Office of Human Protections
Project Modification Template

Project Information OHP 21-931.M1 v5

Project Number: 21-931.M1 v5
Project Title: *COVID-19 Vaccination Perceptions & Messaging Formative Evaluation (Addendum)*
Project Lead(s): Ms. Mamie Carlson
Portfolio and Program or equivalent: Health Promotion and Wellness, Public Health Assessment Division
Date: 14 July 2021, **19 July 2021 OHP received v5 following Scientific Review edits**

1 Non-Technical Description/Summary of Modification

Purpose

This modification outlines revisions to the Office of Human Protections (OHP) Rapid Response Project Plan #21_931, *COVID-19 Vaccination Perceptions & Messaging Formative Evaluation* that was approved in February 2021 in response to a tasker from U.S. Army Medical Command (MEDCOM) to develop messaging to address COVID-19 vaccination hesitancy among Army health care workers. The Office of the Surgeon General (OTSG)/Army Public Health Center (APHC) COVID-19 Task Force and the APHC Public Health Communication Directorate (PHCOM) requested formative evaluation support (evaluation development, implementation, and analysis) from the Public Health Assessment Division (PHAD).

In response to COVID-19 Task Force Task 860, this modification is a follow-on to Phase 1 interviews that aims to identify perceptions and beliefs surrounding mandatory COVID-19 vaccination in anticipation of a COVID-19 vaccine mandate in September 2021 to support risk communication product development. The project will follow a similar qualitative design; however, data collection will occur via focus groups and, as necessary, key informant interviews. Findings will be used to inform messaging and communications to address a potential future COVID-19 vaccination mandate.

Nine changes are summarized in this modification (Highlighted in yellow within the modification and the semi-structured focus group/interview guide located in Appendix A):

1. Modified objectives from the original project plan:
    a. Revised original objective #1 to be more specific and capture perceptions and beliefs regarding a potential COVID-19 vaccination mandate vs. COVID-19 vaccination more broadly. Revised language from “Identify perceptions of and factors affecting COVID-19 vaccination at the installation level” to “Identify perceptions, and the factors that shape these perceptions, in regard to the potential of mandatory COVID-19 vaccination among installation personnel.”
    b. Deleted the original objective #2 from the original project plan as this information was already captured and did not require follow-on data collection.
    c. Replaced original objective #2 with new objective, “Understand information needs of installation personnel if COVID-19 vaccination were to be mandated.”

2. Modified the guiding questions to capture perceptions and beliefs regarding a potential COVID-19 vaccination mandate, including:
    a. Revised first guiding question “What perceptions, beliefs, attitudes and behaviors exist among MTF personnel and the broader installation population related to COVID-19 and COVID-19 vaccination?” to “What perceptions, beliefs and attitudes exist among installation personnel related to COVID-19 vaccination becoming mandatory?”
    b. Revised second guiding question “What factors (i.e., facilitators/barriers) affect COVID-19 vaccine uptake and hesitancy at the installation level?” to “What factors (i.e., facilitators/barriers) impact mandatory COVID-19 vaccination perceptions among installation personnel?”
    c. Deleted guiding question: “How aware are participants of APHC COVID-19 and COVID-19 vaccine/vaccination messaging?”

d. Added guiding question: “What information needs do interviewees anticipate among installation personnel if COVID-19 vaccination were to be mandated?”
e. Revised fourth guiding question “What are participant perceptions and suggestions regarding the APHC COVID-19 vaccination messaging concepts?” to “What are participant perceptions and suggestions regarding APHC mandatory COVID-19 vaccination messaging concepts?”

3. Updated the target population to include Command Surgeons, in addition to the target population of Public Health Emergency Officers (PHEOs) and Assistant Public Health Emergency Officers (APHEOs) previously approved in OHP Project Plan #21-931.

4. Revised the data collection approach to two focus groups, one focus group of PHEOs and another focus group of Command Surgeons, and, as necessary depending on OCONUS participant availability, 1-2 key informant interviews.

5. Revised sampling strategy to convenience sampling only, without snowball sampling augmentation.

6. Audio recordings will not be transcribed for this phase of data collection.

7. Updated the timeline and deliverables.

8. Updated the list of project personnel who will support data collection, analyses and reporting.

9. Developed a semi-structured focus group/interview guide to align with the modified objectives and guiding questions.

Objective(s)

The primary objectives of the evaluation are the following:

1. Identify perceptions, and the factors that shape these perceptions, in regard to the potential of mandatory COVID-19 vaccination among installation personnel.
2. Understand information needs of installation personnel if COVID-19 vaccination were to be mandated.
3. Inform and guide current and future APHC COVID-19 vaccination messaging and follow-on COVID-19 data collection efforts.

Project Design

The design for this modification will be semi-structured focus groups and, as necessary, key informant interviews to capture the ‘pulse’ of mandatory COVID-19 vaccination, specifically perceptions, attitudes and beliefs in regard to a vaccine mandate. The goal of the modification is to use gather information to understand the information and messaging needs if COVID-19 vaccination is mandated to inform the development of messaging concepts and products to address this emergent need.

The target population for this modification is civilian or military PHEOs/APHEOs and Command Surgeons due to the unique nature of their role in the COVID-19 pandemic on the installation. The PHAD evaluation team and project stakeholders (OTSG/APHC COVID-19 Task Force and PHCOM COVID Communications Working Group) believe these personnel have visibility on mandatory COVID-19 vaccination perceptions and beliefs at their respective MTFs and within the broader installation population.

The project will utilize a convenience sample of PHEOs/APHEOs who participated in the Phase 1 interviews regarding vaccine hesitancy and Command Surgeons. The PHAD evaluation team will utilize several channels to reach Command Surgeons to include:

- Commanders Ready and Resilient Integrators and Commanders Ready and Resilient Council Project Officers, who are APHC colleagues, and may provide an entry point to identify Command Surgeons and gauge participation interest and
- TRADOC and FORSCOM Surgeons’ Offices to assist in identifying Command Surgeons who may be available to participate in the focus group.

The PHAD evaluation team will complete two semi-structured focus groups, one with PHEOs/APHEOs and one with Command Surgeons. As necessary, based on OCONUS participant availability for focus group attendance and/or if a participant does not agree to being recorded during a focus group, the PHAD evaluation team may also conduct up to two key informant interviews. The PHAD evaluation team will use the same focus group/interview guide for PHEOs/APHEOs and Command Surgeons focus groups and interviews.

The current project aims to answer the following guiding questions, which have been revised from the approved OHP Project Plan #21-931 in accordance with current focus on potential mandatory COVID-19 vaccination.

1. What perceptions, beliefs and attitudes exist among installation personnel related to COVID-19 vaccination becoming mandatory?

2. What factors (i.e., facilitators/barriers) impact mandatory COVID-19 vaccination perceptions among installation personnel?

3. What information needs do interviewees anticipate among installation personnel if COVID-19 vaccination were to be mandated?

4. What are interviewees' perceptions and suggestions regarding APHC mandatory COVID-19 vaccination messaging concepts?

Semi-structured Focus Group/Interview Guide

The previous interview guide approved in OHP Project Plan #21_931 has been revised to a focus group/interview protocol to optimize the number of individuals data is collected from within the short timeframe that we have to collect data and provide findings to inform messaging in anticipation of a COVID-19 vaccine mandate in September 2021. Additionally, data collection questions were updated to examine more specific perceptions, attitudes and beliefs of COVID-19 vaccination, specifically those pertaining to a COVID-19 vaccination mandate. The factors that shape perceptions, attitudes and beliefs will also be explored in addition to anticipated information needs if COVID-19 vaccination were to be mandated. The aim is for the findings from this data collection effort to inform messaging developed by APHC and in coordination with other MEDCOM and Army communication entities. The core focus group/interview questions will allow participants to share their experiences and perceptions and the PHAD evaluation team to follow-up or probe on relevant information shared.

Data Collection

An evaluation team member with relevant experience will conduct focus groups/interviews via telephone or via a virtual platform [e.g. Microsoft (MS) Teams/Defense Collaboration Services (DCS)]. In addition, one or more team members will serve as note taker(s) to capture information shared by the participants. Data collection will occur in July 2021. Focus groups are expected to last 60-90 minutes. If conducted, interviews are expected to last 45-60 minutes. Focus groups/interviews will be recorded using audio recorders with participant permission and will be utilized to verify/complete notes prior to coding and analysis.

Data Analysis

The data collected will be stored, managed and analyzed as outlined in the OHP Project Plan #21_931. Data will be coded and analyzed using the same methodology used in the original project plan. Data will be coded and analyzed in pairs, using a primary and secondary approach. A codebook will be developed that is informed by the guiding questions and the focus group/interview guide. Coded references will be analyzed using a directed content analytic approach to identify patterns and themes that emerge from the data. These themes and their corresponding properties and dimensions will be documented and reported as findings.

Timeline and Deliverables

Activity / Deliverable	Date
Conduct 2 focus groups	Post Human Protection Director Approval – 26 July 2021
If necessary, conduct up to 2 key informant interviews	NLT 26 July 2021
Conduct rapid action analysis of qualitative data	NLT 30 July 2021
Develop slide deck draft	NLT 10 August 2021
Deliver slide deck	NLT 13 August 2021

Project Personnel

Changes to project personnel are proposed given changes in the data collection approach. An updated list of project personnel, and their role in the project, is provided below.

Name	Institution Affiliation	Division	Civilian	Contractor	Role
Ms. Mamie Carlson	APHC	PHAD	X		Oversight/Project Lead
Dr. Stephanie Meier	APHC	PHAD		X	Facilitator/Project Analyst
Dr. Charsey Cherry	APHC	PHAD		X	Project Analyst
Ms. Nkechinyere Nweke (Chichi) Gibson	APHC	PHAD	X		Project Analyst
Ms. Kimberly Remis	APHC	PHAD		X	Project Analyst

2 Data Protection Plan

The Phase 1 data protection plan was submitted for review by APHC Information Management Division personnel in February 2021 and approved on 24 February 2021. The following updated data protection plan was approved on 14 July 2021 (see Appendix B).

The PHAD evaluation team (as defined in this document) will collect data from Public Health Emergency Officers (PHEOs)/Assistant Public Health Emergency Officers (APHEOs) and Command Surgeons identified using a convenience sampling approach. The evaluation team will utilize a semi-structured focus group/interview guide with questions and complementary probes that align with the project's Public Health Guiding Questions outlined above. Two focus groups, one with PHEOs/APHEOs and one with Command Surgeons will be conducted. If necessary, [If OCONUS participants cannot attend their corresponding FG or choose to not be recorded) up to 2 interviews will be conducted. Due to the timeline the team is unable to conduct and analyze more than 2 additional data collection events.

At least two members of the PHAD evaluation team will conduct each focus group/interview, with one member designated as the facilitator and the other member(s) as note taker(s). Focus group/interviews will be audio recorded with participant permission. Because voices can be identifiable, care will be taken to ensure data protection protocols are enacted to keep the files secure between data collection and saving audio files and notes on the S: drive. Audio files will be downloaded to a CAC-enabled computer and saved on the secure APHC S: drive in a folder only accessible to the PHAD evaluation team. The evaluation team will also save typed focus group/interview notes on the APHC S: drive in a folder only accessible to the team.

The notes will be analyzed by members of the PHAD evaluation team using a rapid action approach to provide initial aggregate findings and recommendations to PHCOM. As part of the data cleaning process, the evaluation team will listen to the audio files and revise the notes captured during data collection events to ensure accuracy and completeness. The notes will then be coded and analyzed by members of the PHAD evaluation team followed by direct content analysis and theming using NVivo 12. Any potentially identifiable information provided by participants during their focus group/interview will be redacted as part of the notetaking and cleaning process.

1) *From where will the data be obtained?*
   From virtual platform (i.e. MS Teams, DCS) or telephone focus group/interviews with PHEOs/APHEOs and Command Surgeons.

2) *If obtaining the data from an external source, how will the data be transferred?*
   Not applicable

3) *Are there data use agreements (DUAs) in place?*
   Not applicable

4) *Where will the data be stored? How is the data protected in this location?*
   Electronic data files are stored on secure, CAC-enabled computers on protected network drives, and all electronic data will be stored on a secure drive that is only accessible to the PHAD evaluation team (i.e., the PHAD S: drive). Upon completion, the PHAD evaluation team will destroy all collected information in accordance with U.S. Government security standards.

5) *Are you collecting PII*? (See definition below)*
   We will not be asking participants to identify themselves or provide any demographic information about themselves, other than installation location and command affiliation (i.e., medical, garrison or tactical).

6) *Are you collecting PHI*?*
   Not applicable

7) *If using PII and/or PHI, give the data elements you wish to use and explain how they are the minimal amount needed to answer your question(s).*
   To minimize PII collection, the evaluation team is not collecting PII or PHI specific to the participant other than installation location and command affiliation (i.e., medical, garrison or tactical). We will only report findings in aggregate by participant type (i.e., PHEOs/APHEOs or Command Surgeons)

8) *Will the data be identified, de-identified, or limited?*
   If the data will be de-identified, what is the de-identification process?
   How do you assure the data cannot be re-identified – or if it can, explain what you will do with key?
   Participants will not be asked to identify themselves by name or provide any demographic information about themselves, other than the installation location and command affiliation (i.e., medical, garrison or tactical). The study will collect information to better understand perceptions regrading COVID-19 vaccination being mandated, and identify anticipated information needs if COVID-19 vaccination is mandated. Any potentially identifiable information that is shared by the participant will be redacted during the data cleaning process and will not be reported in the findings. All members of the evaluation team have taken the following mandatory trainings: HIPAA, Information Assurance, Collaborative Institutional Training Initiative (CITI) Training, and Ethics. The PHAD evaluation team will take every precaution to ensure the protection, privacy, and confidentiality of all PII.

3 Additional References

All references remain unchanged from the original OHP Project Plan *#21-931 COVID-19 Vaccination Perceptions & Messaging Formative Evaluation* that was approved in February 2021.

Focus Group/Interview Guide

COVID-19 Vaccination Perceptions & Messaging Formative Evaluation: Phase II
Appendix A

Introduction

Hello, my name is [insert facilitator name] and this is [insert note taker name]. We are part of an evaluation team from the U.S. Army Public Health Center (APHC), at Aberdeen Proving Ground, Maryland. As you are aware, the COVID-19 vaccination is of critical interest in regard to Force Readiness. We are collecting information about this topic to improve the responsiveness of the APHC's COVID-19 messaging for Soldiers, Army health care workers, and the Total Army Family in support of force health protection and readiness.

You were asked to participate in this focus group due to your role as a [Public Health Emergency Officer/Command Surgeon] and you are someone who might be aware of the COVID-19 vaccination perceptions at your installation. Based upon your role and experience, we will ask a set of questions in which we hope to hear what you've seen or heard directly and what your experiences are. I want to assure you that we are not part of any investigation and we are not inspecting your agency, the military treatment facility (MTF), or any other program at your installation.

The purpose of this focus group is to listen and capture your perceptions and experiences regarding a potential future COVID-19 vaccination mandate among personnel at your installation. To date, the vaccine is voluntary for Service members, Civilians, contractors and Family members; however, we want to be prepared to address concerns that beneficiaries may have if and when a mandate is issued. We encourage you to participate freely in this discussion and to answer questions openly. There are no right or wrong answers and we are interested in your honest opinion.
*Our discussion will likely last [**Focus Group** 60-90 minutes/ **Interview** 45-60 minutes].*

We would like the discussion to be recorded using a digital audio recorder, but nothing you say will be tied specifically to you in any reports generated from discussion today. [Insert note taker name] will be taking notes, but in our experience this only allows us to capture about 30% of what is said. Recording the session will help to ensure that we capture what you share in its entirety, so that we do not miss anything essential that you share today. The only people with access to the interview recordings and notes are the APHC Evaluation Team members. Does anyone in attendance have any objection to having the focus group recorded?

[If a participant does not want to be recorded, explain that we want to make sure that we do not miss anything shared within the group and ask if we can follow-up with them separately to collect their thoughts.].

Thank you for your consent.
Do you have any questions before we begin?

1. Based upon your recent experiences and observations, how would you describe current perceptions or attitudes of COVID-19 vaccination at your installation?

   Probe: What do you think are the primary drivers of the perceptions/attitudes that you mentioned? Does it vary across any particular groups?

2. What perceptions or attitudes toward a COVID-19 vaccination mandate have you seen or heard among installation personnel?

   Probe: Can you share some examples?

   Probe: Why do you think some view mandatory COVID-19 vaccination more favorably? Less favorably?

3. What, if any, concerns have installation personnel raised? Why?

   Probe: How common do you think concerns about a COVID-19 vaccination mandate are among installation personnel? Why?

4. What, if any, differences in perceptions, attitudes, and/or concerns about mandatory COVID-19 vaccination exist among installation personnel (e.g. general Soldier population, health care workers/providers, leaders, etc.)?

   Probe: What key factors do you think shape the differences shared?

   Probe: Are there any military-specific drivers that haven't already been shared?

5. What, if any, questions have you heard or personally been asked about COVID-19 vaccination being mandated?

   Probe: Have you noticed any differences in the types or volume of questions asked by different groups (e.g. general Soldier population, health care workers/providers, leaders, etc.)?
   - [If yes] Why do you think there are differences?

   Probe: What, if any, successful strategies have you employed to answer questions and/or address concerns regarding a COVID-19 vaccination mandate? Why do you think it was helpful?

6. What specific information/resources would help you in your role if/when COVID-19 vaccination is mandated?

Probe: How would you prefer to receive this information (e.g. channel(s), formats such as toolkits and FAQs)?

7. If/When COVID-19 vaccine is mandated across the DoD, what information needs would you expect or anticipate (e.g., general Soldier population, health care workers/providers, leaders, etc.)?

   Probe: What kinds of information do you think would help vaccine hesitant Soldiers to feel more comfortable getting the COVID vaccine?

   Probe: What suggestions do you have for how to address the information needs mentioned (e.g., key information, messaging concepts, data, images/visuals, channels, formats)?

8. Is there anything else that you would like to share about the topics that we discussed today?

   [Insert note taker(s) name(s)], do you have any additional questions?

Thank you for taking time to talk with us today. APHC intends to use what we learn to inform future APHC COVID-19 messaging and we aim to incorporate what you shared into our messaging and communications.

Appendix B. Data Protection Plan Approval

From: Haley, Scott C Jr CIV USARMY MEDCOM APHC (USA) <scott.c.haley5.civ@mail.mil>
Sent: Wednesday, July 14, 2021 9:10 AM
To: Meier, Stephanie J CTR USARMY MEDCOM APHC (USA) <stephanie.j.meier3.ctr@mail.mil>
Cc: USARMY APG MEDCOM APHC List QSARC OHP <usarmy.apg.medcom-aphc.list.qsarc-ohp@mail.mil>; Carlson, Mamie R CIV USARMY MEDCOM APHC (USA) <mamie.r.carlson.civ@mail.mil>; Malozi, Dawn L CIV USARMY MEDCOM APHC (USA) <dawn.l.malozi.civ@mail.mil>; Gyory, Dawn M CIV USARMY MEDCOM APHC (USA) <dawn.m.gyory.civ@mail.mil>
Subject: RE: 'Data Protection Plan Approval,' Project Modification #21-931 COVID-19 Vaccination Perceptions & Messaging Formative Evaluation, Carlson (UNCLASSIFIED)

Good morning,

This revised Data Protection Plan has been approved.

Scott Haley
IT Specialist
Information Management Division
MEDCOM Army Public Health Center
8968 Depot Rd, Building E1930
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scott.c.haley5.civ@mail.mil

From: Meier, Stephanie J CTR USARMY MEDCOM APHC (USA) <stephanie.j.meier3.ctr@mail.mil>
Sent: Monday, July 12, 2021 9:09 AM
To: USARMY APG MEDCOM APHC List Org-BUSOPS-IMD-NMT-CST <usarmy.apg.medcom-aphc.list.org-busops-imd-nmt-cst@mail.mil>
Cc: USARMY APG MEDCOM APHC List QSARC OHP <usarmy.apg.medcom-aphc.list.qsarc-ohp@mail.mil>; Carlson, Mamie R CIV USARMY MEDCOM APHC (USA) <mamie.r.carlson.civ@mail.mil>
Subject: 'Data Protection Plan Approval,' Project Modification #21-931 COVID-19 Vaccination Perceptions & Messaging Formative Evaluation, Carlson (UNCLASSIFIED)

Good Morning,

I am reaching out to request your review and approval/feedback on the updated Data Protection Plan for Project Modification #*21-931* COVID-19 Vaccination Perceptions & Messaging Formative Evaluation project plan. Changes from the initial data protection plan are highlighted in yellow.

Thank you so much for your review!

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Data Protection Plan

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1) *From where will the data be obtained?*
   From virtual platform (i.e. MS Teams, DCS) or telephone focus group/interviews with PHEOs/APHEOs and Command Surgeons at selected installations.

2) *If obtaining the data from an external source, how will the data be transferred?*
   Not applicable

3) *Are there data use agreements (DUAs) in place?*
   Not applicable

4) *Where will the data be stored? How is the data protected in this location?*
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Training Initiative (CITI) Training, and Ethics. The PHAD evaluation team will take every precaution to ensure the protection, privacy, and confidentiality of all PII.

Very Respectfully,
Stephanie

Stephanie Meier, PhD, MA
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