

Disrupted Care National Study: Advancing Research on the Effects of the Pandemic and Disrupted Care on Veteran Mortality and Health Outcomes

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Background: The COVID-19 pandemic has had profound effects on VHA healthcare and the Veterans it serves. Over this period, the VA has experienced significant changes in the volume and nature of care delivered and has documented worrying increases in all-cause mortality that may exceed the mortality directly attributable to COVID-19. HSR&D is initiating a new program of research to examine the possible connection(s) between pandemic-related disruptions in care and social support and possible increases in Veteran mortality and morbidity across chronic, acute, and mental health care settings. The aim of these efforts is to prepare VHA to better serve Veterans during the ongoing pandemic response and recovery and understand how to manage responses to future disruptions. This program will include (1) a national mortality study to be performed by a research team selected through this solicitation; (2) advanced coordination facilitated by this same research team; and (3) additional individual research studies and research supplements solicited and funded through separate service-directed requests (SDR) for applications.

Purpose: HSR&D is making funding available for one Disrupted Care National Study to conduct research as well as support and coordinate projects examining how disrupted and/or deferred care across VHA may have contributed to Veteran health outcomes, including observed excess mortality, during the pandemic. This research team will have three primary objectives: **1) Conduct a high-level national study of changes in all-cause and cause specific mortality; 2) Direct a data and methods work group** to identify data needs and promote use of common measures of pandemic impact, disrupted care, and disease outcomes; and **3) manage coordination and communications among researchers, stakeholders, and leadership** across individual studies to promote alignment with other VA and Federal efforts and ensure a collaborative and cohesive set of projects examining disrupted care.

- 1. Conduct National Mortality Study.** Internal reports from VHA have documented an increase in all-cause mortality among VA-enrolled Veterans that coincides with the pandemic. This excess mortality significantly exceeds the number of VA deaths officially attributed to COVID. However, it is uncertain the extent to which this excess mortality reflects undiagnosed COVID deaths, deaths due to disrupted or delayed care, or deaths attributable to other social disruptions and stressors. The objective of this national mortality study is to understand the type and level of various contributors to excess mortality observed during the pandemic, including decreased access and utilization of care or reduced quality of care. The primary aim is to examine broad trends in total mortality; the contribution of individual causes to the total; the effects in specific patient subgroups; and the relationship to temporal and geographic trends in severity of the pandemic and changes in access or utilization of care. HSR&D encourages a range of methodological approaches and conceptual frameworks to conduct this study. Researchers should be prepared to justify their proposed approach. This work in the design and analysis of this study, and preliminary results, will serve as a foundation for additional studies examining in more detail cause-specific mortality and morbidity for specific health outcomes.
- 2. Data and Methods Work Group.** The research team will be responsible for establishing and managing a Data and Methods Work Group (WG) on Disrupted Care.
 - The WG should consist of VA investigators with expertise in examining public health and/or EHR data, in deploying methods for observational research (including causal inference methods), and/or who are working on research questions in disrupted care. The WG will be a community of researchers to discuss, share, and collaborate around preliminary work of the National Mortality study and individual projects funded by HSR&D through supplements and IIR mechanisms. The WG

will be chaired by senior members of the Disrupted Care National Study team but include individuals from independently funded HSR&D research projects or operations projects in the area of disrupted and deferred care. Milestones for the Data and Methods WG will be established in concert with HSR&D.

- Possible goals of the WG include:
 - Engage and encourage investigators from funded HSR&D studies to share methodologies and measures best suited for disruption of care, intensity of the pandemic, assignment of cause of death, among others.
 - Curate and share recommended practices for defining important variables such as:
 - Clinical outcomes, including mortality, hospitalizations, morbidity, and intermediate measures of chronic disease
 - Healthcare utilization and care interruption, including processes of care (e.g., face-to-face visits for primary and specialty care, telehealth visits, procedures and lab tests) and hospital level factors (e.g., staffing, capacity, ER visits, and state of elective procedures)
 - Pandemic effects on isolation, economic activity, and access to medical care due to COVID-level restrictions
 - As projects are developed and funded by HSR&D in disrupted care, the WG will determine if there is value in harmonizing how researchers measure relevant variables, including moderators (e.g. pandemic severity, economic stress), to define disrupted care
 - Provide a forum for discussion around improving assignment of cause of death from COVID, including deaths outside of hospitals

3. Stakeholder Coordination and Communications. The Disrupted Care National Study team will serve as a central point of contact for VA partners and other Federal partners interested in engaging with VA research on disrupted care questions. The team will provide coordination with partners and communication of results by establishing an executive committee consisting of representatives of relevant program offices and other relevant Federal partners (e.g. CDC, AHRQ, CMS). The executive committee will help ensure alignment with other VA and Federal efforts to inform priorities for new projects. The executive committee will serve as an administrative coordinating and support center for individual projects examining the impact of the pandemic on specific health outcomes, including ensuring communication and collaboration between studies, hosting regular meetings for studies to report on progress and share initial insights, ensuring efficient communication with HSR&D and with stakeholders, and disseminating work products of the Data and Methods WG.

Process: HSR&D will fund one Disrupted Care National Study during an off-cycle scientific merit review. HSR&D will also fund investigator-directed IIRs and supplements through separate solicitations to drill down into the effects of pandemic-related care disruptions on specific health outcomes and care settings. The Disrupted Care National Study will work with these HSR&D-funded studies to create a community of disrupted care research that will discuss and share methodologies, metrics, and data sources for assessing care disruption and pandemic effects.

Funding: HSR&D will commit up to \$500,000 per year for one Disrupted Care National Study for a minimum of two years, with the possibility of non-competitive renewal based on findings and additional work needed. The allocation of funding to different activities is up to the PIs.

Who can apply: To be eligible to submit a proposal to serve as the leader of the HSR&D Disrupted Care National Study the PD/PI of the project must have a MD, PhD, or equivalent, have a VA paid appointment of at least 25 hours per week (5/8ths), be registered in ePromise, and meet other requirements of HSR&D eligibility. **Waivers**

will not be granted for these projects. Collaborative projects involving multiple sites are encouraged. Multiple-PI proposals are welcome.

Application Requirements (BOTH Steps Required):

- 1) Submit an Intent to Submit (ITS) of your proposed Disrupted Care National Study to the Disrupted Care Mailbox (VHACOHSRDDisruptedCa@va.gov) by March 12th. **You must submit an ITS before submission of your full proposal.**
- 2) A full proposal must be submitted by the PI's research office to the Disrupted Care Mailbox (VHACOHSRDDisruptedCa@va.gov) by April 12th. **Only research teams that have submitted an ITS will have their proposals reviewed.**

Your Intent to Submit should include the following information

- **Abstract (1 page maximum):** Outline your proposed plan and its relevance to addressing the research priorities laid out in the solicitation, including how your study will lead to important foundational conclusions about national excess mortality and how you will accelerate HSR&D's efforts to understand disrupted care during the COVID-19 pandemic. Describe why your team and approach will be effective in accomplishing these objectives.
- **Research Team List:** List all researchers and their affiliations involved in the study including the relevant Lead(s) (i.e., PI), Co-Investigators involved, as well as a list of other relevant research and program collaborators. This list will be used to identify reviewers so please be as complete as possible so we may avoid conflicts of interest.

Your full proposal is required to include the following information (12 pages maximum, cover page and references do not count): **NOTE: Only teams who have submitted an ITS may submit a full proposal.**

1. **Cover Page:** Title Project; PI Name; Institution; operational and program partners
2. **Background and Significance:** Describe the research agenda needed to advance understanding of the impact of deferred and disrupted care in the VA. Outline your proposed plan and its relevance to addressing the research priorities laid out in the solicitation, including how your study will lead to important foundational conclusions about national excess mortality and how your coordination will accelerate HSR&D's plans to understand disrupted care during the COVID-19 pandemic. Describe why your team and approach will be effective. **(1-2 pages)**
3. **National Mortality Study Project Plan and Methodology:** Describe your plan for conducting a national study to examine excess mortality, including the key research questions above. Please outline the data challenges that exist, how you plan to address them, and why your proposed approach will provide a solid foundation for additional studies on these research questions. Describe how results and conclusions emanating from your National Mortality study will be made available to partners and the research community. **(5-6 pages)**
4. **Data and Methods Work Group Plan:** Describe the organization and leadership of the data and methods work group, including plans for developing relationships with other research projects and providing a forum for discussion and curation of data metrics, methodologies, and data sources. A secondary goal of this research study is to create a community of research, building connections between researchers to accelerate the efficiency and impact of the work funded by HSR&D- explain how you plan to accomplish this. **(2 pages)**
5. **Stakeholder Coordination and Communications Plan:** Describe how you plan to facilitate and encourage HSR&D investigators to engage with and align their work with VA partners and other federal

agencies, including a plan to structure and foster collaborations between researchers and partners. (2 pages)

Additional Information (Does not count toward page limit)

- **Research Team Description.** Describe the general management structure of the project with relevant Lead (i.e., PI), Co-Investigators involved, as well as a list of other relevant research and program collaborators, including the necessary expertise related to data quality and analysis.
 - Please note: No letters of support should be submitted with the application, and established partnerships are not required at time of application.
- **Summary budget table and budget justification** must be included as an attachment to the proposal, detailing the planned use and justification of funding. Provide budget details for all relevant personnel, including lead teams, associate leads, coordinator, investigators, etc.

Review Criteria

- Demonstrated understanding of the significance of the disrupted care research agenda, critical evidence gaps, and the key challenges in addressing them
- Scientific merit and feasibility of proposed approach to National Mortality Study
- Clarity and credibility of Data and Methods Work Group plan
- Clarity and credibility of Stakeholder Coordination and Communications plan
- Research Team Qualifications, including expertise and experience related to data quality and analysis, experience with leading and organizing a research consortium and engaging other federal partners, experience examining care utilization and quality, experience with COVID research, and management experience

Abstracts are due to HSR&D by COB March 12th

Please submit ITS in PDF format as follows:

Include Subject Heading: PI last name_DisruptedCareITS (Save abstract with same title)

Send to mailbox: VHACOHSRDDisruptedCa@va.gov

Proposals are due to HSR&D by COB April 12th

NOTE: Only teams who have submitted an ITS are permitted to submit a full proposal.

Please submit proposals in PDF format as follows:

Include Subject Heading: PI last name_DisruptedCareproposal (Save proposal with same title)

Send to mailbox: VHACOHSRDDisruptedCa@va.gov