Development and Implementation of Work Engagement Strategies in a Clinical Research Consortium During the Coronavirus Disease 2019 (COVID-19) Pandemic: A Reflective Inquiry

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Abbreviations

VA	*Department of Veterans Affairs*
VAMC	*VA Medical Center*
CSP	*Cooperative Studies Program*
ORD	*Office of Research and Development*
NODES	*Network of Dedicated Enrollment Sites*
COVID-19	*Coronavirus Disease 2019*
IT	*Information Technology*

Abstract: *Work engagement is defined as a positive work-related state of mind that is characterized by vigor, dedication, and absorption. The engagement of staff has been associated with their performance and efficiency, productivity, safety, attendance and retention, customer service and satisfaction, and several other organizational success factors. The Coronavirus Disease 2019 (COVID-19) is an infectious disease caused by the most*

recently discovered coronavirus and is now a pandemic that is affecting many countries globally. The literature surrounding the employment of measures and strategies to increase work engagement amongst clinical research staff during pandemics is scarce, and to date, focuses primarily on health care and community health workers.

The Cooperative Studies Program (CSP) Network of Dedicated Enrollment Sites (NODES) is a clinical research consortium of ten medical centers that are embedded within the Department of Veterans Affairs (VA) Health Care System. The consortium developed and implemented strategies during the pandemic that were intended to maintain work engagement amongst clinical research staff at each of the sites within the consortium.

In this manuscript, we describe the development and deployment of these strategies to clinical research study teams in our clinical research consortium. It is our hope that the opportunities, successes, and challenges described here will serve as a useful resource for other clinical research consortia that are working to identify approaches to keep their staff members engaged during the current pandemic, as well as in other potential future situations in which their primary operations may be altered during other times of crises.

Keywords: *Department of Veterans Affairs, CSP, NODES, COVID-19, Work Engagement*

Background

Work engagement is defined as a positive work-related state of mind that is characterized by vigor, dedication, and absorption, and the engagement of staff has been associated with their performance, safety, attendance and retention, customer service and satisfaction, and several other organizational success factors (Schaufeli et al., 2009; Jeve et al., 2015; Johnson & Bullard, 2020; Knight et al., 2017). The Coronavirus Disease 2019 (COVID-19) is an infectious disease caused by the most recently discovered coronavirus and is now a pandemic that is affecting many countries globally (World Health Organization, 2020a, 2020b; Holshue et al., 2020; Centers for Disease Control and Prevention, 2020). People all around the nation have been practicing self-isolation and social distancing to protect the health and well-being of their own and others. The viral outbreak created disruptions in people's routine lives causing increased stress, anxiety, and fear (Lu et al., 2020; Huang & Zhao, 2020; Khan et al., 2020). The literature surrounding the employment of strategies to increase work engagement amongst clinical research staff during pandemics is scarce. To date, the literature in this area focuses primarily on health care and community health workers (Ives et al., 2009; Weber et al., 2020; Boyce et al., 2019).

In this manuscript, we describe the development and deployment of strategies for the work engagement of clinical research study teams in our consortium during the COVID-19 pandemic. It is our hope that the opportunities, successes, and challenges described here will serve as a useful resource for other clinical research consortiums that are working to identify approaches to keep their staff members engaged during the current pandemic and in situations in which their primary operations may be altered during other times of crises.

During the COVID-19 pandemic, there was a growing sentiment of fear, anxiety, and stress across staff in our consortium. This was not surprising as the entire nation and world were grappling with the same feelings of uncertainty. During the spring of 2020, myself and several colleagues from the VA CSP NODES program started developing strategies to keep our staff engaged during the pandemic. Given our role as clinical research administrators, we felt that determining how to both establish and maintain staff engagement across our consortium would be paramount to ensuring the continued success of our program. Establishing a safe and productive way of keeping our staff engaged would also help us fulfil our commitment of providing exceptional health care to our nation's Veterans through research.

Before moving forward it is important that we describe the structure of our program. Having this foundational information will provide you with a better sense of the opportunities and challenges associated with the deployment of these strategies across our consortium. The Cooperative Studies Program (CSP), a division of the Department of Veterans Affairs (VA) Office of Research and Development (ORD), was established as a clinical research infrastructure to provide coordination and enable cooperation on multi-site clinical trials and epidemiological studies that fall within the purview of VA (Huang et al., 2010). Currently the program maintains expertise in multi-site studies through central coordination of activities within VA Central Office, a network of 5 data coordinating centers (CSPCCs) that support clinical trial planning, execution, and analysis; 5 epidemiological research centers that conduct large cohort studies and maintain registries (CSPECs); and a clinical research pharmacy coordinating center (CRPCC) that supports the manufacture (when necessary) and distribution of drugs (including placebos), management of medical devices, and trial monitoring, auditing, and regulatory compliance activities (Huang et al., 2010).

In 2012, CSP also established a consortium of ten VA medical centers (VAMCs) called the Network of Dedicated Enrollment Sites (NODES) that offers innovative approaches in addressing challenges to clinical trial execution (Condon et al., 2017; Johnson et al., 2018; Velarde et al., 2018; Bakaeen et al., 2014). Each Node site is led by a Clinical Director (or team of Clinical Co-/Associate Directors), an Associate Director-Operations (ADO), and other clinical research support staff, e.g. Managers, Clinical Research Nurses, and Clinical Research Assistants (Figure 1). Brief descriptions of these roles can be found in Appendix A. The CSP infrastructure offers support to VAMCs that participate in its clinical trials and studies in the form of the aforementioned support provided by the CSP Centers. NODES also provides an invaluable benefit to both the CSP Centers and the study sites by providing feedback and support as it relates to the numerous "site-level" operational challenges encountered during various phases of a clinical research study (Kutner et al., 2010; Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation, 2010; Fogel, 2018).

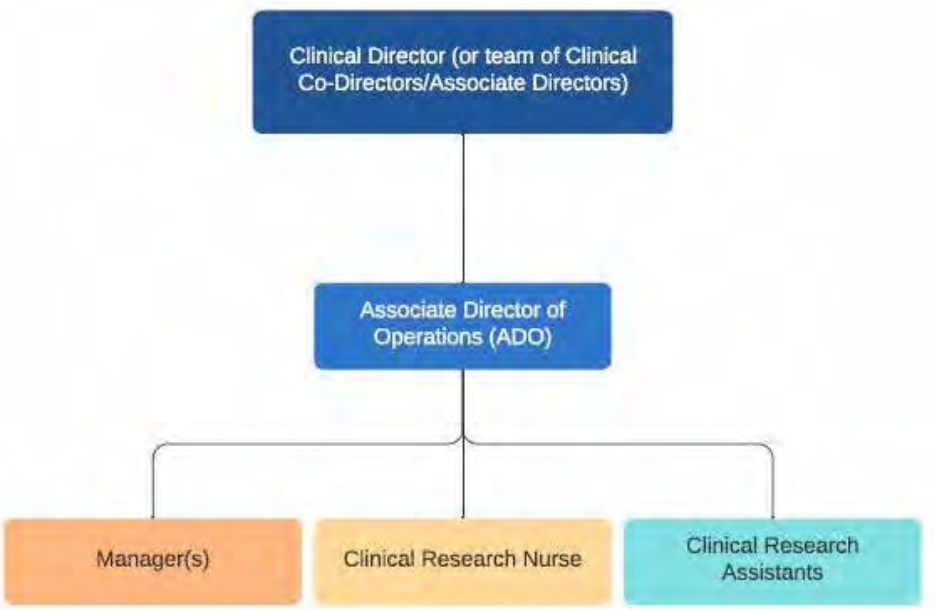

Figure 1. NODES Organizational Structure (Site Level)

Given NODE's role in CSP, we believe that we are well poised to drive innovation and the dissemination of clinical research best practices both within and external to CSP and/or VA. The development and deployment of strategies for the work engagement of clinical research study teams that other groups can use, particularly during times of crises, is also consistent with our program's mission.

Approach

Now that we have established our group's role in CSP and VA, we can further reflect on our experiences during the onset of the COVID-19 outbreak (Spring 2020), and our subsequent actions around staff engagement during that pivotal time. During this period, we observed that in the onset of the COVID-19 outbreak, many state and local government authorities had issued "shelter-in-place" or "stay-at-home" orders to businesses not considered "essential" in order to limit the spread of the infection (Courtemanche et al., 2020; Santoli et al., 2020). Concurrently, on March 17th, 2020, the VA Office of Research & Development (ORD) put an administrative hold on all non-critical, in-person interactions with human research subjects for ORD funded studies. Given these circumstances, the leadership teams at each of the Node sites needed to execute rapid, pragmatic, and strategic steps to ensure the safety of the CSP research personnel at their sites.

The NODES ADOs worked with their local Research and Development (R&D) offices to obtain ad hoc approvals for their CSP research team members to work remotely (off-site). Some R&D leadership teams approved full-time remote work requests while others approved part-time remote work requests for these personnel. A REDCap™ survey (Appendix B) was administered to the ADOs from each of the ten Node sites to glean data on the remote working options that were offered to the personnel, as well as to inquire about the various strategies that were employed at each site to maintain work engagement among their respective workforces during the pandemic (Harris et al., 2019).

Like the rest of the nation and the world, CSP site clinical research personnel had to navigate uncertainties in both their professional and personal lives during the COVID-19 pandemic. The NODES ADOs at each Node site offered opportunities and extended resources to their respective study personnel to keep them engaged in work-related activities, as well as to provide information on coping, wellness, and daily living resources during the current outbreak. It was expected that such work engagement would have a positive psychological impact amongst the workforce, and would also enhance staff knowledge and the skills that are required for their jobs, e.g., good clinical practice (GCP), risk-based monitoring, ethics and human subject protection, patient-centered informed consent, etc. (Vijayananthan & Nawawi, 2008; Agrafiotis et al., 2018; Jaguste, 2019; Department of Health, Education, and Welfare, & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Moreno et al., 1998; Krishnamurti & Argo, 2016; Abujarad et al., 2018). These work engagement strategies are highlighted below for your review.

Regular Check-Ins

Each Node established regularly scheduled, open virtual communication channels with their personnel to discuss work-related updates. Conference calls were scheduled on a consistent basis via Microsoft Skype for Business®, Microsoft Teams® and/or Zoom®, and emails between the NODES teams and CSP site study team members were also exchanged on a regular basis. NODES ADOs disseminated general and facility-level updates related to the COVID-19 pandemic and VA ORD guidelines and recommendations to site personnel to keep them abreast of rapidly evolving research policy and operational changes. This approach was implemented as a tool to keep CSP research personnel unified and to create a strong sense of community at each site.

Newsletters

Some VA CSP Node sites have produced and distributed newsletters with information on site- and program-level CSP-related activities to their CSP study team personnel on a quarterly basis since 2014. Two Node sites maintained their ongoing efforts and generated new issues of these newsletters amidst the outbreak to keep their study personnel engaged. These newsletters not only contained updated information about CSP but also incorporated general information related to the COVID-19 outbreak along with self-care tips. The newsletters also included details on accessible research-related training opportunities, COVID-19 related webinars that study personnel could avail and included photos of research staff obtaining their COVID-19 vaccinations to encourage vaccine adoption (Appendices C & D).

Training Opportunities

To make the work experience interesting and productive during the pandemic, VA CSP NODES ADOs advised their CSP site personnel to explore clinical research training opportunities that were available to them. Examples of these training opportunities are noted below:

i. VA Talent Management System (TMS) Trainings

VA provides virtual training opportunities through its Talent Management System (TMS) in an effort to keep its workforce up to date on their skills and competencies, as well as to make them aware of VA policy and operational changes (Schaa et al., 2014). Most trainings are classified around topic areas that are aimed to enhance the expertise of VA professionals e.g., workplace harassment, contracting, clinical research operations, business compliance, etc. Similarly, mandatory annual trainings are provided to research personnel to refresh their knowledge and skillsets, and to ensure their compliance with Good Clinical Practice (GCP). Recommendations were made that CSP personnel complete their annual mandatory trainings during the time of the pandemic while some research activities were on administrative hold. NODES ADOs also encouraged their site study personnel to explore the TMS online learning catalog for non-mandatory trainings, and to self-assign courses that they found interesting and helpful.

ii. VA Health Services Research & Development Cyber-seminars

VA Health Services Research & Development (HSR&D) offers state-of-the-art training sessions on various research-related topics via live web conferences (U.S. Department of Veterans Affairs Health Services Research and Development, 2020a). These presentations are then archived and made accessible to VA personnel and the general public. These cyber-seminars select research topics that are current and applicable to the studies conducted within the VA health care system. The CSP team members at each Node site were encouraged to access these valued resources and to think through how they might apply the content in their respective work environments.

iii. The Association of Clinical Research Professionals eLearning Catalog

CSP has an existing contract with the Association of Clinical Research Professionals (ACRP)™ that secures 200 user accounts to provide free learning and training opportunities for its staff (CSPCCs, CSPECs, NODES) and its clinical research site study teams (Hastings et al., 2012). The ACRP™ offers numerous virtual research-related learning sessions to CSP. Personnel can also use credits from the completed coursework towards a number of Clinical Research Professional certifications, e.g., Clinical Research Associate (CCRA)®, Clinical Research Coordinator (CCRC)®, etc. The NODES ADOs recommended that personnel who were able to access these learning resources utilize them to enhance their knowledge and competencies.

NODES Webinars

At the peak of the current pandemic, many research-related activities (such as study recruitment and enrollment, in-person follow-up visits with study participants, etc.) were on administrative hold to ensure the safety of study participants, providers, and clinical and research personnel. Therefore, it seemed essential to organize events to keep study team members inspired and

motivated through positive work experiences. With that understanding, the NODES ADOs arranged for a series of webinars through Microsoft Skype for Business® and/or Microsoft Teams® for CSP study team personnel at each of the Node sites. Some of the topics that were selected for presentation for these webinars were as follows: 1) General Updates on the COVID-19 Pandemic, 2) Coping Strategies for Stress and Fear During the COVID-19 Pandemic, and 3) An Overview of the CSP Quality Assurance Program.

NODES Virtual Poster Contest

VA celebrates "National VA Research Week (Research Week)" on an annual basis each May. (U.S. Department of Veterans Affairs Office of Research and Development, 2020b). During this month, each VA Medical Center (VAMC) dedicates a week to acknowledge the importance of VA research and its contributions to the VA health care system and the general medical community. The various events that are held during this week are intended to inform Veterans and VA providers/staff about past, current, and upcoming VA research activities. Over recent years, NODES and VA CSP site study teams have organized local/site events during Research Week that showcased and promoted their research work. Because of the COVID-19 pandemic, VA facilities were unable to organize such celebratory research events in 2020. However, to maintain the tradition of Research Week, the VA CSP NODES organized a virtual poster contest amongst their ten sites. The theme of the poster contest was "CSP Culture" and each NODES ADO was asked to organize a poster team comprised of NODES and CSP study team members. These poster teams worked collaboratively to design a poster that demonstrated how NODES and the CSP study site teams defined "CSP Culture" at their site, as well as how they had implemented that culture amongst the CSP study teams at their sites. This activity stimulated excitement amongst the study personnel at each site for a number of reasons including, likely in large part, the fact that the winning site, i.e., the site that had the highest score (as determined by a pre-selected panel of judges), would receive travel funding for all team members to attend a clinical research professional development event (e.g., conference, training, etc.). This effort also provided a sense of community during this time of crisis.

NODES Cookbook

Forming and maintaining social relationships is fundamental to human motivation and well-being (Michalski et al., 2020). The NODES Program took a "community approach" to support and strengthen social relationships across our consortium by developing a cookbook that included selected recipes from NODES and CSP study staff . This effort was an attempt to keep team members energized, engaged, and active through their participation in this extracurricular activity. The cookbook was released in October 2020 and titled, "VA CSP NODES Presents Shelter in Place Recipes." We believe that working on this project provided a strong sense of community to staff members who were working remotely and were not able to have in-person contact with their teammates. This literary product featured more than 100 recipes that included appetizers, entrees, desserts, and beverages, along with pictures of each dish.

Employee work engagement during times of crisis is critical to an organization's productivity and to the well-being of its employees. The creative strategies and required resources extended to the

CSP site personnel at Node sites were intended to keep their workforce engaged in work-related activities. These approaches were executed with the intention of transforming the feelings of stress and anxiety amongst site study personnel into productiveness and constructive vigor.

Lessons Learned

Lessons learned from our collective experiences with deploying these resources are further described in this paper. An increased demand from employees to work from home is among several societal changes the COVID-19 outbreak has become an impetus for. According to the U.S. Bureau of Labor Statistics, only 29% of Americans could work from home in their primary job and 25% did work at home at least occasionally (U.S. Bureau of Labor Statistics, 2020). A recent Gallup poll reported the percentage of workers who say their employer is offering flextime or remote work options has grown from 39% to 57% between March 30 and April 2, 2020 (Gallup, 2020). Many organizations including the VA have undergone creative transitions to allow staff to complete tasks from home that typically would not have been approved for them to do so. Our Node sites have developed remote work contingency plans for staff that take several factors into consideration including VA, ORD, and statewide orders, as well as study-specific contingency plans, and information technology (IT) remote capabilities.

Node sites have an average of 13.2 CSP clinical research study team members at their respective sites. Each of our sites also have CSP study team members that have been offered the flexibility to work remotely for at least some duration of their work schedule. Half of them (Hines, Houston, Minneapolis, Palo Alto, and Portland) have offered their study team members the option to work from home entirely, though only two of these sites reported that 100% of their study team staff members chose to do so. Most Node sites have varied remote work schedules among the CSP personnel at their sites and have transitioned all CSP site personnel at their respective locations to work remotely on a periodic basis. One site (San Diego) offered only a select number of staff members any option to work remotely.

The transition to working from home has caused a shift in daily tasks for CSP site personnel at our sites. Opportunities for participating in TMS trainings, VA cyber-seminars, ACRP™ learning sessions, NODES webinars, the creation of a group cookbook, and a virtual research poster contest have encouraged staff to stay engaged with our organization during a time of uncertainty. Professional development has always been a primary focus of NODES, including during the ORD administrative hold. The NODES webinars have had regular attendance of approximately 75–100 attendees. Among CSP Node site personnel (9/10 Node sites), 44 individuals have obtained ACRP™ accounts through CSP's existing contract. Due to a limited number of available accounts at the program-level (CSP), and subsequently at the NODES consortium level, there are plans to determine the feasibility of increasing the number of ACRP™ accounts available to CSP staff in future revisions to the existing contract.

In addition to the trainings and webinars staff are actively involved with taking, most of the Node sites (80%) reported that they had staff members that were reassigned by their respective VAMCs and/or facility research leadership to work on COVID-19 study-related activities.

These tasks included coordination and management of new COVID-19 clinical trials and studies, research programs, and study planning activities (study feasibility surveys, preparation for new study proposal submissions, protocol feasibility reviews, etc.). Moreover, the VA has implemented resource labor pools in which staff at a given facility may be mandatorily reassigned for a designated period to new positions that the facility determines as high priority. Depending on the staff position held (clinical versus non-clinical), labor pool duties may include new unit/floor assignments, facility entrance screening, and scrubs/personal protective equipment (PPE) collection and distribution.

Discussion

Work engagement has been demonstrated as being positively associated with several organizational and staff characteristics such as productivity, human error in the workplace, low sickness absence frequency, good service quality, and innovativeness (Okazaki et al., 2019; Shimazu et al., 2018). While the concept of work engagement is not unique, our creation and implementation of strategies to keep staff engaged across a clinical research consortium during a time of crises was novel. We hope that our work will serve as a useful resource for other clinical research consortia, and other groups, as those entities work to identify approaches for staff work engagement during the current pandemic and in other situations where disruptions in the general public's routine lives might cause increased stress, anxiety, and fear. The NODES consortium was successful in developing and deploying these strategies with our staff.

The VA health care system is somewhat nuanced in that different VAMCs within the health system often have variability in their general healthcare operations, which subsequently leads to inconsistency in how clinical research operations are conducted at any given site. For example, over the course of the current pandemic, some VAMCs have established policies that allow a significant number of personnel to work remotely due to considerations such as patient and employee safety, and "shelter in place orders" that were implemented within the various states in which these facilities are located. Other VAMCs have maintained the "status quo" in terms of their day-to-day operations, with staff continuing to come into work at their respective facilities. Therefore, the sites in our consortium vary with regards to whether the clinical research teams at those locations are working at their VAMCs as they would during normal day-to-day operations or are working from home due to the guidance provided by leadership at their respective medical center. NODES' "boots-on-the-ground" approach to solving operational issues and challenges at the clinical research site-level (VAMC) puts the program in an ideal position to develop strategies aimed at maintaining work engagement amongst clinical research staff during the COVID-19 pandemic at each of the Node sites within the consortium. Although the impact of the pandemic on day-to-day operations varied across the NODES consortium, the work engagement strategies that were employed across its sites demonstrates a convincing connection between employee engagement and the cultural characteristics of well-being, communication practices, professional development, and organizational resilience.

Working remotely can induce feelings of professional isolation, but using the strategy of regular

check-ins (phone, email, video chats, texts, Skype, etc.) enforces connections with teammates whereby staff are able to participate in brainstorming activities, assign and breakdown project tasks, and share quick tips for completing work remotely (Golden et al., 2008; Martin et al., 2019; Wakerman et al., 2019). In the absence of staff gatherings, e.g., in-person meetings, social outings, etc., staff were able to share family news related to celebrations and announcements, and/or exchange shared and personal feelings around the pandemic to reduce anxiety. Sites that produced newsletters communicated their organizational or team culture, as well as their sense of empathy and community at their respective locations. These newsletters were also used to honor fellow colleagues' contributions to their facility labor pools (or in healthcare roles) and participation in the treatment of COVID-19 patients. Implementing work engagement strategies that promote sharing and participating in group dynamics, the opportunity to talk with colleagues, the continuation of personal relationships, and opportunities to address difficulties or successes enables individuals to increase job resources, such as social support and influence in decision-making, leading to positive outcomes (Knight et al., 2017).

The creative strategy to engage staff in designing and presenting a virtual poster for Research Week created synergy, enthusiasm, a sense of healthy competitiveness, and feelings of significance amongst teammates who previously may not have had opportunities to work together on a shared project. Competitive behavior has been defined as the actual actions people take, or are inclined to take, in a specific job or life environment to compete for resources or succeed over others (Wang et al., 2018). Literature suggests that it is closely related to job behavior and performance, i.e., people showing more competitive behavior tend to outperform others and are more likely to do their best at work, thereby potentially resulting in better job performance (Wang et al., 2018). The poster contest and the prize for the first-place winner generated a competitive climate that allowed participants to demonstrate competitive behavior, which potentially resulted in better job performance in this instance.

Previous work has demonstrated a positive relationship between the job resources that are offered by an organization (for example, support from supervisors, learning opportunities, etc.) and employees' work engagement levels (Van den Broeck et al., 2017). By providing staff with study-specific contingency plans, direct communication and guidance from ORD, and the option to transition to remote work, staff were able to remain engaged and productive in study-related activities. Training opportunities from the VA Talent Management System (TMS) kept staff involved in learning opportunities, while NODES educational webinars and VA Health Services Research and Development (HSR&D) cyber-seminars provided avenues for advanced research education and professional development by research staff.

There are several potential limitations related to this effort that may impact the generalizability of our work. Until the onset of the current pandemic, the option for remote work at most Node sites had been non-existent. The REDCap™ survey that was disseminated across Node sites gathered data on remote working options and strategies that were being employed to maintain employee work engagement. Although most staff have welcomed the opportunity to work remotely, our survey did not query how research study staff viewed the opportunity to transition to remote work under the associated circumstances, therefore we were not able to effectively tailor our strategies

for staff based on their attitudes around remote work. The data that could be potentially gleaned from the inclusion of this type of survey question might have allowed us to create and employ higher-intensity engagement strategies for those staff that had strong feelings of opposition to remote work. Alternatively, we could have potentially created lower-intensity engagement strategies for those staff who demonstrated an appreciation for remote work and may have had higher existing levels of engagement due to their attitudes around remote work settings. Informal communication to staff members highlighted that they experienced varying levels of frustration and difficulties with remote access and other IT issues, including obtaining access to various study SharePoint™ sites, study files, and study contact information. While working through these challenges, they were also dealing with suboptimal workspaces at home, unexpected parental responsibilities, and fear and anxiety associated with the COVID-19 pandemic itself (Watkins, 2013). Although our intent was that these strategies would encourage workplace engagement, we do not know if research staff felt they were effective. Having additional input from staff on what approaches they felt might help to keep staff engaged during this difficult time may provide useful suggestions that could be employed at some point in the future.

In summary, we have been able to successfully implement several approaches that were designed to maintain staff work engagement in the NODES consortium during the COVID-19 pandemic. Additional work is needed to assess the impact of these strategies in terms of their potential ability to improve the level of work engagement amongst staff. It is anticipated that surveys administered to staff both pre- and post-implementation of similar strategies might provide insight into their benefit and would allow for formal evaluation of these methods. We have confidence that the work presented in this manuscript will benefit other clinical research consortia that are striving to maintain work engagement amongst their staff during the current pandemic. Furthermore, these strategies may be beneficial to organizations during other potential future national and/or global crises that warrant the development and implementation of mitigation strategies to decrease the impact of these situations on their operational activities.

Disclaimer

The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the government of the United States.

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Conflicts of Interest
The authors report no conflicts of interest.

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[a] – Required Position

Appendix A. NODES Position Descriptions	
Role	**Responsibilities**
Clinical Director (or team of Clinical Co-Directors/Associate Directors) [a]	*Provides oversight, leadership and mentorship to local Node and CSP study teams and ensures the successful conduct of CSP studies at the local Node site *Identifies, mentors and collaborates with prospective and existing Site Investigators *Works closely with medical center leadership at the site to promote and encourage clinical trial efforts throughout the institution *Ensures appropriate resources and support for CSP research efforts including space requests, laboratory needs, or study specific needs *Works with the NODES Associate Director-Operations to develop the Node site budget *Ensures CSP and NODES research procedures, process improvements, initiatives and projects are successfully executed at the site *Strengthens connections within the CSP network to provide greater opportunities for interdisciplinary research *Collaborates with local and national stakeholders to achieve CSP objectives *Engages with CSP Coordinating Centers in the feasibility, planning, and implementation of CSP trials *Participate in programmatic strategic planning of CSP and NODES

	*Provides mentorship for non-Node Sites, new Node Sites/NODES Expansion efforts * Facilitates the submission of CSP study Letters of Intent (LOI) from the site for review and potential funding
Associate Director-Operations [a]	*Provides supervision, leadership and mentorship to local Node and CSP study teams *Identifies, mentors and collaborates with prospective and existing Site Coordinators and other CSP study team members *Works with the NODES Director to develop the Node site budget *Works with study team members to develop site study budgets for each site's respective studies *Ensures appropriate resources and support for CSP and NODES research efforts *Ensures research process improvement initiatives and projects are successfully executed *Strengthens connections within the CSP network to provide greater opportunities for interdisciplinary research *Collaborates with local and national stakeholders to achieve CSP objectives *Engages with CSP Coordinating Centers in the feasibility, planning, and implementation of CSP trials *Participates in programmatic strategic planning of CSP and NODES

	*Provides mentorship for non-Node Sites, new Node Sites/NODES Expansion efforts *Provides mentorship and support for CSP study team members *Provides/arranges for back-up coverage for study team members that are on planned and unexpected leave *Human Resources: Facilitates job posting, interviewing, hiring, and training for study staff (study coordinators, research nurses, study research assistants, etc.) *Conducts meetings with site study teams to share best practices, deliver education and training, and to discuss successes/challenges as it relates to clinical trial execution *Completes local and national study auditing, as well as data and adverse event reporting *Assists with special projects/workgroups locally & nationally
Manager(s) [b]	*Provides oversight, direction and guidance to local CSP study teams on all clinical trial related activities *Collaborates with local and national stakeholders to achieve CSP objectives *Assists Director and Associate Director-Operations in engagement with CSP Coordinating Centers in the feasibility, planning, and implementation of CSP trials *Human Resources: Facilitates job posting, interviewing, hiring, and training for study staff (study coordinators, research nurses, study research assistants, etc.)

	*Provides back-up coverage for study team members that are on planned and unexpected leave *Completes local and national study auditing, as well as data and adverse event reporting *Assists with coordinating and executing meetings with site study teams to share best practices, deliver education and training, and to discuss successes/challenges as it relates to clinical trial execution *Assists with special projects/workgroups locally & nationally
Clinical Research Nurse[b]	*Provides back-up coverage for study team members that are on planned and unexpected leave (for all studies) *Provides medical informatics expertise as it relates to the Electronic Medical Record. *Assists with lab alerts, CPRS required documentation into CPRS, creation of CPRS templates and study progress notes/ templates. *Assists with special projects/workgroups locally & nationally *Administers investigational drug products or vaccines. Provides education on study drug administration and anticipated adverse effects. *Activates/triggers pharmacy orders following randomizations

	*Performs and assists other research personnel with medical tests, biometric measurements, venipunctures, and medical procedures within the RN scope of practice and competency. Obtains samples during infusion studies, processes and aliquots samples as appropriate. * Initiates lab order entries and scheduling of diagnostic tests; creates pre-set study lab orders. *Provides guidance and knowledge to non-clinical research staff of hospital organization and hospital services in managing research participants in various study settings, including ambulatory care, specialty areas, inpatient and critical care. *Provides clinical expertise for study adverse events and query resolution, eligibility, data collection activities, adjudications, and drug accountability. * Completes R&D submissions for non-clinical CSP staff in sections regarding safety, scientific review, and impact statements for clinical services/pharmacy/ pathology services. *Identifies to the LSI any problems that arise during conduct of the trials and assists in their solutions. *Provides mentorship and in-services to clinic/hospital staff on the clinical aspects of studies and clinical roles of staff for those studies conducted outside of the outpatient setting (inpatient units, OR, radiology) *Initiates lab order entries and scheduling of diagnostic tests; creates pre-set study lab orders.

Clinical Research Administrator[b]	*Provides back-up coverage for study team members that are on planned and unexpected leave (for studies not requiring an RN) *Coordinates required performance data submissions for program evaluation efforts *Produces Bi-Annual local NODES Newsletter *Schedules meetings, prepares agendas, & minutes *Organizes/Plans/Arranges travel *Maintains Director's calendar *Assists with special projects/workgroups locally & nationally
NODES Assistant (Clinical Research Assistant)[b]	* Coordinates monthly meetings with site study teams to share best practices, deliver education and training, and to discuss successes/challenges as it relates to clinical trial execution * Assists site teams with travel coordination for CSP-related study kick-off/annual meetings *Assists site teams with CSP related purchase orders *Assists new hires with completion of VA trainings

[b] – Optional Position depending on the site's determination of what its needed resources are to meet program and site metrics as defined in the NODES FY21-22 OKRs.

Appendix B. NODES Survey

NODES Study Teams Work Engagement Survey

Please complete the survey below.

Thank you!

NODE Site: _____
(e.g., Salt Lake City)

1. How many CSP staff (FTE) does your site have working with NODES (do not include MVP staff)?
_____
(e.g., 7.5)

2. a) How many of those staff members are working remotely for their entire tour of duty (TOD) due to COVID-19?
_____

2. b) How many are working remotely for part of their TOD due to COVID-19?
_____

3. What tasks have your staff been working on during the pandemic?
_____
(Please specify any training, new projects, assignments etc.)

4. a) Have staff been working on any COVID-19 related research studies (CSP or non-CSP) ? Please do not include educational training (i.e. webinars, reading daily updates etc.).
◯ Yes
◯ No

4. b) Please specify COVID-19 studies:
_____

5. a) Have any of your staff been reassigned to general labor pool duties?
◯ Yes
◯ No

5. b) How many RNs have been reassigned to the labor pool?
_____

5. c) Please state newly assigned role/ position(s):
_____

5. d) How many non-clinical staff have been reassigned to the labor pool?
_____

5. e) Please state newly assigned role/position(s):
_____

Appendix C. CSP Houston NODES Newsletter

CSP RESEARCH HOUSTON NEWSLETTER

FEBRUARY 2021

CSP and COVID-19

It was shortly after the presidential election in November 2020 that the first vaccine trial results were released to the general public. And the results were promising. With measures of effectiveness in the 90th percentile, a new hope blossomed for an end to the COVID-19 pandemic. Our question changed from can we be vaccinated to when can we be vaccinated. And it turns out the answer was soon.

Hardly a month later we received the first emails assessing interests in receiving the vaccine from the VA. By mid-December, the first vaccines were being administered to frontline personnel with RSL employees soon to follow. Those of us who chose to receive the vaccine will recall a hopeful, almost giddy atmosphere when they entered the 4th floor auditorium. From the nurses administering the shots to the staff running the check-in, everyone seemed eager to be a part of this historic vaccination effort.

Needless to say, we're all very grateful to everyone involved in the process to get us vaccinated. These men and women's professionalism and compassion does great credit to the VA. Let's also not forget to give thanks to our co-workers in the Research Service Line who took the time and effort to assess our levels of interest in receiving the COVID-19 vaccine and get us scheduled in an efficient, timely manner.

The following page is a snapshot of the vaccination effort in our CSP community. Thanks to all who sent a picture of themselves receiving the vaccine. We are nearly as happy to have a picture of you getting your vaccine as you were to receive the it!

As a final note, please report any side-effects you may have experienced after receiving the vaccine to VHA-HOUSCOVID19AdverseEvent@va.gov. Understanding the negative side effects that may occur as a result of receiving the vaccine is a crucial part of the vaccination effort, so please don't hesitate to report your own post-vaccine experience!

Appendix D. CSP Minneapolis NODES Newsletter

IN THE NODE

DURING COVID-19

VISN 23
Minneapolis-618

NODES: Rise Up to COVID-19 Challenges

Volume 7 Issue 1

April 2020

The COVID-19 pandemic imposed several new challenges to research including mitigating risks to staff, participants and study data integrity. On March 4th, 2020 the first COVID+ veteran was reported at the Palo Alto VAMC which was our catalyst for the opportunities for action. Simultaneously, national and local research departments and study teams rose up to these obstacles and began preparation of the Continuity of Operations Plans (COOP). The Minneapolis VA CSP-NODES team worked on a multi-factor COOP to address risks.

While some CSP studies had already implemented holds on recruitment, the VA ORD Administrative hold directive was not officially released until March 17th, 2020. The first challenge noted was mitigation of risk of our CSP Staff. Due to VA policies and local standard operating procedures, our research staff was not authorized to telework until March 17th. NODES worked with local Research ACOS to advocate for telework and to field questions from CSP staff to set up and prepare telework agreements. Preparation included NODES assessing current CSP staff capabilities, guiding in the process to obtain the correct access, equipment and authorization. Staff facing extra challenges with telework ability due to COVID-19 were addressed Individually and back up plans were created between study teams and NODES as required. Due to steps taken by NODES, CSP staff and LSIs, the majority of our local, telework eligible, CSP team staff were able to telework by March 18th. To date, 100% of Minneapolis CSP research staff are telework eligible under the COOP.

A second risk to address was the risk to CSP participants. The administrative hold halted in person visits and new consents for all local CSP trials. NODES as a support team engaged with local CSP staff to compile direction from CSP study chairs offices, local and national directives. By answering questions, guiding logistics and providing coverage as needed, the NODES team was able to assist with the transition to no-contact visits.

Mitigating risk to CSP study data integrity helped to guarantee the reduction of missing data and capture of serious adverse events and primary outcomes. Telework was the primary factor in maintaining our ability to obtain this data. In addition, the CSP cross training contributes to the available pool of trained staff to ensure study coverage in the event the primary staff is unavailable. The second tier back up NODES staff is also a safety net ensuring there are no lapses in coverage.

Teams and departments worked together to RISE UP to the challenges of COVID-19. The persistent advocacy for staff and patient safety while maintaining our study data integrity reiterates the amazing team of Minneapolis VA CSP Research.

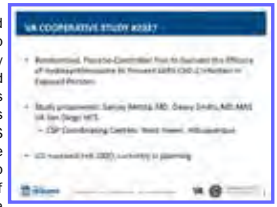
Special points of interest:

- COVID-19 Challenges
- COVID-19 Opportunities

Inside this issue:

In The Spotlight: COVID-19 Research Opportunities

COVID-19 has provided opportunities for Minneapolis to reassess our abilities to quickly mobilize study start up and address potential obstacles prior to them creating barriers to research. The NODES Director collaborated with the Infectious Disease team to assess the availability of potential LSIs if selected for a CSP trial. The NODES Assistant Director of Operations communicated directly with local R&D to assess abilities to streamline approval of CSP research



directly related to COVID-19. The NODES team assessed the status of current study, cross training and ability of current staff to shift to cover an expedited start up. CSP teams were surveyed to address staff ability and desire to work on a COVID trial. The results were overwhelming at >90% of respondents ready to participate in COVID research. Opportunities are available for COVID-19 proposals prompting several of our local CSP coordinators to dedicate time assisting LSIs in these expedited submissions.