

Studies on behavioral factors for Veterans' COVID-19 vaccine uptake Request for Concept Papers

Background

The COVID-19 vaccines, including those from Pfizer and Moderna, are being distributed to VA healthcare workers and high-risk Veteran populations shortly after the FDA's emergency use authorization in December 2020. The VA National Center for Health Promotion and Disease Prevention (NCP) has developed the vaccination prioritization framework, initial training materials and communication tool kits for healthcare workers and they are releasing educational materials and resources to inform Veterans about COVID-19 vaccines and encourage Veterans to receive the vaccinations.

With the rapid development of COVID-19 vaccines, it is imperative to conduct systematic assessments of Veterans' and VHA clinicians' attitudes toward COVID-19 vaccines and how they impact success of VA's vaccination program. Understanding current beliefs among these populations in addition to effectiveness of current messaging could inform long-term strategic efforts by the VA in its COVID-19 vaccine rollout.

Purpose and Scope

The VHA Health Services Research & Development (HSR&D), Office of Research and Development (ORD) program announces an opportunity to compete for planning/startup funds for bolstering a novel research agenda on COVID vaccine uptake in the VA health care system. A recently published study showed that nearly 70% of adults in the US would be willing to get a COVID-19 vaccine. However, vaccine acceptability was lower among several demographic groups, including participants who were non-Latinx black, were of lower socioeconomic status, or had no health insurance (Reiter 2020). In another survey study, fewer than half of Black adults (48%) are interested in receiving a vaccine if it was free while among Latinx adults, 66% are interested (Sparks,2020). The pattern among non-Latinx black participants is concerning as data suggests that non-Latinx Blacks have among the highest COVID-19 incidence and mortality rates among non-VA users in the United States (APM Research Lab 2020; Gross 2020) with differences in access and exposure risk possibly driving these higher rates (Mackey 2020). Participants in the study were also less open to receiving a vaccine if they reported a higher level of perceived potential vaccine harms. However, the researchers of the same study noted that one of the strongest correlates of vaccine acceptability was whether participants thought their healthcare provider would recommend they get vaccinated against COVID-19, further highlighting the importance of proper communication of medical therapies to patients (Reiter 2020, Leak 2012).

In order to ameliorate the disproportionate burden of COVID-19 on individuals and society, it is imperative to develop an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance among the different demographic groups, including racial and ethnic minority groups (NASEM, 2020). The National Academies of Science, Engineering, and Medicine (NASEM) strongly recommends additional research on optimizing COVID-19 vaccine risk communication and community engagement programs to build an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance. Adopting this research agenda is an important step toward ensuring equitable allocation of COVID vaccines (NASEM, 2020). This research initiative aims to develop better understanding of Veterans' attitudes and beliefs about COVID-19 vaccines, facilitators and barriers for vaccine uptake, and the role of these factors as potential contributors to health disparities. As part of the scope of this research initiative, VHA clinicians' attitudes and beliefs towards COVID-19 vaccination will be systematically assessed, as previous studies show that a clinician's recommendation is one of the most influential facilitator of vaccine acceptance among U.S adults (Reiter 2020).

Phased Funding and Timeline

The HSR&D COVID-19 vaccine uptake RFA will utilize a phased approach: 1) **Phase I** is a planning and startup phase that will provide funding up to \$100,000 for up to 6 months and 2) **Phase II** will involve the full conduct and implementation of the COVID-19 vaccine uptake research. We anticipate a single award for both phases. The RFA for Phase II will be released in the second quarter of FY 2021 and will be open only to one group of VA investigators who receive planning/start up awards during Phase I. The award for Phase II will be up to \$500,000 per year for up to 2 years with a possibility of extension in order to inform a longer-term research agenda on vaccine deployment. The use of a phased approach permits innovative research to start quickly and allows the final research plan to be developed with close coordination with VHA stakeholders (such as NCP, Office of Minority Health, Office of Health Equity), Center for Disease and Control (CDC)'s Vaccine with Confidence Program, National Institutes of Health Community Engagement Alliance (CEAL) Against COVID-19 Disparities program, and other federal partners along the way. Findings and products of noteworthy interest or significance may be disseminated incrementally to the clinical, operational, research, and Veterans community.

For Concept Paper preparation, applicants are discouraged from directly contacting the NCP leadership. This office provides frequent communications with the field, including weekly “Office Hours” that are a good source of up-to-date information on vaccination planning, progress, and emerging issues. Once we select the awardee of the planning phase of this research initiative, we expect the awardee will have full collaboration with the NCP leadership to optimize impact of this initiative.

Timelines

Release of a request for a concept paper	December 16, 2020
Concept paper due	January 22, 2021
Selection of one awardee	January 31, 2021 (tentative)
Planning phase funding start	February 1, 2021 (tentative)
Full proposal due	March 1, 2021 (tentative)
Research phase start	May 1, 2021 (tentative)

Concept papers should be submitted by email to Miho Tanaka (miho.tanaka@va.gov) by 3:00 pm ET, January 22, 2021. The most qualified team(s) will be funded for Phase I and invited to submit a full proposal. If multiple teams submit excellent and complementary concept papers, HSR&D may ask teams to consider merging prior to the submission of full proposals.

The Scope of Work

During the planning phase, the selected team will be expected to conduct a range of work preparatory for research work, which can begin prior to IRB approval of a final research protocol. This work includes developing and strengthening collaborative relationships with the VHA stakeholders, NIH CEAL workgroup, and other federal workgroups; developing a full research proposal reflecting input of stakeholders; and initiating an IRB or other regulatory approval process. The applicants to this RFA are strongly encouraged to collaborate and coordinate with three QUERI Program Rapid Response Teams who will have begun assessing the initial COVID-19 vaccine distribution and conducting some initial survey work upon which this research can build. The successful team will have four main responsibilities

during the research phase. Since the landscape of the COVID-19 vaccination has been evolving rapidly, it is possible that additional research questions in health service research domain may emerge in coming 2 years. In that case, the awardee of this initiative will be asked to help conduct research studies on the new research topics.

1. Coordination and Communication Function for COVID-19 Vaccine Research

This should involve at least 0.5 FTE and will perform following functions:

- Coordination with early QUERI survey/evaluation efforts
- Coordination with major VA stakeholders (NCP, Population Health, PBM, Emergency Management)
- Coordination with other national efforts to study vaccine roll-out (e.g. CDC's Vaccine with Confidence Program, NIH's CEAL)
- Dissemination of key findings
- Monitoring and reporting of progress of individual projects
- Report to Scientific Program Manager assigned to this initiative.

2. Research on COVID-19 vaccine attitudes among Veterans

- Conduct a survey with Veterans at multiple sites to assess their vaccine attitudes, perceived risks and benefits of COVID-19 vaccination, drivers of those attitudes and beliefs, and factors that might shape their willingness or hesitancy to accept vaccine by using validated survey instruments or instruments developed by the NIH CEAL group and/or CDC. Note: the scope of this survey will extend beyond the 5 initial roll-out sites in which QUERI teams are focused.
- Conduct focus groups or other qualitative studies with Veterans to complement findings of the survey work (appropriate sequences of qualitative and quantitative work proposed could be discussed in a research phase application in details)
- Analyze changes in Veterans' attitudes, beliefs, and trust towards COVID-19 vaccines during the study period and identify factors that contribute to the changes.
- Examine differences in vaccine uptake and changes over time in different subgroups including race/ethnicity and urban/rural, and other variables related to social determinants of health.
- Examine variation in COVID-19 vaccine uptake success across different sites and factors associated with success, with specific attention to high-risk populations.
- Examine if attitudes and beliefs towards mask wearing, social distancing, and hand washing and other non-pharmacological interventions are associated with attitude and beliefs about COVID-19 vaccination.

3. Tailored risk communication/public health promotions/community engagement:

- Identify current sources of information and communication about COVID-19 and COVID-19 vaccines among Veterans at multiple sites (e.g. healthcare providers, educational resources distributed at VAMCs, secure messaging, MyHealtheVet, Annie texting, Facebook and other social media channels, Veteran Service Organizations) and examine if the COVID-19 vaccine uptake is associated with exposure to sources of the information and communication.
- Develop tailored educational and public health messaging strategy (or strategies) towards Veteran patients as a whole as well as ethnic/racial subgroups

- Examine how well clinician-delivered educational/coaching interventions¹ facilitates Veterans vaccine update and address vaccine hesitancy in VHA clinical contexts.
 - Conduct pilot tests of the tailored educational and public health messaging strategy (or strategies)
 - Implement an interventional study at multiple sites by incorporating multi-faceted public health messaging approaches and VHA clinician-delivered educational/coaching interventions
 - Examine differences in different subgroups including race/ethnicity and urban/rural, and other social determinants of health.
4. Assessment of healthcare workers attitude towards COVID-19 vaccinations
- Conduct a survey with VHA healthcare providers at multiple sites to assess their vaccine uptake, attitudes, perceived risks and benefits of COVID-19 vaccination, drivers of those attitudes and beliefs, factors that might shape their willingness or hesitancy to accept vaccine by using validated survey instruments or instruments developed by other research studies. The survey will also assess healthcare workers' attitudes, beliefs and perceived competence in influencing vaccine acceptance among Veterans, as well as perceptions of what would help them to feel more competent in influencing Veteran's vaccine acceptance
 - Conduct focus groups or other qualitative studies with VHA care providers to complement findings of the survey work
 - Analyze changes in their attitudes, beliefs, and trust towards COVID-19 vaccines during the study period and identify factors that contribute to the changes
5. Factors associated with effective implementation of vaccination program
- Examine variation in success of vaccination programs across different facilities, and barriers and facilitators of initial vaccination efforts. Examine variation in approaches taken for identifying priority groups in accordance with CDC and VA recommendations.
 - Examine variation in implementation processes across different sites, including structure and staffing of vaccination clinics, communication strategies, additional outreach programs, and other innovative approaches.
 - Examine changes in programs over time, including changes in vaccination rates; patient and provider attitudes; strategies for reaching vaccine-resistant populations; involvement of community outreach, etc.
 - Examine variation in implementation factors for different vaccine products over time.

Eligibility

To be eligible to submit a Concept Paper to this solicitation, the Project Director/Principal Investigator of the project must have a VA paid appointment of at least 25 hours per week (5/8ths). The VA employment status, including a 5/8ths appointment of each PD/PI must be indicated in the letter of support of the Medical Center Director in the application. If a clinician PD/PI does not have a current, 5/8ths VA paid appointment then the letter of support from the Medical Center Director must include a commitment to offer the PD/PI a 5/8ths (or greater) appointment at the VAMC if the application is approved for funding. Multi-PI, multi-site collaborations are encouraged for this award.

Desired Qualifications of the Team

- Available to start the work in Q3 of FY21

¹ Clinician-delivered educational/coaching interventions utilize the health care team as a source of a communication/educational intervention (e.g., use of Veteran-centered communication, motivational interviewing, health coaching, etc.)

- Sites with ability to conduct quick IRB/local R&D review
- A collaborative team of experts with strong background in risk communications, decision psychology/behavioral science, patient-provider communication, preventive health behaviors, public health promotion, diverse populations, implementation science, survey methodology, and/or on-line survey tools (e.g. Qualtrics)
- Experience in collaborating and coordinating with multiple VHA stakeholders (including QUERI Rapid Response Teams and other health service researchers) and other federal partners to optimize impact of ORD-funded initiatives
- Ability to respond to address quick requests by VHA partners
- Experiences in working with Veteran Advisory Councils at VAMCs or Veteran-centered community organizations. Inclusion of Veteran Scientist encouraged
- Cross-VAMC collaborations are encouraged.

Concept paper outline

Interested teams should submit concept papers by the deadline. The concept papers (10 pages) should sketch out activities for the planning phase as well as subsequent 2-year research effort. Include each of the following sections (page number distributions are suggested):

- 1. Cover (~1 page).**
 - i. Lead (corresponding) PI Name, Institution, Research site name
 - ii. All additional Co-PIs (maximum 3 including lead): Name, Institution, Research site name
 - iii. Additional co-investigators
 - iv. Title of Concept Paper
- 2. Background (~1 page).** Describe the significance of better understanding of COVID-19 vaccine uptake behavior among Veterans and VHA healthcare providers, and its unique contribution to advancing the missions of VHA services and improving Veteran health.
- 3. Specific Aims and Approach (~2-3pages).** Describe the specific aims, activities, and approaches that will be completed during the planning phase, a current vision and aims for the research phase, and how the planning phase activities will feed into elaboration of the research phase. Discuss important questions addressed and impactful outcomes with potential for sustainability; justifications for the proposed research methods, sequences of activities, and anticipated challenges.
- 4. Research Team and Relevant Experience (~2-3 pages).** Describe the key members of the research team (co-investigators and organizations) and their relevant expertise and experience in relation to *the Desired Qualifications of the Team* in this solicitation. Include documentation of the VA eligibility to conduct research (current number of VA eighths). Include bio-sketch of proposed Principal Investigators and Key Personnel in Appendix.
- 5. Organizational Structure/Management Plan/Timeline (~2.5page).** Describe the project management plan, including roles and specific responsibilities of each member of the research team during both the planning, measurable milestones matched to scope and budget, and how the work will be communicated and coordinated with multiple internal and external stakeholders during both the planning and research phases (note: the plan for the research phase may be less refined at the submission of the Concept Papers.) In addition, describe resources available at the facility of the principal investigator (PI) that will support the team's success, as well as any proposed collaboration with institutions or investigators outside the PI's facility.

6. **Timeline (~0.5 page).** Provide a brief description (or a Gantt chart) outlining the projected timeframe for key project activities.
7. **Budget (NOT included in the 10-page limit).** Provide a summary budget table and budget justification for planning phase only. The budget may be for up to 6 months and should only be used for work needed to accomplish the specified objectives and deliverables. *Due to the time-sensitive nature of this solicitation, projects with TBH (to be hired) staff are discouraged; any TBH positions must be accompanied by a plan for expediting the onboarding process.*
8. **Letters of support** of the Medical Center Director for the PD/PI sites (NOT included in the 10-page limit).

General Criteria for Review and Scoring of Concept Papers

Concept Papers will be reviewed as per HSR&D policy for Service Directed Research (SDR) reviews with non-conflicted reviewers, content experts and partners.

Concept papers will be reviewed, and funding awarded, based on the following criteria:

1. Clear demonstration of conceptual understanding of the objectives of this new research initiative
2. Investigators' experience, expertise, and capacity to conduct the work within the stated timeframe (See the Desired Qualifications of the Team above.)
3. Clarity and credibility of the proposed organizational structure/management plan
4. Validity and feasibility of the proposed research plan (planning and extension phases)

References

APM Research Lab. The color of coronavirus: COVID-19 deaths by race and ethnicity in the U.S. 2020. Available at: <https://www.apmresearchlab.org/covid/deaths-by-race>

Fisher KA, Bloomstone SJ, Walder J, Crawford S, Fouayzi H, Mazor KM. Attitudes Toward a Potential SARS-CoV-2 Vaccine: A Survey of U.S. Adults. *Ann Intern Med.* 2020 Sep 4:M20-3569. doi: 10.7326/M20-3569. Epub ahead of print. PMID: 32886525; PMCID: PMC7505019.

Gross CP, Essien UR, Pasha S, Gross JR, Wang S, Nunez-Smith M. Racial and ethnic disparities in population level COVID-19 mortality. 2020.

Leask J, Kinnersley P, Jackson C, Cheater F, Bedford H, Rowles G. Communicating with parents about vaccination: a framework for health professionals. *BMC Pediatr.* 2012 Sep 21;12:154. doi: 10.1186/1471-2431-12-154. PMID: 22998654; PMCID: PMC3480952.

Mackey K, Ayers CK, Kondo KK, Saha S, Advani SM, Young S, Spencer H, Rusek M, Anderson J, Veazie S, Smith M, Kansagara D. Racial and Ethnic Disparities in COVID-19-Related Infections, Hospitalizations, and Deaths : A Systematic Review. *Ann Intern Med.* 2020 Dec 1. doi: 10.7326/M20-6306. Epub ahead of print. PMID: 33253040.

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Reiter PL, Pennell ML, Katz ML. Acceptability of a COVID-19 vaccine among adults in the United States: How many people would get vaccinated?. *Vaccine*. 2020;38(42):6500-6507. doi:10.1016/j.vaccine.2020.08.043

Sparks S, et al. COVID Collaborative Survey: Coronavirus Vaccination Hesitancy in the Black and Latinx Communities. 2020

NCP resources for supporting vaccine acceptance and confidence

<https://dvagov.sharepoint.com/sites/vhacovidvaccine/SitePages/Education-and-Training-Page.aspx>



NCP-HLM-Clinician
CoreApproaches.pdf