
Statistician (WOC)	1

4.0 STUDY DESCRIPTION

4.1 STUDY DESIGN

TIMELINE				
	Startup Activities	Pre Nudge (control period)	Active Nudge Period	Post intervention period
Month (-12) to Month 0	Month 0-6	Month 7-9	Month 10-12	Month 13-18
	PROCESS EVALUATION			
	Interviews with clinicians; focus group with Veteran Council	Follow-up interviews and questionnaires with clinicians, follow-up focus group with Veteran Council		Focus groups with clinicians.
	NUDGE EFFECTIVENESS			
Patient data collection (to create peer comparison emails, need prior 12 month prescription information)				

AIM 1. – PROCESS EVALUATION. At the beginning of the study, we will conduct **interviews and focus groups** of SAVAHCs primary care and cardiology clinicians to understand clinician workflow, barriers, and feedback on proposed nudge interventions. We will also obtain **conduct focus groups with SAVAHCs Veteran Advisory Council**. After completing Aim 2, near the end of the study we will interview clinicians again and have them complete questionnaires regarding their opinions on the nudge interventions.

AIM 2. NUDGE EFFECTIVENESS. This is a pragmatic trial of cardiology and primary care clinicians at a single VA medical center. The trial will include a 3-month preintervention (observation) period and 3-month intervention period. In the intervention period, clinicians will be randomized to one of four nudge arms: usual care, informational alert, peer comparison feedback, and combination of alert and peer comparison.

Table 2. Study design			
	Peer comparison		
		Yes	No
Informational alert	Yes		
	No		

4.2 SUBJECT POPULATION

Study groups	Type of interaction	# screened for eligibility	# consent / chart review	# analysis	Comments
SAVAHCS prescribing clinicians (Primary Care, Cardiology)	Interview, focus group	Up to 100 (send invite to all Primary Care and Cardiology)	Up to 100 (consent for interview/focus group everyone accepting the invite)	Up to 100	ICF
	Nudge Interventions (alerts and emails)	N/A (all clinicians will be randomized)	Up to 100 (waiver of consent requested)	Up to 100	Waiver of consent
	Questionnaires	Up to 100	Up to 100 (waiver of documentation of consent requested)	Up to 100	Waiver of documentation consent
SAVAHCS Veteran and Family Advisory Panel	Focus group	Up to 20 (all panel members invited)	Up to 20	Up to 20	ICF – waiver of documentation (no recording)
SAVAHCS Patients with HF	Medical record review only	3000	1400	1400	HIPAA/PHI waiver

4.3 STUDY INTERVENTIONS

Aim 1. PROCESS EVALUATION

Interviews/questionnaires, and focus groups with clinicians:

Up to 100 cardiology and primary care prescribing clinicians [defined as: primary care NP/PA, physicians & cardiology NP/PA, physicians and cardiology specialty pharmacists] will be invited via email to participate in interviews. Qualitative interviewers will use a system thinking approach to map out steps and barriers and facilitators to the incorporation of the informational alert and peer comparison email into clinician workflow (Interview guide).

After the 3-months of informational alerts, all SAVAHCS clinicians who received a nudge will receive an email link to a 5-minute or less voluntary and confidential VA Redcap questionnaire with general questions about clinician demographics, work history, and the nudge's Acceptability, Feasibility, and Appropriateness.

Results from these interviews will be compiled to improve prescribing patterns and fit within the existing daily work that will be discussed in focus groups (up to 10 different cohorts [1 cohort can have 10 subjects, therefore 10 cohorts required] and up to 3 focus group sessions/cohort) of prescribing clinicians. Focus groups will include usability discussion of the alert and peer comparison prototypes (Figure 1). Aggregated de-identified information obtained in each focus group will be summarized and provided to all participants to check for accuracy.

Figure 1. Two Nudge Prototypes.

<u>A. Informational alert</u>	<u>B. Peer comparison Email (Adapted ¹³)</u>
<p>Your patient has been identified in VA HF Dashboard as potentially eligible for an SGLT2 inhibitor. This alert is provided for informational purposes.</p> <p>SGLT2 inhibitors are indicated in the 2022 ACC/AHA HF Guidelines (URL link provided) for patients with HFrEF (EF≤40%, NYHA class II-IV HF). Contraindications include urinary tract infection, eGFR < 25, type I diabetes.</p> <p><u>Relevant data for this patient include:</u> Prescription for beta blocker No prescription for ACE inhibitor LVEF 40% BNP 1550 Renal function: eGFR > 25</p> <p><u>Suggested actions:</u> Prescribe empagliflozin 10mg daily Alert primary care</p> <p><u>If prescribing:</u> Recommend checking renal function after starting therapy; reduce diuretic; watch for dehydration</p>	<p>Dear Dr. _____,</p> <p>SAVAHCS Cardiology is working on new ways to help clinicians improve their patient's HF treatment. Based on AHA/ACC guidelines and the VA HF Dashboard, you have patients who could be on an SGLT2 inhibitor but have not been prescribed one.</p> <p>Among eligible patients, your rolling 90-day SGLT2 prescribing rate: XX% [one of the following] Average of your peers at SAVAHCS: XX% Your top performing peers at SAVAHCS: XX%</p> <p>If you have any questions, please email study coordinator XXX</p> <p>Sincerely, XXXX Clinical Research Coordinator XXXX Study Principal Investigator</p>

Focus group with SAVAHCS Veteran and Family Advisory Council

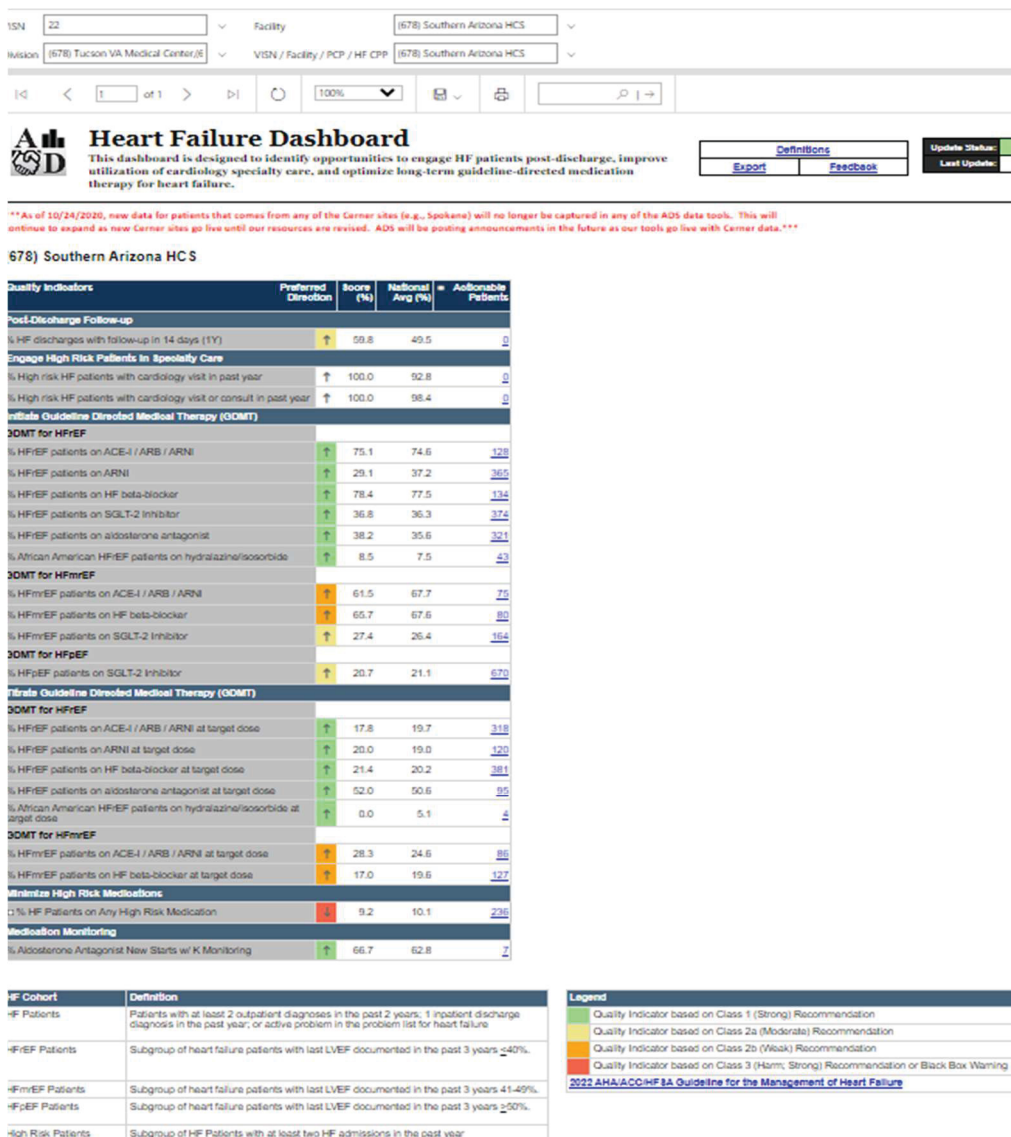
We will meet twice virtually with the Advisory Council during the study. We will ask for their feedback on their perceptions of study benefit and any suggestions for improvement. Unlike the other focus groups and interviews with clinicians, we will only take notes, but no audio

recording will occur. We will not ask for any individually identifiable information, only general feedback on the study.

Aim 2. NUDGE EFFECTIVENESS

Table 2. Study design			
	Peer comparison		
		Yes	No
Informational alert	Yes		
	No		

Informational Alert (in CPRS) and Peer Comparison Email for clinicians. (See Figure 1 above) During department meetings and by email, Primary Care and Cardiology clinicians will be notified about the goals of the study and will receive education on HF treatment guidelines to encourage optimal standard of care at baseline. Over the next 3 months, we will measure baseline rates of prescribing (SGLT2, MRAs); this will serve as control (pre-intervention period). Next, during the 3-month intervention period, clinicians will receive ‘nudges’ per their assignment to one of four groups. Those in the usual care arm will receive no other interventions. Clinicians in the alert only arm will receive an alert approximately two business days prior to a patient’s upcoming appointment. Clinicians will receive approximately one to two alerts per week or less. Clinicians assigned to peer comparison only, will receive messages by unencrypted email approximately every two weeks or even less often regarding their SGLT2i and MRA prescribing performance relative to their peers. We will review their prescribing activity for HF patients using VINCI/CDW data from the prior 12 months in order to generate these peer comparisons. Emails will be unencrypted because there is no PHI/PII. The clinicians in the combined alert and peer comparison arm will receive both interventions. All alerts and emails are based on HF patient data from VA PBM HF Dashboard, an operational/quality improvement dashboard available to all VA clinicians (https://vaww.pbi.cdw.va.gov/PBIRS/Pages/ReportViewer.aspx?/GPE/PBM_AD/SSRS/HeartFailure/HF_Dashboard) but most heavily utilized by pharmacists. (See sample screen from HF Dashboard below – no PHI)



5.0 STUDY & SUBJECT PROCEDURES

5.1 RECRUITMENT METHODS

Study Groups / subjects	Type of interaction	When	How	By whom	Materials	Procedures under consent or PHI waiver for recruitment
AIM 1. PROCESS EVALUATION						
SAVAHCS clinicians (Primary)	Interview/ focus group	Upon IRB approval,	Obtain list of clinicians from dept. Chiefs by	Coordinator, qualitative researchers	Email to clinicians (Dev Nudge Provider)	Recruitment waiver not applicable

Care, Cardiology)		beginning of study	email; email and message clinicians to participate.	on study staff, PI	email request) and ICF	because VA employee names/emails are public record. Interested subjects will sign ICF with VA electronic signature.
	Receive nudge interventions (alerts and emails)	N/A	N/A	N/A	N/A	N/A (Clinicians identified by reviewing patient charts via patient PHI – see PHI recruitment waiver chart review)
	Questionnaires	After nudge	Email provided to clinicians who received a nudge	Study coordinator	Email to clinicians	Waiver of documentation of informed consent
SAVAHCS Veteran and Family Advisory Panel	Focus group	We will attend a SAVAHCS Patient and Family Advisory Panel virtual meeting	Email / message SAVAHCS coordinator to get on meeting agenda	Coordinator, qualitative researchers on study staff, PI	Email to Advisory Council	Waiver of documentation of informed consent (no recording)
Aim 2 NUDGE EFFECTIVENESS						
SAVAHCS Patients with HF	Data collection only / chart review	Daily review of VA PBM dashboard	VA PBM website	Coordinator, study staff, PI	N/A	PHI waiver for recruitment

Aim 1. PROCESS EVALUATION

SAVAHCS clinicians (Primary Care, Cardiology). The study staff will provide information to introduce the project to the Primary Care and Cardiology providers during a routine staff meeting. The study staff will also contact Primary Care and Cardiology leadership to provide a list of all clinicians in each department. We will then email and/or Teams message clinicians to invite them to be interviewed. Informational handout will be sent via email that will include who to contact if s/he is interested in participating in the interviews and/or focus groups. Contacted up to three (3) times.

Questionnaire links will be emailed to all clinicians who received nudges. Those who wish to participate, will click on the link within the email. The questionnaire is voluntary and confidential. Contacted up to three (3) times.

SAVAHCS Veteran and Family Advisory Panel.

The study team will email/message the Advisory Panel coordinator to ask permission to be placed on the monthly Panel virtual meeting agenda. The study team will introduce the study objectives and explain that no individually identifiable data will be collected, only general study feedback.

Aim 2. NUDGE EFFECTIVENESS. A waiver of informed consent and PHI waiver are requested to review patient charts. The study staff will review the Pharmacy HF Dashboard to identify patient with upcoming primary care/cardiology appointments from which we will identify the patient and their corresponding clinician for whom to deliver the Alert or Email.

5.2 INFORMED CONSENT & PHI AUTHORIZATION PROCEDURES (OR DISCLOSURES)

Summary of Consent/HIPAA			
Activity		When	Rationale
Aim 1.			
Interview/ focus groups of clinicians	Informed consent	Prior to participation in activity	
Questionnaire	Waiver of documentation of informed consent	After nudge Email provided to all clinicians who received a nudge	The questionnaires will not be linked to any provider. No PHI/PII will be collected.
Veterans and Family Advisory Council	Waiver of documentation of informed consent		Only document linking subject to research is the consent document. No PHI/PII will be collected. The interaction will not be recorded, only notetaking.

	Aim 2.		
Collect baseline patient information and clinician prescribing activity: Identify actionable HF patient encounters and record baseline patient characteristics using CPRS/HF Dashboard / VINCI/CDW.	Waiver of consent, HIPAA waiver	Dates: Prior 12 months to nudge delivery	Need specific information on patients and corresponding clinician prescribing behavior
Create peer comparison reports based on prior prescribing history	Waiver of consent, HIPAA waiver	Dates: Prior 12 months to nudge delivery	Need specific information on patients and corresponding

using HF Dashboard and CDW.			clinician prescribing behavior
Deliver nudges (CPRS alerts and peer comparison emails) to clinicians	Waiver of consent	Dates: up to 90-day nudge delivery period	See justification below. Study could not be completed if consent required.
Review CPRS, HF Dashboard, and VINCI/CDW for clinician and patient outcomes in response to nudges	HIPAA waiver	Dates: up to 90 days after nudges delivered	Patient-level outcome data collection after HF nudges delivered

This section provides further detail on above table.

Aim 1: Interview/questionnaires, focus groups of clinicians.

Project information will be presented to the clinicians of Primary Care and Cardiology during a department meeting prior to pre- and post-intervention of the study. Also, all clinicians in Primary Care & Cardiology within SAVAHCs will receive invitation emails (contacted up to three (3) times) regarding the study. Those clinicians who would like to be interviewed and/or participate in the focus groups will contact the study team to begin the informed process. The clinician will be emailed the informed consent document and a meeting time will be arranged for its discussion. The informed consent process will occur via MS Teams where the study team member will discuss the project, provide time for the clinician to ask questions, then obtain consent should the potential subject agree to do so. The study team member will ask the potential subject to sign the consent via PIV certificate or ink signature and return to the study team. The signed consent will be stored within the VA secured study folder within the compliance binder.

After the intervention, the study team will present the next phase to the clinicians during staff meetings. Questionnaire link (REDCap) will be emailed to all the clinicians receiving the nudges after the 3-month nudge intervention was implemented to obtain feedback regarding the actual nudge. We are requesting a waiver of documentation of informed consent because the activity is minimal risk, and the participants are not under any obligation to provide his/her feedback. A started or completed questionnaire indicates his/her willingness to participate. We are requesting a waiver of documentation of consent based on the following rationale, which addresses the requirements for a waiver.

2a. The research involves no more than minimal risk to subjects.

It is common in daily life for VA clinicians to provide process feedback. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. The short questionnaire utilizes standardized questions. The questions focus totally on the nudge(s) s/he had received. The Primary Care and Cardiology services have endorsed this study which is in line with their quality goals. The use of VA REDCap provides various layers of security for the data.

2b. The research could not be carried out practicably without the waiver or alteration.

The research outcomes are informative only when the results include clinicians' feedback to ensure process improvement. By including all clinicians who received nudges, there is a possibility that more will participate in a short <5 minute questionnaire. It is not practical to consent clinicians in Primary Care/Cardiology at all SAVAHCs facilities for a less than 5 minute questionnaire.

- 2c. The waiver or alteration will not adversely affect the rights and welfare of the subjects. VA clinicians commonly receive requests for feedback in daily clinical practice. There is no risk of penalties or consequences if they ignore the request to participate.

Aim 1. Veterans and Family Advisory Council

At the time of the Council meeting, the study team will review the written summary that embodies the elements of the ICF. All subjects will receive via Teams messaging an information sheet on the study. Subjects will be given the option of not participating. No PHI will be collected, and no recording will occur. We are requesting a waiver of documentation of informed consent because the activity is minimal risk and there is no physical contact with the subject.

Aim 2:

Collect baseline patient information and clinician prescribing activity.

We are requesting a HIPAA waiver to identify actionable HF patient encounters and record baseline patient characteristics using CPRS/HF Dashboard / VINCI/CDW. We will also use CDW/VINCI to develop peer comparison reports which display clinician prescribing activity. A waiver is required because although the study interventions are directed only at clinicians, we need to identify which patient encounters to target. Further, the study team is not directly interacting with patients and only passively collecting patient/clinician outcome data. Requiring informed consent to review PHI would make the study impossible to perform.

Aim 2. Deliver CPRS alerts and peer comparison emails to clinicians.

We are requesting a waiver of consent based on the following rationale, which addresses the requirements for a waiver.

2a. The research involves no more than minimal risk to subjects.

This is common in daily life for VA clinicians to receive CPRS reminders for recommended care, and therefore the study nudges are not different than those encounter in daily clinical practice. All of the recommendations follow established national and VA HF guidelines. The Primary Care and Cardiology services have endorsed this study which is in line with their quality goals.

2b. The research could not be carried out practicably without the waiver or alteration.

In real-world VA clinical practice, clinicians receive EMR/CPRS alerts that are delivered whenever there is an eligible patient encounter. It is critical that these nudges are therefore tested in the environment that would be utilized in clinical practice, i.e., to all clinicians. If clinicians are allowed to opt-out of receiving the study interventions (nudges), the objectives of the research could not be achieved. In other words, the research outcomes are informative only when the results demonstrate the effect on all clinicians, not only those who are interested in receiving nudges. By including all clinicians, this design will avoid an overly optimistic treatment effect in which nudges appear effective, that is, effective only for

those clinicians interested in receiving them. Conversely, if some clinicians do not respond to nudges or are dissatisfied with them, this knowledge would be important to know and would potential avoid wasteful or futile efforts to scale up nudge interventions in VA. In other words, we are testing nudges at the department / health system level, not to individual consenting clinicians.

2c. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

VA clinicians commonly receive EMR / CPRS alerts and reminders in daily clinical practice. In this study, they are not obligated to follow any of these care recommendations; there is no risk of penalties or consequences if they ignore the nudges. Further, the study team will obtain clinician input via interviews/focus groups as well as Veteran input which could mitigate any unintended consequences and provide an opportunity to co-design the nudges.

2d. If the research involves identifiable private information or identifiable biospecimens, this research could not be carried out practicably without using the information/specimen in an identifiable form.

The research does not collect private information regarding the subjects (clinicians).

5.3 INCLUSION/EXCLUSION CRITERIA

Activity	Aim 1.
Interview, focus groups of clinicians	All clinicians in Primary Care and Cardiology
Veterans and Family Advisory Council focus group	All participants at Council meeting
	Aim 2.
Patient record review to deliver nudges (CPRS alerts and peer comparison emails) to clinicians	<p>Patients meeting these criteria:</p> <p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • HF patient • Scheduled cardiology or primary care appointment • Not being prescribed SGLT2 or MRA class medication <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • eGFR < 20 ml/min/1.73m² or potassium > 5.0

5.4 SUBJECT PROCEDURES

5.4.1 SCREENING/ENROLLMENT/RANDOMIZATION

Activity	Screen	Enroll	Randomize
Interview, focus groups of clinicians	Invite all clinicians in Primary Care and Cardiology	Consent clinicians via Outlook/Teams	N/A
Questionnaires	Invite all clinicians who received nudges	Study Coordinator will send an email. (waiver of documentation of consent request)	N/A
Veterans and Family Advisory Council	Invite all Council members at scheduled Council meeting to participate	Interested Council members will verbally indicate consent to proceed with focus group	N/A
Deliver nudges (CPRS alerts and peer comparison emails) to clinicians	Study coordinator will identify eligible HF patient encounters (see inclusion/exclusion above)	Study coordinator will deliver nudge based on assigned nudge group (waiver of consent request)	VA Redcap will be utilized to randomly assign each clinician to nudge type (alert, email)

5.4.2 SUBJECT EVALUATIONS

Aim 1.

Subject	Data	Data source
Clinician	Verbal feedback: nudge intervention, workflow Quantitative measures of intervention suitability: questionnaires (Acceptability, Appropriateness, Feasibility) & Clinician general demographics: sex, practice site, specialty/subspecialty, and percent full-time effort, years of experience	Interview, focus group (see attached Interview Guides) Questionnaires (administered via VA Redcap)
Veteran and Family Advisory Panel	Feedback on intervention, workflow	Focus Group

Aim 2.

Subject	Data	Data source
Patient (12 months before baseline, during and post-nudge)	Name, full SSN, dates, demographics, vitals, zip-code level median household income, clinical encounters, Charlson Comorbidity Index, and medications; # alerts delivered, # new HF prescriptions (MRA or SGLT2), # HF	CPRS, HF Dashboard, CDW/VINCI

	medication discontinuations, adverse events, mortality	
--	--	--

5.4.3 FOLLOW-UP PROCEDURES

None

5.5 WITHDRAWAL OF SUBJECTS

Aim 1. PROCESS EVALUATION. The clinician or Veteran Advisory Council member has a right to withdraw from the interview, questionnaire, and/or focus groups. The subject withdrawal will occur either by stopping the interview/questionnaire or leaving the focus group. The data collected prior to the subject withdrawing will be used for the study. The data will be maintained in accordance with the Records Control Standards RCS-10.

Aim 2. NUDGE EFFECTIVENESS.
N/A - Waiver of consent requested.

5.6 SUBJECT COMPENSATION/COSTS

There is no compensation nor costs incurred by clinicians to participate in this study.

5.7 DATA COLLECTION

Aim 1. PROCESS EVALUATION

Data will be collected via note taking (Veteran and Family Advisory Panel) and audio recording (Clinicians). Note taking will occur during the Veteran and Family Advisory Panel. The study team taking notes will not collect and PHI/PII. The recordings will be performed via MS Teams. The completed interview or focus group's audio files will be immediately downloaded to the VA secured project folder and then deleted from where it is initially held (MS Stream). Audio transcripts will be analyzed using Atlas.ti located behind VA firewall. The MS Teams transcript will immediately be deidentified by the study team member, as MS Teams utilizes the name of the person speaking, downloaded to the VA study folder and deleted from the Teams site. The audio and transcripts will be maintain/destroyed in accordance with RCS 10-1. We are not collecting data on drug or alcohol abuse, sickle cell anemia and/or HIV status.

The audio files and transcripts will be stored behind two password protected firewalls for which only the study team will have access to at the SAVAHCS.

R:\Research_Investigator_Projects\Medicine\Dev\Nudge Study\

After the Nudge intervention, all clinicians who received nudges will receive email link to VA REDCap to complete <5 minute validated questionnaire about nudge intervention Acceptability, Feasibility and Appropriateness.

Aim 2. NUDGE EFFECTIVENESS

Data will be collected from one or more of: CDW/VINCI, PBM HF Dashboard, CPRS and stored in within the VA secured project folder utilizing MS Excel and VA Redcap databases. The study folder is restricted to IRB study team members. CDW/VINCI data will always reside within VINCI.

6.0 RISKS/BENEFITS

6.1 RISKS

AIM 1. PROCESS EVALUATION

Interviews and focus groups: Risks to clinicians and Veteran Advisory council are minimal because we are asking questions about a nudge intervention and not personal or sensitive matters. We are not asking questions related to PHI or PII.

AIM 2. NUDGE EFFECTIVENESS. Risks to subjects (clinicians) are minimal given the benign nature of this behavioral intervention, which recommends guideline-driven prescribing. Though clinicians are the recipient of the study interventions, it is worth noting that patient risks are also minimal because clinician prescribing behavior (or lack of prescribing) reflects their best professional judgment for that specific patient.

There is small risk of loss of privacy and confidentiality to clinicians and patients; see risk mitigation statement below in 6.3.

6.2 BENEFITS

Clinicians. There are no direct benefits of study participation. However, the study may contribute to generalizable knowledge about using nudges to improve quality of care. In addition, clinicians might increase his/her knowledge regarding HF treatment and be prompted to improve their HF prescribing practices.

Patients. There is no direct benefit. However, there is a potential benefit to patients if they are prescribed a recommended HF medication that otherwise would not have been prescribed without the study intervention.

6.3 RISK/BENEFIT ASSESSMENT

AIM 1. PROCESS EVALUATION

Interviews and focus groups: The potential risks of discomfort will be minimized by allowing the subject to skip any question or to stop the interview. Further, we are asking questions about a nudge intervention and not personal or sensitive matters. There is no risk to providers should they choose not to participate as this project will not affect his/her employment e.g., performance evaluation, pay, nor standing. Therefore, we believe the potential benefit to generalizable knowledge is greater than the risk. Any potential loss of privacy and confidentiality to clinicians is minimized by following all VA recommended practices (see Section 9.0 for detail).

AIM 2. NUDGE EFFECTIVENESS. Risks to subjects (clinicians) and their patients are minimal given the benign nature of this behavioral intervention recommending guideline-

driven prescribing which is common in routine clinical practice (e.g. EMR reminders). We believe the potential benefits to generalizable knowledge exceeds the risk. Any potential loss of privacy and confidentiality to patients is minimized by following all VA recommended practices (see Section 9.0 for detail).

7.0 DATA MONITORING FOR SUBJECT SAFETY

Aim 1. PROCESS EVALUATION. There is no data monitoring for clinician and Veteran Advisory Council members subject safety as this is a study regarding work practices and is minimal risk to the clinicians.

Aim 2. NUDGE EFFECTIVENESS. These are not experimental therapies, and DSMB is not required. SGLT2 inhibitors and MRAs are HF medications prescribed in routine standard of care and are guideline-recommended.

8.0 DATA ANALYSIS & STATISTICAL CONSIDERATIONS

Power calculation. One study reported a 14% absolute increase in beta-blocker prescription with enhanced alert compared to usual alert/usual care. Another reported a 7% absolute increase in new prescription of any GDMT in 30 days, also driven by beta-blocker. We anticipate a 5% absolute increase in new prescriptions (SGLT2 or MRA) per intervention arm, compared to usual care. We are anticipating a lower treatment effect because SGLT2 inhibitors are newer, potentially seen as requiring interdisciplinary collaboration, and MRAs require serial lab monitoring. To detect this difference with an 80% power and alpha of 0.05, a sample size of 168 patients who are eligible to activate the alert are required in each treatment group, for a total study sample size of 672 patients encounters. We anticipate that we can achieve this number of patient encounters across the approximately sixty participating clinicians including any possible attrition.

Data Analysis. Though randomization occurs at the clinician level, we will measure outcomes at the patient level. The dataset used for analysis will be limited to all MRA- and SGLT2i-eligible identified in the HF dashboard (this includes patients in the control group-- even though no alert will be generated). This sample allows us to compare differences in rate of prescription of the same patient types between the three intervention groups and control group. Descriptive statistics will comprise patient and provider demographics, including practitioner specialty and type, and part-time status. General Linear Models (GLM) and chi square tests will be used to compare continuous and categorical demographic variables, respectively, between the three interventions and control groups. Significant differences will be defined with p values < 0.05. Generalized Linear Mixed Models (GLMM) will be used to compare rates of both SGLT2 or MRA (in separate, univariate analyses) between the nudge intervention and control groups. Practitioner specialty and type, part time status, years of experience, and patient visit number will be included as covariates, and the patient, clinician, and clinic assignment (clustering of providers), will be entered as random effects. While these covariates are strata for randomization, it is unlikely, due to the study sample size, that all combinations will be equally distributed between the two groups. We will therefore need to employ statistical control of these potential influences. The GLMMs will be specified as random coefficient models or growth curve models to evaluate changes in prescription behavior over time, as well as between groups. Models will include the preintervention baseline as a covariate and will use all patient visits until the conclusion of the data collection period. Significant differences will be concluded with odds ratio and 95% confidence intervals that do not contain the value 1.0. This statistical approach

permits the evaluation of prescription rates by groups while controlling for covariates and the correlated and hierarchical effects of repeated measures nested within clusters. Statistical significance of the treatment group and the other covariates will be determined using odds ratio with 95% confidence intervals that do not contain 1.0. For the Secondary RE-AIM Outcomes, the GLMM, with the same random effects specification, will be used to estimate the safety risk for prescriptions of SGLT2 and MRA within 30 days of the nudge interventions and compare this risk between the intervention and control groups. These metrics will be evaluated to estimate the risk of discontinuation of the prescribed medications based on adverse effects. The outcome for this analysis will be the continuation or stoppage of the prescribed medication. The other metrics identified in the secondary outcomes above will be calculated as descriptive statistics and will inform revisions to the interventions.

Qualitative Analysis: To ensure analytic rigor, all analysts have experience in qualitative methods. Data collection and analysis will be conducted concurrently using deductive and inductive content analysis. Transcripts will be uploaded to ATLAS.ti for coding and data management. Coding is conducted using audio recordings and transcriptions simultaneously to ensure transcription fidelity and capture participant inflection not contained in transcript. Deductive content analysis consists of identifying quotes and phrases that fit within pre-identified and defined a-priori categories. A-priori categories include general behavioral economics principles, prism, RE-AIM domains. Inductive content analysis involves open/unstructured coding, and allows for the identification of emergent, previously unidentified and to capture data that did not fit into a-priori categories. For open coding, we will use a three-step process described by Strauss and Corbin to code the data, starting with open codes, followed by axial codes, and ending with theoretical codes (Strauss & Corbin, 1998). Coding will continue until thematic saturation (Sandelowski, 1995).

9.0 PRIVACY & CONFIDENTIALITY

Upsetting questions/uncomfortable

If interview, focus group or questionnaire questions are upsetting or make the person uncomfortable the subject can decline to answer the question or stop the session.

Privacy

Aim 1. No subject (clinician or Veteran Advisory Council) PHI will be collected. All audio files, audio transcript and questionnaire responses will be handled as confidentially as possible and in accordance with all laws, regulations, and VA directives. All data files will be labeled with a code number. The list that matches the subject's name with the code number will be kept in a separate password-protected computer file. The data will be kept in a password protected computer file to which only the study team has access.

Aim 2. Study team will collect patient PHI but will not be disclosed. There are no study visits; all data collection is via chart review or CDW extraction. Only minimum PHI necessary will be collected to meet study objectives.

Confidentiality.

Study team will use only VA, password-protected computer systems and software (VA Redcap, VINCI CDW, MS Teams, Atlas.ti) and utilize encryption for any emails containing PHI. All staff is up-to-date with VA research training including CITI. We will not use paper records. Study members who have WOC status at SAVAHCS who

will analyzing audio transcripts will be accessing Atlas.ti (VA-approved) on their VA GFE workstations issued by Cleveland VA.

10.0 REGULATORY OBLIGATIONS

10.1 INSTITUTIONAL REVIEW BOARD

The investigator will submit study information to the SAVAHCS VA IRB as required by all applicable guidelines and requirements. The research will not begin until IRB approval is obtained. A copy of all submitted and approved documents will be maintained in the regulatory files. The investigator will obtain IRB approval for subsequent protocol amendments and modifications to informed consents, etc. No changes will be implemented prior to IRB approval except to eliminate an immediate hazard to study subjects. This investigator will submit reports for continuing review until completion of the project.

10.2 PERSONNEL TRAINING

Study personnel will be up-to-date with human subjects protections requirements and the PI will be responsible for any additional compliance or modifications. Study coordinator is experienced in obtaining informed consent. The PI is responsible for ensuring the study is conducted in accordance with the IRB-approved protocol.

10.3 REPORTING REQUIREMENTS

The investigator will notify the SAVAHCS IRB of deviations from the protocol and serious adverse events occurring at SAVAHCS.

10.4 STUDY DOCUMENTATION & ARCHIVING

Study documentation will be maintained per regulations. Study documentation will be archived per regulatory requirements, included within the RCS 10-1 Records Control Schedule.

11.0 COORDINATING CENTER COMMUNICATION PLAN

This is not applicable for this study which is a local, single-site projects at SAVAHCS only.

12.0 REFERENCES

Chen, Y., Harris, S., Rogers, Y., Ahmad, T., & Asselbergs, F. W. (2022). Nudging within learning health systems: next generation decision support to improve cardiovascular care. *European Heart Journal*, 43(13), 1296-1306. doi:10.1093/eurheartj/ehac030

- Cheng, R., Mooney, D., Chien, C., Shah, K., Vest, A., & Jefferies, J. (2021). SGLT2 Inhibitors: Who Should Prescribe Them for Patients With Heart Failure? *Journal of the American College of Cardiology*, 10, 1375-1377.
- Dev, S., Hoffman, T. K., Kavalieratos, D., Heidenreich, P., Wu, W.-C., Schwenke, D., & Tracy, S. J. (2016). Barriers to Adoption of Mineralocorticoid Receptor Antagonists in Patients With Heart Failure: A Mixed-Methods Study. *Journal of the American Heart Association*, 5(3), 1-11.
- Dev, S., Lacy, M. E., Masoudi, F. A., & Wu, W.-C. (2015). Temporal Trends and Hospital Variation in Mineralocorticoid Receptor Antagonist Use in Veterans Discharged With Heart Failure. *Journal of the American Heart Association*, 4(12), 1-12.
- Gao, Y., Peterson, E., & Pagidipati, N. (2020). Barriers to prescribing glucose-lowering therapies with cardiometabolic benefits. *American Heart Journal*, 224, 47-53.
- Lamprell, K., Tran, Y., Arnolda, G., & Braithwaite, J. (2021). Nudging clinicians: A systematic scoping review of the. *Journal of Evaluation in Clinical Practice*, 27(1), 175-192.
- Sandelowski, M. (1995). Sample size in qualitative research. *Research in Nursing & Health*, 18(2), 179-183. doi:10.1002/nur.4770180211
- Strauss, A., & Corbin, J. (1998). *Basics of qualitative research: techniques and procedures for developing grounded theory*. Sage Publications.
- U.S. Department of Veterans Affairs. (2022). *VA Heart Failure Dashboard*. Washington, DC: VA National Academic Detailing Services. Retrieved from <https://dvagov.sharepoint.com/sites/vhaacademicdetailing/sitepages/heartfailure.aspx>
- Yancy, C., Januzzi, J. J., Allen, L., Butler, J., Davis, L., Fonarow, G., . . . Masoudi, F. M. (2018). 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Task Force on Expert Consensus Decision. *Journal of the American College of Cardiology*, 71(2), 201-230.