Protocol Summary

National Questionnaire Assessing VHA Patient and Provider Perceptions of Point-of-Care Research (POC-R)
Draft Protocol Summary

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Sponsor:

VA CLINICAL SCIENCE RESEARCH & DVLPMT	Federal Government	U.S. Department of Veterans Affairs - 810 Vermont Avenue, NW - Washington, DC 20420

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Background and Introduction

Veteran's Affairs is a leader in innovations and electronic medical records. As a national, public institution, the VA has a responsibility to provide the best clinical care for the veterans who have served our nation. Clinical trials are the medical standard for evidence based practice and are regularly conducted with VA. The expense of conducting clinical trials, difficulties recruiting providers and patients, and concerns about applicability for general practice make such trials of less than ideal practical significance. Observation studies are highly practical but are problematic methodologically as the lack of randomization results in limitations of possible conclusions.

Point-of-Care research (POC-R) is an intermediary approach to bridge the gap between clinical trials and observation studies. In POC-R, randomization of equivalent care options takes place during clinical care and permits pragmatic clinical guidance in the context of rigorous randomization. The POC-R technique permits potential subject identification, criteria for enrollment, and follow-up via electronic medical records (EMR) eliminating the need for resources to support dedicated clinical trial staff thereby reducing randomized trial costs significantly. The POC-R provides a potential mechanism for improving the breadth and significance of clinical research programs in VA. To maximize the utility of POC-R and to facilitate effective implementation throughout the VA, it is important to understand the concerns patients and providers might have regarding POC-R policies, how implementation of POC-R would impact clinical care workflow within VA hospital settings, and how to best support informed decision making for POC-R execution. Implementing POC-R also requires significant resources in terms of informatics support and these issues are not entirely clear.

The purpose of this study is to develop and validate a survey to assess providers and patients perceptions to the proposed POC-R program in the VA, particularly focusing on the beliefs, knowledge and attitudes of providers and patients. The outcomes of this study will inform implementation practices, design of educational materials and the overall approach for program development within the VA and will be useful to the larger clinical research community.

Rigorous criteria and complex study requirements contribute significantly to difficulties in enrollment of clinical trials. Failure to recruit patients into clinical trials has been explained by busy clinic patterns (e.g., forgetting to identify potential patients) and concerns that interventions at the point of care should consider clinic demands for effective use. It is critical to clearly identify how this innovation can be incorporated into clinical workflow by healthcare providers and staff. These findings points to the importance of understanding the priorities for clinicians that would increase their support for implementation of POC-R. Incorporating research into clinical settings is difficult because of the speed of work and demands of delivering the highest quality clinical care. In one study, recruitment of providers was as low as 2% due to workflow and time issues. Other studies have found that improving the quality of care was a valued outcome among providers. Providing implementation support, including informatics assistance for screening and follow-up was found in one study to be important. Project management support is essential to assisting providers and patients in making informed decisions related to enrollment and concerns that develop at the bedside related to workflow.

Understanding how the concepts of "clinical equipoise," "randomization" and 'patient consent" are perceived by providers and patients is a key component of this proposed work because it is known that these concepts are difficult to grasp and not well understood. Healthcare providers often prefer to consult local colleagues when deciding on care, and may have concerns related to equipoise in care. Patients, although supportive of participation in clinical research, generally do not understand many aspects of clinical research including equipoise and randomization. Concerns over equivalence of care is an issue in all clinical trial research, and not unique to the POC-R approach, however, misunderstandings related to clinical trials will need to be addressed before patients can make informed decisions related to POC-R. Clear and understandable presentation of information - even very complex information - allows patients of varying backgrounds to understand their options and make informed choices. For successful implementation of POC-R such information presentation support will be provided for providers, patients, administrators, and staff alike.

Patients are a vital resource for contributing to successful implementation of Point-of-Care innovations. Past research demonstrates that patients may be inclined to support many of the objectives that underlie POC-R. Patients understand the importance of reducing costs and maintaining clinical care during clinical trials. Clinical researchers have incorporated patient preferences in clinical design and found that such patient involvement supports effective randomized trials. Breast cancer focus group patients expressed willingness to have routine records accessed to identify patients suitable for participation in clinical trials and for follow-ups suggesting that some patients may support liberal access to EMR records to support evidence based improvements. However, breast cancer patients may particularly identify with the importance of research in

cancer and the personal significance of diagnoses may contribute to fewer privacy concerns. Patients coping with chronic conditions can confidently report what "usually happens" or what "should happen" during their clinical care experience. The expectations they bring to clinical care interactions are important to consider when they are approached to participate in research, particularly using an innovation that may require explanation.

The potential translation impact of POC-R research within VA is impressive in scope. If clinical questions are appropriately chosen to fit POC-R guidelines and clinician priorities, patients are sensitively informed in a tailored manner, and VA workflow in a variety of clinical and hospital settings is understood, POC-R will be well-positioned for implementation. However, even the best innovations can have difficulty generating grass roots support within an organization. Therefore, our research will use Roger's perspectives on diffusions of innovations to inform understanding of the best ways to incorporate POC-R.

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Purpose and Objectives

The objective of this study is to conduct a nationwide study utilizing two questionnaires – one for Veteran patients and one of VA providers. The questionnaires are designed to identify the barriers and facilitators to the implementation of Point-of-Care Research (POC-R). POC-R is an innovative program currently being proposed to do research in the VA. The questionnaires were piloted by the Salt Lake City VA in a previously-approved IRB study entitled: Questionnaire Assessing VHA Patient and Provider Perceptions of Point-of-Care Research (#55833).

The goal of the study is to assess the perceptions and attitudes of patients and providers. The focus will be on issues of privacy, patient-provider relationships, ethical issues, and concerns regarding the equivalence of care. Implementation factors such as workflow and barriers to patient enrollment, implementation strategies, and CPRS functionality will also be addressed.

The ultimate objective is to produce national VHA guidelines for regarding implementation of POC-R, focusing on: a) effective implementation strategies and workflow modifications; b) tailored recommendations for overcoming identified barriers to adoption; c) requirements for marketing and education content for providers; d) requirements for marketing and education for patients; e) institutional policy requirements; and f) key functional requirements for utilizing CPRS to support POC-R patient identification, tracking, and decision support.

Study Population

Age of Participants:	18+	
Sample Size:	At Utah:	N/A
	All Centers:	22,500 (up to 16,500 patients; up to 6,000 providers)

Inclusion Criteria:

Patient population: Any Veteran who has had at least three or more visits per year in the last two years for care within Veterans Affairs.

Provider population: Providers who work at any Veterans Affairs Medical Center.

Exclusion Criteria:

Any Veteran who has not had a least three or more visits per year in the last two years to a Veterans Affairs Medical Center. Any patients who have a diagnosis of dementia. Any non-English speaking patient or provider. Any patient new to the system within the past two years.

Design

Survey/Questionnaire Research

Study Procedures

Recruitment/Participant Identification Process:

PATIENTS: Two methods will be used to recruit up to 16,500 Veteran participants.

The first method will randomly sample Veterans from a patient demographic CDW file within VINCI*. The PI and co-investigators, and anyone else approved on the study team and selected by the PI, will review the random sampling and data selection. We will randomly sample from any Vet that's had three or more visits per year in the past two years. Participant names and addresses will be extracted from the dataset.

Once we have the names and addresses of these Veterans, they will be sent an authorization cover letter that will describe the study and invite them to complete the patient questionnaire. Veterans will have the choice of either completing the questionnaire online or on a paper copy. Included in the text of the letter will be a link to the online questionnaire hosted on the University of Utah's REDCap server. Two-weeks later, if they have not completed the survey online, the participants will be mailed a cover letter and a paper questionnaire with an enclosed self-addressed, postage paid envelope. A postcard reminder will be sent out two weeks later, if still no response. The postcard will have the internet link to take the questionnaire online. A third reminder will be sent out on colored paper two weeks later, again if no response, with the full questionnaire again and a self-addressed, stamped envelope. A reminder phone call will be conducted one week after this last mailing reminder. There will be no further contact with the Veterans after this point. If they answer the questionnaire immediately, there will be no further contact either.

The questionnaires will have an alphanumeric code that will be linked to the participants' names in a separate file. This will allow us to determine who has refused, completed the questionnaire, or has not responded so we can follow up. Once all questionnaires have been completed, the file with the patient names and addresses will be destroyed.

During the sampling processes we will also be collecting data on the participants about their age, institution (i.e. VAMC), and mental health diagnoses (yes/no). Their questionnaire data will be linked by the alphanumeric code to this data. The final data set will be completely de-identified.

Additionally, we will use the social media site Facebook to recruit participants. Veterans United has a Facebook page (http://www.facebook.com/veteransunitednetwork) where items can be posted without restriction. We plan to post a link to our online REDCap questionnaire for the duration of time it takes to get 500 responses. These questionnaires will be completely anonymous and s[illegible]re will be no linking to personal information. There will be no contact with these participants.

*VA Informatics and Computing Infrastructure (VINCI) is Transformation for the 21st Century Initiative #13 to provide researchers a nation-wide view of high value VA patient data. While VINCI brings together data sources and provides the analytical environment for performing studies, VHA National Data Services (NDS) authorizes research access to patient data. New research projects are granted access to snapshots of data that can be updated as needed. In addition to data storage, VINCI includes a cluster of servers set aside for tasks like analysis, data processing, and extracting information from text. This means that VA researchers will have access to the data and the applications they need to select, transform, and analyze patient data in a central, secure location accessible from the VA intranet.

PROVIDERS: Provider participants will consist of all physicians working in a VA medical center. We will initially approach 6,000 providers and expect a 50% response rate totaling 3,000 responses. First, we will retrieve provider emails any of the following three ways: 1) Contact the Chief of Staff at each VAMC to ask to procure their provider listserv(s); and/or 2) Contact the Administrative Assistant of the Chief of Staff at each VAMC and ask that the Chief of Staff office send out the recruitment email to their provider listserv(s) immediately; and/or 3) download provider emails from the ALL EMPLOYEE file within the VA Outlook email system. If we collect the emails ourselves or receive the listservs, we will immediately send the recruitment email to providers. The recruitment email will include a link to the online questionnaire in REDCap. Second, 2 weeks after the initial email, we will send out an email reminder to providers to complete the survey. Third, after an additional 1 week (3 weeks from initial email), we will mail out a postcard reminder with the link to the survey in REDCap. Fourth, after an additional 2 weeks (5 weeks from initial email), we will send out a paper copy of the questionnaire to the providers at their respective VAMC with a self-addressed, postage paid envelope and the cover letter. Fifth, after an additional 1 week (6 weeks from initial email), a member from the SLC study

team will call the provider at their VAMC office and ask them to complete the survey. The team will try to contact the provider no more than 3 times by phone. There will be no further follow-up with the provider. The questionnaire will ask providers some demographic questions such as age, discipline, role, number of years since graduation, and number of years at VA. Only the provider name and email will be entered into REDCap. All other information will be kept on a secure VA research drive. Once all data has been collected, the file containing providers' contact information will be destroyed.

BOTH: The data from the paper copies for each questionnaire will be entered into the REDCap database. REDCap will be located on the University secure CHCP server. Only those specified by the PI will have access to the database. The data set will be de-identified. Data analysis will be conducted from this data.

Informed Consent:

Description of location(s) where consent will be obtained:

We are requesting a waiver of documentation of informed consent and a waiver of authorization. We will use authorization cover letters instead of signed consent forms. The phrase, "By answering this questionnaire, you are giving your consent to participate" will be included in the patient and provider cover letters. There will be no physical contact with the participants.
Patients will receive the cover letter the first time they are asked to participate by mail. The patient cover letter will be the recruitment letter they receive. They will receive it again with reminder information. For those completing the questionnaire online, the cover letter is the first screen and requires the participant to read the cover letter before entering the questionnaire. Providers will also receive a cover letter if they request a paper copy of the questionnaire, or, again, the cover letter will be the first page of the online questionnaire if they choose to complete it that way. They will have to read the cover letter before proceeding to the questionnaire. They also will receive the cover letter with reminders to complete the questionnaire.

Description of the consent process(es), including the timing of consent:
A waiver of documentation of informed consent and waiver of authorization are being requested. We will use a patient and a provider questionnaire cover letter instead of a signed consent. The cover letter will include the statement: "By answering this questionnaire, you are giving your consent to participate."
The authorization cover letter is also the recruitment letter that the patients will receive in the mail, and the first page of the online questionnaire. It will also be included with the questionnaire if the providers ask for a paper copy, and will be the first page of the online questionnaire for providers as well. Participants will have whatever time they'd like between the time they're first recruited and read the cover letter and when they complete the questionnaire. The cover letter is also the first page of the online questionnaire. The participants must read the cover letter before proceeding to the actual questionnaire. Those recruited through Facebook will see the cover letter before they can proceed to the actual questionnaire.

Requested Waivers/Alterations of Consent:

02. Type of Request	01. Purpose
Waiver of Informed Consent	Return of the survey will constitute consent

Procedures:

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Statistical Methods, Data Analysis and Interpretation

Data analysis will consist of three steps: step one will be descriptive summaries with means and variances; step two will be to conduct data reduction techniques including exploratory factor analysis and scale development; and step three will consist of correlations and regressions to identify predictors of willingness to participate. The sample size was determined based upon a standard predicted return rate of 50%.