QUX 16-003, Implementing Guidelines for Shared Decision Making in Lung Cancer Screening, QUE 16-003

Study Protocol and Statistical Analysis Plan

September 15, 2020

This study was conducted as a non-research quality improvement initiative primarily to improve the quality of preventive services in the VA as part of an ongoing partnership with the VA National Center for Health Promotion and Disease Prevention (see letter from Linda Kinsinger, MD, MPH; Chief Consultant for Preventive Medicine). Given the non-research quality improvement designation, this study did not have a protocol reviewed by an Institutional Review Board, but the following is an excerpt from the study proposal which was peer reviewed and approved for funding in June 2015 as part of a VA Quality Enhancement Research Initiative field program at the VA Ann Arbor Healthcare System (aka PROVE QUERI). This document provides an excerpt from the nationally reviewed proposal that describes the study aims, procedures, design, and analysis plan for this trial.

Excerpt from PROVE QUERI Program Proposal:

Project #1:
Implementing Guidelines for Shared Decision Making in Lung Cancer Screening

1.0 Specific Aims

The goal of this project is to test two strategies for implementing shared decision making into clinical practice with the aid of the Decision Precision lung cancer screening tool. To accomplish this goal we have three aims:

Aim 1: To determine effectiveness of LEAP plus Audit and Feedback (A&F) versus A&F alone. **Hypothesis**: VAMCs with LEAP + A&F will have better implementation outcomes (defined by RE-AIM[104]) than VAMCs with A&F alone.

Aim 2: To determine the effectiveness of allowing providers to set risk threshold algorithms. **Hypothesis**: Implementation outcomes will improve when providers are allowed to set risk thresholds.

Aim 3: To conduct a formative evaluation to determine the factors most important for successful implementation of risk-based shared decision making tools.

2.0 Rationale

Lung cancer is both prevalent and deadly. It is the third most common cancer and is the leading cause of cancer-related deaths in the US. Lung cancer is both more prevalent and associated with worse outcomes among Veterans than among the general US population.[105,106]

Based on the results of the National Lung Screening Trial (NLST), the United States Preventive Services Task Force (USPSTF) recommends low-dose computed tomography (LDCT) screening for patients who meet age and smoking criteria.[107,108] The NLST found that eligible heavy smokers are significantly less likely to die from lung cancer if screened with LDCT vs. chest x-rays. For perspective, the reduction in deaths from lung cancer with screening is larger than the reduction in deaths from the target cancers of other common screening tests, such as mammograms for breast cancer. In 2013, VHA rolled out a two-year clinical demonstration project in eight VA medical centers to determine the resources needed to "provide screening and follow-up…with accuracy, efficiency, and safety similar to that achieved in the NLST."[109]

However, the NLST also found substantial harms associated with LDCT screening, including high false- positive rates which can lead to unnecessary and harmful invasive procedures. Because lung cancer screening has substantial benefits and harms, and the net benefit can vary dramatically across eligible smokers, the USPSTF strongly advocated for shared decision making and asserted that "the decision to begin screening should be the result of a thorough discussion of the possible benefits, limitations, and known and uncertain harms."[110] Furthermore, in a February 5, 2015, decision memo, the Centers for Medicare and Medicaid Services (CMS) required a shared decision making consultation between patients and providers for payment of initial lung cancer LDCT screening. The role of shared decision making was specified within CMS guidelines as "including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure."

Shared decision making (SDM) is the process wherein the provider communicates medical information about the screening options and patients are responsible for sharing their values and screening preferences. Following the sharing of information by both parties, patients and providers collaborate to decide on the course of screening that reflects both the best medical evidence as well as the patient's preferences and values.[111,112]

The mandate for shared decision making by the USPSTF and CMS is reflective of the strong evidence that it can improve patient-centered outcomes. Research has found that *patients who participate in medical decisions tend to be more satisfied with their care,[113] report a better quality of life,[114] and are more adherent to recommendations[115] than those who do not.* Furthermore, models of informed consent and SDM emphasize the importance of presenting the pros and cons of all treatment options to patients,[116] and shared decision making is strongly advocated by many as an optimal method to promote patient-centered care, including in VA[117] (e.g., 2006 priorities and patients' rights brochures).

To meet this need for shared decision making, we created "Decision Precision", a provider facing web-based decision support tool. This tool provides a method for providers to implement evidence-based guidelines for SDM in lung cancer screening. Our goal is to have the tool facilitate SDM within the confines of a busy clinical schedule. This web tool goes beyond current VA patient materials in several ways. It provides: 1) personalized

quantitative risk assessment of the trade-offs; 2) patient-friendly language; 3) graphics that have been empirically demonstrated to help patients understand their personalized risks and benefits; and 4) quick and easy documentation of personalized SDM after using the tool.

"Decision Precision" Tool Development. To determine the best method for communicating the benefits and harms of lung cancer screening, we first conducted a randomized survey experiment with 1,612 adults aged 18 years or older who reported smoking daily or almost daily. We compared comprehension and perception of lung cancer screening benefits and harms when the information was presented using four different evidence- based formats, including the pictograph currently used vin VHA's patient lung cancer screening materials. We found that participants who viewed the VHA pictograph had better knowledge about the magnitude of the benefit and how this benefit compared with important harms. Thus, we used the VHA pictograph in the tool. In addition, we iteratively designed four versions of the web tool based on usability testing with decision aid researchers, PCPs, and patients. The final version will be developed during Year 1 and will incorporate additional content and features suggested by front-line providers and patients, along with a module to enable personalized screening recommendations based on provider-determined risk thresholds.

3.1 Procedures

3.2 Proposed Implementation Strategies

We will compare the effect of adding the LEAP implementation strategy (see Implementation Core) to more typical and widely studied strategies that we will consider standard (i.e., audit and feedback and introductory webinar discussing use and benefits of the tool). We will also slowly roll out risk threshold tailoring to determine if that improves implementation outcomes.

Implementation Strategies: Control

1. *Webinar, Promotion, and Tool Access.* All sites will receive a professionally developed, 15-minute webinar that describes the tool's development (e.g., how the algorithm was designed) and a tutorial on how to use the web-site. We will promote the webinar and using the tool through key local leaders. A web-link to use the tool will be placed within the lung cancer screening clinical reminder.

2. *Audit and Feedback.* Due to the demonstrated importance of audit and feedback for changing provider behavior, we will deploy an audit and feedback system to all sites.[102,118] This system will provide feedback on the screening and shared decision making process (e.g., number of provider's eligible patients screened for lung cancer, use of the tool, patient knowledge and satisfaction from patient surveys). When we visit the intervention sites to conduct usability testing (see below), our informationist from the Implementation Core will accompany us and meet with users to identify their needs and preferences for feedback (see Implementation Core). We will use this information to design an audit and feedback system to be implemented in all of the sites.

Implementation Strategies: Two Interventions

1. An additional part of LEAP will be *user-centered design*. Prior to the implementation of the web-based tool, we will also visit the "intensive" implementation sites and conduct usability testing on the tool.[119] Usability testing will be conducted with providers, nurses, lung cancer screening coordinators, and patients. We will go through the tool page by page to get feedback on the tool. We have done this in numerous studies and have specific protocols in place to do so. To the extent possible, we will use this feedback to modify the tool for these sites. Evidence suggests that when providers feel more engaged in the design of the tool, **they will be more likely to value and use it.**[124-126] During this time we will also meet with the local Clinical Applications Coordinators to discuss adding a link to the Decision Precision website within clinical reminders.

2. *Risk Threshold Tailoring.* Providers at all sites will determine their own risk thresholds for making personalized recommendations within the tool. This will be done in a stepped-wedge design and will add a new site every two months until providers at all sites have been given the opportunity to tailor their thresholds. After completing a risk tailoring tutorial, they will identify two risk thresholds: 1) a low risk/low benefit threshold below which the provider would generally suggest that most patients not get screened (e.g., a number needed to screen of >500 to avoid one lung cancer death) and 2) a high risk/high benefit threshold above which they would generally suggest that most patients get screened (e.g., a number needed to screen of <100 to avoid one lung cancer death). In between these two thresholds is a gray zone where screening and not screening are presented as equally good options. We will provide significant leeway in allowing providers to make these cut-offs, but will impose certain constraints to make sure the thresholds do not violate professional standards. Of course, every screening recommendation will be accompanied by a recommendation for shared decision- making. We believe this strategy will address several potential barriers to implementation of clinical support systems—including provider's lack of

comfort with making decisions based on numeric risk-benefit information, lack of agreement with tool content, or a feeling of being taken out of the decision making process.[120-123]

3.3 Study design and methods

Aim 1: To determine effectiveness of LEAP plus Audit and Feedback (A&F) versus A&F alone.

We will use multi-site, cluster-based randomization to evaluate the effect of the LEAP implementation strategy. Currently, there are eight VHA sites involved in the LDCT demonstration project and each site has agreed to be involved in our implementation initiative (see attached letters of support). We decided to only use these sites because they already have a successful lung cancer screening program in place and thus provide an ideal situation to test different implementation strategies for a decision support intervention. NCP will randomize which of the eight sites receive the LEAP implementation strategy.

Aim 2: To determine the effectiveness of allowing providers to set risk threshold algorithms.

Once the providers have experience with using the tool in practice, we can then start to roll out the risk threshold tailoring. We will roll this out at a rate which is limited by our capacity to do the tailoring and accompanying training in only one site at a time, but eventually reaching all of the sites by 18 months into the study. We will evaluate this additional part of the implementation strategy by comparing at different time points the sites that have received the training and tailoring to those who have not yet in what is effectively a stepped wedge analysis. Thus, we will enroll one site every two months into this strategy, stratified by whether the site is receiving the LEAP strategy, over 16 consecutive months.

Evaluation Framework. We will use the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) to evaluate our two implementation strategies. Specific measures for the implementation evaluation are detailed in Table 2. Our primary goal is to determine whether these strategies lead to more frequent use of the Decision Precision Tool and align screening utilization with the magnitude of the mortality benefit from screening. While lung cancer screening is a preference sensitive decision and thus for any given patient, we cannot assess whether they made a "good decision", it is possible to evaluate the strength of the association between mortality benefit and screening utilization. If our tool is successful in communicating the benefit-harm information to providers and patients, we would expect that those with the largest potential to benefit would be more likely to be screened than those patients who have limited potential to benefit (we are calling this "precision decision making"). Based on these goals, our primary outcomes will be: 1) the proportion of eligible Veterans for whom the Precision Decision tool is used; and 2) ability of intensive implementation to promote precision decision making.

Data Collection. The majority of the data will be collected from Health Factors data within the VA Corporate Data Warehouse (CDW) and from 'paradata' automatically generated from use of the tool—i.e., data recorded by the website, which allows us to determine use of the various components of the Decision Precision tool. We should emphasize that paradata do not contain PHI—rather it includes which pages were viewed and for how long. Patients will also complete surveys to provide data for the audit and feedback system. We will query the Health Factors table on a weekly basis to identify patients who had initial screening conversations with a provider that week (i.e., clinical reminder completed) and will mail surveys to these patients.

Table 2: Implementation Evaluation Measures using RE-AIM

RE-AIM Construct	Study Measures
Reach Participation rate in the target population (patient level).	Proportion of eligible patients with documented tool use after screening discussions (primary outcome).
Effectiveness (Aim 1) The impact of the intervention on targeted outcomes.	• Precision decision making (primary outcome) • High quality decision making • Patient satisfaction with decision and process
Adoption (Aim 2) Percent of providers who adopted the guidelines.	• # of tool assessments for each provider • % of provider's eligible patients with documented tool use
Implementation (Aim 2) The quality and consistency with which the guidelines were followed.	# of tool assessments where: • Patient decision aid was printed • Shared decision making documentation was copied • Dynamic pictograph depicting personalized benefit and harm was opened for display
Maintenance (Aim 2) Degree to which the guidelines were followed over time.	A re-assessment of each measure defined above will be completed during the maintenance phase.

Outcome measures. The outcome measures are specified in Table 2. The proportion of eligible patients with screening discussions is defined as those patients without documented exclusions for screening who have had initial lung cancer screening clinical reminders resolved. Documented tool use is defined as provider selection of the "use tool" radio-button that will be inserted into the clinical reminder ('Reach' construct). "Precision decision making" is defined as screening utilization aligning with Veterans' potential screening benefit. This will be estimated by inputting CDW data into a validated model.[110,127,128] High quality decision making, obtained from patient surveys, will be defined as 1) adequate knowledge about the benefits and harms, and 2) values consistent with the screening decision.[129-131] Additional outcome measures include decisional conflict,[112] patient perception of communication with physician,[132] participation in shared decision making,[133] and satisfaction with decision and decision making process.[134]

Power Considerations. Our unit of analysis is site. Randomizing interventions by provider or PACT team is not feasible and would also likely result in significant contamination between arms. LEAP Strategy: Even with our small sample size (n=4 in each arm), we will still be able to detect an absolute difference of 25-35% from a control rate of 50% documented tool use, for an ICC of .05 to .10 and 400 total patients undergoing screening discussions in each site. We believe it would be necessary to see substantial differences in tool uptake in this range with the LEAP strategy relative to the control strategy to justify the resources that would be needed for widespread dissemination. We should note that it should be feasible to achieve this sample size as roughly 50 patients were eligible for the tool per month at each site during January, February, and March of 2015 (based on personal communication from NCP). Risk Threshold Tailoring Strategy: For this the stepped-wedge design with an average of 400 total patients undergoing screening discussions per site, we can detect a much smaller absolute difference in documented tool use of 7.5% from a control rate of 50%. We can also readily detect a small effect size (0.15 standard deviations) in any of our continuous variables.

Analysis. To compare statistical differences in outcomes between LEAP implementation and control sites, we will use generalized estimating equations (GEE) to control for the clustering of observations within sites. Models will include the specific outcomes from Table 2 as the dependent variables and each of the two treatment variables (LEAP and Risk Tailoring) as we effectively have a form of factorial design that allows us to separately test the effects of each strategy while conditioning on the presence of the other. We will also include the estimated lung cancer risk for each individual patient as a pre-specified, pre-treatment variable in each regression. As this variable is likely to be associated with many of our key outcome variables (like screening rate), it can substantially increase our power as described by Raudenbush.[135] For the models examining one of the primary outcomes for the risk tailoring intervention, precision decision making, we will look at whether the odds of screening as a function of the patients estimated risk of cancer increase after the risk tailoring intervention. This reduces to testing the significance of the interaction between estimated cancer risk and the treatment variable indicating the risk tailoring strategy.

Aim 3: To conduct a formative evaluation to determine the factors most important for successful implementation of risk-based shared decision making tools.

Near the end of the study, our qualitative analysts from the Implementation Core will conduct telephone interviews with those providers at each of the sites who identify themselves as participating in the shared decision making process with patients. Prior to the meeting, we will conduct a separate telephone interview with the clinician from each site who oversees the lung cancer screening program. The interview will consist of a survey (Appendix B) that briefly describes each of the CFIR constructs, and the provider will be asked to consider how important each factor was in affecting successful implementation of the Decision Precision tool. Those items that the lead clinicians across sites deem to be very important in the successful implementation of the guidelines will form the basis for developing our semi-structured interview guide to use with the other participating providers at the sites. The purpose of these questions will be to gain a better understanding of the barriers that occurred, as well as those factors that facilitated implementation. Coding and analysis of the responses will be done according to the protocol described on the CFIR website and in Appendices C and D.

In addition, we will survey all providers for their feedback on tool usability, including: 1) perceived use of the tool, 2) satisfaction with the tool, 3) satisfaction with engaging in shared decision making with patients where the tool was used, and 4) their preference to use the tool going forward. Finally, we will ask providers whether any of the implementation strategies we used (audit and feedback, involvement in user-centered design, determination of risk thresholds, LEAP) influenced their use of the tool.

4.0 Impacts

Unfortunately, even though there is strong evidence of the benefits of shared decision making, there is equally strong evidence of the failure to implement SDM into practice.[136] While research studies are able to use ample resources (e.g., research assistants, participant incentives) to successfully use decision aids or other interventions to facilitate SDM, implementation of these methods often fails without the structure of research. A number of barriers to implementing SDM within primary care have been consistently documented, including provider perceptions about the time it will take and limited provider comfort with risk communication tasks.[121,137,138] Within the context of lung cancer screening in VHA, a pilot study conducted by Dr. Wiener on our team revealed poor understanding of the pros and cons of LDCT screening among both Veterans getting screened and the VA PCPs offering the service. **Given the critical importance of shared decision making in the context of LDCT screening, we must do better.**

5.0 Partnerships/Management

Expertise and specific responsibilities of the team are detailed in the budget justification.

PI: Angela Fagerlin, PhD, Core Investigator, VA CCMR; Associate Professor of Internal Medicine, University of Michigan, and Co-Director of the Center for Bioethics and Social Sciences in Medicine.

Co-PI: Tanner Caverly, MD, MPH, HSR&D Advanced Fellow, VA CCMR; Clinical Lecturer, Department of Medicine, University of Michigan.

Co-Investigator: Renda Wiener, MD, MPH, Physician and Core Investigator, Bedford/Boston Center for Healthcare Organization & Implementation Research; Assistant Professor of Medicine, Boston University School of Medicine.

Staff from the **University of Michigan Center for Health Communications Research (CHCR)** will be responsible for making changes to the Decision Precision tool and will work closely with Drs. Caverly and Fagerlin on changes in content.

Support for project management, data management, and data analysis will come from QUERI core staff.

Partnerships. As the office responsible for overseeing the lung cancer screening demonstration project, NCP (Linda Kinsinger) has already informed the sites that NCP supports the use of this tool and encourages participation in this project. If the tool proves to be successful, they will include it as part of the lung cancer screening guidelines to be disseminated throughout VHA. Primary Care Services (Gordon Schectman) will also indicate their support to primary care teams for their participation in LEAP. In addition, as tools from this project are vetted by the sites and are viewed positively by providers and patients, Primary Care Services will work with us to design ways to promote dissemination throughout VHA. We will schedule annual conference calls (at a minimum; more frequently as issues and findings of interest arise) with our partners to update them on our progress and obtain their input on next steps.

Figure 3 depicts the proposed timeframe for the project. Roll-out to all of the sites will be completed by Y3Q4; we plan to continue with audit and feedback through Y4 to allow one year of follow-up to evaluate implementation outcomes over the longer term (maintenance).

Figure 3: Timeframe for Project Activities

	Project Period: 10/1/15–9/30/19															
Activity	**Year 1**				**Year 2**				**Year 3**				**Year 4**			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Materials development																
User testing of tool																
Revision of Decision Precision																
RA training																
Implementation																
Qualitative interviews																
Analysis																
Manuscript and report writing																

Letter of Support from Linda S. Kinsinger, MD, MPH, Chief Consultant for Preventive Medicine, VA National Center for Health Promotion and Disease Prevention, dated May 26, 2015 describing that this project is quality improvement and not research:

OMB Exemption Brief	
Project Title: Implementing Guidelines for Shared Decision Making in Lung Cancer Screening	
Principal Investigator: Angie Fagerlin, PhD	
Site: VA Ann Arbor Healthcare System, Ann Arbor, Michigan	
Date: August 10, 2015	
OMB Review Determination: Signature of PI Signature of R&D representative	☒ Exempt from OMB Review: (check all that apply): ☐ Clinical Trial ☐ Clinical Examination ☐ Direct Treatment ☒ Prevention of Clinical Disorder ☐ Interpretation of Biological Analyses

Project Overview

Lung cancer is more prevalent and associated with worse outcomes among Veterans than among the general US population. Based on the results of the National Lung Screening Trial (NLST), the United States Preventive Services Task Force (USPSTF) recommends low-dose computed tomography (LDCT) screening for patients who meet age and smoking criteria. In 2013, VHA rolled out a two-year clinical demonstration project in eight VA medical centers to determine the resources needed to "provide screening and follow-up...with accuracy, efficiency, and safety similar to that achieved in the NLST."

However, the NLST also found substantial harms associated with LDCT screening. Because lung cancer screening has substantial benefits and harms, and the net benefit can vary dramatically across eligible smokers, the USPSTF strongly advocated for shared decision making, and a 2015 Centers for Medicare and Medicaid Services (CMS) decision memo now requires a shared decision making consultation between patients and providers for payment of initial lung cancer LDCT screening. Shared decision making (SDM) is the process wherein the provider communicates medical information about the screening options and patients are responsible for sharing their values and screening preferences. Following the sharing of information by both parties, patients and providers collaborate to decide on the course of screening that reflects both the best medical evidence as well as the patient's preferences and values.

To meet this need for shared decision making, we created "Decision Precision", a provider facing web-based decision support tool. This tool provides a method for providers to implement evidence-based guidelines for SDM in lung cancer screening. Our goal is to have the tool facilitate SDM within the confines of a busy clinical schedule. This web tool goes beyond current VA patient materials in several ways. It provides: 1) personalized quantitative risk assessment of the trade-offs; 2) patient-friendly language; 3) graphics that have been empirically demonstrated to help patients understand their personalized risks and benefits; and 4) quick and easy documentation of personalized SDM after using the tool.

The goal of this project is to test two strategies for implementing shared decision making into clinical practice with the aid of the Decision Precision lung cancer screening tool.

Patients who have discussed lung cancer screening with their providers will be asked to complete surveys measuring: 1) their knowledge about the benefits and harms of lung cancer screening; 2) their preferences for avoiding specific risks and achieving specific outcomes associated with screening; and 3) their satisfaction with their screening decision and the decision-making process. These data will be used to give feedback to

providers on the quality of the decision process, including whether patients have an accurate understanding of the benefits and harms, and whether the ultimate screening decision is consistent with patients' values.

Justification for Exemption of this Study under 5 CFR Part 1320.3:

This is a Quality Improvement project designated by the National Center for Health Promotion and Disease Prevention (NCP) and the Office of Primary Care Services (PCS). Results from this study will be shared with NCP, PCS, and other policymakers and VA stakeholders. NCP supports the use of the Decision Precision tool and encourages participation in this project. If the tool proves to be successful, NCP will include it as part of the lung cancer screening guidelines to be disseminated throughout VHA. PCS will also indicate their support to primary care teams to participate in the project. In addition, as tools from this project are vetted by the sites and are viewed positively by providers and patients, PCS will work with us to design ways to promote dissemination throughout VHA.

This research will prevent clinical disorders by:

Use of the Decision Precision Tool with risk threshold tailoring will help align lung cancer screening utilization with the magnitude of the mortality benefit from screening. If our tool is successful in communicating the benefit-harm information to providers and patients, we would expect that those with the largest potential to benefit would be more likely to be screened than those patients who have limited potential to benefit.

Justification that the Surveys are Not Duplicative:

The survey is not duplicative because:

QUERI has funded this project based on its originality in addressing the specified RFA requesting projects to improve the health of Veterans by supporting the more rapid implementation of effective clinical practices into routine care. This decision was based upon merit review. This quality improvement project is unique in that it will implement and evaluate effectiveness and use of a shared decision making tool for lung cancer screening to inform practice in VA nationwide. Patient surveys conducted in this project are not duplicative of any other survey with this population.

OMB Exemption Brief	
Project Title: Quality Improvement and Personalization for Statins (QUIPS)	
Principal Investigator: Jeremy Sussman, MD, MS	
Site: VA Ann Arbor Healthcare System, Ann Arbor, Michigan	
Date: August 10, 2015	
OMB Review Determination: Signature of PI Signature of R&D representative	☒ Exempt from OMB Review: (check all that apply): ☐ Clinical Trial ☐ Clinical Examination ☐ Direct Treatment ☒ Prevention of Clinical Disorder ☐ Interpretation of Biological Analyses

Project Overview

The VA/DoD Committee on Clinical Practice Guidelines for the Management of Dyslipidemia for Cardiovascular Risk Reduction has created clinical practice guidelines that are similar, but not identical, to the ACC/AHA guidelines. The VA/DoD practice guidelines are well-designed and have been officially adopted. In practice, however, they are not yet standard of care within VA, and they are somewhat more complicated than the previous guidelines, which focused solely on patients' cholesterol levels. However, VA is planning to adopt HEDIS (Healthcare Effectiveness Data and Information Set) performance measures for managing dyslipidemia, which are loosely based on the ACC/AHA guidelines, but are different from either the ACC/AHA or the VA/DoD guidelines. Working with VA's Center for Analytics and Reporting (CAR), we have created novel performance measures that are perfectly aligned with the VA/DoD practice guidelines, but still consistent with the HEDIS performance measures.

The backbone of the intervention will be the VA/DoD guidelines and the newly-created CAR performance measure that aligns with them. One of the measures of whether or not our implementation strategy is successful is the rate at which providers engage patients in a discussion of their statin medications. Such a discussion will be particularly important in the event that a patient's medication is changed as a result of the new guidelines. This will be difficult to measure directly; but we will try to get a rough idea of patients' participation with a brief survey that will be sent to all guideline discordant patients immediately following their visit with their primary care teamlet. The survey will consist of approximately five questions that will ask whether or not there was any discussion about their statin (cholesterol) medications, whether any changes were made, what changes were made (from a multiple choice list), did they understand the changes, and did they get a chance to ask questions or express their opinions/concerns about the changes.

Justification for Exemption of this Study under 5 CFR Part 1320.3:

This research study is exempt from 5 CFR Part 1320.3 because its primary objective is to prevent clinical disorders related to cardiovascular disease. The new cholesterol guidelines have the capacity to prevent CVD events and make care more patient-centered. If not implemented carefully, however, the guidelines also have the capacity to create confusion and frustration about one of the most commonly used and important classes of medication in the world. Clinical change can be difficult for providers, and the paradigm shift from treating cholesterol levels to lowering CVD risk can be cognitively difficult. This project is an important step in preparing for the next generation of clinical practice guidelines while trying to limit the problems it can create. By designing a novel performance measure, reporting it in a way that is meaningful and useful to providers, addressing organizational barriers to guideline adoption, and using a relatively simple educational approach and decision support tool, we hope to improve the prevention of cardio-vascular disease.