



PLEASE MUTE IF NOT SPEAKING!

Clinical Coordinating Center (CCC) Training

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CCC Director, PREVENT II

September 15, 2022

Agenda

Key Personnel and Sites

Objectives and Design

Recruitment

Screening

Consent and Enrollment

Data collection overview

Subcontracts

Key personnel

UCLA/OV-UCLA ERI	University of Iowa	CDC
<p>David Talan, MD Co-PI, PREVENT PI, <i>EMERGE</i>ncy ID NET dtalan@ucla.edu</p>	<p>Nicholas Mohr, MD Co-PI, PREVENT Co-I, <i>EMERGE</i>ncy ID NET Nicholas-mohr@uiowa.edu</p>	<p>Ian Plumb, MBBS, MSc Tamara Pilishvili, PhD Melissa Briggs Hagen, MD, MPH Glen Abedi, MPH Matthew McCullough, MPH David McCormick, MD, MPH Jade James Gist, MPH</p>
<p>Clinical Coordinating Center Anusha Krishnadasan, PhD - Director Kavitha Pathmarajah, MPH Eva Gonzalez, BA Denise Tritt/ Olive View-UCLA ERI idnet@ucla.edu</p>	<p>Data Coordinating Center Kari Harland, PhD - Director Kelli Wallace, MS Anne Zepeski PharmD, BCPS Tracy Young, MS Priyanka Vakkalanka, PhD Nathan Kramer, MPH Patrick Ten Eyck, PhD Eliezer Santos, PhD candidate Emergencyidnet-prevent@iowa.edu</p>	<p>Vaccine Effectiveness Team Vaccine Task Force COVID-19 Response</p>

PREVENT II sites and site PIs

Site	Location	Site PIs
Baystate Medical Center	Springfield, Massachusetts	Howard Smithline, MD
Brigham and Women's Hospital	Boston, Massachusetts	Peter Hou, MD
Duke University	Durham, North Carolina	Stephanie Eucker, MD, PhD
Jackson Memorial Hospital	Miami, Florida	Lilly Lee, MD, MS
Johns Hopkins Hospital	Baltimore, MD	Richard Rothman, MD, PhD
Oregon Health and Sciences Univ	Portland, OR	Jon Jui, MD, MPH & Marcel Curlin, MD
Thomas Jefferson University	Philadelphia, Pennsylvania	Elizabeth Krebs MD, MSc & Efrat Kean, MD
University Health/ UMKC	Kansas City, Missouri	Mark Steele, MD & Amy Stubbs, MD
University Medical Center/LCMC	New Orleans, LA	Stephen Lim, MD
University of Alabama	Birmingham, Alabama	Walt Schrading, MD, James Crosby, MD
University of California, Los Angeles	Los Angeles, California	William Mower, MD, PhD
University of San Francisco, Fresno	Fresno, California	Brian Chinnock, MD
University of Chicago	Chicago, Illinois	David Beiser, MD, MS
University of Iowa	Iowa City, Iowa	Brett Faine, PharmD, MS
University of Massachusetts	Worcester, Massachusetts	John Haran, MD, PhD
University of Mississippi	Jackson, Mississippi	Utsav Nandi, MD, MSCI
University of New Mexico	Albuquerque, NM	Jon Femling, MD, PhD
University of Utah	Salt Lake City, UT	Matthew Fuller, MD
University of Washington	Seattle, WA	Anne Chipman, MD, MS
Valleywise Medical Center	Phoenix, AZ	Frank Lovecchio, DO, MPH



Primary Objective

Evaluate SARS-CoV-2 vaccine effectiveness (VE) in preventing COVID-19 infection among health care personnel (HCP), specifically focusing on the effect of vaccine boosters and temporal changes in VE.

Secondary Objectives

- 1) identifying differences in VE by age group and comorbidity categories,
- 2) evaluating VE within job categories and clinical practice settings,
- 3) estimating the comparative effectiveness of different SARS-CoV-2 vaccines, vaccine schedules, and time periods between doses,
- 4) evaluating VE as related to participant reported history of past infection,
- 5) measuring effectiveness of SARS-CoV-2 vaccine boosters,
- 6) elucidating the role of vaccination in preventing prolonged symptoms of COVID-19, and
- 7) evaluating VE for illness related to emerging variants.

Project Design

- Multi-center case-control design conducted at 20 PREVENT U.S. hospital sites and 10 EIP sites
 - Cases (symptomatic) - positive SARS-CoV-2 RT-PCR or SARS-CoV-2 antigen test.
 - Controls (symptomatic or asymptomatic) - negative SARS-CoV-2 RT-PCR test, or tests negative within 14 days before or after the date of their last negative test. **Can not be an antigen test!**
- 2 years of surveillance/ ~15,000 participants completing baseline survey

Major changes from PREVENT I

All sites recruiting HCP through employee health department to obtain weekly testing lists of HCP

Selecting 6:1 control to case ratio

Removed replacement of negative controls who were ineligible, declined participation, or nonresponsive

Including HCP with prior COVID infection

Positive cases must be symptomatic, and negative controls can be asymptomatic or symptomatic.

Added two participant surveys at 12 weeks and 6 months after index timepoint to assess long term symptoms

Recruitment Log

REQUIRED

- names
- emails
- test date
- test result (pos=1, neg=0)
- date added to log

Optional but RECOMMENDED

- test type (PCR, antigen)
- job location
- symptomatic/asymptomatic
- phone numbers,
- job category
- age
- sex

***Weekly list generated from Sunday (12:00am) to Saturday (11:59pm)**


***Keep track of total number positives and total tested each week – report of weekly facility form**

Date added	Last Name	First Name	Phone	eMail Address	Test Date	Results
9/26	Andrews	Alfred	(111) 111-1111	artichoke@a.com	9/18/2022	0
9/26	Baker	Bill	(123) 456-7890	banana@b.com	9/18/2022	0
9/26	Caldwell	Carla	(323) 333-3333	cherry@c.com	9/18/2022	0
9/26	Draper	Darla	(444) 222-3333	date@d.com	9/18/2022	0
9/26	England	Elliot	(555) 121-2121	elderberry@3.com	9/18/2022	1
9/26	Frank	Furter	(666) 666-6666	fig@f.com	9/18/2022	0
9/26	George	Garland	(777) 777-7777	grape@g.com	9/19/2022	1
9/26	Harry	Hiliard	(888) 888-8888	honeydew@h.com	9/20/2022	0
9/26	Ivan	Isaacson	(999) 999-9999	idunno@i.com	9/23/2022	0
9/26	Janelle	Johnson	(100) 100-1000	jackfruit@j.com	9/20/2022	0
9/26	Kathy	Kennedy	(100) 111-1111	keylime@k.com	9/20/2022	0
9/26	Larry	Larson	(100) 222-2222	lemonjello@l.com	9/23/2022	0
9/26	Mario	McIntosh	(100) 333-3333	melon@m.com	9/20/2022	0
9/26	Nancy	Noel	(100) 444-4444	nillawafer@n.com	9/20/2022	0
9/26	Orlando	Ostrand	(100) 555-5555	orange@o.com	9/24/2022	0
9/26	Paul	Peterman	(100) 666-6666	papaya@p.com	9/20/2022	0
9/26	Quincy	Qdoba	(100) 777-7777	quince@q.com	9/24/2022	0
9/26	Reba	Richardson	(100) 888-8888	raspberry@r.com	9/20/2022	0

Other ways to recruit HCP



Do not recruit cases and controls differentially!

Have you been tested for COVID-19 in the last 60 days?



If you are interested in participating in a CDC COVID surveillance study, scan the QR code or go to www.prevent-project.org

- Voluntary & Confidential
- \$100 for completion of four online surveys over 6 months
- OVMC employees only



Scan To Be Contacted

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Scan To Be Contacted

Recruitment activities may begin soon!

- U Iowa – HCP tested week of Sept 11-17, 2022
- All other sites – HCP tested week of Sept 18-24, 2022

Site enrollment Launch

PRIOR TO enrollment launch date (i.e., begin selecting and inviting HCP to project from Recruitment Log):

- 1) approval of recruitment plan,
- 2) test Recruitment plan
- 3) site readiness call,
- 4) complete project trainings and abstractors complete medical records abstraction quiz
- 5) all site team members have access to REDCap,
- 6) receipt of project invitation link for HCP from the DCC,
- 7) subcontract executed (or at least in process)

Selecting HCP

- All those with positive test results (cases) will be selected
- 6 controls per case selected from HCP tested THE SAME WEEK
- Use Selection Macro when necessary (i.e., HCP list has more than the 6:1 control to case ratio)

Selection macro



Subject Heading: CDC- funded surveillance Project PREVENT Invitation

<Institutional Letterhead>

Dear <Institution> Employee,

The <Institution> is partnering with the Centers for Disease Control and Prevention (CDC) to conduct Project PREVENT. **Project PREVENT (PReventing Emerging Infections Through Vaccine EffectiveNess Testing) is evaluating the effectiveness of COVID-19 vaccines and its impact on health care providers. You were recently tested for COVID-19 and may be able to participate in this important project.**

Your participation in this project is voluntary and choosing to participate or not participate will not impact your employment or standing with <Institution>. If you are interested in learning more about the project, please click on this link to **PROJECT PREVENT**.

The link will take you to a screening page to see if you meet the criteria to participate in this project. If you meet the screening criteria then you will be invited into the project and asked to complete four online surveys. **You will be paid \$25 by the PREVENT Project Team after completing each of the four surveys for a total of \$100.** The checks will be mailed to you by the **University of Iowa project coordinating center**.

You will not be given any vaccines or other medications as part of this project. Being vaccinated is not a requirement for participating. No information about you has been given to the project team.

The initial results from this project which currently includes over 10,000 U.S. health care workers have been published in the New England Journal of Medicine ([NEJM Link](#))

For more information or if you have any questions about the project, please contact the <Institution> project team members at **<Insert contact info of site team>** or visit www.prevent-project.org. If you would not like to receive any further emails about this project, please click here to **DECLINE**.

Sincerely,

<Site PI name and contact information>

Inviting HCP to the project

- Email the link to participate to selected HCP a minimum of 14 days and up to 60 days after their test date
- If possible, text the link to HCP –talk to your IT dept about bulk text messaging
- **Pick one day of the week to send invites weekly for the HCP tested two weeks earlier, and send reminder invites up to a minimum of 4 attempts.**

EXAMPLE PROJECT LINK

https://redcap.icts.uiowa.edu/redcap/redcap_v10.6.2/ExternalModules/?prefix=public_survey_dag&page=survey&pid=9075&NOAUTH&dag=NzY00Q%3D%3D

Screening Log example

First name	Last name	Email address	Test result (pos/neg)	Date email invite sent	Date text invite sent	Declined participation prior to Screening (Y/N)	Completed Screening Form (Y/N)	Eligible (Y/N)	Reason ineligible	Consented (Y/N)	REDCap Record ID if consented
England	Elliot	elderberry@3.com	1	10/10/2022	10/10/2022	N	Y	Y		Y	25
Frank	Furter	fig@f.com	0	10/10/2022	10/10/2022	N	Y	Y		Y	26
Caldwell	Carla	cherry@c.com	0	10/10/2022	10/10/2022	N	N				
Draper	Darla	date@d.com	0	10/10/2022	10/10/2022	Y					
Baker	Bill	banana@b.com	0	10/10/2022	10/10/2022	N	Y	N	Works remotely		
Orlando	Ostrand	orange@o.com	0	10/10/2022	10/10/2022	N	Y	N	Negative Ag test		
Paul	Peterman	papaya@p.com	0	10/10/2022	10/10/2022	N	Y	N	Negative Ag test		
George	Garland	grape@g.com	1	10/10/2022	10/10/2022	N	Y	N	Asymptomatic		
Larry	Larson	lemonjello@l.com	0	10/10/2022	10/10/2022	N	Y	Y		Y	27
Kathy	Kennedy	keylime@k.com	0	10/10/2022	10/10/2022	N	Y	Y		Y	28
Andrews	Alfred	artichoke@a.com	0	10/10/2022	10/10/2022	N	Y	N	Test date >60 days ago		
Harry	Hiliard	honeydew@h.com	0	10/10/2022	10/10/2022	N	Y	Y		N	
Janelle	Johnson	jackfruit@j.com	0	10/10/2022	10/10/2022	N	Y	N	Planning to leave current job next month		
Quincy	Qdoba	quince@q.com	0	10/10/2022	10/10/2022	N	Y	N	Does not speak Spanish or English		

Other Logs

Enrolled Participants who
completed baseline survey

HCP who are ineligible who will
not be eligible in the future

HCP who declined participation
or do not want to be contacted

Screening

The link on Invitation email takes them to Screening Form:

“You have received this link because you have been tested for COVID-19. We are enrolling some people who have COVID-19 and some who do not - you do NOT need to have COVID-19 to participate. You may be eligible to participate whether or not you have received the COVID-19 vaccine. As part of this project, we will not be giving you vaccines. If you are eligible, project participation will require 4 surveys and documentation of COVID vaccines, COVID testing, and any healthcare related to your illness. All information you provide will be kept strictly confidential, and it will not be available to your employer, supervisor, or anyone outside the project team. You will be compensated for your time, and your participation will last approximately 6 months. Based on your understanding of this project, would you like to continue with the screening process?”

If yes, they proceed to screening

If no, they are asked to type in their name so we have a record of who declined to screen. **Note this in your log!**

Inclusion criteria

1. Any HCP (employee or volunteer) tested for COVID-19 in the past 60 days and after launching the project at a site;
2. HCP who have the potential for direct or indirect exposure to patients or infectious materials; and

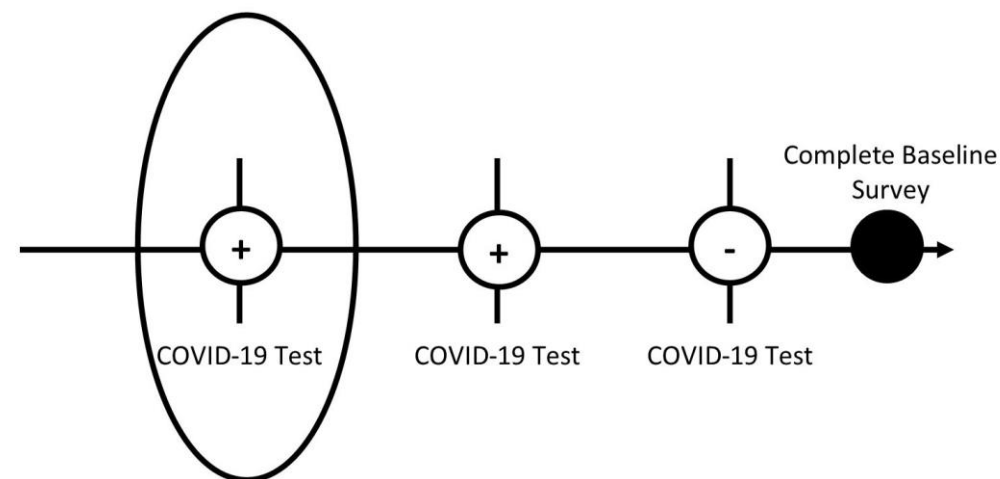
Inclusion criteria (con)

3. HCP who test positive must have at least one of the following symptoms during a period from 14 days prior to their first positive test COVID-19 test to 14 days after that test:

Abdominal pain; Bruised toes or feet; Changes in my ability to smell or taste; Chest pain or chest tightness; Chills; Cough; Diarrhea; Fatigue; Fever; Headache; Loss of appetite; Myalgia; Nausea or vomiting; Rhinorrhea; Rigors; Severe respiratory illness, including pneumonia; Shortness of breath or difficulty breathing; Sinus or nasal congestion; or Sore throat.

For HCP who test negative for COVID-19, no symptoms are required for enrollment

First positive test



Exclusion criteria

1. HCP unable to confirm test results or vaccine administration using an approved method;
2. previously enrolled HCP who did not complete follow-up surveys during a previous enrollment will be ineligible for re-enrollment;
3. do not intend to be working, studying, or volunteering in the participating health care facility for at least 6 weeks after enrollment;
4. does not speak English or Spanish; or
5. works remotely from home (defined as not working at least one day in a healthcare facility over the last 2 weeks).

Eligibility criteria – other notes

HCP may be enrolled more than once (if the employee tested negative during a prior enrollment), but they must meet the following criteria:

1. at least 6 months since previous enrollment;
2. completed all follow-up surveys from previous enrollment; and
3. complete resolution of symptoms from time of first episode of testing.

If HCP is ineligible, REDCap captures their name, so site team can track and log this information.

Informed consent

- If eligible, REDCap will present Informed Consent document

By selecting "yes," you acknowledge that you have read the information presented, and that you agree to participate in this project.

If they select no, **enter this into your log!**

- **HCP are considered enrolled only after completing baseline survey and assigned a REDCap Record ID**

Data collection Overview

Participant

- Baseline Survey
- Follow-up Surveys
 - 6 weeks, 12 weeks, and 6 months after index symptoms/test date
 - email and text, reminders
- Compensation by check \$25/survey
- Can be done by interview (MOP Sections 4.6.1 and 5.2.3)

Site Team

- Weekly facility form
- COVID-19 Test results verification
- COVID-19 Vaccination results verification
- Health care utilization/medical records verification

Subcontract payments – Fixed Costs

Start up Fee of \$20,000 to be invoiced for after subcontract execution, the site is released to initiate enrollment, and enrollment of first participant.

Quarterly Fees of \$15,000 to be invoiced *quarterly during enrollment* after site addresses all Data Coordinating Center (DCC) queries up to that timepoint.

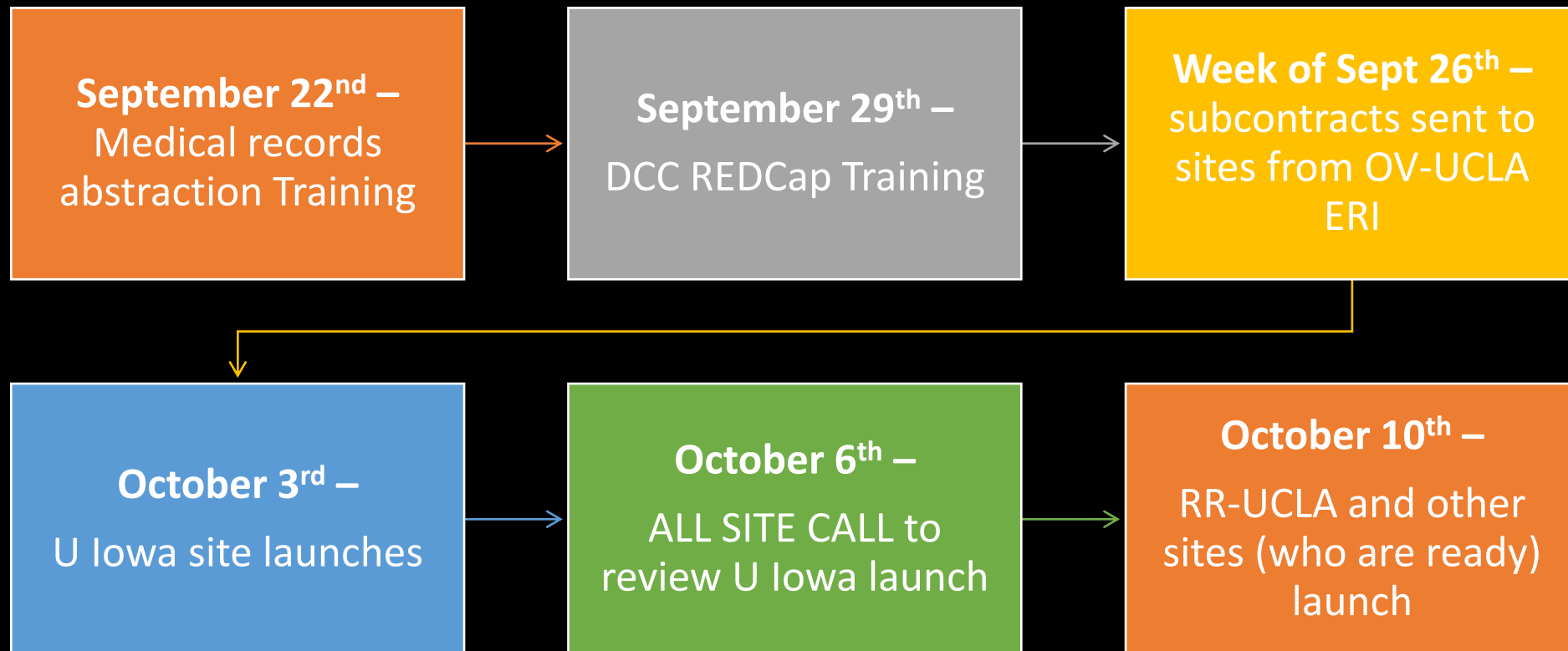
Close out Fee of \$20,000 to be invoiced for after enrollment is closed at that site, all DCC queries have been addressed, and submission of final weekly facility form.

Subcontract payments – Variable Costs

Sites will be paid per participant enrolled for completion of the following project tasks. Sites will receive a spreadsheet summarizing their completion of these tasks quarterly from the DCC for invoicing purposes.

1. Participant Survey completion
 - a. Baseline survey - \$50
 - b. Follow up surveys @ 6 weeks, 12 weeks and 6 months - \$30/survey
2. COVID vaccine verification completion
 - a. \$20/vaccine verified prior to their index date
3. COVID test verification completion
 - a. \$20 for verifying any COVID test during the index period
4. Healthcare Utilization verification completion
 - a. \$50 for verifying any qualifying visit during the index period

Project Launch Timeline



Questions?

CCC –
idnet@ucla.edu

DCC –
[emergencyidnet-
prevent@uiowa.edu](mailto:emergencyidnet-prevent@uiowa.edu)

