From: Gretchen Rothrock
Sent: Thu, 6 May 2021 19:20:49 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Gretchen Rothrock;Reingold, Arthur MD (CDC berkeley.edu);Pam Daily;Chai, Shua (CDC cdph.ca.gov)
Subject: ABCs publication guidelines, CA EIP data request form (Modified) + misc doc from CDC
Attachments: CEIP Data Request_update_Feb2016.docx, 5 FluSurv-NET proposals_11092016.pptx, ABCs Authorship Guidance 2014_updated May 2021.docx

Hi Marc,

In reviewing our data request form, it seems that many of the fields would be valid on a form for COVID/Breakthrough etc. It has not been modified.

Attached are the ABCs publication guidelines. The FN, HAI and influenza guidelines are identical, word for word.

I stumbled on the PPT presented by Shikha which I thought was worth throwing in, since it addresses several of the questions that will no doubt arise: time for review prior to conferences, publication etc ..

Have at it!

Best,
Gretchen

Gretchen Rothrock, MPH
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California Emerging Infections Program
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Oakland, CA 94602
Phone: (510) 350-3361
Email: grothrock@ceip.us
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www.ceip.us

DATA REQUEST

California Emerging Infections Program (CEIP) Data Request

NOTE: Any data analysis resulting in dissemination or publication of CEIP data will require approval from a CEIP co-director, may involve CEIP collaborators/co-authors, and may require submission through the CDPH clearance process.

Date of request: ____/____/_____

Requestor's name, title, and affiliation: _____

Contact information: Tel_____ Email_____

Address:_____

Background

Briefly state research question/interest (what question(s) are you trying to answer?):

_____

_____

How will CEIP data help answer this question?

_____

_____

Intended Use of Data

☐ Conference abstract/presentation

Name of conference: _____ Abstract submission due date: ____/____/_____

☐ Publication—Proposed CEIP collaborators/co-authors: _____

☐ MPH/Master or ☐ PhD project/thesis/dissertation:_____

☐ Data for program evaluation ☐ Audit/complete case ascertainment

☐ Other:_____

Data Request Details

Date data are needed by: ____/____/_____ Geographic area:_____

Pathogen(s) of interest: _____

Variables of interest: _____

Time period for data requested: from _____ to _____

☐ Cumulative ☐ By year ☐ Other grouping/filter: _____

Data format requested: _____

☐ Individual records (linelist) ☐ Summary data (describe in comments) ☐ Both

Delivery method: ☐ Email ☐ Mail ☐ Fax: _____

Additional Comments: _____

_____

The California Emerging Infections Program (CEIP), a Program of Public Health Foundation Enterprises, Inc., is a joint project of the California Department of Public Health, U.C. Berkeley School of Public Health, and Centers for Disease Control and Prevention, in collaboration with the Alameda County Health Care Services Agency, San Francisco Department of Public Health, Contra Costa County Health Services Department, and the City of Berkeley Health and Human Services Department.

Updated 12/27/2021

By submitting this data request I agree to the following provisions:

1. Protecting confidentiality is our foremost concern. The release of data containing individually identifying information is strictly prohibited. The terms and conditions for the release of data must be consistent with applicable laws.

2. Identifiable data will only be provided as allowed by state law (i.e., to appropriate public health authorities).

3. We will suppress data to maintain case confidentiality. Data tables will not contain potentially identifying information, small cell values, or information on small population subgroups.

4. All publications using CEIP data provided must a) be approved by a CEIP Co-Director and b) acknowledge CEIP. The following is a suggested citation: California Emerging Infections Program, provisional infectious diseases data provided per Data Request, <date>.

5. The dissemination of any interpretations or findings based upon the data provided must be accompanied by the following disclaimer: The authorized release of infectious diseases data by the California Emerging Infections Program should not be construed as an endorsement of any analyses, interpretations, or conclusions reached by the author(s).

6. The data provided will be used only for the purposes stated in the data request form.

7. The data are provisional. Local Health Jurisdictions can modify or delete past case reports at any time, even months or years after they are initially reported due to the dynamic nature of the reporting surveillance system.

8. Data will not be released to a third party. Third party requests should be referred directly to the California Emerging Infections Program.

9. Research proposals involving human subjects may require approval of the California Health and Human Services Agency, Committee for the Protection of Human Subjects, 400 R Street, Suite 359, Sacramento, CA 95811-6213, telephone: (916) 326-3660, websites: cphs-mail@oshpd.ca.gov, or www.oshpd.ca.gov/boards/cphs.

10. Requesters agree not to use de-identified data to determine the identity of individual persons. An attempt to do so from public data is a violation of the federal Privacy Act, 5 U.S.C, the HIPAA Rule, and state law.

11. Computer or paper files must be protected under lock and key and/or by encryption.

Signature:	Type or print name of the requester:	Date:

Note: If you email this form to expedite the process, you are still required to print out, sign, and fax or mail it to CEIP.

FOR CEIP USE ONLY

CEIP staff who received initial request: _____

CEIP point person(s) who will handle this request and/or collaborate with data analysis:

_____

CEIP Director approving this request: _____

Instructions for Completing Data Request Form

Intended Use of Data

Check all that apply.

Data Request Details

Geographic Area: There are three county local health jurisdictions and one city health jurisdiction within the CEIP catchment area: Alameda, Contra Costa, and San Francisco counties, and the City of Berkeley.

Pathogen(s) of Interest: Please refer to the attached CEIP surveillance document.

Time Period: Specify both lower and upper bound for time period requested (month/year). The time period for data requests is based on collection date of the specimen that was positive for the pathogen.

Delivery Method: Results will be emailed to specified address if no method is selected.

Additional Comments: Use this area to add any special instructions that were not covered elsewhere. CEIP will do its best to address your request.

How to Propose an Analysis, Request Data and Clear a FluSurv-NET Abstract or Manuscript

Shikha GargFluSurv-NET PI Call11/8/2016

Rationale

- To provide the opportunity for active and early involvement by appropriate co-authors at FluSurv-NET sites and CDCTo plan for adequate time for CDC clearance and to meet submission deadline dates

Site-led Analysis Using Site-Specific Data

- For meeting abstracts or manuscripts that are citable, project lead should inform FluSurv-NET CDC medical director about the analysisFosters information sharing and improved communicationNo need for project lead to inform FluSurv-NET sites about analysisCDC will provide updates regarding site-led analyses using site -specific data on PI and SO calls throughout the yearCDC clearance is not required if there are no CDC co-authorsCDC clearance is required if there are 1 or more CDC co-authors

Site-led Analysis Using Multi-Site FluSurv-NET Data: Submitting a Proposal

- The proposal should first be submitted to the FluSurv-NET CDC medical director Once the FluSurv-NET CDC medical director and project lead review/discusses and agree on the proposalThe proposal should be circulated to all FluSurv-NET sites for review by the CDC FluSurv-NET CoordinatorThe proposal should be presented by project lead on upcoming PI and SO callThe proposal is approved once all sites sign off on the proposalIndividual sites may have specific requirements regarding approval that should be adhered to (e.g. geocoded data)

Site-led Analysis Using Multi-Site FluSurv-NET Data: Submitting a Data Request/Receiving Data

- The project lead will submit a data request specifying data elements and seasons of data to be included in the dataset The project lead will sign a data use agreement prior to receiving any dataThe FluSurv-NET data manager will work with the project lead to complete the data request within an agreed upon time frame and will transmit the data to the project lead via SAMSDatasetData dictionary

Site-led Analysis Using Multi-Site FluSurv-NET Data: Submitting an Abstract or Manuscript for Publication

- CDC clearance is required for all abstracts and manuscripts that include 1 or more CDC co-authors before the work can be submitted to a conference or for publicationDocumented approval from each site whose data is being used in the analysis is required before the work can be submitted to a conference or for publicationProject lead should work closely with CDC FluSurv-NET coordinator to receive/track approvals from coauthorsFluSurv-NET contact lists constantly changing

Site-led Analysis Using Multi-Site FluSurv-NET Data: Submitting an Abstract or Manuscript for Publication

- Once abstract/manuscript finalized, send email to CDC FluSurv-NET coordinator and medical director with final version of product and additional details as appropriateConference title and submission deadline dateName of journal and submission deadline dateCDC FluSurv-NET coordinator will email abstract/manuscript to all FluSurv-NET PIs/SOs (cc'ing project lead) using a template email and requestingSite's designated co-authorFull name of individual(s) to be included in acknowledgments for manuscriptCo-author comments and/or statement of approval for submission by certain date CDC FluSurv-NET coordinator will track responses and let the project lead know when all site responses have been received and whether there are any approvals still pending

Site-led Analysis Using Multi-Site FluSurv-NET Data: Submitting an Abstract or Manuscript for Publication

- Abstract/Manuscript may be submitted once the following requirements are metAll co-author comments addressed All CDC clearance comments addressedAll co-author approvals for submission are received

Site-led Analysis Using Multi-Site FluSurv-NET Data: Ideal Timelines for Submission of Abstracts

- Send final abstract to CDC FluSurv-NET coordinator and medical director at least 6 weeks prior to conference submission deadlineCDC will forward abstract to all FluSurv-NET sites and allow 2 weeks for feedback/submission of approval statementsProject lead to incorporate all feedback and send abstract to CDC FluSurv-NET coordinator and medical director for submission to CDC clearance 4 weeks prior to conference submission deadlineAllow at least 2 weeks for CDC clearance of abstract (may be faster)Project lead will have 2 remaining weeks to incorporate feedback from CDC clearance and submit final abstract to conference

Site-led Analysis Using Multi-Site FluSurv-NET Data: Ideal Timelines for Submission of Manuscripts

- Send final manuscript to CDC FluSurv-NET coordinator and medical director at least 8 weeks prior to planned journal submission dateCDC will forward manuscript to all FluSurv-NET sites and allow 2 weeks for feedback/submission of approval statementsProject lead to incorporate all feedback and send manuscript to CDC FluSurv-NET coordinator and medical director for submission to CDC clearance 6 weeks prior to conference submission deadlineAllow at least 4-6 weeks for CDC clearance of manuscript

Elements that should be included in initial proposal

- Proposal titleCDC investigatorsSite-specific investigatorsBackground and rationale (emphasizing public health importance)Study objectivesStudy design and methodsStatistical analysisProposed table shells (optional)Timetable for project completionReferences

Authorship GuidelinesforABCsAbstracts and Manuscripts

Last revised
November 2014

1. General Principles
   a. Each co-author should contribute to (1) conception and design, or analysis and interpretation of data; and to (2) drafting the article or revising it critically for important intellectual content; and (3) approve the final version of the manuscript or abstract.
   b. On multi-site abstracts or publications, each site will determineits co-author(s); each putative co-author mustbegiven thetime and opportunityto contributesubstantiallyto the elements listed above.On multi-sitepapers asitemayproposemorethan one author. Ifmorethan one author is proposed byan ABCs site ormorethan oneCDC author is proposed byCDC, each site coauthor and/or CDC coauthor must meet the ICMJE authorship criteria (see#7). Each site and CDCmaydeclineauthorship on a particular multi-sitepaper.If necessary, thepathogen-specific committeewillbethe arbiter ofthe final authors list for a manuscript. Acknowledgements on manuscriptmayincludemore than oneperson per site.
   c. Authorship does not depend upon organizational position orsite; Principal Investigators, SurveillanceOfficers, orotherinvestigators maybe authors on anygivenabstract or manuscript. Authorship criteria applyequallyto CDC and non-CDC authors.

2. Levels of authorship— multi-site projects
   a. Reporting on fundamental objectives of ABCs: each site will be given the opportunity for one or more co-author(s).Examples:
      "Epidemiologyof invasive pneumococcal disease, 1995-1998"
      "Analysis of population-based group A streptococcal surveillance and *emm* types" (describes epidemiology, emm genotypes, and risk factors for severe GAS disease)
   b. Using essential ABCs data for secondary analyses: "ABCs Team" listed as co-author, with members listed at the end of the article. Secondary analyses are those which do not report on the "fundamental"objectives of ABCs.Examples:
      "Molecular epidemiology of meningococcal isolates"
      "Comparison of ABCs pneumococcal resistance surveillance system with two other surveillance systems"
   c. Using ABCs data or isolates for analyses, the primary purposes of which are not fundamental to the ABCs mission: ABCs should be acknowledged as the source of the data or isolates. Such analyses may include cost-effectiveness analyses, development of new laboratory tests, or modeling of different vaccination strategies. Examples:
      "Newly recognized *emm* typing of invasive GAS isolates detected through the ABCs national surveillance system" (describes 20 new *emm* types identified byCDC's lab; correlates demographic and clinical findings.)
      "Surveillance for meningococcal disease and strategies for use of conjugate meningococcal vaccinesin theUnited States"
   f. The pathogen-specific committee or ABCs Steering Group will be the final arbiter of the category into which a given analysis falls.

3. Abstracts
In general, the same principles for authorship on journal articles apply to abstracts submitted for presentation at meetings. However, given the preliminary nature of data contained in abstracts and theseeminglyinevitable rush to meet deadlines, some flexibilityis appropriate. In particular, lead authors mayneed to limitthe abstract authorlist because of space restrictions. Submissionof an abstract should be considered a"sentinel event" that a manuscript on thetopicwillbeprepared, and thoseinterested in co-authoringthe manuscript should communicate with the principle author ofthemanuscript. Co-authors for an abstract should generallybeco-authors of anycorrespondingmanuscript; it is understood, however, that, because of personnel turnover and otherreasons, this maynot alwaysbepossible.

4. Single-siteprojects/publications
   a. CDC should be notified early in the course of development of an abstract ormanuscript prepared byasingle site. At this time,decisions should be madebetween thesite and CDC on whetherthereshould be at least one CDCco-author.
   b. CDC should have an opportunityto review and provide comments on allsite-specific abstracts/manuscripts—includingthose forwhich thereis no CDCco-author.

5. Laboratory_analyses
When laboratorians at CDC or elsewhere_undertake analyses using_ABCs isolates and/or data, ABCs should be acknowledged as the source of the isolates. The_appropriate pathogen-specific committee should alsobemade awareof thesemanuscripts priorto publicationand non-laboratory authors included if warranted.The requestor should send to his/her point of contact at ABCs any publications or reports that arise from this work or activity.

6. Communication
   1. Early in the course of preparing a manuscript, each site should be notified, and those interested invited to participate in data analysis and writing.
   2. Those planning to submit abstracts should notify CDC and all other sites 1 month ahead of the submission deadline.
   3. When drafts ofmanuscripts or abstracts arecirculated, each site should respond within 2 weeks (manuscripts) and 3 business days (abstracts) of receipt. At or near thedeadline the first authorwillcallthose co-authors who havenotyetresponded toensure co- authors agreement.
   4. Each site should designate a contact for communications concerning data analysis and authorship; communication within a given site is the site's responsibility.
   5. Because of our commoninterest in the qualityofarticles involvingABCs,the need to avoid duplicate publication ofdata, and theavailabilityof pathogen-specific expertise at CDC, the latter should be apprised of and allowed time to review all abstracts or manuscripts involving ABCs data, including single-site data. The Steering Group will arbitrate conflicts that arise among single-site and multi-site projects.

7. Authorship criteria
Criteria for authorship on an ABCs article should follow the Uniform requirements published

by the International Committee of Medical Journal Editors (ICMJE) (see www.icmje.org).

The following is taken from ICMJE,Uniform Requirements for Manuscripts Submitted to Biomedical Journals. NEnglJ Med1997;336:309-315.

All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

Editors may ask authors to describe what each contributed; this information maybe published.

Increasingly, multicenter trials are attributed to a corporate author. All members of the group who are named as authors, either in the authorshipposition below the title or in a footnote, should fullymeet theabove criteria forauthorship. Group members who donot meet these criteria should be listed,with their permission, in the Acknowledgments ion in an appendix.

From: Pam Daily
Sent: Tue, 13 Apr 2021 18:52:20 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Gretchen Rothrock;Chai, Shua (CDC cdph.ca.gov);Joelle Nadle;Reingold, Arthur MD (CDC berkeley.edu)
Subject: CA availability for Breakthrough Study call next week

Hi Marc,
Please see below for the availability of CA site for a Study call with all sites:

Eastern times	Tue, Apr 20	Wed, Apr 21	Thu, Apr 22	Fri, Apr 23
1:00-2:00pm	Yes	Yes	Yes	Same time as COVID-Net PI call
2:00-3:00pm	No	Yes	No	Yes

Best, Pam

Pam Daily Kirley
California Emerging Infections Program
COVID-19, Influenza and RSV Surveillance Coordinator

From: Jernigan, John A. (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 15 Mar 2021 13:39:14 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Martin, Stacey (CDC/DDID/NCEZID/DVBD)
Subject: FW: Management of fully vaccinated residents in LTCF with pos. COVID 19 tests

FYI-we've responded to CDPH.
JJ

From: HAI Outbreak - COVID-19 (CDC) <haicovid@cdc.gov>
Sent: Monday, March 15, 2021 9:06 AM
To: Siegel, Jane (CDC cdph.ca.gov) <Jane.Siegel@cdph.ca.gov>
Cc: CDC 2019 NCOV Response Lab TF Strain Surveillance Coord <eocevent506@cdc.gov>; HAI Outbreak - COVID-19 (CDC) <haicovid@cdc.gov>; Reddy, Sujan C. (CDC/DDID/NCEZID/DHQP) <kuj0@cdc.gov>; Jacobs Slifka, Kara (CDC/DDID/NCEZID/DHQP) <ipf8@cdc.gov>; Jernigan, John A. (CDC/DDID/NCEZID/DHQP) <jqj9@cdc.gov>; Laufer Halpin, Alison S. (CDC/DDID/NCEZID/DHQP) <vif0@cdc.gov>; CDC IMS 2019 NCOV Response VTF Implementation Planning Unit <eocevent480@cdc.gov>; CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>
Subject: RE: Management of fully vaccinated residents in LTCF with pos. COVID 19 tests

Hi Jane,

We received your question from our lab colleagues.

In both situations, we would recommend that those individuals be treated as infectious (vaccine breakthroughs with high Ct values or vaccine breakthroughs who had prior infection ~90 days ago). Although high viral loads are associated with ability to identify replication competent virus, Ct values are not standardized across platforms and a clear threshold has not been established for this purpose. Especially in the setting of vaccine breakthrough, there is a paucity of data to inform practice at this time. There is an ongoing study of breakthrough infections that involves performing viral culture on these samples. This type of investigation may shed light on the question you are posing.
In terms of the use of serology, there has been a suggestion that antibody response is associated with a decreased likelihood of recovering replication competent virus, however to our understanding those types of studies were often performed during earlier phases of infection. We know that antibody positive individuals can become infected, and it is unclear whether antibody response >90 days from initial could help determine the likelihood that the individual is infectious.

Thanks.
Kiran

From: Siegel, Jane@CDPH <Jane.Siegel@cdph.ca.gov>
Sent: Thursday, March 11, 2021 6:22 PM
To: CDC IMS 2019 NCOV Response VTF Implementation Planning Unit <eocevent480@cdc.gov>; CDC 2019 NCOV Response Lab TF Strain Surveillance Coord <eocevent506@cdc.gov>
Subject: Management of fully vaccinated residents in LTCF with pos. COVID 19 tests

Hello, CDC experts.
Thank you for all that you do to support us throughout this pandemic.

We have received many calls asking for advice about the following situations:
LTCF residents who are fully vaccinated and are 21 days from dose #2 and are asymptomatic, tested as part of response testing and are pos. with Ct values in the mid 30s.
2 different situations:

1. Residents who have had frequent testing and have always previously been negative. Now they are pos. as part of response testing, Ct value mid 30s.
   These people could be vaccine breakthroughs, but we cannot do WGS since Ct values so high. How should they be managed re: isolation and indication to continue to do response testing? My understanding is that they are very unlikely to transmit and therefore, I would think that they should not require isolation or trigger continued response testing. Will serology that measures and distinguishes antibody to spike protein and to nucleocapsid be helpful to R/O infection?
2. More complicated is the same situation, but with residents who have tested positive 90-93 days previously during the last surge. My current understanding is that > 90 days after last positive requires isolation and is a trigger for response testing. This seems unreasonable. Same question about antibody for these patient.
   Will you be extending the time > 90 days since last episode, especially for fully vaccinated ?

I submitted this question on today's CDC call, but I don not think that my question was clear enough, so I did not received an answer to the specific management questions above.
Thanks,

Jane

Jane D.Siegel, M.D.
PHMO III HAI Program
California Department of Public Health
850 Marina Bay Parkway, Building E1-11
Richmond, California 94804
Jane.Siegel@cdph.ca.gov
Cell phone: [redacted]
Fax: 510-620-3989

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Fri, 12 Mar 2021 21:57:40 +0000
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD);Lindsey, Nicole (CDC/DDID/NCEZID/DVBD);Spratling, Robin (CDC/DDID/NCIRD/ID) (CTR)
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI);CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team
Subject: FW: Management of fully vaccinated residents in LTCF with pos. COVID 19 tests

Robin, Nicole, and Stacey.

Please see the questions below from Jane Siegel at the California Department of Health which were forwarded to me by the Lab TF strain surveillance team. The original emails was also sent to the VTF Implementation Planning Unit and do not know if they replied or forwarded on to someone else.

The email is about LTCF residents who have been vaccinated and have asymptomatic infection identified during routine screening (i.e., vaccine breakthrough infections). However, the questions are about isolation and risk of transmission of these patients.

[redacted] Could you or someone help direct them to the correct place in the response?

Thanks,
Marc

From: Siegel, Jane@CDPH <Jane.Siegel@cdph.ca.gov>
Sent: Thursday, March 11, 2021 6:22 PM
To: CDC IMS 2019 NCOV Response VTF Implementation Planning Unit <eocevent480@cdc.gov>; CDC 2019 NCOV Response Lab TF Strain Surveillance Coord <eocevent506@cdc.gov>
Subject: Management of fully vaccinated residents in LTCF with pos. COVID 19 tests

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Thanks,

Jane

Jane D.Siegel, M.D.
PHMO III HAI Program
California Department of Public Health
850 Marina Bay Parkway, Building E1-11
Richmond, California 94804
Jane.Siegel@cdph.ca.gov
Cell phone: [redacted]
Fax: 510-620-3989

From: Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD)
Sent: Sun, 18 Jul 2021 23:23:05 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Subject: FW: Post vaccine infection

[redacted]

From: MacNeil, Adam (CDC/DDID/NCIRD/DVD) <aho3@cdc.gov>
Sent: Sunday, July 18, 2021 12:32 PM
To: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>; Hall, Aron (CDC/DDID/NCIRD/DVD) <esg3@cdc.gov>; Scobie, Heather (CDC/DDPHSIS/CGH/GID) <vih8@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>
Cc: Fry, Alicia (CDC/DDID/NCIRD/ID) <agf1@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>; Azziz-Baumgartner, Eduardo (CDC/DDID/NCIRD/ID) <eha9@cdc.gov>; Mead, Paul (CDC/DDID/NCEZID/DVBD) <pfm0@cdc.gov>
Subject: RE: Post vaccine infection

All,

Just checking on this. Kiersten, since you are preparing slides for the IM this week, would you mind also presenting on this call? Ben, are you following up with LA county?

Regards,

Adam

From: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>
Sent: Friday, July 16, 2021 2:57 PM
To: Hall, Aron (CDC/DDID/NCIRD/DVD) <esg3@cdc.gov>; Scobie, Heather (CDC/DDPHSIS/CGH/GID) <vih8@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>
Cc: Fry, Alicia (CDC/DDID/NCIRD/ID) <agf1@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>; MacNeil, Adam (CDC/DDID/NCIRD/DVD) <aho3@cdc.gov>; Azziz-Baumgartner, Eduardo (CDC/DDID/NCIRD/ID) <eha9@cdc.gov>; Mead, Paul (CDC/DDID/NCEZID/DVBD) <pfm0@cdc.gov>
Subject: RE: Post vaccine infection

Thanks Aron. We can follow up directly with LA County colleagues no problem.

CSTE wants another CDC/CSTE CORE call on Tuesday to continue discussing vaccine breakthrough surveillance. I am wondering if you and others would support us pulling together a few expert speakers who can share data/resources that I assume would be of interest nationally. Some ideas---

[redacted]

[redacted]

From: Hall, Aron (CDC/DDID/NCIRD/DVD) <esg3@cdc.gov>
Sent: Friday, July 16, 2021 2:27 PM
To: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>; Scobie, Heather (CDC/DDPHSIS/CGH/GID) <vih8@cdc.gov>
Cc: Fry, Alicia (CDC/DDID/NCIRD/ID) <agf1@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>; MacNeil, Adam (CDC/DDID/NCIRD/DVD) <aho3@cdc.gov>; Azziz-Baumgartner, Eduardo (CDC/DDID/NCIRD/ID) <eha9@cdc.gov>
Subject: RE: Post vaccine infection

Ben and Heather,

[redacted]

Thanks,
Aron

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Sent: Wednesday, July 14, 2021 5:42 PM
To: Balter, Sharon (CDC ph.lacounty.gov) <sbalter@ph.lacounty.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>
Cc: Hall, Aron (CDC/DDID/NCIRD/DVD) <esg3@cdc.gov>; Fry, Alicia (CDC/DDID/NCIRD/ID) <agf1@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>
Subject: RE: Post vaccine infection

John and Sharon.

Sorry that we were not able to participate in this call today. In past months, we had discussed with Prabhu reporting of vaccine breakthrough cases from LA County to the national surveillance system but were nota able to sort out how they would come through the state health department.

Let us know if there is any need for follow-up.

Best wishes,
Marc

Marc Fischer, MD, MPH
Co-lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Epidemiology Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

-----Original Appointment-----
From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov> **On Behalf Of** Balter, Sharon (CDC ph.lacounty.gov)
Sent: Wednesday, July 14, 2021 9:00 AM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI); Hall, Aron (CDC/DDID/NCIRD/DVD); Fry, Alicia (CDC/DDID/NCIRD/ID)
Subject: FW: Post vaccine infection
When: Wednesday, July 14, 2021 1:00 PM-2:00 PM (UTC-08:00) Pacific Time (US & Canada).
Where: Microsoft Teams Meeting

Sharon Balter has reached out from LA County and would like to review their data **on post-vaccine infections** today at 4 pm Eastern (1 pm Pacific). Please join if you can. I suggest limiting the size of this group so we can ensure a productive discussion. We can regroup again with a larger group if needed based on what's discussed and after reporting out to Peggy.

Thanks!

-john

-----Original Appointment-----
From: Sharon Balter <SBalter@ph.lacounty.gov>
Sent: Wednesday, July 14, 2021 12:53 PM
To: Sharon Balter; Jain, Seema (CDC cdph.ca.gov); Rebecca Fisher; Elizabeth Traub; Phoebe Danza
Cc: Brooks, John T. (CDC/DDID/NCHHSTP/DHP); Simon, Paul (CDC ph.lacounty.gov); Zachary Rubin; Keren Landman
Subject: Post vaccine infection

When: Wednesday, July 14, 2021 1:00 PM-2:00 PM (UTC-08:00) Pacific Time (US & Canada).
Where: Microsoft Teams Meeting

Microsoft Teams meeting

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From: John Woolfolk
Sent: Tue, 25 May 2021 09:26:42 -0700
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Subject: news reporter question re: COVID-19 vaccine breakthrough infections

Hi Dr. Fischer, I'm a reporter for the San Jose Mercury News and Bay Area News Group in California. I had a couple questions about today's report on vaccine breakthrough cases and you were listed as the contact for that study.
1) The study indicates 10,262 breakthrough infections among the vaccinated, and 101 million persons fully vaccinated as of April 30. Is it fair to say then that the reported vaccine breakthrough infections amount to 0.01% of the 101 million vaccinated?
2) I'm a bit confused by the data on those who were asymptomatic and the fatalities. The study indicates that 27% were asymptomatic and 10% were hospitalized, and 2% died. But 29% of the hospitalized were asymptomatic, and 18% of those who died were asymptomatic or died of something else. Is there a figure for how many of the breakthroughs were hospitalized with COVID-19 symptoms and how many of the breakthrough's died from COVID-19?
3) The definition of a vaccine breakthrough:
"The detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after receipt of all recommended doses of an FDA-authorized COVID-19 vaccine."
has been questioned by some health experts who say that many of those who have positive PCR tests aren't ill and aren't contagious, that their bodies are effectively fighting off the COVID-19 infection and that they shouldn't be considered a "breakthrough" at all. Why does the CDC use this definition, and is it considering changing it?
Thank you very much,
John Woolfolk
San Jose Mercury News
408-859-5266
--

John Woolfolk Assistant Metro Editor | Editorial
jwoolfolk@bayareanewsgroup.com
408-920-5782 Direct
@JohnWoolfolk1

From: Niccolai, Linda
Sent: Thu, 6 May 2021 17:47:18 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Meek, James;Yousey-Hindes, Kimberly (CDC yale.edu);Clogher, Paula
Subject: On more assay

Hi Marc,

We might have one more assay: Panther TMA (which is distinct from Panther Fusion).

If you go with listing all 200+, this won't matter, but just wanted you to be aware.

Thanks,
-Linda

Linda M. Niccolai, PhD ScM
Professor, Epidemiology of Microbial Diseases
Director, Connecticut Emerging Infections Program
Yale School of Public Health

From: "Fischer, Marc (CDC/DDID/NCEZID/DPEI)" <mxf2@cdc.gov>
Date: Wednesday, May 5, 2021 at 10:28 PM
To: Allison Roebling <aroebling@gaeip.org>, "kopeno@gaeip.org" <kopeno@gaeip.org>, "Bamberg, Wendy (CDC state.co.us)" <Wendy.Bamberg@state.co.us>, "Schmoll, Emma (CDC state.co.us)" <emma.schmoll@state.co.us>, "Alden, Nisha (CDC state.co.us)" <nisha.alden@state.co.us>, "isaac.armistead@state.co.us" <isaac.armistead@state.co.us>, Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>, "Talbot, H. Keipp" <keipp.talbot@vumc.org>, "Markus, Tiffanie M" <tiffanie.m.markus@vumc.org>, James Meek <james.meek@yale.edu>, Linda Niccolai <linda.niccolai@yale.edu>, Ghinwa Dumyati <Ghinwa_Dumyati@URMC.Rochester.edu>, "Muse, Alison T (HEALTH)" <alison.muse@health.ny.gov>, "Felsen, Christina" <Christina_Felsen@URMC.Rochester.edu>, Patricia Ryan -MDH- <patricia.ryan@maryland.gov>, "Crum, David (CDC maryland.gov)" <david.crum@maryland.gov>, Gretchen Rothrock <grothrock@ceip.us>, Pam Daily <pdaily@ceip.us>, Joelle Nadle <jnadle@ceip.us>, "Chai, Shua (CDC cdph.ca.gov)" <shua.chai@cdph.ca.gov>, "Reingold, Arthur MD (CDC berkeley.edu)" <reingold@berkeley.edu>, "Sosin, Daniel (CDC state.nm.us)" <Daniel.Sosin@state.nm.us>, "Lathrop, Sarah" <slathrop@salud.unm.edu>, "Lynfield, Ruth (CDC state.mn.us)" <Ruth.Lynfield@state.mn.us>, "Como-Sabetti, Kathy (MDH)" <kathy.como-sabetti@state.mn.us>, "Eikmeier, Dana (MDH)" <dana.eikmeier@state.mn.us>, Paula Clogher <paula.clogher@yale.edu>, Kim Yousey-Hindes <kimberly.yousey-hindes@yale.edu>, "Plano, Julie" <julie.colburn@yale.edu>, "Kevin_Popham@urmc.rochester.edu" <Kevin_Popham@urmc.rochester.edu>
Cc: "Nolen, Leisha (CDC/DDID/NCEZID/DPEI)" <xdf8@cdc.gov>, "Susan M. Conner"

<ZKV0@cdc.gov>, "Langley, Gayle E. (CDC/DDID/NCEZID/DFWED)" <fez7@cdc.gov>, "Lee, Justin (CDC/DDID/NCEZID/DSR)" <psd8@cdc.gov>, "Armstrong, Gregory (CDC/DDID/NCEZID/OD)" <gca3@cdc.gov>, "Taylor, Christopher A. (CDC/DDID/NCIRD/DVD)" <iyq3@cdc.gov>, "Bressler, Sara S. (CDC/DDID/NCEZID/DPEI)" <xbe9@cdc.gov>
Subject: EIP vaccine breakthrough project call agenda and materials (May 6)

Meeting information
Day/Date: Thursday, May 6
Time: 1:00-2:00pm Eastern time
Location: Teams (information below)

Meeting agenda

1. Roll call
2. Status and timeline updates from each site
3. Finalize REDCap database (**please review attached materials prior to the call**)
4. Use of site-specific data for other analyses
5. Defining authorship
6. Wrap-up and next steps

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United States (Toll-free)
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From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Thu, 15 Jul 2021 18:07:32 +0000
To: Pam Daily;Bressler, Sara S. (CDC/DDID/NCEZID/DPEI)
Cc: Brenna Hall;Reingold, Arthur MD (CDC berkeley.edu);Gretchen Rothrock;Chai, Shua (CDC cdph.ca.gov);Mariah S Wood;Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD)
Subject: RE: A few Question about Data collection for the Breakthrough study

Pam.

I apologize for the delay in getting back to you. Sara is working on an SOP or instruction manual to pull together previously circulated materials and provide additional information regarding inclusion and matching criteria and variable definitions. In general, we will use the COVID-NET criteria for symptoms and underlying medical conditions since most EIP sites are comfortable and familiar with those. We plan to circulate a draft document next week for review and discussion on our next project call.

Pending that, I will try to address your specific questions below:

1. Would a person who received a moderna dose and a Pfizer dose be considered fully vaccinated? Or only if 2 doses of the same product
    a. The 2 doses need to be from the same product
2. The field "**overweight**" – should we use a BMI number or other terminology if mentioned in the chart (obese, obesity, morbid or severe obesity, other term)?
    a. COVID-NET collects a specific BMI and also records "obesity" if it is reported in the medical record.
    b. Our variable is confusing because the variable name is "overweight" but the operational definition refers to obesity. Since we do not separately record BMI, I will suggest we use this variable to note if the patient is obese based on a recorded BMI ≥30 or obesity being noted in their medical record.
3. For the field symptom status- should we mark Y only if one or more of the listed symptoms (#36-49) are present?
    a. Yes, mark "Y" if there are symptoms listed. There may be cases where you know the patient is symptomatic but you are not able to mark the exact symptoms. In that case you can mark "Y" for symptom status and not mark any of the specific symptoms below.
4. For the field "Hospitalization related to SARS-CoV-2 infection (as best understood)" are there specific parts of the medical record to consistently review- discharge diagnoses, admission notes (?) and/or chief complaint?
    a. The best source for this information should be the discharge summary and/or diagnosis codes. If that is not available, you can look at the admission note and/or an infectious diseases consult note. If they were performed as part of the public health investigation, you can also use information from interviews with the healthcare provider but we do not expect you to perform those for the purpose of the project.

5. For the field "Death Related to SARS-CoV-2 Infection (As best understood)" are there specific criteria to review to determine this? Discharge diagnosis, death summary, other sources to review?
    a. The best source for this information should be the death certificate or autopsy report. If those are not available and the patient was hospitalized, you can also look at the discharge/death summary and/or an infectious diseases consult note. If they were performed as part of the public health investigation, you can also use information from interviews with the medical examiner/coroner or healthcare provider but we do not expect you to perform those for the purpose of the project.
6. Noted that the casestatus field doesn't include a response for controls- what should be enter for this field for control records?
    a. "Controls" are the "Unvaccinated cases, included". We also have options for "Unvaccinated cases, not included" and "Not a case" because some sites wanted options to put those in the database although we do not need those data.

Please let us know if you have additional questions.

Thanks,
Marc

From: Pam Daily <pdaily@ceip.us>
Sent: Friday, July 9, 2021 2:58 PM
To: Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) <xbe9@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Brenna Hall <bhall@ceip.us>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Gretchen Rothrock <grothrock@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Mariah S Wood <Mariah.S.Wood@kp.org>
Subject: A few Question about Data collection for the Breakthrough study

Hi Marc and Sara,

After the study call today Brenna and I reviewed all of the data collection elements and came up with questions about a few fields. Just to be sure that we are using the most updated description of the data elements –I've attached the most recent version that we have (dated 05-11).

Questions:

1. Would a person who received a moderna dose and a Pfizer dose be considered fully vaccinated? Or only if 2 doses of the same product
2. The field "**overweight**" – should we use a BMI number or other terminology if mentioned in the chart (obese, obesity, morbid or severe obesity, other term)?
3. For the field symptom status- should we mark Y only if one or more of the listed symptoms (#36-49) are present?
4. For the field "Hospitalization related to SARS-CoV-2 infection (as best understood)" are there specific parts of the medical record to consistently review- discharge diagnoses, admission notes (?) and/or chief complaint?

5. For the field "Death Related to SARS-CoV-2 Infection (As best understood)" are there specific criteria to review to determine this? Discharge diagnosis, death summary, other sources to review?
6. Noted that the casestatus field doesn't include a response for controls- what should be enter for this field for control records?

   Thank you, some of these fields will be extracted from the EMR so I would like to give the data analyst the best instructions possible.

   Best, Pam

Pam Daily Kirley
California Emerging Infections Program
Viral Respiratory Diseases Project Manager

From: Felsen, Christina
Sent: Wed, 12 May 2021 20:22:47 +0000
To: Nolen, Leisha (CDC/DDID/NCEZID/DPEI);Popham, Kevin;Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Subject: RE: Access to EIP vaccine breakthrough REDCap database

Hey Leisha,
Thanks for the quick reply and the info. Yes, we can definitely do that. We have experience importing into REDCap; just wanted to double check what your preferred output method was as for other projects like COVID-NET, we send a SAS file via SAMS.

Thanks again!
Christina

From: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>
Sent: Wednesday, May 12, 2021 4:09 PM
To: Popham, Kevin <Kevin_Popham@URMC.Rochester.edu>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Subject: [EXT] RE: Access to EIP vaccine breakthrough REDCap database

Hi Christina (Again!!),

We would have you download the CSV file from you REDCap instance and then upload it into our REDCap instance. It is actually quite simple. I have attached our guide. If you have problems or questions we can plan a time to have a call.

Leisha

From: Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>
Sent: Wednesday, May 12, 2021 11:25 AM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Popham, Kevin <Kevin_Popham@URMC.Rochester.edu>
Subject: RE: Access to EIP vaccine breakthrough REDCap database

Hi Marc,
For Rochester, please include the following in our DAG:

Christina Felsen
Kevin Popham

Both Kevin of us already have SAMS access.

We were planning on using our instance of REDCap for this project. If we do that, how will you expect data to be transmitted – output file via SAMS or uploaded directly into the CDC instance of REDCap?

Thank you,
Christina

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Sent: Wednesday, May 12, 2021 2:47 PM
To: Allison Roebling <aroebling@gaeip.org>; kopeno@gaeip.org; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Schmoll, Emma (CDC state.co.us) <emma.schmoll@state.co.us>; Alden, Nisha (CDC state.co.us) <nisha.alden@state.co.us>; isaac.armistead@state.co.us; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; Gretchen Rothrock <grothrock@ceip.us>; Pam Daily <pdaily@ceip.us>; Joelle Nadle <jnadle@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Sosin, Daniel (CDC state.nm.us) <Daniel.Sosin@state.nm.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; Como-Sabetti, Kathy (MDH) <kathy.como-sabetti@state.mn.us>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>; Clogher, Paula <paula.clogher@yale.edu>; Yousey-Hindes, Kimberly (CDC yale.edu) <kimberly.yousey-hindes@yale.edu>; Plano, Julie <julie.colburn@yale.edu>; Popham, Kevin <Kevin_Popham@URMC.Rochester.edu>
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) <xbe9@cdc.gov>
Subject: [EXT] Access to EIP vaccine breakthrough REDCap database

We are creating Data Access Groups to provide each site the ability to enter, upload, and view your data in the combined EIP vaccine breakthrough REDCap database.

Please provide the name(s) of staff from your site that will enter or upload data into the CDC database. They will require CDC SAMS access.

Let us know if you have questions.

Thanks again,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Pam Daily
Sent: Thu, 20 May 2021 20:52:22 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI)
Subject: RE: Access to EIP vaccine breakthrough REDCap database

Hi Marc, We are hiring a new Surveillance Officer who will need access, but I don't have a name yet. For now, please add me to the DAG group, and I will send the contact information for the new SO when they are on board.
Thanks, Pam

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Wednesday, May 12, 2021 11:47 AM
To: Allison Roebling <aroebling@gaeip.org>; kopeno@gaeip.org; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Schmoll, Emma (CDC state.co.us) <emma.schmoll@state.co.us>; Alden, Nisha (CDC state.co.us) <nisha.alden@state.co.us>; isaac.armistead@state.co.us; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; Gretchen Rothrock <grothrock@ceip.us>; Pam Daily <pdaily@ceip.us>; Joelle Nadle <jnadle@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Sosin, Daniel (CDC state.nm.us) <Daniel.Sosin@state.nm.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; Como-Sabetti, Kathy (MDH) <kathy.como-sabetti@state.mn.us>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>; Clogher, Paula <paula.clogher@yale.edu>; Yousey-Hindes, Kimberly (CDC yale.edu) <kimberly.yousey-hindes@yale.edu>; Plano, Julie <julie.colburn@yale.edu>; Kevin_Popham@urmc.rochester.edu
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) <xbe9@cdc.gov>
Subject: Access to EIP vaccine breakthrough REDCap database

We are creating Data Access Groups to provide each site the ability to enter, upload, and view your data in the combined EIP vaccine breakthrough REDCap database.

Please provide the name(s) of staff from your site that will enter or upload data into the CDC database. They will require CDC SAMS access.

Let us know if you have questions.

Thanks again,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team

COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Chai, Shua@CDPH
Sent: Wed, 10 Mar 2021 20:42:40 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Subject: RE: Additional option for call to discuss revised protocol for EIP vaccine breakthrough project

Pls see below

Shua Chai, MD, MPH
Science and Policy Advisor
Division of Communicable Disease Control
California Department of Public Health
(470) 553-4078
Shua.Chai@cdph.ca.gov

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Sent: Wednesday, March 10, 2021 12:38 PM
To: linda.niccolai@yale.edu; Melissa.Sutton@dhsoha.state.or.us; keipp.talbot@vumc.org; Chai, Shua@CDPH <Shua.Chai@cdph.ca.gov>; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; aroebling@gaeip.org; dana.eikmeier@state.mn.us; tiffanie.m.markus@vumc.org
Subject: Additional option for call to discuss revised protocol for EIP vaccine breakthrough project

Please let me know your availability during the following days and times:

Eastern time	Friday, March 12	Monday, March 15	Tuesday, March 16	Wednesday, March 17	Thursday, March 18
1:00-2:00pm	Y		Y		Y
2:00-3:00pm	Y			Y	Y

Thanks to those who have already responded.

Marc

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Wednesday, March 10, 2021 10:48 AM
To: linda.niccolai@yale.edu; Melissa.Sutton@dhsoha.state.or.us; keipp.talbot@vumc.org; Chai, Shua@CDPH <Shua.Chai@cdph.ca.gov>; Bamberg - CDPHE Contractor, Wendy

<wendy.bamberg@state.co.us>; aroebling@gaeip.org; dana.eikmeier@state.mn.us; tiffanie.m.markus@vumc.org

Subject: Call to discuss revised protocol for EIP vaccine breakthrough project

EIP vaccine breakthrough project working group.

I would like to schedule a call to discuss a revised protocol and next steps.

Please let me know your availability during the following days and times:

Eastern time	Monday, March 15	Tuesday, March 16	Wednesday, March 17	Thursday, March 18
1:00-2:00pm				
2:00-3:00pm				

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

From: Ed Beardsworth
Sent: Fri, 16 Jul 2021 17:56:45 -0700
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Subject: Re: Breakthrough covid and immune compromise

Thank you, Marc, for your quick and thoughtful response.

Just saw this in Wash. Post. High hopes for the upcoming meeting!
Hard to see much of a downside to giving the 3rd shot to immunocompromised patients.

https://www.washingtonpost.com/health/2021/07/15/covid-booster-shots-immunocompromised/
CDC advisers to consider additional coronavirus dose for immunocompromised patients (ICP)

Also seeing more comments in the news about breakthrough covid in ICP.

The two references on vaccine effectiveness do speak of underlying conditions, but without any specfic regard to ICP. Appears doubtful that people in trials were specifically queried on treatments leading to IC.

On 7/13/21 7:03 PM, Fischer, Marc (CDC/DDID/NCEZID/DPEI) wrote:
Mr. Beardsworth.

Thank you for your email. I am sorry to hear that you do not have detectable antibodies after vaccination. While antibodies are an important means of protection against SARS-CoV-2 infection, they are not the only one. Despite the lack of antibodies, you still may have derived some protection against infection or severe disease.

CDC guidance says that if you have a condition or are taking medications that weaken your immune system, you may not be fully protected even if you are fully vaccinated. You should talk to your healthcare provider. Even after vaccination, you may need to continue taking additional precautions. More information is at When You've Been Fully Vaccinated | CDC.

Our national surveillance for vaccine breakthrough infections receives some information on persons with underlying medical conditions or therapies. However, the best information on the protection provided by vaccines for people with certain underlying conditions will come from clinical studies that evaluate how well the vaccine works. More information is at How CDC Measures COVID-19 Vaccine Effectiveness | CDC and COVID-19 Vaccine Effectiveness Research | CDC.

I have also forwarded your inquiry to CDC-INFO for a more complete response regarding what CDC is doing to monitor vaccine effectiveness and breakthrough infections. If you have additional questions, you can contact CDC-INFO by calling 1-800-CDC-INFO (800-232-4636) or submitting a webform inquiry at www.cdc.gov/info.

Sincerely,

Marc Fischer, MD, MPH
Centers for Disease Control and Prevention

From: Ed Beardsworth <edbeards@ufto.com>
Sent: Tuesday, July 13, 2021 2:11 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Subject: Breakthrough covid and immune compromise

You are listed on a CDC paper on Breakthrough cases. I hope you can respond to my query.

[redacted]

Any organ transplant patient, any one taking cancer treatments or other drugs will block the production of (spike protein) antibodies will have this this problem, but it seems unlikely that many people know about it.

Is anyone tracking whether "breakthru infections" are correlated with this situation?

Edward Beardsworth
Palo Alto, CA
650-722-0540

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Tue, 15 Jun 2021 23:17:19 +0000
To: Rivera, Maria I. (CDC/DDNID/NCCDPHP/DRH)
Cc: CDC IMS 2019 NCOV Response Epi TF Communications Team
Subject: RE: Breakthrough q: FW: [EXT] Second dose completion
Attachments: Thompson 2021. MMWR. COVID VE in first responders.pdf, Tenforde 2021. MMWR. COVID VE against hospitalization.pdf, Tenforde 2021. MMWR. COVID VE in older adults.pdf, Pilishvili 2021. MMWR. HCP VE study.pdf

Maria.

For the purposes of national surveillance, a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after receipt of all recommended doses of an FDA-authorized COVID-19 vaccine. We do not include or collect information regarding cases that occur among people who are partially vaccinated.

Data regarding vaccine effectiveness and hospitalization among people who are partially vaccinated are available from several vaccine effectiveness studies. Attached are some examples.

Thanks,
Marc

From: Rivera, Maria I. (CDC/DDNID/NCCDPHP/DRH) <wux6@cdc.gov>
Sent: Tuesday, June 15, 2021 2:04 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: CDC IMS 2019 NCOV Response Epi TF Communications Team <eocevent101@cdc.gov>
Subject: FW: Breakthrough q: FW: [EXT] Second dose completion
Importance: High

Hi Marc,

Please see the media inquiry directed to us from public affairs.

Can you confirm whether or not the breakthrough cases reported from states may include partial vaccination? I have not heard about these being tracked separately anywhere, but wanted to make sure we were accurate in saying that the reported breakthrough cases are exclusively among fully vaccinated people.

Thanks!
Maria

From: Fowlie, Kate (CDC/DDID/NCEZID/OD) <hvz3@cdc.gov>
Sent: Tuesday, June 15, 2021 4:42 PM
To: Reed, Jasmine (CDC/OD/OADC) <pvz1@cdc.gov>; Rivera, Maria I. (CDC/DDNID/NCCDPHP/DRH)

<wux6@cdc.gov>
Subject: FW: Breakthrough q: FW: [EXT] Second dose completion
Importance: High

Sorry this is coming to you late, but this needs to go to Epi TF do we have ay response for this reporter? Deadline is today 8 pm EST
And one additional question – do you track new cases, hospitalizations or deaths among people who have been partially vaccinated? I know you track breakthrough cases of hospitalizations and deaths among people who've been fully vaccinated, but I haven't come across that for people who are partially vaccinated.

If not, I have sent her to the breakthrough cases page.

Thanks,

Kate Fowlie
CDC Public Affairs
404-639-4538 (office)
404-314-2111 (cell)
KFowlie@cdc.gov

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <hok4@cdc.gov>
Sent: Tuesday, June 15, 2021 3:46 PM
To: Fowlie, Kate (CDC/DDID/NCEZID/OD) <hvz3@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>; Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: RE: Breakthrough q: FW: [EXT] Second dose completion

[redacted]

From: Ho, Catherine <CHo@sfchronicle.com>
Sent: Monday, June 14, 2021 7:59 PM
To: Fowlie, Kate (CDC/DDID/NCEZID/OD) <hvz3@cdc.gov>
Subject: Re: [EXT] Second dose completion

Hi Kate, I wanted to check if that 90% rate (the % of people who've gotten their 1st dose but not yet their 2nd dose) has changed since last week? If so, what's the most updated number?

And one additional question – do you track new cases, hospitalizations or deaths among people who have been partially vaccinated? I know you track breakthrough cases of hospitalizations and deaths among people who've been fully vaccinated, but I haven't come across that for people who are partially vaccinated.

My deadline is Tuesday, 6/15, at 8pm ET/5pm PT.

Thanks,
Catherine

From: "Fowlie, Kate (CDC/DDID/NCEZID/OD)" <hvz3@cdc.gov>
Date: Tuesday, June 8, 2021 at 2:23 PM
To: "Ho, Catherine" <CHo@sfchronicle.com>
Subject: RE: [EXT] Second dose completion

Hi, the last time I checked it was at about 8% in early May
We don't have county-level second dose completion but we do have county vaccination rates here (not to be confused with second dose completion):
https://covid.cdc.gov/covid-data-tracker/#vaccinations-county-view

Kate Fowlie
CDC Public Affairs
404-639-4538 (office)
404-314-2111 (cell)
KFowlie@cdc.gov

From: Ho, Catherine <CHo@sfchronicle.com>
Sent: Tuesday, June 8, 2021 5:15 PM
To: Fowlie, Kate (CDC/DDID/NCEZID/OD) <hvz3@cdc.gov>
Subject: Re: [EXT] Second dose completion

Sorry, two more questions occurred to me after I sent that last email:
-What time period was the 92% for? I recall that was around April, just wanted to double check.
-Do you have vaccine completion status data by county? If so, can you share that or point me to the best place to download that?

Thanks,
Catherine

From: "Ho, Catherine" <CHo@sfchronicle.com>
Date: Tuesday, June 8, 2021 at 2:05 PM
To: "Fowlie, Kate (CDC/DDID/NCEZID/OD)" <hvz3@cdc.gov>
Subject: Re: [EXT] Second dose completion

Got it, thank you Kate. Do you happen to have vaccine completion status data (that 90% in U.S.) for each state as well? I'm looking for California's rate.

Thanks,
Catherine

From: "Fowlie, Kate (CDC/DDID/NCEZID/OD)" <hvz3@cdc.gov>
Date: Tuesday, June 8, 2021 at 1:16 PM
To: "Ho, Catherine" <CHo@sfchronicle.com>
Subject: [EXT] Second dose completion

Hi Catherine,

Here's the info you requested:

According to CDC data on COVID-19 vaccine completion status through June 7, among people with sufficient time to get second doses, about 90% have received their second dose. This is slight decrease from 92% earlier this year and not unexpected. We'd anticipate a greater proportion of delayed or missed second doses with priority populations expanding beyond those for whom adherence was easiest because the second dose was offered at their work site (healthcare providers) or their residence (long-term care facility residents).
For background, you can find a previous CDC report on second dose completion earlier in the year here.

Let me know if you need anything else,

Kate Fowlie
CDC Public Affairs
404-639-4538 (office)
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KFowlie@cdc.gov

Inquiry Description:

Hi,

This is Catherine Ho at the SF Chronicle. Hope you're well. I'm looking into a potential story on whether people are skipping their second dose of the covid vaccine. Does the CDC track how many people have gotten their first dose but did not get their second dose within the recommended period of time? If so, can you share those figures with me or point me to where I can find them? How much of a concern is this (or is not a major concern)? If there is a gap, has that gap narrowed, widened or stayed the same over time?

My deadline is Thursday, June 10, at 5pm PT.

Thanks

Catherine

--

Catherine Ho

Reporter

San Francisco Chronicle

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C: [redacted]

cho@sfchronicle.com

Twitter: @Cat_Ho

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
March 29, 2021

Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021

Mark G. Thompson, PhD[1]; Jefferey L. Burgess, MD[2]; Allison L. Naleway, PhD[3]; Harmony L. Tyner, MD[4]; Sarang K. Yoon, DO[5]; Jennifer Meece, PhD[6]; Lauren E.W. Olsho, PhD[7]; Alberto J. Caban-Martinez, DO[8]; Ashley Fowlkes, ScD[1]; Karen Lutrick, PhD[2]; Jennifer L. Kuntz, PhD[3]; Kayan Dunnigan, MPH[9]; Marilyn J. Odean, MS[10]; Kurt T. Hegmann, MD[5]; Elisha Stefanski[6]; Laura J. Edwards, MPH[7]; Natasha Schaefer-Solle, PhD[8]; Lauren Grant, MS[1]; Katherine Ellingson, PhD[2]; Holly C. Groom, MPH[3]; Tnelda Zunie[9]; Matthew S. Thiese, PhD[5]; Lynn Ivacic[6]; Meredith G. Wesley, MPH[7]; Julie Mayo Lamberte, MSPH[1]; Xiaoxiao Sun, PhD[2]; Michael E. Smith[9]; Andrew L. Phillips, MD[5]; Kimberly D. Groover, PhD[7]; Young M. Yoo, MSPH[1]; Joe Gerald, MD[2]; Rachel T. Brown, PhD[5]; Meghan K. Herring, MPH[7]; Gregory Joseph, MPH[1]; Shawn Beitel, MSc[2]; Tyler C. Morrill, MS[7]; Josephine Mak, MPH[1]; Patrick Rivers, MPP[2]; Katherine M. Harris, PhD[7]; Danielle R. Hunt, PhD[7]; Melissa L. Arvay, PhD[1]; Preeta Kutty, MD[1]; Alicia M. Fry, MD[1]; Manjusha Gaglani, MBBS[9,11]

Messenger RNA (mRNA) BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) COVID-19 vaccines have been shown to be effective in preventing symptomatic COVID-19 in randomized placebo-controlled Phase III trials (*1*,*2*); however, the benefits of these vaccines for preventing asymptomatic and symptomatic SARS-CoV-2 (the virus that causes COVID-19) infection, particularly when administered in real-world conditions, is less well understood. Using prospective cohorts of health care personnel, first responders, and other essential and frontline workers* in eight U.S. locations during December 14, 2020–March 13, 2021, CDC routinely tested for SARS-CoV-2 infections every week regardless of symptom status and at the onset of symptoms consistent with COVID-19–associated illness. Among 3,950 participants with no previous laboratory documentation of SARS-CoV-2 infection, 2,479 (62.8%) received both recommended mRNA doses and 477 (12.1%) received only one dose of mRNA vaccine.† Among unvaccinated participants, 1.38 SARS-CoV-2 infections were confirmed by reverse transcription–polymerase chain reaction (RT-PCR) per 1,000 person-days.§ In contrast, among fully immunized (≥14 days after second dose) persons, 0.04 infections per 1,000 person-days were reported, and among partially immunized (≥14 days after first dose and before second dose) persons, 0.19 infections per 1,000 person-days were reported. Estimated mRNA vaccine effectiveness for prevention of infection, adjusted for study site, was 90% for full immunization and 80% for partial immunization. These findings indicate that authorized mRNA COVID-19 vaccines are effective for preventing SARS-CoV-2 infection, regardless of symptom status, among working-age adults in real-world conditions. COVID-19 vaccination is recommended for all eligible persons.

HEROES-RECOVER¶ is a network of longitudinal cohorts in eight locations (Phoenix, Tucson, and other areas in Arizona; Miami, Florida; Duluth, Minnesota; Portland, Oregon; Temple, Texas; and Salt Lake City, Utah) that share a common protocol and methods.** Enrollment in this longitudinal

* Occupational categories: primary health care personnel (physicians, physician assistants, nurse practitioners, and dentists), other allied health care personnel (nurses, therapists, technicians, medical assistants, orderlies, and all other persons providing clinical support in inpatient or outpatient settings), first responders (firefighters, law enforcement, corrections, and emergency medical technicians), other essential and frontline workers (workers in hospitality, delivery, and retail; teachers; and all other occupations that require contact within 3 feet of the public, customers, or coworkers as a routine part of their job).

† An additional five participants received the Janssen COVID-19 vaccine (Johnson & Johnson), resulting in 2,961 vaccinated participants.

§ Person-days is an estimate of the time-at-risk (to SARS-CoV-2 infection) that each participant contributed to the study.

¶ Arizona Healthcare, Emergency Response and Other Essential Workers Surveillance Study (HEROES); Research on the Epidemiology of SARS-CoV-2 in Essential Response Personnel (RECOVER).

** https://preprints.jmir.org/preprint/28925

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

study started in July 2020 and included health care personnel, first responders, and other essential and frontline workers who provided written consent. The current vaccine effectiveness analytic study period began on the first day of vaccine administration at study sites (December 14–18, 2020) and ended March 13, 2021. Active surveillance for symptoms consistent with COVID-19–associated illness (defined as fever, chills, cough, shortness of breath, sore throat, diarrhea, muscle aches, or loss of smell or taste) occurred through weekly text messages, e-mails, and direct participant or medical record reports. Participants self-collected a midturbinate nasal swab weekly, regardless of COVID-19–associated illness symptom status and collected an additional nasal swab and saliva specimen at the onset of COVID-19–associated illness. Specimens shipped on cold packs were tested by RT-PCR assay at Marshfield Clinic Laboratory (Marshfield, Wisconsin) to determine SARS-CoV-2 infections (PCR-confirmed infection). Receipt of COVID-19 vaccines was documented by multiple methods: by self-report in electronic surveys, by telephone interviews, and through direct upload of vaccine card images at all sites; records were also extracted from electronic medical records at the Minnesota, Oregon, Texas, and Utah sites. Among 5,077 participants, those with laboratory documentation of SARS-CoV-2 infection before enrollment starting in July 2020 (608) or identified as part of longitudinal surveillance up until the first day of vaccine administration (240) were excluded. Another 279 were excluded because of low participation (i.e., failed to complete surveillance for ≥20% of study weeks and did not contribute COVID-19–associated illness specimens). Overall, 3,950 participants in the vaccine effectiveness analytic sample were analyzed.

Hazard ratios were estimated by the Andersen-Gill extension of the Cox proportional hazards model, which accounted for time-varying vaccination status. Hazard ratios of unvaccinated person-days to partial immunization person-days (≥14 days after first dose and before second dose) and to full immunization person-days (≥14 days after second dose) were calculated separately. The 13 person-days between vaccine administration and partial or full immunization were considered excluded at-risk person-time because immunity was considered to be indeterminate. Unadjusted vaccine effectiveness was calculated as 100% × (1–hazard ratio). An adjusted vaccine effectiveness model included study site as a covariate. All analyses were conducted with SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[††]

[††] 45 C.F.R. part 46; 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d), 5 U.S.C. Sect. 552a, 44 U.S.C. Sect. 3501 et seq.

Approximately one half of the participants (52.6%) were from the Arizona study sites (Table 1). Participants included physicians and other clinical leads (primary health care personnel) (21.1%), nurses and other allied health care personnel (33.8%), first responders (21.6%), and other essential and frontline workers (23.5%). The majority of participants were female (62.1%), aged 18–49 years (71.9%), White (86.3%), and non-Hispanic (82.9%) and had no chronic medical conditions (68.9%). Over the 13-week study period, adherence to weekly surveillance reporting and specimen collection was high (median = 100%; interquartile range = 82%–100%).

Most (75.0%) of the participants received one or more doses of vaccine during the study period (Table 1); 477 (12.1%) received their first dose and had not received their second dose by the end of the study period, and 2,479 (62.8%) received both recommended mRNA vaccine doses. Most (60.5%) were vaccinated with their first dose during December 14–31, 2020. Both mRNA vaccine products were administered to participants in all locations but differed in the timing of their availability; 62.7% of vaccinated participants received Pfizer-BioNTech vaccine and 29.6% received Moderna vaccine. The remaining mRNA vaccines (7.7%) are pending product verification. Receipt of at least one vaccine dose was significantly higher among participants who were female, White, non-Hispanic, health care personnel, or living in Minnesota or Oregon; vaccine coverage was lowest in Florida (Table 1).

SARS-CoV-2 infection was diagnosed by RT-PCR in 205 (5.2%) participants; PCR-confirmed infection was significantly higher among participants who were male, Hispanic, first responders, or living in Arizona, Florida, and Texas (Table 1). The majority of PCR-confirmed infections were identified by weekly specimens (58.0%), whereas 42.0% were identified from specimens collected at the onset of COVID-19–associated illness. Nonetheless, the majority (87.3%) of PCR-confirmed infections were associated with symptoms consistent with COVID-19–associated illness. The remaining PCR-confirmed infections were associated with other symptoms not part of the COVID-19–associated illness definition (e.g., headache, fatigue, and rhinorrhea) (2.0%) or no symptoms (10.7%). Only 22.9% of PCR-confirmed infections were medically attended, including two hospitalizations; no deaths occurred.

During the 116,657 person-days when participants were unvaccinated, 161 PCR-confirmed infections were identified (incidence rate = 1.38/1,000 person-days). During the 13 days after first-dose or second-dose vaccination when immune status was considered indeterminate (67,483 person-days), 33 PCR-confirmed infections were identified and excluded from the outcome. Two sources of partially immunized person-days were reported. Five PCR-confirmed infections were reported

TABLE 1. Characteristics of health care personnel, first responders, and other essential and frontline workers with reverse transcription–polymerase chain reaction (RT-PCR)–confirmed SARS-CoV-2 infections and percentage receiving one or more doses of a messenger RNA (mRNA) COVID-19 vaccine — eight U.S. locations, December 14, 2020–March 13, 2021

Characteristic	No. (column %) of participants	SARS-CoV-2 infection		Unvaccinated	Vaccinated with ≥1 dose*	
		No. (row %)	p-value†	No. (row %)	No. (row %)	p-value†
Total	**3,950 (100)**	**205 (5.2)**	—	**989 (25.0)**	**2,961 (75.0)**	—
Cohort location						
Phoenix, Arizona	555 (14.1)	39 (7.0§)	<0.001	147 (26.5)	408 (73.5)	<0.001
Tucson, Arizona	1,199 (30.4)	79 (6.6§)		325 (27.1)	874 (72.9)	
Other, Arizona	320 (8.1)	16 (5.0§)		88 (27.5)	232 (72.5)	
Miami, Florida	221 (5.6)	19 (8.6§)		118 (53.4)	103 (46.6¶)	
Duluth, Minnesota	448 (11.3)	12 (2.7)		47 (10.5)	401 (89.5¶)	
Portland, Oregon	468 (11.8)	4 (0.9)		61 (13.0)	407 (87.0¶)	
Temple, Texas	289 (7.3)	18 (6.2§)		71 (24.6)	218 (75.4)	
Salt Lake City, Utah	450 (11.4)	18 (4.0)		132 (29.3)	318 (70.7)	
Sex						
Female**	2,453 (62.1)	109 (4.4)	0.007	529 (21.6)	1,924 (78.4)	<0.001
Male	1,497 (37.9)	96 (6.4)		460 (30.7)	1,037 (69.3)	
Age group, yrs						
18–49	2,839 (71.9)	146 (5.1)	0.83	735 (25.9)	2,104 (74.1)	0.48
≥50	1,111 (28.1)	59 (5.3)		254 (22.9)	857 (77.1)	
Race						
White	3,408 (86.3)	178 (5.2)	0.92	814 (23.9)	2,594 (76.1)	<0.001
Other	542 (13.7)	27 (5.0)		175 (32.3)	367 (67.7)	
Ethnicity						
Hispanic/Latino	674 (17.1)	57 (8.5)	<0.001	236 (35.0)	438 (65.0)	<0.001
Other	3,276 (82.9)	148 (4.5)		753 (23.0)	2,523 (77.0)	
Occupation††						
Primary health care personnel	835 (21.1)	16 (1.9)	<0.001	65 (7.8)	770 (92.2)	<0.001
Other allied health care personnel	1,335 (33.8)	67 (5.0)		242 (18.1)	1,093 (81.9)	
First responder	852 (21.6)	75 (8.8)		308 (36.2)	544 (63.8)	
Other essential and frontline worker	928 (23.5)	47 (5.1)		374 (40.3)	554 (59.7)	
Chronic condition						
None§§	2,723 (68.9)	141 (5.2)	0.92	711 (26.1)	2,012 (73.9)	0.11
≥1	1,227 (31.1)	64 (5.2)		278 (22.7)	949 (77.3)	

* Total vaccinated includes 477 participants who received one mRNA vaccine dose, 2,479 who received two mRNA vaccine doses, and five who received a single dose of the Janssen COVID-19 vaccine (Johnson & Johnson); these five participants contribute unvaccinated person-days until their vaccination date and then no longer contribute to the analysis.

† P-values (comparing the percentage of SARS-CoV-2 infections by sociodemographic and health categories and comparing the percentage vaccinated by these categories) calculated using Pearson's chi-square test (cells with ≥5 observations) or Fisher's exact test (cells with <5 observations).

§ Sites identified had statistically higher percentages of participants with RT-PCR-confirmed SARS-CoV-2 infections than the other sites (chi-square = 31.0, p-value <0.001).

¶ The Minnesota and Oregon sites had the statistically highest percentage vaccinated with at least one vaccine dose. Florida had the lowest (chi-square = 62.1, p-value <0.001).

** 10 participants were missing biologic sex and were imputed as the more common category (female).

†† Occupational categories: primary health care personnel (physicians, physician assistants, nurse practitioners, and dentists), other allied health care personnel (nurses, therapists, technicians, medical assistants, orderlies, and all other persons providing clinical support in inpatient or outpatient settings), first responders (firefighters, law enforcement, corrections, and emergency medical technicians), other essential and frontline workers (workers in hospitality, delivery, and retail; teachers; and all other occupations that require contact within 3 feet of the public, customers, or coworkers as a routine part of their job).

§§ 133 participants who did not respond to the self-report question were imputed as "none."

during 15,868 person-days ≥14 days after their first dose among those who did not receive their second dose during the study period; three PCR-confirmed infections were reported during 25,988 person-days ≥14 days after the first dose and through receipt of the second dose. Taken together, this represents eight PCR-confirmed infections that occurred during 41,856 person-days with partial immunization (≥14 days after first dose and before second dose; incidence rate = 0.19/1,000 person-days). Three PCR-confirmed infections occurred during 78,902 person-days with full immunization (≥14 days after second dose; incidence rate = 0.04/1,000 person-days). Estimated adjusted vaccine effectiveness of full immunization was 90% (95% confidence interval [CI] = 68%–97%); vaccine effectiveness of partial immunization was 80% (95% CI = 59%–90%) (Table 2). In sensitivity analyses, inclusion of other covariates (sex, age, ethnicity, and occupation) were entered individually in the vaccine effectiveness model; the change in vaccine effectiveness point estimates were <3%.

TABLE 2. Person-days, SARS-CoV-2 infections, and vaccine effectiveness among health care personnel, first responders, and other essential and frontline workers, by messenger RNA immunization status — eight U.S. locations, December 14, 2020–March 13, 2021

COVID-19 immunization status	Person-days	SARS-CoV-2 infections		Unadjusted vaccine effectiveness*	Adjusted vaccine effectiveness*,†
		No.	Incidence rate per 1,000 person-days	% (95% CI)	% (95% CI)
Unvaccinated	116,657	161	1.38	N/A	N/A
Partially immunized	41,856	8	0.19	82 (62–91)	80 (59–90)
≥14 days after receiving first dose only§	15,868	5	0.32		
≥14 days after first dose through receipt of second dose	25,988	3	0.12		
Fully immunized					
≥14 days after second dose	78,902	3	0.04	91 (73–97)	90 (68–97)

Abbreviations: CI = confidence interval; N/A = not applicable.
* Vaccine effectiveness was estimated using a Cox proportional hazards model accounting for time-varying immunization status.
† Hazard ratio is adjusted for study site.
§ Participants received first dose but had not received second dose by the end of the study period.

Discussion

Prospective cohorts of health care personnel, first responders, and other essential and frontline workers over 13 weeks in eight U.S. locations confirmed that authorized mRNA COVID-19 vaccines (Pfizer-BioNTech's BNT162b2 and Moderna's mRNA-1273) are highly effective in real-world conditions. Vaccine effectiveness of full immunization with two doses of mRNA vaccines was 90% (95% CI = 68%–97%) against RT-PCR–confirmed SARS-CoV-2 infection. These findings are consistent with those from the mRNA vaccines' Phase III trials (*1*,*2*) and recent observational studies of the mRNA vaccine effectiveness against severe COVID-19 (*3*). The findings complement and expand upon these preceding reports by demonstrating that the vaccines can also reduce the risk for infection regardless of COVID-19–associated illness symptom status (*4*,*5*). Reducing the risk for transmissible infection, which can occur among persons with asymptomatic infection or among persons several days before symptoms onset (*6*), is especially important among health care personnel, first responders, and other essential and frontline workers given their potential to transmit the virus through frequent close contact with patients and the public.

Partial immunization (≥14 days after first dose but before second dose) provided preventive benefits with vaccine effectiveness of 80%. This finding is similar to an analysis of Phase III trial results (*1*,*2*,*7*) and two other recent estimates of vaccine effectiveness for partial immunization with Pfizer-BioNTech vaccine among health care personnel, including a vaccine effectiveness (≥21 days after first dose) of 72% (95% CI = 58%–86%) against PCR-confirmed infection identified by routine testing in the United Kingdom (*4*) and a vaccine effectiveness (>14 days after first dose) of 60% (95% CI = 38%–74%) against PCR-confirmed infection identified by records review in Israel (*5*). This finding is also consistent with early descriptive findings of SARS-CoV-2 employee and clinical testing results by mRNA vaccination status in the United States (*8*,*9*).

Summary

What is already known about this topic?

Messenger RNA (mRNA) COVID-19 vaccines have been shown to be effective in preventing symptomatic SARS-CoV-2 infection in randomized placebo-controlled Phase III trials.

What is added by this report?

Prospective cohorts of 3,950 health care personnel, first responders, and other essential and frontline workers completed weekly SARS-CoV-2 testing for 13 consecutive weeks. Under real-world conditions, mRNA vaccine effectiveness of full immunization (≥14 days after second dose) was 90% against SARS-CoV-2 infections regardless of symptom status; vaccine effectiveness of partial immunization (≥14 days after first dose but before second dose) was 80%.

What are the implications for public health practice?

Authorized mRNA COVID-19 vaccines are effective for preventing SARS-CoV-2 infection in real-world conditions. COVID-19 vaccination is recommended for all eligible persons.

The findings in this report are subject to at least three limitations. First, vaccine effectiveness point estimates should be interpreted with caution given the moderately wide CIs attributable in part to the limited number of postimmunization PCR-confirmed infections observed. Second, this also precluded making product-specific vaccine effectiveness estimates and limited the ability to adjust for potential confounders; however, effects were largely unchanged when study site was included in an adjusted vaccine effectiveness model and when adjusted for sex, age, ethnicity, and occupation separately in sensitivity analyses. Finally, self-collection of specimens and delays in shipments could reduce sensitivity of virus detection by PCR (*10*); if this disproportionately affected those who received the vaccine (e.g., because of possible vaccine

attenuation of virus shedding), vaccine effectiveness would be overestimated.

The scientific rigor of these findings is enhanced by its prospective design and the participants' very high adherence to weekly specimen collection. As the study progresses, viruses will be genetically characterized to examine the viral features of breakthrough infections. Given that there is uncertainty related to the number of days required to develop immunity postvaccination (*3–5,7*), future research examining vaccine effectiveness at different intervals is warranted.

These interim vaccine effectiveness findings for both Pfizer-BioNTech's and Moderna's mRNA vaccines in real-world conditions complement and expand upon the vaccine effectiveness estimates from other recent studies (*3–5*) and demonstrate that current vaccination efforts are resulting in substantial preventive benefits among working-age adults. They reinforce CDC's recommendation of full 2-dose immunization with mRNA vaccines. COVID-19 vaccination is recommended for all eligible persons, which currently varies by location in the United States.

Acknowledgments

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Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥65 Years — United States, January–March 2021

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Adults aged ≥65 years are at increased risk for severe outcomes from COVID-19 and were identified as a priority group to receive the first COVID-19 vaccines approved for use under an Emergency Use Authorization (EUA) in the United States (*1–3*). In an evaluation at 24 hospitals in 14 states,* the effectiveness of partial or full vaccination† with Pfizer-BioNTech or Moderna vaccines against COVID-19–associated hospitalization was assessed among adults aged ≥65 years. Among 417 hospitalized adults aged ≥65 years (including 187 case-patients and 230 controls), the median age was 73 years, 48% were female, 73% were non-Hispanic White, 17% were non-Hispanic Black, 6% were Hispanic, and 4% lived in a long-term care facility. Adjusted vaccine effectiveness (VE) against COVID-19–associated hospitalization among adults aged ≥65 years was estimated to be 94% (95% confidence interval [CI] = 49%–99%) for full vaccination and 64% (95% CI = 28%–82%) for partial vaccination. These findings are consistent with efficacy determined from clinical trials in the subgroup of adults aged ≥65 years (*4,5*). This multisite U.S. evaluation under real-world conditions suggests that vaccination provided protection against COVID-19–associated hospitalization among adults aged ≥65 years. Vaccination is a critical tool for reducing severe COVID-19 in groups at high risk.

Randomized clinical trials of vaccines that have received an EUA in the United States showed efficacy of 94%–95% in preventing COVID-19–associated illness (*4,5*).§ However, hospitalization is a rare outcome among patients with COVID-19–associated illness of any severity, so most cases detected in the trials did not lead to hospitalization; therefore, the studies had limited power to assess protection against severe COVID-19 among older adults. Postmarketing observational studies are important to assess VE against COVID-19–associated hospitalizations in adults aged ≥65 years under real-world conditions and to strengthen evidence from clinical trials of vaccine efficacy. A standard

* Patients were enrolled from 24 medical centers in 14 states (University of California Los Angeles and Stanford University [California], UCHealth University of Colorado Hospital [Colorado], Johns Hopkins Hospital [Maryland], Beth Israel Deaconess Medical Center and Baystate Medical Center [Massachusetts], University of Michigan, Henry Ford, and St. Joseph [Michigan], Hennepin County Medical Center [Minnesota], Montefiore Healthcare Center [New York], Wake Forest University [North Carolina], Ohio State University [Ohio], Oregon Health & Science University [Oregon], University of Pittsburgh Medical Center, Shadyside, Mercy, Passavant, St. Margaret, and Presbyterian Hospitals [Pennsylvania], Vanderbilt University Medical Center [Tennessee], Baylor Scott & White Medical Center, Temple, Round Rock, Hillcrest/Waco [Texas], and Intermountain Health [Utah]).

† Partially vaccinated is defined as receipt of 1 dose of a 2-dose vaccine series (Pfizer-BioNTech or Moderna vaccines) ≥14 days before illness onset or 2 doses with the second dose received <14 days before illness onset. Fully vaccinated is defined as receipt of both doses of a 2-dose vaccine series, with the second dose received ≥14 days before illness onset.

§ Pfizer-BioNTech and Moderna COVID-19 vaccines are approved for use under an EUA in the United States. The Vaccine Adverse Event Reporting System (VAERS) is used to detect possible signals of adverse events associated with vaccines. Adverse events related to these COVID-19 vaccines can be reported at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/vaccine-adverse-events or https://vaers.hhs.gov/reportevent.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Summary

What is already known about this topic?

Clinical trials suggest high efficacy for COVID-19 vaccines, but evaluation of vaccine effectiveness against severe outcomes in real-world settings and in populations at high risk, including older adults, is needed.

What is added by this report?

In a multistate network of U.S. hospitals during January–March 2021, receipt of Pfizer-BioNTech or Moderna COVID-19 vaccines was 94% effective against COVID-19 hospitalization among fully vaccinated adults and 64% effective among partially vaccinated adults aged ≥65 years.

What are the implications for public health practice?

SARS-CoV-2 vaccines significantly reduce the risk for COVID-19–associated hospitalization in older adults and, in turn, might lead to commensurate reductions in post-COVID conditions and deaths.

approach to postmarketing VE evaluation involves the test-negative design in which vaccine performance is assessed by comparing the odds of antecedent vaccination among case-patients with acute laboratory-confirmed COVID-19 and control-patients without acute COVID-19 (*6*).

During January 1, 2021–March 26, 2021, adults with COVID-19–like illness[¶] admitted to 24 hospitals in 14 states within two networks (the Hospitalized Adult Influenza Vaccine Effectiveness Network [HAIVEN] and the Influenza and Other Viruses in the Acutely Ill [IVY] Network) were enrolled. Patients were eligible if they were aged ≥65 years on the date of hospital admission, received clinical testing for SARS-CoV-2 (the virus that causes COVID-19) by reverse transcription–polymerase chain reaction (RT-PCR) or antigen test within 10 days of illness onset, and had onset of symptoms 0–14 days before admission. Case-patients were those who received one or more positive test results for SARS-CoV-2. Patients meeting eligibility criteria who received negative SARS-CoV-2 RT-PCR test results served as controls. Baseline demographic and health information, details about the current illness, and SARS-CoV-2 testing history were obtained by patient or proxy interviews with trained study personnel and electronic medical record review. Patients or proxies were asked about SARS-CoV-2 vaccination history including number of doses, dates and location of vaccination, and availability of vaccination record cards documenting receipt. Secondary electronic medical records and state immunization registry searches for SARS-CoV-2 vaccination records were conducted during March 26, 2021–April 19, 2021, for all included patients without vaccination record cards to verify reported or unknown vaccination status.

Participants were considered to have received COVID-19 vaccine doses based on documentation by CDC vaccination record card, state immunization registry search, electronic medical record search, or by plausible self-report if they provided vaccination dates and location. Documented record of vaccination dates was used when any potential discordance was identified between self-reported and documented dates. Participants with unverified COVID-19 testing status or vaccination status, or vaccination with Janssen COVID-19 vaccine (Johnson & Johnson), which was in limited use during the evaluation period, were not included. SARS-CoV-2 vaccination status included four categories: 1) unvaccinated, defined as no receipt of any SARS CoV-2 vaccine before illness onset; 2) single-dose vaccinated <14 days before illness, defined as receipt of the first vaccine dose <14 days before COVID-19–like illness onset; 3) partially vaccinated, defined as receipt of 1 dose of a 2-dose vaccination series (Pfizer-BioNTech or Moderna vaccines) ≥14 days before illness onset or 2 doses, with the second dose received <14 days before illness onset[**] (*7*); and 4) fully vaccinated, defined as receipt of both doses of a 2-dose vaccine series, with the second dose received ≥14 days before illness onset. Estimates of VE were calculated by comparing the odds of SARS-CoV-2 vaccination in case-patients and controls using the equation VE = 100% × (1 − odds ratio), determined from logistic regression models (*8*). The 95% CIs were calculated as $1 - CI_{OR}$, where CI_{OR} is the confidence interval of the odds ratio estimates. Models were adjusted a priori for suspected confounders, including U.S. Census region, calendar month, age (as a continuous variable), sex, and race/ethnicity. Other factors were included in the model if they changed the adjusted odds ratio of vaccination by >5%. Primary VE estimates were stratified by partial versus full vaccination. VE for patients reporting illness onset <14 days after receipt of the first dose of a 2-dose vaccine was also assessed. Because protective immunity is unlikely to be achieved immediately after vaccination (*4,5,7*), absence of VE within 14 days of the first dose was used as a proxy indicator of absence of bias in the primary VE estimates (*6*). Statistical analyses were conducted using SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and the other participating institutions and was conducted consistent with applicable federal law and CDC policy.[††]

[¶] IVY Network criteria for COVID-19–like illness included presence of fever, feverishness, cough, sore throat, myalgias, shortness of breath, chest pain, loss of taste, loss of smell, respiratory congestion, increased sputum production, new oxygen saturation <94% on room air, new requirement for invasive or noninvasive mechanical ventilation, or new pulmonary findings on chest imaging consistent with pneumonia. HAIVEN criteria included fever without a known non–COVID-19 cause, new or worsening cough, a change in sputum production, or new or worsening shortness of breath.

[**] Based on postmarketing findings from Israel, where VE was observed at 14 days after vaccination after 1 dose.

[††] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

During January 1–March 26, 2021, 489 patients were eligible for participation, 72 (15%) of whom were excluded for the following reasons: 30 had SARS-CoV-2 testing >10 days after illness onset, 19 were hospitalized >14 days after illness onset, eight had onset of COVID-19–like illness after admission, three received the Janssen COVID-19 vaccine, and 12 had incomplete vaccination verification. Among the 417 patients included in the final analysis (including 187 case-patients and 230 controls), median age was 73 years for case-patients and controls, 48% were female, 17% were non-Hispanic Black, 6% were Hispanic (any race), 48% had one or more earlier hospitalizations in the last year, and 4% lived in a long-term care facility before admission (Table). Among the 187 case-patients, 19 (10%) had received at least 1 dose of Pfizer-BioNTech or Moderna vaccine ≥14 days before illness onset (including 18 [10%] who were partially vaccinated and one [0.5%] who was fully vaccinated) compared with 62 (27%) of 230 test-negative controls (including 44 [19%] and 18 [8%] who were partially and fully vaccinated, respectively). Prevalence of receipt of Pfizer-BioNTech and Moderna vaccines was similar (53% and 47%, respectively, among those vaccinated with ≥1 doses). Adjusted VE for full vaccination using Pfizer-BioNTech or Moderna vaccine was 94% (95% CI = 49%–99%), and adjusted VE for partial vaccination was 64% (95% CI = 28%–82%) (Figure). There was no significant effect for receiving the first dose of a 2-dose COVID-19 vaccine series within 14 days before illness onset (adjusted VE = 3%, 95% CI = −94%–51%).

Discussion

Monitoring the effectiveness of SARS-CoV-2 vaccination under routine public health use and specifically against severe outcomes in patients at higher risk, including older adults, is a high priority. In this multistate analysis of adults aged ≥65 years, receipt of an authorized COVID-19 vaccine was associated with significant protection against COVID-19 hospitalization. Effectiveness was 94% among adults who were fully vaccinated and 64% among adults who were partially vaccinated (i.e., onset of COVID-like illness ≥14 days after the first vaccine dose in a 2-dose series but <14 days after the second dose). These findings are consistent with efficacy determined from clinical trials in the subgroup of adults aged ≥65 years (*4,5*). Early reports from Israel have also documented the real-world effectiveness of SARS-CoV-2 vaccination, including among older adults (*7,9*). However, those postmarketing reports only represented the Pfizer-BioNTech vaccine. In the current report, Pfizer-BioNTech and Moderna vaccine products were equally represented, and approximately one half of the patients were aged ≥75 years, providing evidence of real-world effectiveness of both vaccines against an important measure of severe COVID-19 in older adults. Moreover, in assessing the impact of receiving only a single dose, no significant vaccine effectiveness <14 days after the first dose of a SARS-CoV-2 vaccine was detected. This suggests that bias is unlikely in the primary estimates of vaccine effectiveness from partial and full vaccination. This also highlights the continued risk for severe illness shortly after vaccination, before a protective immune response has been achieved and reinforces the need for vaccinated adults to continue physical distancing and prevention behaviors, such as use of face masks and recommended hand hygiene at least 14 days after the second dose of a 2-dose vaccine. The findings suggest that SARS-CoV-2 vaccines can reduce the risk for COVID-19–associated hospitalization and, as a consequence of preventing severe COVID-19, vaccination might have an impact on post-COVID conditions (e.g., "long COVID") and deaths (*2,10*).

The findings in this report are subject to at least six limitations. First, the CIs for VE estimates were wide because of the small sample size, and the number of participants was too small to assess VE by vaccine product, age group, or underlying conditions. Second, as an interim analysis that included self-reported data, vaccination status might have been misclassified, or participants might have had imperfect recollection of vaccination or illness onset dates. Third, selection bias and residual confounding cannot be excluded. Fourth, although the analysis included hospitalized adults from 14 states, the participants were not geographically representative of the U.S. population. Fifth, the case-control design infers protection based on associations between disease outcome and previous vaccination but cannot establish causation. Finally, duration of VE and VE for nonhospitalized COVID-19 was not assessed.

During January–March 2021, in a multistate network of U.S. hospitals, vaccination was associated with a reduced risk for COVID-19–associated hospitalization among adults aged ≥65 years. These data suggest that continuing to rapidly vaccinate U.S. adults against COVID-19 will likely have a marked impact on COVID-19 hospitalization and might lead to commensurate reductions in post-COVID conditions and deaths (*2,10*).

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TABLE. Characteristics of adults aged ≥65 years with COVID-19–like illness* tested for SARS-CoV-2 infection, by COVID-19 case status† — 24 medical centers in 14 states,§ January–March 2021

Characteristic	Total (N = 417)	Case status, no. (column %) Case-patients (n = 187)	Control participants (n = 230)	p-value
Month of admission				
January	**80 (19)**	52 (28)	28 (12)	<0.01
February	**153 (37)**	74 (40)	79 (34)	
March	**184 (44)**	61 (33)	123 (53)	
U.S. Census region¶				
Northeast	**174 (42)**	61 (33)	113 (49)	<0.01
South	**135 (32)**	77 (41)	58 (25)	
Midwest	**68 (16)**	23 (12)	45 (20)	
West	**40 (10)**	26 (14)	14 (6)	
Age group, yrs				
65–74	**244 (59)**	106 (57)	138 (60)	0.49
≥75	**173 (41)**	81 (43)	92 (40)	
Female sex	**200 (48)**	83 (44)	117 (51)	0.19
Race/Ethnicity				
White, non-Hispanic	**303 (73)**	129 (69)	174 (76)	0.32
Black, non-Hispanic	**70 (17)**	34 (18)	36 (16)	
Other, non-Hispanic	**14 (3)**	9 (5)	5 (2)	
Hispanic, any race	**26 (6)**	12 (6)	14 (6)	
Unknown	**4 (1)**	3 (2)	1 (0.4)	
Medical insurance (missing = 1)				
Yes	**408 (98)**	180 (96)	228 (99)	0.01
No	**8 (2)**	7 (4)	1 (0.4)	
Resident in long-term care facility (missing = 1)**	**16 (4)**	6 (3)	10 (4)	0.55
≥1 previous hospitalization in last year (missing = 12)**	**195 (48)**	63 (35)	132 (59)	<0.01
Received current season influenza vaccination (missing = 18)**	**312 (78)**	134 (76)	178 (80)	0.38
Current tobacco use (missing = 8)**				
Yes	**35 (9)**	8 (4)	27 (12)	<0.01
No	**374 (91)**	174 (96)	200 (88)	
SARS-CoV-2 vaccination status†				
Unvaccinated	**287 (69)**	146 (78)	141 (61)	<0.01
Single-dose vaccinated <14 days before illness onset	**49 (12)**	22 (12)	27 (12)	
Partially vaccinated	**62 (15)**	18 (10)	44 (19)	
Fully vaccinated	**19 (5)**	1 (0.5)	18 (8)	
Vaccine type, if vaccinated (missing = 11)				
Pfizer-BioNTech	**63 (53)**	15 (42)	48 (58)	0.10
Moderna	**56 (47)**	21 (58)	35 (42)	
Admission characteristic				
Days from illness onset to admission, median (IQR)	**3 (1–6)**	4 (1–7)	2 (0–4)	<0.01
Days from illness onset to SARS-CoV-2 testing, median (IQR)	**2 (0–4)**	3 (0–5)	1 (0–4)	<0.01

Abbreviations: HAIVEN = Hospitalized Adult Influenza Vaccine Effectiveness Network; IQR = interquartile range; IVY = Influenza and Other Viruses in the Acutely Ill.

* Clinical criteria for hospitalized COVID-19–like illness varied by hospital network. IVY Network criteria for COVID-19–like illness included presence of fever, feverishness, cough, sore throat, myalgias, shortness of breath, chest pain, loss of taste, loss of smell, respiratory congestion, increased sputum production, new oxygen saturation <94% on room air, new requirement for invasive or noninvasive mechanical ventilation, or new pulmonary findings on chest imaging consistent with pneumonia. HAIVEN criteria included fever without a known non–COVID-19 cause, new or worsening cough, a change in sputum production, or new or worsening shortness of breath.

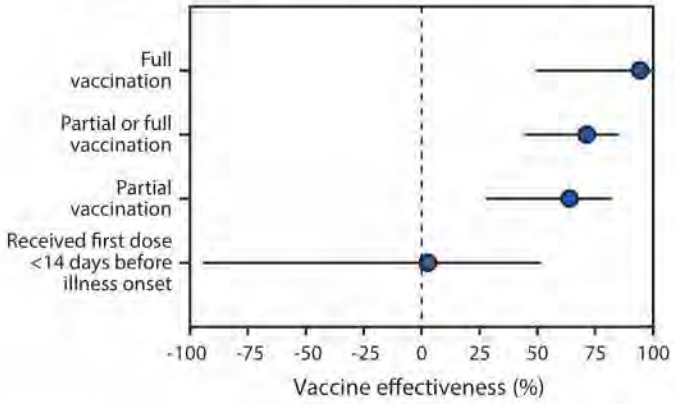
† SARS-CoV-2 vaccination status included the following four categories: 1) unvaccinated, defined as no receipt of any SARS CoV-2 vaccine; 2) single-dose vaccinated <2 weeks before illness onset, defined as receipt of the first vaccine dose within 14 days before onset of COVID-like illness; 3) partially vaccinated, defined as receipt of 1 dose of a 2-dose vaccine series (Pfizer-BioNTech or Moderna) ≥14 days before illness onset or receipt of 2 doses, with the second dose received <14 days before illness onset; 4) fully vaccinated, defined as receipt of both doses of a 2-dose vaccine series, with the second dose received ≥14 days before illness onset.

§ Patients were enrolled from 24 medical centers in 14 states (University of California Los Angeles and Stanford University [California], UCHealth University of Colorado Hospital [Colorado], Johns Hopkins Hospital [Maryland], Beth Israel Deaconess Medical Center and Baystate Medical Center [Massachusetts], University of Michigan, Henry Ford, and St. Joseph [Michigan], Hennepin County Medical Center [Minnesota], Montefiore Healthcare Center [New York], Wake Forest University [North Carolina], Ohio State University [Ohio], Oregon Health & Science University [Oregon], University of Pittsburgh Medical Center, Shadyside, Mercy, Passavant, St. Margaret, and Presbyterian Hospitals [Pennsylvania], Vanderbilt University Medical Center [Tennessee], Baylor Scott & White Medical Center, Temple, Round Rock, Hillcrest/Waco [Texas], and Intermountain Health [Utah]).

¶ *Northeast*: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; *Midwest*: Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; *South*: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia; *West*: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

** Information was obtained by patient or proxy self-report.

FIGURE. Adjusted* vaccine effectiveness (with 95% confidence intervals) against COVID-19 among hospitalized† adults aged ≥65 years, by vaccination status§ — 24 medical centers in 14 states,¶ January–March 2021



Abbreviations: HAIVEN = Hospitalized Adult Influenza Vaccine Effectiveness Network; IVY = Influenza and Other Viruses in the Acutely Ill.

* Vaccine effectiveness estimates were adjusted for U.S. Census region, calendar month, continuous age in years, sex, race and ethnicity (non-Hispanic White, non-Hispanic Black, non-Hispanic other or unknown, or Hispanic of any race), and one or more versus zero self-reported previous hospitalizations in the past year.

† Clinical criteria for hospitalized COVID-19–like illness varied by hospital network. IVY Network criteria for COVID-19–like illness included presence of fever, feverishness, cough, sore throat, myalgias, shortness of breath, chest pain, loss of taste, loss of smell, respiratory congestion, increased sputum production, new oxygen saturation <94% on room air, new invasive or noninvasive ventilation, or new pulmonary findings on chest imaging consistent with pneumonia in the IVY Network; criteria included fever without a known non–COVID-19 cause, new or worsening cough, a change in sputum production, or new or worsening shortness of breath in the HAIVEN network.

§ SARS-CoV-2 vaccination status included the following four categories: 1) unvaccinated, defined as no receipt of any SARS CoV-2 vaccine; 2) first vaccine dose <14 days before illness onset, defined as a single dose of vaccine within 14 days prior to onset of COVID-19–like illness; 3) partially vaccinated, defined as receipt of 1 dose of a 2-dose vaccine series (Pfizer-BioNTech or Moderna) ≥14 days before illness onset or 2 doses with the second dose received <14 days before illness onset); 4) fully vaccinated, defined as receipt of both doses of a 2-dose vaccine series ≥14 days before illness onset.

¶ Patients were enrolled from 24 medical centers in 14 states (University of California Los Angeles and Stanford University [California], UCHealth University of Colorado Hospital [Colorado], Johns Hopkins Hospital [Maryland], Beth Israel Deaconess Medical Center and Baystate Medical Center [Massachusetts], University of Michigan, Henry Ford, and St. Joseph [Michigan], Hennepin County Medical Center [Minnesota], Montefiore Healthcare Center [New York], Wake Forest University [North Carolina], Ohio State University [Ohio], Oregon Health & Science University [Oregon], University of Pittsburgh Medical Center, Shadyside, Mercy, Passavant, St. Margaret, and Presbyterian Hospitals [Pennsylvania], Vanderbilt University Medical Center [Tennessee], Baylor Scott & White Medical Center, Temple, Round Rock, Hillcrest/Waco [Texas], and Intermountain Health [Utah]).

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Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥65 Years — United States, January–March 2021

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Adults aged ≥65 years are at increased risk for severe outcomes from COVID-19 and were identified as a priority group to receive the first COVID-19 vaccines approved for use under an Emergency Use Authorization (EUA) in the United States (*1–3*). In an evaluation at 24 hospitals in 14 states,* the effectiveness of partial or full vaccination† with Pfizer-BioNTech or Moderna vaccines against COVID-19–associated hospitalization was assessed among adults aged ≥65 years. Among 417 hospitalized adults aged ≥65 years (including 187 case-patients and 230 controls), the median age was 73 years, 48% were female, 73% were non-Hispanic White, 17% were non-Hispanic Black, 6% were Hispanic, and 4% lived in a long-term care facility. Adjusted vaccine effectiveness (VE) against COVID-19–associated hospitalization among adults aged ≥65 years was estimated to be 94% (95% confidence interval [CI] = 49%–99%) for full vaccination and 64% (95% CI = 28%–82%) for partial vaccination. These findings are consistent with efficacy determined from clinical trials in the subgroup of adults aged ≥65 years (*4,5*). This multisite U.S. evaluation under real-world conditions suggests that vaccination provided protection against COVID-19–associated hospitalization among adults aged ≥65 years. Vaccination is a critical tool for reducing severe COVID-19 in groups at high risk.

Randomized clinical trials of vaccines that have received an EUA in the United States showed efficacy of 94%–95% in preventing COVID-19–associated illness (*4,5*).§ However, hospitalization is a rare outcome among patients with COVID-19–associated illness of any severity, so most cases detected in the trials did not lead to hospitalization; therefore, the studies had limited power to assess protection against severe COVID-19 among older adults. Postmarketing observational studies are important to assess VE against COVID-19–associated hospitalizations in adults aged ≥65 years under real-world conditions and to strengthen evidence from clinical trials of vaccine efficacy. A standard approach to postmarketing VE evaluation involves the test-negative design in which vaccine performance is assessed by comparing the odds of antecedent vaccination among case-patients with acute laboratory-confirmed COVID-19 and control-patients without acute COVID-19 (*6*).

During January 1, 2021–March 26, 2021, adults with COVID-19–like illness¶ admitted to 24 hospitals in 14 states within two networks (the Hospitalized Adult Influenza Vaccine Effectiveness Network [HAIVEN] and the Influenza and Other Viruses in the Acutely Ill [IVY] Network) were enrolled.

* Patients were enrolled from 24 medical centers in 14 states (University of California Los Angeles and Stanford University [California], UCHealth University of Colorado Hospital [Colorado], Johns Hopkins Hospital [Maryland], Beth Israel Deaconess Medical Center and Baystate Medical Center [Massachusetts], University of Michigan, Henry Ford, and St. Joseph [Michigan], Hennepin County Medical Center [Minnesota], Montefiore Healthcare Center [New York], Wake Forest University [North Carolina], Ohio State University [Ohio], Oregon Health & Science University [Oregon], University of Pittsburgh Medical Center, Shadyside, Mercy, Passavant, St. Margaret, and Presbyterian Hospitals [Pennsylvania], Vanderbilt University Medical Center [Tennessee], Baylor Scott & White Medical Center, Temple, Round Rock, Hillcrest/Waco [Texas], and Intermountain Health [Utah]).

† Partially vaccinated is defined as receipt of 1 dose of a 2-dose vaccine series (Pfizer-BioNTech or Moderna vaccines) ≥14 days before illness onset or 2 doses with the second dose received <14 days before illness onset. Fully vaccinated is defined as receipt of both doses of a 2-dose vaccine series, with the second dose received ≥14 days before illness onset.

§ Pfizer-BioNTech and Moderna COVID-19 vaccines are approved for use under an EUA in the United States. The Vaccine Adverse Event Reporting System (VAERS) is used to detect possible signals of adverse events associated with vaccines. Adverse events related to these COVID-19 vaccines can be reported at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/vaccine-adverse-events or https://vaers.hhs.gov/reportevent.html.

¶ IVY Network criteria for COVID-19–like illness included presence of fever, feverishness, cough, sore throat, myalgias, shortness of breath, chest pain, loss of taste, loss of smell, respiratory congestion, increased sputum production, new oxygen saturation <94% on room air, new requirement for invasive or noninvasive mechanical ventilation, or new pulmonary findings on chest imaging consistent with pneumonia. HAIVEN criteria included fever without a known non–COVID-19 cause, new or worsening cough, a change in sputum production, or new or worsening shortness of breath.

Summary

What is already known about this topic?

Clinical trials suggest high efficacy for COVID-19 vaccines, but evaluation of vaccine effectiveness against severe outcomes in real-world settings and in populations at high risk, including older adults, is needed.

What is added by this report?

In a multistate network of U.S. hospitals during January–March 2021, receipt of Pfizer-BioNTech or Moderna COVID-19 vaccines was 94% effective against COVID-19 hospitalization among fully vaccinated adults and 64% effective among partially vaccinated adults aged ≥65 years.

What are the implications for public health practice?

SARS-CoV-2 vaccines significantly reduce the risk for COVID-19–associated hospitalization in older adults and, in turn, might lead to commensurate reductions in post-COVID conditions and deaths.

Patients were eligible if they were aged ≥65 years on the date of hospital admission, received clinical testing for SARS-CoV-2 (the virus that causes COVID-19) by reverse transcription–polymerase chain reaction (RT-PCR) or antigen test within 10 days of illness onset, and had onset of symptoms 0–14 days before admission. Case-patients were those who received one or more positive test results for SARS-CoV-2. Patients meeting eligibility criteria who received negative SARS-CoV-2 RT-PCR test results served as controls. Baseline demographic and health information, details about the current illness, and SARS-CoV-2 testing history were obtained by patient or proxy interviews with trained study personnel and electronic medical record review. Patients or proxies were asked about SARS-CoV-2 vaccination history including number of doses, dates and location of vaccination, and availability of vaccination record cards documenting receipt. Secondary electronic medical records and state immunization registry searches for SARS-CoV-2 vaccination records were conducted during March 26, 2021–April 19, 2021, for all included patients without vaccination record cards to verify reported or unknown vaccination status.

Participants were considered to have received COVID-19 vaccine doses based on documentation by CDC vaccination record card, state immunization registry search, electronic medical record search, or by plausible self-report if they provided vaccination dates and location. Documented record of vaccination dates was used when any potential discordance was identified between self-reported and documented dates. Participants with unverified COVID-19 testing status or vaccination status, or vaccination with Janssen COVID-19 vaccine (Johnson & Johnson), which was in limited use during the evaluation period, were not included. SARS-CoV-2 vaccination status included four categories: 1) unvaccinated, defined as no receipt of any SARS CoV-2 vaccine before illness onset; 2) single-dose vaccinated <14 days before illness, defined as receipt of the first vaccine dose <14 days before COVID-19–like illness onset; 3) partially vaccinated, defined as receipt of 1 dose of a 2-dose vaccination series (Pfizer-BioNTech or Moderna vaccines) ≥14 days before illness onset or 2 doses, with the second dose received <14 days before illness onset** (*7*); and 4) fully vaccinated, defined as receipt of both doses of a 2-dose vaccine series, with the second dose received ≥14 days before illness onset. Estimates of VE were calculated by comparing the odds of SARS-CoV-2 vaccination in case-patients and controls using the equation VE = 100% × (1 − odds ratio), determined from logistic regression models (*8*). The 95% CIs were calculated as $1 - CI_{OR}$, where CI_{OR} is the confidence interval of the odds ratio estimates. Models were adjusted a priori for suspected confounders, including U.S. Census region, calendar month, age (as a continuous variable), sex, and race/ethnicity. Other factors were included in the model if they changed the adjusted odds ratio of vaccination by >5%. Primary VE estimates were stratified by partial versus full vaccination. VE for patients reporting illness onset <14 days after receipt of the first dose of a 2-dose vaccine was also assessed. Because protective immunity is unlikely to be achieved immediately after vaccination (*4,5,7*), absence of VE within 14 days of the first dose was used as a proxy indicator of absence of bias in the primary VE estimates (*6*). Statistical analyses were conducted using SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and the other participating institutions and was conducted consistent with applicable federal law and CDC policy.††

During January 1–March 26, 2021, 489 patients were eligible for participation, 72 (15%) of whom were excluded for the following reasons: 30 had SARS-CoV-2 testing >10 days after illness onset, 19 were hospitalized >14 days after illness onset, eight had onset of COVID-19–like illness after admission, three received the Janssen COVID-19 vaccine, and 12 had incomplete vaccination verification. Among the 417 patients included in the final analysis (including 187 case-patients and 230 controls), median age was 73 years for case-patients and controls, 48% were female, 17% were non-Hispanic Black, 6% were Hispanic (any race), 48% had one or more earlier hospitalizations in the last year, and 4% lived in a long-term care facility before admission (Table). Among the 187 case-patients, 19 (10%) had received at least 1 dose of Pfizer-BioNTech or Moderna vaccine ≥14 days before illness onset (including 18 [10%] who were partially vaccinated and one [0.5%] who was fully vaccinated) compared with 62 (27%) of 230 test-negative controls (including 44 [19%] and 18 [8%] who were partially and fully vaccinated, respectively). Prevalence

** Based on postmarketing findings from Israel, where VE was observed at 14 days after vaccination after 1 dose.

†† 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

TABLE. Characteristics of adults aged ≥65 years with COVID-19–like illness* tested for SARS-CoV-2 infection, by COVID-19 case status† — 24 medical centers in 14 states,§ January–March 2021

Characteristic	Total (N = 417)	Case status, no. (column %) Case-patients (n = 187)	Control participants (n = 230)	p-value
Month of admission				
January	**80 (19)**	52 (28)	28 (12)	<0.01
February	**153 (37)**	74 (40)	79 (34)	
March	**184 (44)**	61 (33)	123 (53)	
U.S. Census region¶				
Northeast	**174 (42)**	61 (33)	113 (49)	<0.01
South	**135 (32)**	77 (41)	58 (25)	
Midwest	**68 (16)**	23 (12)	45 (20)	
West	**40 (10)**	26 (14)	14 (6)	
Age group, yrs				
65–74	**244 (59)**	106 (57)	138 (60)	0.49
≥75	**173 (41)**	81 (43)	92 (40)	
Female sex	**200 (48)**	83 (44)	117 (51)	0.19
Race/Ethnicity				
White, non-Hispanic	**303 (73)**	129 (69)	174 (76)	0.32
Black, non-Hispanic	**70 (17)**	34 (18)	36 (16)	
Other, non-Hispanic	**14 (3)**	9 (5)	5 (2)	
Hispanic, any race	**26 (6)**	12 (6)	14 (6)	
Unknown	**4 (1)**	3 (2)	1 (0.4)	
Medical insurance (missing = 1)				
Yes	**408 (98)**	180 (96)	228 (99)	0.01
No	**8 (2)**	7 (4)	1 (0.4)	
Resident in long-term care facility (missing = 1)**	**16 (4)**	6 (3)	10 (4)	0.55
≥1 previous hospitalization in last year (missing = 12)**	**195 (48)**	63 (35)	132 (59)	<0.01
Received current season influenza vaccination (missing = 18)**	**312 (78)**	134 (76)	178 (80)	0.38
Current tobacco use (missing = 8)**				
Yes	**35 (9)**	8 (4)	27 (12)	<0.01
No	**374 (91)**	174 (96)	200 (88)	
SARS-CoV-2 vaccination status†				
Unvaccinated	**287 (69)**	146 (78)	141 (61)	<0.01
Single-dose vaccinated <14 days before illness onset	**49 (12)**	22 (12)	27 (12)	
Partially vaccinated	**62 (15)**	18 (10)	44 (19)	
Fully vaccinated	**19 (5)**	1 (0.5)	18 (8)	
Vaccine type, if vaccinated (missing = 11)				
Pfizer-BioNTech	**63 (53)**	15 (42)	48 (58)	0.10
Moderna	**56 (47)**	21 (58)	35 (42)	
Admission characteristic				
Days from illness onset to admission, median (IQR)	**3 (1–6)**	4 (1–7)	2 (0–4)	<0.01
Days from illness onset to SARS-CoV-2 testing, median (IQR)	**2 (0–4)**	3 (0–5)	1 (0–4)	<0.01

Abbreviations: HAIVEN = Hospitalized Adult Influenza Vaccine Effectiveness Network; IQR = interquartile range; IVY = Influenza and Other Viruses in the Acutely Ill.

* Clinical criteria for hospitalized COVID-19–like illness varied by hospital network. IVY Network criteria for COVID-19–like illness included presence of fever, feverishness, cough, sore throat, myalgias, shortness of breath, chest pain, loss of taste, loss of smell, respiratory congestion, increased sputum production, new oxygen saturation <94% on room air, new requirement for invasive or noninvasive mechanical ventilation, or new pulmonary findings on chest imaging consistent with pneumonia. HAIVEN criteria included fever without a known non–COVID-19 cause, new or worsening cough, a change in sputum production, or new or worsening shortness of breath.

† SARS-CoV-2 vaccination status included the following four categories: 1) unvaccinated, defined as no receipt of any SARS CoV-2 vaccine; 2) single-dose vaccinated <2 weeks before illness onset, defined as receipt of the first vaccine dose within 14 days before onset of COVID-like illness; 3) partially vaccinated, defined as receipt of 1 dose of a 2-dose vaccine series (Pfizer-BioNTech or Moderna) ≥14 days before illness onset or receipt of 2 doses, with the second dose received <14 days before illness onset; 4) fully vaccinated, defined as receipt of both doses of a 2-dose vaccine series, with the second dose received ≥14 days before illness onset.

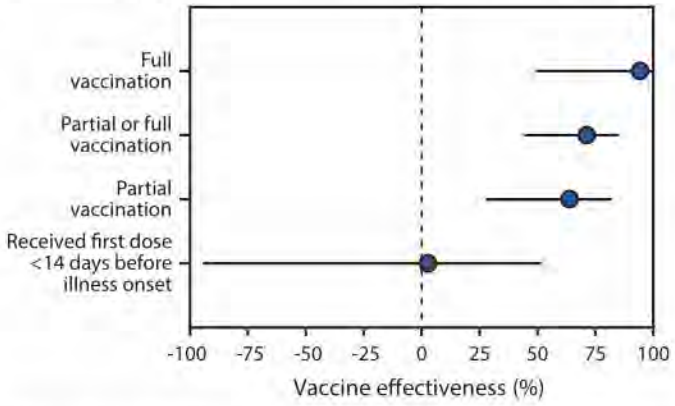
§ Patients were enrolled from 24 medical centers in 14 states (University of California Los Angeles and Stanford University [California], UCHealth University of Colorado Hospital [Colorado], Johns Hopkins Hospital [Maryland], Beth Israel Deaconess Medical Center and Baystate Medical Center [Massachusetts], University of Michigan, Henry Ford, and St. Joseph [Michigan], Hennepin County Medical Center [Minnesota], Montefiore Healthcare Center [New York], Wake Forest University [North Carolina], Ohio State University [Ohio], Oregon Health & Science University [Oregon], University of Pittsburgh Medical Center, Shadyside, Mercy, Passavant, St. Margaret, and Presbyterian Hospitals [Pennsylvania], Vanderbilt University Medical Center [Tennessee], Baylor Scott & White Medical Center, Temple, Round Rock, Hillcrest/Waco [Texas], and Intermountain Health [Utah]).

¶ *Northeast*: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; *Midwest*: Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; *South*: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia; *West*: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

** Information was obtained by patient or proxy self-report.

of receipt of Pfizer-BioNTech and Moderna vaccines was similar (53% and 47%, respectively, among those vaccinated with ≥1 doses). Adjusted VE for full vaccination using Pfizer-BioNTech or Moderna vaccine was 94% (95% CI = 49%–99%), and adjusted VE for partial vaccination was 64% (95% CI = 28%–82%) (Figure). There was no significant effect for receiving the first dose of a 2-dose COVID-19 vaccine series within 14 days before illness onset (adjusted VE = 3%, 95% CI = –94%–51%).

FIGURE. Adjusted* vaccine effectiveness (with 95% confidence intervals) against COVID-19 among hospitalized† adults aged ≥65 years, by vaccination status§ — 24 medical centers in 14 states,¶ January–March 2021



Abbreviations: HAIVEN = Hospitalized Adult Influenza Vaccine Effectiveness Network; IVY = Influenza and Other Viruses in the Acutely Ill.

* Vaccine effectiveness estimates were adjusted for U.S. Census region, calendar month, continuous age in years, sex, race and ethnicity (non-Hispanic White, non-Hispanic Black, non-Hispanic other or unknown, or Hispanic of any race), and one or more versus zero self-reported previous hospitalizations in the past year.

† Clinical criteria for hospitalized COVID-19–like illness varied by hospital network. IVY Network criteria for COVID-19–like illness included presence of fever, feverishness, cough, sore throat, myalgias, shortness of breath, chest pain, loss of taste, loss of smell, respiratory congestion, increased sputum production, new oxygen saturation <94% on room air, new invasive or noninvasive ventilation, or new pulmonary findings on chest imaging consistent with pneumonia in the IVY Network; criteria included fever without a known non–COVID-19 cause, new or worsening cough, a change in sputum production, or new or worsening shortness of breath in the HAIVEN network.

§ SARS-CoV-2 vaccination status included the following four categories: 1) unvaccinated, defined as no receipt of any SARS CoV-2 vaccine; 2) first vaccine dose <14 days before illness onset, defined as a single dose of vaccine within 14 days prior to onset of COVID-19–like illness; 3) partially vaccinated, defined as receipt of 1 dose of a 2-dose vaccine series (Pfizer-BioNTech or Moderna) ≥14 days before illness onset or 2 doses with the second dose received <14 days before illness onset); 4) fully vaccinated, defined as receipt of both doses of a 2-dose vaccine series ≥14 days before illness onset.

¶ Patients were enrolled from 24 medical centers in 14 states (University of California Los Angeles and Stanford University [California], UCHealth University of Colorado Hospital [Colorado], Johns Hopkins Hospital [Maryland], Beth Israel Deaconess Medical Center and Baystate Medical Center [Massachusetts], University of Michigan, Henry Ford, and St. Joseph [Michigan], Hennepin County Medical Center [Minnesota], Montefiore Healthcare Center [New York], Wake Forest University [North Carolina], Ohio State University [Ohio], Oregon Health & Science University [Oregon], University of Pittsburgh Medical Center, Shadyside, Mercy, Passavant, St. Margaret, and Presbyterian Hospitals [Pennsylvania], Vanderbilt University Medical Center [Tennessee], Baylor Scott & White Medical Center, Temple, Round Rock, Hillcrest/Waco [Texas], and Intermountain Health [Utah]).

Discussion

Monitoring the effectiveness of SARS-CoV-2 vaccination under routine public health use and specifically against severe outcomes in patients at higher risk, including older adults, is a high priority. In this multistate analysis of adults aged ≥65 years, receipt of an authorized COVID-19 vaccine was associated with significant protection against COVID-19 hospitalization. Effectiveness was 94% among adults who were fully vaccinated and 64% among adults who were partially vaccinated (i.e., onset of COVID-like illness ≥14 days after the first vaccine dose in a 2-dose series but <14 days after the second dose). These findings are consistent with efficacy determined from clinical trials in the subgroup of adults aged ≥65 years (*4*,*5*). Early reports from Israel have also documented the real-world effectiveness of SARS-CoV-2 vaccination, including among older adults (*7*,*9*). However, those postmarketing reports only represented the Pfizer-BioNTech vaccine. In the current report, Pfizer-BioNTech and Moderna vaccine products were equally represented, and approximately one half of the patients were aged ≥75 years, providing evidence of real-world effectiveness of both vaccines against an important measure of severe COVID-19 in older adults. Moreover, in assessing the impact of receiving only a single dose, no significant vaccine effectiveness <14 days after the first dose of a SARS-CoV-2 vaccine was detected. This suggests that bias is unlikely in the primary estimates of vaccine effectiveness from partial and full vaccination. This also highlights the continued risk for severe illness shortly after vaccination, before a protective immune response has been achieved and reinforces the need for vaccinated adults to continue physical distancing and prevention behaviors, such as use of face masks and recommended hand hygiene at least 14 days after the second dose of a 2-dose vaccine. The findings suggest that SARS-CoV-2 vaccines can reduce the risk for COVID-19–associated hospitalization and, as a consequence of preventing severe COVID-19, vaccination might have an impact on post-COVID conditions (e.g., "long COVID") and deaths (*2*,*10*).

The findings in this report are subject to at least six limitations. First, the CIs for VE estimates were wide because of the small sample size, and the number of participants was too small to assess VE by vaccine product, age group, or underlying conditions. Second, as an interim analysis that included self-reported data, vaccination status might have been misclassified, or participants might have had imperfect recollection of vaccination or illness onset dates. Third, selection bias and residual confounding cannot be excluded. Fourth, although the analysis included hospitalized adults from 14 states, the participants were not geographically representative of the U.S. population. Fifth, the case-control design infers protection based on associations between disease outcome and previous

vaccination but cannot establish causation. Finally, duration of VE and VE for nonhospitalized COVID-19 was not assessed.

During January–March 2021, in a multistate network of U.S. hospitals, vaccination was associated with a reduced risk for COVID-19–associated hospitalization among adults aged ≥65 years. These data suggest that continuing to rapidly vaccinate U.S. adults against COVID-19 will likely have a marked impact on COVID-19 hospitalization and might lead to commensurate reductions in post-COVID conditions and deaths (*2*,*10*).

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Interim Estimates of Vaccine Effectiveness of Pfizer-BioNTech and Moderna COVID-19 Vaccines Among Health Care Personnel — 33 U.S. Sites, January–March 2021

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Throughout the COVID-19 pandemic, health care personnel (HCP) have been at high risk for exposure to SARS-CoV-2, the virus that causes COVID-19, through patient interactions and community exposure (*1*). The Advisory Committee on Immunization Practices recommended prioritization of HCP for COVID-19 vaccination to maintain provision of critical services and reduce spread of infection in health care settings (*2*). Early distribution of two mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) to HCP allowed assessment of the effectiveness of these vaccines in a real-world setting. A test-negative case-control study is underway to evaluate mRNA COVID-19 vaccine effectiveness (VE) against symptomatic illness among HCP at 33 U.S. sites across 25 U.S. states. Interim analyses indicated that the VE of a single dose (measured 14 days after the first dose through 6 days after the second dose) was 82% (95% confidence interval [CI] = 74%–87%), adjusted for age, race/ethnicity, and underlying medical conditions. The adjusted VE of 2 doses (measured ≥7 days after the second dose) was 94% (95% CI = 87%–97%). VE of partial (1-dose) and complete (2-dose) vaccination in this population is comparable to that reported from clinical trials and recent observational studies, supporting the effectiveness of mRNA COVID-19 vaccines against symptomatic disease in adults, with strong 2-dose protection.

A test-negative design case-control study of mRNA COVID-19 VE is underway, with HCP being enrolled at 33 sites across 25 U.S. states; the planned interim analysis presented in this report includes data collected during January–March 2021.* A majority (75%) of enrolled HCP worked at acute care hospitals (including emergency departments), 25% worked in outpatient or specialty clinics, and <1% worked in long-term care facilities and urgent care clinics. HCP with the potential for exposure to SARS-CoV-2 through direct patient contact or for indirect exposure (e.g., through infectious materials) were eligible for enrollment.† Case-patients and control participants (controls) were identified through routine employee testing performed based on site-specific occupational health practices. HCP with a positive SARS-CoV-2 polymerase chain reaction (PCR) or antigen-based test result and at least one COVID-19–like illness symptom§ were enrolled as case-patients, and HCP with a negative SARS-CoV-2 PCR test result, regardless of symptoms, were eligible for enrollment as controls. Controls were frequency matched to case-patients (aiming for a ratio of three controls per case-patient) by site and week of test. HCP who reported having received a positive SARS-CoV-2

* https://www.cdc.gov/vaccines/covid-19/downloads/hcp-early-phase-protocol-508.pdf
† https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html
§ Health care personnel are considered symptomatic if one or more of the following signs and symptoms are present 14 days before or after the test date: fever (documented ≥100.4°F [38.0°C] or subjective), chills, cough (dry or productive), shortness of breath, chest pain or tightness, fatigue or malaise, sore throat, headache, runny nose, congestion, muscle aches, nausea or vomiting, diarrhea, abdominal pain, altered sense of smell or taste, loss of appetite, or red or bruised toes or feet.

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PCR or antigen-based test result >60 days earlier (i.e., with a previous SARS-CoV-2 infection) were excluded. Information on demographics, COVID-19–like illness symptoms within 14 days before or after the testing date, and presence of underlying conditions and risk factors for severe COVID-19[¶] were collected through HCP interviews or self-completed surveys. Medical records were reviewed to collect data on SARS-CoV-2 test dates, type, and results and on medical care sought for COVID-19–like illness. Vaccination records, including dates and type of COVID-19 vaccine received, were obtained from occupational health or other verified sources (e.g., vaccine card, state registry, or medical record).

HCP were defined as unvaccinated if they had not received any COVID-19 vaccine doses or had received their first dose after the test date. The interval of 0–13 days from receipt of the first dose was defined as the time before first dose vaccine effect. The effectiveness of a single dose was measured during the interval from 14 days after the first dose through 6 days after the second dose. Because of the potential for vaccine-related reactions to influence HCP testing behaviors, sensitivity analyses of single-dose VE were conducted 1) excluding participants tested within 0–2 days of receiving the second dose and 2) measuring VE before receiving the second dose. Effectiveness of 2 doses was measured ≥7 days after the receipt of the second dose, consistent with the Pfizer-BioNTech clinical trial procedure (*3*). Sensitivity analyses measuring 2-dose effectiveness ≥14 days after the second dose were conducted, consistent with the Moderna clinical trial procedure (*4*). Conditional logistic regression was used to estimate matched odds ratios (mORs) adjusted for age, race/ethnicity, and presence of underlying conditions. VE was estimated as 100% × (1–mOR) for 1 or 2 doses, compared with no doses. Because of the small sample size, analyses could not be stratified by COVID-19 vaccine type. All statistical analyses were conducted using SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[**]

As of March 18, 2021, 623 case-patients and 1,220 controls had been enrolled. The median ages of case-patients and controls were 38 years (range = 19–69 years) and 37 years (range = 19–76 years), respectively (Table 1). The majority of HCP (60% of case-patients and 64% of controls) worked in occupational categories with substantial anticipated direct patient contact and were aged 19–49 years (75% and 76%, respectively), female (84% and 82%, respectively), and non-Hispanic White (64% and 70%, respectively). Underlying conditions associated with increased risk for severe COVID-19 were reported by 77% of case-patients and 75% of controls. Case-patients were significantly more likely than controls to have fever (40% versus 23%, p<0.001), cough (56% versus 22%, p<0.001), or shortness of breath (26% versus 7%, p<0.001); 5% of case-patients and 14% of controls reported only mild symptoms (sore throat, headache, runny nose, or congestion; p<0.001); 17% of controls reported no symptoms. Only 12 (2%) case-patients and 10 (1%) controls had severe illness requiring hospitalization, and no deaths occurred in either group.

Ten percent of case-patients and 20% of controls had received 1 dose of COVID-19 vaccine ≥14 days before the test date, and 3% of case-patients and 15% of controls had received 2 doses ≥7 days before the test date (Table 2). Among vaccinated persons, 76% of case-patients and 78% of controls received the Pfizer-BioNTech vaccine; the remainder received the Moderna vaccine. The adjusted single-dose VE was 82% (95% CI = 74%–87%) and was similar for both 1-dose sensitivity analyses (before dose 2: VE = 74%, 95% CI = 62%–82%; excluding days 0–2 after dose 2: VE = 78%, 95% CI = 68%–84%). The adjusted 2-dose VE was 94% (95% CI = 87%–97%); effectiveness ≥14 days after the second dose was similar (VE = 90%, 95% CI = 77%–96%).

Discussion

This multisite test-negative design case-control study found that authorized mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) are highly effective against symptomatic COVID-19 among HCP. Effectiveness of a complete 2-dose regimen of these vaccines was estimated to be 94%, consistent with findings from two clinical trials (*3,4*). Although the case definition applied in this study was broader than that used in both clinical trials (*3,4*), 93% and 88% of cases included in this study met the respective Pfizer-BioNTech and Moderna trial case definitions. The results are also consistent with findings from an observational study among the general adult population from Israel (*5*), two cohort studies among HCP from the United Kingdom,[††] and recently reported interim results from a U.S. cohort evaluation among HCP and frontline workers (*6*).

Effectiveness of a single dose, estimated to be 82% in this report, has also been demonstrated in phase III trials and recent observational studies. The estimated effectiveness found in this report is higher than estimates of single-dose effectiveness found in the Pfizer-BioNTech clinical trial (efficacy 52%; 95% CI = 30%–68%) (*3*) and an observational study from Israel (*5*). In the Israeli study, the Pfizer-BioNTech VE against

[¶] Underlying conditions grouped based on CDC guidelines identifying conditions associated or potentially associated with risk for severe COVID-19 illness. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

[**] This investigation was defined as having met the requirements for public health surveillance as defined in 45 C.F.R. part 46.102(l)(2) 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

[††] https://doi.org/10.1101/2021.03.09.21253218; https://doi.org/10.1101/2021.03.11.21253275

TABLE 1. Characteristics of health care personnel case-patients and controls — 33 U.S. sites, January–March 2021

Characteristic	No. (%) Case-patients* (N = 623)	Controls* (N = 1,220)
Age group, yrs		
Median (range)	**38 (19–69)**	**37 (19–76)**
19–49	470 (75)	931 (76)
50–64	144 (23)	257 (21)
≥65	7 (1)	24 (2)
Missing	2(<1)	8 (<1)
Sex		
Male	99 (16)	223 (18)
Female	521 (84)	996 (82)
Other	3 (<1)	1 (<1)
Race/Ethnicity		
White, non-Hispanic	401 (64)	853 (70)
Black, non-Hispanic	64 (10)	64 (5)
Hispanic/Latino	81 (13)	124 (10)
Other†	77 (13)	179 (15)
Anticipated level of HCP patient contact based on occupational category		
Substantial§	375 (60)	785 (64)
Moderate¶	60 (10)	120 (10)
Minimal**	147 (24)	221 (18)
Undefined††	41 (7)	94 (8)
Presence of one or more underlying conditions or risk factors associated with increased risk for severe COVID-19§§	**480 (77)**	**920 (75)**
Obesity (BMI >30 kg/m^2 or listed in medical record)	217 (35)	395 (32)
Overweight (BMI 25–29 kg/m^2 or listed in medical record)	186 (30)	355 (29)
Asthma	98 (16)	211 (17)
Hypertension	92 (15)	159 (13)
Diabetes mellitus¶¶	28 (4)	57 (5)
Immunocompromising condition***	25 (4)	46 (4)
Heart disease	15 (2)	61 (5)
Cerebrovascular disease	2 (<1)	4 (<1)
Neurologic condition	2 (<1)	7 (<1)
Chronic kidney disease	1 (<1)	5 (<1)
Chronic obstructive pulmonary disease	1 (<1)	6 (<1)
Other chronic lung disease	6 (<1)	16 (1)
Chronic liver disease	2 (<1)	6 (<1)
Current or former smoking†††	130 (21)	255 (21)
Pregnancy (proportion among female HCP)	13 (3)	40 (4)
Reported symptoms of illness		
Fever (measured temperature ≥100.4°F [38.0°C] or subjective)§§§	249 (40)	281 (23)
Cough (dry or productive)§§§	348 (56)	267 (22)
Shortness of breath§§§	161 (26)	80 (7)
Chills§§§	275 (44)	324 (27)
Muscle pain§§§	289 (46)	342 (28)
Altered sense of smell or taste§§§	351 (56)	45 (4)
Sore throat§§§	215 (35)	344 (28)
Diarrhea§§§	154 (25)	173 (14)
Nausea or vomiting§§§	132 (21)	186 (15)
Other symptoms¶¶¶	560 (90)	796 (65)
Hospitalized	**12 (2)**	**10 (1)**
COVID-19 vaccine status		
Unvaccinated	340 (54)	302 (25)
Received >1 dose before test date, by vaccine type	283 (46)	918 (75)
Pfizer-BioNTech	214 (76)	712 (78)
Moderna	68 (24)	200 (22)
Mixed product****	0	1 (0.4)
Missing product information	1 (0.4)	5 (0.5)

See table footnotes on page 4.

TABLE 1. (*Continued*) Characteristics of health care personnel case-patients and controls — 33 U.S. sites, January–March 2021

Abbreviations: HCP = health care personnel; PCR = polymerase chain reaction.

* Case-patients: HCP who received positive SARS-CoV-2 PCR or antigen-based test results and had one or more symptoms of COVID-19–like illness; controls: HCP who received negative SARS-CoV-2 PCR test results.

† Includes Asian or Pacific Islander (44 case-patients, 109 controls), American Indian or Alaska Native (23 case-patients, 35 controls), multiple races (5 case-patients, 19 controls), and missing race (5 case-patients, 16 controls).

§ Substantial patient contact occupational categories: health care providers (physicians, residents, fellows, attending physicians, nurse practitioners, and physician assistants), nurses (registered nurses, other nursing providers including intensive care unit nurses, nurse managers, and midwives), direct patient assistants (licensed practical nurses, certified nursing assistants, patient care technicians and assistants, medical assistants, COVID-19 testers, phlebotomists, home health care providers, emergency medical services providers, and paramedics), and medical therapists (physical therapists; physical therapy assistants; rehabilitation providers; rehabilitation aides; occupational therapists; speech and language pathologists; respiratory therapists; radiology technicians; dental health care providers, including dentists or dental hygienists; and surgical, medical, or emergency technicians).

¶ Moderate patient contact occupational categories: behavioral/social services providers (behavioral health providers [excluding physician psychiatrists], chaplains, social workers and assistants, care coordinators, interpreters, patient registration personnel, health educators, genetic counselors, ambulance dispatchers, dieticians, and research staff members), and environmental services providers (facilities staff members, food services workers, transport workers, patient transport workers, and drivers).

** Minimal patient contact occupational categories: administrative or ward clerks, symptom checkers, telehealth trainers, clinical support staff members, equipment and sterile processing technicians, medical equipment sales personnel, laboratory personnel, and pharmacists.

†† Undefined patient contact occupational categories: others who could not be classified into any of the preceding categories and those with missing information.

§§ Conditions associated with definite or potential increased risk for severe COVID-19 illness as defined by CDC. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html

¶¶ Among HCP who reported diabetes mellitus, no case-patients and two controls (<1% of all controls) reported type 1 diabetes, eight case-patients (1% of all case-patients) and nine controls (<1% of all controls) reported type 2 diabetes, and 20 case-patients (3%) and 46 controls (4%) did not specify a diabetes type.

*** Immunocompromising conditions include immunosuppression medication (e.g., corticosteroids, chemotherapy, or other immunosuppressive medications), solid organ transplant, hematopoietic stem cell transplant, HIV, thalassemia, or active cancer (current cancer or in treatment or received diagnosis within last 12 months).

††† Smoking includes cigarettes, tobacco, e-cigarettes/vaping, or marijuana use.

§§§ Statistically significant difference between case-patients and controls; chi-square test, p-value<0.001.

¶¶¶ Other symptoms include chest pain or tightness, abdominal pain, loss of appetite, red or bruised toes or feet, headache, runny nose, or congestion.

**** One person's first dose was Moderna vaccine and second dose was Pfizer-BioNTech vaccine.

TABLE 2. COVID-19 vaccine effectiveness among health care personnel case-patients and controls, by number of COVID-19 vaccine doses received before SARS-CoV-2 test date — 33 U.S. sites, January–March 2021

Interval from dose to test date	No. (%)		Vaccine effectiveness† % (95% CI)	
	Case-patients* (N = 623)	Controls* (N = 1,220)	Unadjusted	Adjusted§
Dose 1				
≥14 days	64 (10)	241 (20)	82.2 (75.1–87.3)	81.7 (74.3–86.9)
Dose 2				
≤2 days	5 (<1)	109 (9)		
3–6 days	16 (3)	85 (7)		
≥7 days	19 (3)	184 (15)	93.4 (86.4–96.8)	93.5 (86.5–96.9)

Abbreviations: CI = confidence interval; HCP = health care personnel; mOR = matched odds ratio; OR = odds ratio; PCR = polymerase chain reaction; VE = vaccine effectiveness.

* Case-patients: HCP who received positive SARS-CoV-2 PCR or antigen-based test results and had one or more symptoms of COVID-19–like illness; controls: HCP who received negative SARS-CoV-2 PCR test results.

† VE (Pfizer-BioNTech and Moderna) was estimated using a conditional logistic regression model accounting for matching by site of enrollment and week of test date.

§ OR used in conditional logistic regression model to calculate VE was adjusted for age, race, and presence of underlying conditions: VE = 100% × (1−mOR).

symptomatic illness among the general adult population was 57% (95% CI = 50%–63%) and 66% (95% CI = 57%–73%) measured during 14–20 and 21–27 days, respectively, after the first dose (*5*). These differences might be related to the younger age of the HCP population in this study (<2% of participants aged ≥65 years) compared with the age of the Israeli study population (13% aged ≥70 years). In two cohort studies among HCP, the single-dose effectiveness of the Pfizer-BioNTech vaccine was consistent with the estimates in this report, with 72% effectiveness (95% CI = 58%–86%) 21 days after the first dose in a U.K. study (*7*) and 80% effectiveness (95% CI = 59%–90%) ≥14 days after the first dose in a U.S. cohort study (*6*). Because the single-dose effectiveness estimates in this and other studies were based on a short follow-up, the duration of this level of protection from a single dose is unknown.

The findings in this report are subject to at least four limitations. First, testing for SARS-CoV-2 infection among HCP was based on occupational health practices at each facility, and no changes in routine testing practices were reported after vaccine introduction. If vaccinated HCP were less likely to obtain testing than unvaccinated HCP, the VE might have been underestimated. Alternatively, if postvaccination reactions increased the likelihood that vaccinated HCP would seek testing, the VE might have been overestimated. However, the sensitivity analysis excluding the interval of 0–2 days after receipt of dose 2, the interval during which most postvaccination reactions would be expected to occur, did not significantly change effectiveness estimates. Second, because of the limited sample size, effectiveness by vaccine product, presence of underlying medical conditions, and disease severity could not be estimated. In addition, because of limited statistical power, effectiveness estimates could not be adjusted for other potential confounders, such as use of personal protective equipment, occupational categories, or workplace or community exposures. Third, the VE estimates might not be generalizable to the U.S. adult population because racial/ethnic minority groups disproportionately affected by COVID-19 and who may have had higher exposure risks in the community were underrepresented in this population, and the overall HCP population was younger than the general U.S. adult population.

Summary

What is already known about this topic?

Health care personnel (HCP) are at high risk for COVID-19. The early distribution of two mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) to HCP provided an opportunity to examine vaccine effectiveness in a real-world setting.

What is added by this report?

The first U.S. multisite test-negative design vaccine effectiveness study among HCP found a single dose of Pfizer-BioNTech or Moderna COVID-19 vaccines to be 82% effective against symptomatic COVID-19 and 2 doses to be 94% effective.

What are the implications for public health practice?

The mRNA vaccines are highly effective at preventing symptomatic COVID-19 among U.S. HCP. High vaccination coverage among HCP and the general population is critical to prevent COVID-19 in the United States.

However, the study's geographic coverage was broad, representing the population of U.S. HCP, and vaccination data were obtained from multiple sources. Finally, although HCP with a known past acute SARS-CoV-2 infection were excluded, those whose previous infection was unknown could not be excluded. Data collection for this study is ongoing and will allow effectiveness to be evaluated by vaccine type and among HCP subgroups.

These interim results demonstrate that complete vaccination with authorized mRNA COVID-19 vaccines is highly effective in preventing symptomatic COVID-19 among HCP, supporting the results of phase III trials and additional accruing evidence in recent observational studies. Real-world VE data are critical to guiding evolving COVID-19 vaccine policy. In addition to adherence to recommended infection control and prevention practices, a critical component of controlling the U.S. COVID-19 pandemic and protecting HCP is ensuring high coverage with safe and effective COVID-19 vaccines.

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From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Tue, 1 Jun 2021 21:34:49 +0000
To: Pam Daily
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI);Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) (xbe9@cdc.gov)
Subject: RE: Breakthrough study data collection instrument and instruction or guidance
Attachments: EIP vaccine breakthrough project_Operational Definitions (05-11-2021).xlsx, EIPCOVID19VaccineBreakthroughA_DataDictionary_2021-05-11.csv, COVID vaccine breakthrough case investigation form (03-23-2021).pdf

Pam.

Attached are the final data dictionary and operational definitions for the database variables. With just a few exceptions, the variables will be defined and formatted as you are already doing for COVID-NET.

We assumed all data entry would be performed directly into a REDCap database so did not create a hard copy data collection instrument. Attached is a fillable pdf case investigation form that we created for vaccine breakthrough surveillance. A similar form could be created using the data elements specific to this project.

We are expecting the clinical and epidemiologic data to be collected for cases regardless of whether sequencing is performed. That will allow us to compare cases with the full range of Ct values. The clinical and epidemiologic data may be obtained from the public health case investigation and/or medical record review.

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
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907 201 5223
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From: Pam Daily <pdaily@ceip.us>
Sent: Tuesday, June 1, 2021 12:00 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Subject: Breakthrough study data collection instrument and instruction or guidance

Hi Marc,
I am working with a Kaiser analyst who will be querying the Kaiser data for our cases. Mariah is wondering if there is or will be a data collection instrument (other than the data dictionary and list of variables for the study). Also, will there be an instruction document or more description of the data elements, especially the clinical data.

Also, I wasn't quite sure if every participant (whether or not the specimen is able to be sequenced) will need a chart review done, or if only the study participants who have sequencing information available from their specimen.

Thanks, Pam

Pam Daily Kirley
California Emerging Infections Program
COVID-19, Influenza and RSV Surveillance Coordinator

Variable / Field Name	Description	data format	Additional Details
survey_id	REDCap identification number	number	
local_id	Study identification number	number	unique ID created by EIP site to link a case and specimen
age	age	mm/dd/yyyy	
sex	sex	M, Male | F, Female | U, Unknown	
race	race	ami, American Indian/Alaska Native | asi, Asian | bla, Black | haw, Native Hawaiian/other Pacific Islander | whi, White | unk, Unknown | oth, Other	
ethnicity	ethnicity	H, Hispanic/Latino | N, Non-Hispanic/Latino | Unk, Unknown	
res_state	state of residence	select state from list	
res_county	country of residence	type in county	
casestatus	case type	1, Vaccinated Case | 2, Unvaccinated Case, Included | 3, Unvaccinated Case, Excluded | 4, Not a case	
covtestrslt	COVID test result	1, Positive | 2, Negative | 3, Indeterminate	
covtestdt	COVID test date	mm/dd/yyyy	
covtestassay	Nucleic acid amplification test assay	select test name from drop down list	
ctvalue	Ct value from SARS-CoV-2 test	numberic value	Record a numeric value. If the laboratory reports a "<" or ">" value, please record the next whole number above or below that value. For example, if the report says "< 26", record "25".
covlab	Laboratory where testing was performed	type out name of lab	
vrvac_covid19_dt1	COVID-19 (SARS-CoV-2) Vaccine date (Dose 1)	mm/dd/yyyy	
vrvac_covid19_man1	COVID-19 (SARS-CoV-2) Vaccine Product (Dose 1)	1, Pfizer/BioNTech (BNT162b2 Comirnaty) | 2, Moderna (mRNA-1273) | 3, AstraZeneca (AZD1222) | 4, Janssen (Ad26.COV2.S) | 5, Other	
vrvac_covid19_man1_oth	Other vaccine product (Dose 1)	type in if other vaccine type	
vrvac_covid19_dt2	COVID-19 (SARS-CoV-2) Vaccine date (Dose 2)	mm/dd/yyyy	
vrvac_covid19_man2	COVID-19 (SARS-CoV-2) Vaccine Product (Dose 2)	1, Pfizer/BioNTech (BNT162b2 Comirnaty) | 2, Moderna (mRNA-1273) | 3, AstraZeneca (AZD1222) | 5, Other	
vrvac_covid19_man2_oth	Other vaccine product (Dose 2)	type in if other vaccine type	
housing	Was this person a resident of a long term care facility, nursing home, or assisted living facility at time of diagnosis?	Type of residence at time of diganosis	
pregnant_yn	pregnant	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test.
lung_yn	chronic lung disease	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, see Medical Conditions Tab for further clarification.
htn_yn	hypertension	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, see Medical Conditions Tab for further clarification.
overwt_yn	overweight	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, include if clinically diagnosed obesity
cv_yn	cardiovascular disease	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, see Medical Conditions Tab for further clarification.
diabetes_yn	diabetes	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, include if clinically diagnosed type 1 or 2 diabetes
renaldis_yn	chronic renal disease	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, see Medical Conditions Tab for further clarification.
liverdis_yn	chronic liver disease	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, see Medical Conditions Tab for further clarification.
autoimm_yn	autoimmune disease	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, see Medical Conditions Tab for further clarification.
immsupp_yn	immunocomprimised	1, Yes | 0, No | 9, Unknown	all conditions are at time of SARS-CoV-2 test, see Medical Conditions Tab for further clarification.
immuno_sup_thera_yn	Immunosupressive therapy	1, Yes | 0, No | 3, Unknown	all conditions are at time of SARS-CoV-2 test, see Medical Conditions Tab for further clarification.
symp_status	symptom status	1, Symptomatic | 2, Asymptomatic | 3, Unknown	presence of COIVD-19- like symptoms from 2 days prior to positive test to 14 days post test date.
symp_date	Date of onset of first qualifying symptom	mm/dd/yyyy	
fever_yn	fever	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
chills_yn	chills	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
rigors_yn	rigors	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
myalgia_yn	myalgia	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
headache_yn	headache	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
sthroat_yn	sore throat	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
nauseavomit_yn	nausea or vomiting	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
diarrhea_yn	diarrhea	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
fatigue_yn	fatigue	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
runnose_yn	runny nose	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
cough_yn	cough	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
sob_yn	shortness of breath	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
diffbreathing_yn	difficulty breathing	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
taste_yn	loss of taste or smell	1, Yes | 0, No | 9, Unknown	from 2 days prior to positive test to 14 days post test date.
outpatient	Presented for outpatient medical care (e.g., telemedicine, clinic, urgent care, or emergency room) from 2 days before to 2 weeks after the positive test ([covtestdt]).	Y, Yes | N, No | U, Unknown	from 2 days prior to positive test to 14 days post test date.
inpatient	Hospitalized for ≥1 night in an inpatient facility within 2 weeks after the positive test ([covtestdt]).	Must be admited to the hospital for at least one night. Y, Yes | N, No | U, Unknown	from 2 days prior to positive test to 14 days post test date.
hosp_admindate	Date of hospital admission	mm/dd/yyyy	
hosp_dischdate	Date of hospital discharge	mm/dd/yyyy	

hosp_related	Hospitalization related to SARS-CoV-2 infection (as best understood)	1, Yes | 2, No | 3, UNK	
hosp_info_source	Source of determination that hospitalization was SARS-CoV-2 related	1, Reviewed medical record | 2, Informed by provider | 3, Informed by a healthcare professional other than provider | 4, Other	
icu	Admitted to an intensive care unit during the hospitalization	Y, Yes | N, No | U, Unknown	
vent	Required invasive mechanical ventilation during the hospitalization (excludes BiPAP and CPAP)	Y, Yes | N, No | U, Unknown	
outcome	Outcome at most recent follow up	1, Alive | 2, Died | 9, Unknown	include any deaths that are noted after positive SARS-CoV-2 test
death_related	Death Related to SARS-CoV-2 Infection (As best understood)	1, Yes | 2, No | 3, UNK	
death_info	Source of determination of relationship between death and SARS-CoV-2 infection	1, Reviewed death certificate | 2, Reviewed autopsy result | 3, Informed by medical examiner | 4, Informed by provider | 5, Informed by a healthcare professional other than provider | 6, Reviewed medical records | 7, Other	
dod	Date of death	mm/dd/yyyy	
viral_seqdata	Viral Sequence available:	Y, Yes | N, No | P, Pending	
no_seq	Reason for lack of sequence data	1, Specimen not available | 2, Above Ct cutoff | 3, Sequencing failed	
seq_lab	Name of sequencing laboratory	text	
gisaid	GISAID accession number	text	
genbank	GenBank accession number	text	
viral_seq	Viral testing results (Pangolin Lineage)	text	

Diagnosis	Included conditions
Chronic Lung Disease	1. Active Tuberculosis (TB) 2. Asbestosis 3. Asthma/Reactive airway disease (RAD) 4. Bronchiectasis 5. Bronchiolitis Obliterans 6. Chronic bronchitis 7. Chronic respiratory failure 8. Cystic fibrosis (CF) 9. Emphysema/ Chronic Obstructive Pulmonary Disease (COPD) 10. Interstitial Lung Disease (ILD) 11. Obstructive Sleep Apnea 12. Oxygen (O_2) dependent 13. Pulmonary Fibrosis 14. Restrictive Lung Disease 15. Sarcoidosis
Hypertention	Include only if medically documented health condition
Obesity	Include only if medically documented health condition
Cardiovascular Disease	• Aortic aneurysm (AAA), history of • Aortic/Mitral/Tricuspid/Pulmonic valve replacement, history of • Aortic Regurgitation (AR) • Aortic stenosis (AS) • Atherosclerotic cardiovascular disease (ASCVD) • Atrial fibrillation (A-fib) • Atrioventricular (AV) blocks • Automated implantable devices (AID/AICD)/Pacemaker • Bundle Branch Block (BBB/RBBB/LBBB) • Cardiomyopathy • Carotid Stenosis • Cerebral vascular accident (CVA)/ incident/Stroke, history of Congenital heart disease ○ Atrial septal defect ○ Pulmonic stenosis ○ Tetralogy of Fallot ○ Ventricular septal defect ○ Other, specify

Cardiovascular Disease	• Coronary artery bypass grafting (CABG), history of • Coronary artery disease (CAD) • Deep vein thrombosis (DVT), history of • Heart Failure/Congestive heart failure (CHF) • Myocardial infarction (MI), history of • Mitral regurgitation (MR) • Mitral stenosis (MS) • Peripheral artery disease (PAD) • Peripheral vascular disease (PVD) • Pulmonary embolism (PE), history of • Pulmonary hypertension (PHTN) • Pulmonic regurgitation • Pulmonic stenosis • Transient ischemic attack (TIA), history of • Tricuspid regurgitation (TR) • Tricuspid stenosis • Ventricular fibrillation (VF, VFIB), history of • Ventricular tachycardia (VT, VTACH), history of
Autoimmune conditinos	Ankylosing spondylitis Dermatomyositis Juvenile idiopathic arthritis Kawasaki disease Microscopic polyangiitis Polyarteritis nodosum (PAN) Polymyalgia rheumatica Polymyositis Psoriatic arthritis Rheumatoid arthritis (RA) Systemic lupus erythematosus (SLE)/ Lupus Systemic sclerosis Takayasu arteritis Temporal/ Giant cell arteritis Vasculitis, other
Immunocompromised Conditions	• AIDS or CD4 count <200 • Complement Deficiency • HIV Infection • Immunoglobulin Deficiency/Immunodeficiency • Leukemia* • Lymphoma/Hodgkins/Non-Hodgkins (NHL)* • Metastatic cancer*

	• Multiple Myeloma* • Solid organ malignancy* ○ If yes, which organ? • Steroid Therapy (within 2 weeks of admission) • Transplant, hematopoietic stem cell (Bone marrow transplant (BMT), peripheral stem cell transplant (PSCT)), history of • Transplant, Solid Organ (SOT), history of
Immunosuppressive Therapy	Oral or intravenous corticosteroid Methylprednisolone Dexamethasone Prescription steroids Prednisone Do NOT include inhaled or intranasal steroids or intramuscular or intra-articular injection of steroids
Renal Disease	• Chronic kidney disease/chronic renal insufficiency (CRI) • End stage renal disease (ESRD) • Dialysis (HD) • Glomerulonephritis (GN) • Nephrotic syndrome • Polycystic Kidney Disease (PCKD)
Liver Disease	• Alcoholic hepatitis • Autoimmune hepatitis • Barrett's esophagitis • Chronic liver disease • Cirrhosis/End stage liver disease (ESLD) • Hepatitis B, chronic (HBV) • Hepatitis C, chronic (HCV) • Non-alcoholic fatty liver disease (NAFLD)/NASH

Variable / Field Name	Form Name
survey_id	breakthrough_case_investigation
local_id	breakthrough_case_investigation
redcap_id	breakthrough_case_investigation
age	breakthrough_case_investigation
sex	breakthrough_case_investigation
race	breakthrough_case_investigation
ethnicity	breakthrough_case_investigation
res_state	breakthrough_case_investigation
res_county	breakthrough_case_investigation
casestatus	breakthrough_case_investigation
covtestrslt	breakthrough_case_investigation
no_covtestres	breakthrough_case_investigation
covtestdt	breakthrough_case_investigation
covtestassay	breakthrough_case_investigation
ctvalue	breakthrough_case_investigation
covlab	breakthrough_case_investigation
emb_vrvaccine	breakthrough_case_investigation
error_man3	breakthrough_case_investigation
error_man4	breakthrough_case_investigation
days_bt_pos_vac2	breakthrough_case_investigation
days_bt_pos_vac3	breakthrough_case_investigation
notacasecrit	breakthrough_case_investigation
notacasecrit_2	breakthrough_case_investigation
vrvac_covid19_dt1	breakthrough_case_investigation
vrvac_covid19_man1	breakthrough_case_investigation
vrvac_covid19_man1_oth	breakthrough_case_investigation
vrvac_covid19_dt2	breakthrough_case_investigation
vrvac_covid19_man2	breakthrough_case_investigation
vrvac_covid19_man2_oth	breakthrough_case_investigation
housing	breakthrough_case_investigation
prev_health_con	breakthrough_case_investigation
pregnant_yn	breakthrough_case_investigation
lung_yn	breakthrough_case_investigation
htn_yn	breakthrough_case_investigation
overwt_yn	breakthrough_case_investigation
cv_yn	breakthrough_case_investigation
diabetes_yn	breakthrough_case_investigation
renaldis_yn	breakthrough_case_investigation
liverdis_yn	breakthrough_case_investigation
autoimm_yn	breakthrough_case_investigation
immsupp_yn	breakthrough_case_investigation
immuno_sup_thera_yn	breakthrough_case_investigation
symp_status	breakthrough_case_investigation
symptom_table	breakthrough_case_investigation
symp_date	breakthrough_case_investigation
fever_yn	breakthrough_case_investigation
chills_yn	breakthrough_case_investigation
rigors_yn	breakthrough_case_investigation
myalgia_yn	breakthrough_case_investigation
headache_yn	breakthrough_case_investigation
sthroat_yn	breakthrough_case_investigation

nauseavomit_yn	breakthrough_case_investigation
diarrhea_yn	breakthrough_case_investigation
fatigue_yn	breakthrough_case_investigation
runnose_yn	breakthrough_case_investigation
cough_yn	breakthrough_case_investigation
sob_yn	breakthrough_case_investigation
diffbreathing_yn	breakthrough_case_investigation
taste_yn	breakthrough_case_investigation
outpatient	breakthrough_case_investigation
inpatient	breakthrough_case_investigation
hosp_admindate	breakthrough_case_investigation
hosp_dischdate	breakthrough_case_investigation
hosp_related	breakthrough_case_investigation
hosp_info_source	breakthrough_case_investigation
icu	breakthrough_case_investigation
vent	breakthrough_case_investigation
outcome	breakthrough_case_investigation
death_related	breakthrough_case_investigation
death_info	breakthrough_case_investigation
dod	breakthrough_case_investigation
viral_seqdata	breakthrough_case_investigation
no_seq	breakthrough_case_investigation
seq_lab	breakthrough_case_investigation
pending_alert	breakthrough_case_investigation
gisaid	breakthrough_case_investigation
genbank	breakthrough_case_investigation
viral_seq	breakthrough_case_investigation

Section Header

Patient Information

<h4 style="text-align: center;">CASE STATUS</h4>
<h4 style="text-align: center;">Details of COVID-19 Testing</h4>

<h4 style="text-align: center;">Details of Vaccination</h4>

<h4 style="text-align: center;">Underlying Conditions</h4>

<h4 style="text-align: center;">Clinical Presentation</h4> <p>Instructions: Please

<h4 style="text-align: center;">Sequencing data</h4>

Field Type
text
text
descriptive
text
radio
checkbox
radio
dropdown
text
radio
radio
descriptive
text
dropdown
text
text
descriptive
descriptive
descriptive
calc
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Field Label
Survey ID
State identification number:
REDCap ID: [survey_id]
Age
Sex:
Race: (Check all that apply)
Ethnicity:
State of residence:
County of residence:
Case Status:
COVID-19 NAAT Test Result
 You selected
Specimen collection date (if multiple recent positive
Nucleic acid amplification test assay or platform
Ct Value
Laboratory where testing was performed: </div
  <table style="border-collapse: collapse; width: 100%; height: 263px; bor
 <p style="text-align: left; font-weight: bold
 <p style="text-align: left; font-weight: bold
Number of days between first vaccine dose an
Number of days between second vaccine dose
 <h4 style="font-weight: bold; font-size: 14
 <h4 style="font-weight: bold; font-size: 14
COVID-19 (SARS-CoV-2) Vaccine date ([
COVID-19 (SARS-CoV-2) Vaccine Produc
Other vaccine product:
COVID-19 (SARS-CoV-2) Vaccine date ([
COVID-19 (SARS-CoV-2) Vaccine Produc
Other vaccine product
Was this person a resident of a long term care facility, nursing home, or assisted living facility at time of diagnosis?
Underlying Health Conditions <table style="border-collapse: collapse; wic
Pregnant
Chronic lung disease (i.e., asthma, emphysema, chronic obstructive pulmonary disease)
Hypertension
Severe Obesity
Cardiovascular disease
Diabetes mellitus
Chronic kidney disease
Chronic liver disease
Autoimmune disease
Immunocompromised condition
Systemic immunosuppressive therapy or r
Symptoms present during course of illness:
Symptoms from two days before to within 2 weeks after the positive test ([covt
Date of onset of first qualifying symptom
Fever?
Chills?
Rigors?
Myalgia?
Headache?
Sore throat?

Nausea or vomiting
Diarrhea?
Fatigue?
Congestion or runny nose?
Cough?
Shortness of breath?
Difficulty breathing?
New olfactory and taste disorder(s)
Presented for outpatient medical care (e.g., teleme
Hospitalized for ≥1 night in an inpatient facility withi
Date of hospital admission
Date of hospital discharge
Hospitalization related to SARS-CoV-2 infection (as best understood)
Source of determination that hospitalization was SARS-CoV-2 related
Admitted to an intensive care unit during the hospit
Required invasive mechanical ventilation during the
Outcome at most recent follow up
Death Related to SARS-CoV-2 Infection (As best understood)
Source of determination of relationship between death and SARS-CoV-2 infection
Date of death
Viral Sequence available:
Reason for lack of sequence data
Name of sequencing laboratory
<span style="color: #e03e2d; background-color: #f8cac
GISAID accession number
GenBank accession number
Viral testing results (Pangolin Lineage)

Choices, Calculations, OR Slider Labels

M, Male | F, Female | U, Unknown
ami, American Indian/Alaska Native | asi, Asian | bla, Black | haw, Native Hawaiian/other Pacific Islander | whi, Wh
H, Hispanic/Latino | N, Non-Hispanic/Latino | Unk, Unknown
AL, Alabama (AL) | AK, Alaska (AK) | AZ, Arizona (AZ) | AR, Arkansas (AR) | CA, California (CA) | CO, Colorado (C

1, Vaccinated Case | 2, Unvaccinated Case, Included | 3, Unvaccinated Case, Excluded | 4, Not a case
1, Positive | 2, Negative | 3, Indeterminate
"Negative, Indeterminate, or No result" for the COVID-19 test question, data entry is now complete. This person is
e tests, list earliest positive):</p>
1, 1drop Inc. - 1copy COVID-19 qPCR Multi Kit | 2, 3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.

>
der-style: none; margin-left: auto; margin-right: auto;" border="1"> <tbody> <tr style="height: 55px;"> <td style="wid
l; font-size: 14px;">If you selected [vrvac_covid19_man1] to this question, please consider if this case is appropriat
l; font-size: 14px;">If you selected [vrvac_covid19_man1] to this question, please consider if this case is appropriat
datediff([covtestdt],[vrvac_covid19_dt1],"d")
datediff([covtestdt],[vrvac_covid19_dt2],"d")
4px; text-align: center;">First vaccine date is < 14 days from specimen collection date. Please update Case Status a
4px; text-align: center;">Second vaccine date is < 14 days from specimen collection date. Please update Case Statu
Dose 1)</p>
1, Pfizer/BioNTech (BNT162b2 Comirnaty) | 2, Moderna (mRNA-1273) | 3, AstraZeneca (AZD1222) | 4, Janssen (A

Dose 2)</p>
1, Pfizer/BioNTech (BNT162b2 Comirnaty) | 2, Moderna (mRNA-1273) | 3, AstraZeneca (AZD1222) | 5, Other

1, Yes | 0, No | 2, Unk
dth: 100%; height: 197px;" border="1"> <tbody> <tr style="height: 16px;"> <td style="width: 50%; height: 16px;">Cu
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 3, Unknown
1, Symptomatic | 2, Asymptomatic | 3, Unknown
testdt]) (Select any present):</p> <table style="border-collapse: collapse; width: 100%;" border="1"> <tbody> <tr> <

1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown

1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
1, Yes | 0, No | 9, Unknown
Y, Yes | N, No | U, Unknown
Y, Yes | N, No | U, Unknown

1, Yes | 2, No | 3, UNK
1, Reviewed medical record | 2, Informed by provider | 3, Informed by a healthcare professional other than provide
Y, Yes | N, No | U, Unknown
Y, Yes | N, No | U, Unknown
1, Alive | 2, Died | 9, Unknown
1, Yes | 2, No | 3, UNK
1, Reviewed death certificate | 2, Reviewed autopsy result | 3, Informed by medical examiner | 4, Informed by prov

Y, Yes | N, No | P, Pending
1, Specimen not available | 2, Above Ct cutoff | 3, Sequencing failed

:6;">Please update with sequence data as soon as it is available.</p>

Field Note

iite | unk, Unknown | oth, Other

CO) | CT, Connecticut (CT) | DC, District of Columbia (DC) | DE, Delaware (DE) | FL, Florida (FL) | GA, Georgia (G

not eligible for inclusion.</p>
MM-DD-YYYY
. - TRUPCR SARS-CoV-2 Kit | 3, Abbott Diagnostics Scarborough, Inc. - ID NOW COVID-19 | 4, Abbott Molecular -
If the laboratory reports a "<" or ">" value, please record the next number above or below that value. For example,

lth: 25.033%; border-width: 1pt 1pt 2.25pt; border-style: solid; border-color: windowtext windowtext black; border-im
e to include. Only cases vaccinated with FDA-authorized vaccines are included.</p>
e to include. Only cases vaccinated with FDA-authorized vaccines are included.</p>

as "Not a case".</h4>
us as "Not a case".</h4>
MM-DD-YYYY
Ad26.COV2.S) | 5, Other

MM-DD-YYYY

rrently pregnant?</td> <td style="width: 50%; height: 16px;">{pregnant_yn}</td> </tr> <tr style="height: 16px;"> <tc

<td style="width: 50%;">Fever >100.4F (38C)</td> <td style="width: 50%;">{fever_yn}</td> </tr> <tr> <td style="wid

r | 4, Other

ider | 5, Informed by a healthcare professional other than provider | 6, Reviewed medical records | 7, Other
MM-DD-YYYY

Text Validation Type OR Show Slider Number	Text Validation Min	Text Validation Max	Identifier?
number	16	120	y
autocomplete			
date_mdy	1/1/2021		

- Abbott RealTime SARS-CoV-2 assay | 5, Abbott Molecular Inc. - Alinity m SARS-CoV-2 assay | 6, Acce

number

ıage: initial; padding: 0in 5.4pt; height: 55px;"> <p style="margin-left: 0in; text-align: center;"><span style

date_mdy	12/1/2020		
date_mdy	12/1/2020		

ł style="width: 50%; height: 16px;">Chronic lung disease (ie. Asthma, Emphysema, COPD)?</td> <td sty

lth: 50%;">Chills</td> <td style="width: 50%;">{chills_yn}</td> </tr> <tr> <td style="width: 50%;">Rigor</

date_dmy	1/4/2021		

date_mdy
date_mdy

date_mdy

Branching Logic (Show field only if...)	Required Field?
	y
	y
	y
[covtestrslt] = '2' or [covtestrslt] = '3' or [covtestrslt] = '3'	
	y
ɜss Bio, Inc. - CareStart COVID-19 MDx RT-PCR | 7, Access Genetics, LLC - OraRisk COVID-19 RT-PCR | 8	
[casestatus] = '1' [vrvac_covid19_man1] = '3' or [vrvac_covid19_man1] = '5' [vrvac_covid19_man2] = '3' or [vrvac_covid19_man2] = '5' [casestatus] = '1' [casestatus] = '1' [days_bt_pos_vac2] < 14 [days_bt_pos_vac3] < 14	
	y
[vrvac_covid19_man1]='5' [vrvac_covid19_man1] = '1' or [vrvac_covid19_man1] = '2' or [vrvac_covid19_man1] = '5'	y
[vrvac_covid19_man2]='5'	
yle="width: 50%; height: 16px;">{lung_yn}</td> </tr> <tr style="height: 16px;"> <td style="width: 50%; height:	
[symp_status] = '1'	

[inpatient] = 'Y'
[inpatient] = 'Y'
[inpatient] = 'Y'
[hosp_related] = '1'
[inpatient] = "Y"
[inpatient] = "Y"

[outcome] = '2'
[outcome] = '2'
[outcome] = "2"

[viral_seqdata] = '0'
[viral_seqdata] = '1' or [viral_seqdata] = '2'
[viral_seqdata] = '2'
[viral_seqdata] = 'Y'
[viral_seqdata] = 'Y'
[viral_seqdata] = 'Y'

Custom Alignment | Question Number (surveys only) | Matrix Group Name | Matrix Ranking?

8, Acupath Laboratories, Inc. - Acupath COVID-19 Real-Time (RT-PCR) Assay | 9, Aeon Global

: 16px;">Hypertension?</td> <td style="width: 50%; height: 16px;">{htn_yn}</td> </tr> <tr> <td st

Field Annotation

@NONEOFTHEABOVE = unk
@NONEOFTHEABOVE =Unk

Health - Aeon Global Health SARS-CoV-2 Assay | 10, Akron Children's Hospital - Akron Children's Hospital SARS·

tyle="width: 50%;">Cardiovascular disease?</td> <td style="width: 50%;">{cv_yn}</td> </tr> <tr> <td style="width:

-CoV-2 Assay | 11, Alimetrix, Inc. - Alimetrix SARS-CoV-2 RT-PCR Assay | 12, Alpha Genomix Laborat

50%;">Severe obesity (BMI > or = 40)</td> <td style="width: 50%;">{overwt_yn}</td> </tr> <tr style="he

ories - Alpha Genomix TaqPath SARS-CoV-2 Combo Assay | 13, altona Diagnostics GmbH - RealStar S

eight: 16px;"> <td style="width: 50%; height: 16px;">Diabetes mellitus? </td> <td style="width: 50%; hei

SARS-CoV02 RT-PCR Kits U.S. | 14, Applied BioCode, Inc. - BioCode SARS-CoV-2 Assay | 15, Applied

ght: 16px;">{diabetes_yn}</td> </tr> <tr style="height: 16px;"> <td style="width: 50%; height: 16px;">Ch

ɨ DNA Sciences, Inc. - Linea COVID-19 Assay Kit | 16, Assurance Scientific Laboratories - Assurance S

ıronic kidney disease?</td> <td style="width: 50%; height: 16px;">{renaldis_yn}</td> </tr> <tr style="heiç

;ARS-CoV-2 Panel | 17, Atila BioSystems, Inc. - iAMP COVID-19 Detection Kit | 18, Avellino Lab USA, Ir

ght: 16px;"> <td style="width: 50%; height: 16px;">Chronic liver disease?</td> <td style="width: 50%; he

nc. - AvellinoCoV2 test | 19, BayCare Laboratories, LLC - BayCare SARS-CoV-2 RT PCR Assay | 20, B

eight: 16px;">{liverdis_yn}</td> </tr> <tr style="height: 16px;"> <td style="width: 50%; height: 16px;">Aut

ecton, Dickinson & Company - BD SARS-CoV-2Reagents for BD MAX System | 21, Becton, Dickinson &

toimmune disease?</td> <td style="width: 50%; height: 16px;">{autoimm_yn}</td> </tr> <tr style="heigh

& Company (BD) - BioGX SARS-CoV-2 Reagents for BD MAX System | 22, Beijing Wantai Biological Pł

ıt: 16px;"> <td style="width: 50%; height: 16px;">Immunocompromised?</td> <td style="width: 50%; hei

harmacy Enterprise Co., Ltd. - Wantai SARS-CoV-2 RT-PCR Kit | 23, BGI Genomics Co. Ltd - Real-Tim

ight: 16px;">{immsupp_yn}</td> </tr> <tr style="height: 69px;"> <td style="width: 50%; height: 69px;">S

ıe Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 | 24, BillionToOne, Inc. - qSanger-COVID-19 Ass

ystemic immmunosuppressive therapy or medications (i.e., chemotherapy, corticosteroids, monoclonal a

ıay | 25, BioCore Co., Ltd. - BioCore 2019-nCoV Real Time PCR Kit | 26, Bioeksen R&D Technologies L

antibodies, excludes topical agents and inhaled steroids)?</td> <td style="width: 50%; height: 69px;">{ir

.td. - Bio-Speedy Direct RT-qPCR SARS-CoV-2 | 27, BioFire Defense, LLC - BioFire COVID-19 Test | 2

mmuno_sup_thera_yn}</td> </tr> </tbody> </table>

8, BioFire Diagnostics, LLC - BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) | 29, BioFire Diagnostics, LL

.C - BioFire Respiratory Panel 2.1 (RP2.1) | 30, Biomeme, Inc. - Biomeme SARS-CoV-2 Real-Time RT-F

PCR Test | 31, BioMérieux SA - SARS-COV-2 R-GENE | 32, Bio-Rad Laboratories, Inc - Bio-Rad SARS

-CoV-2 ddPCR Test | 33, BioSewoom, Inc. - Real-Q 2019-nCoV Detection Kit | 34, Boston Heart Diagn

ostics - Boston Heart COVID-19 RT-PCR Test | 35, Boston Medical Center - BMC-CReM COVID-19 Tes

st | 36, Capstone/ISPM Labs - Genus SARS-CoV-2 Assay | 37, Centers for Disease Control and Preven

ıtion (CDC) - Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay | 38. Centers for Disease Control and Pı

revention's (CDC) - CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) | 39, CENTOGENE U

JS, LLC - CentoSure SARS-CoV-2 RT-PCR Assay | 40, CENTOGENE US, LLC - CentoFast-SARS-CoV

/-2 RT-PCR Assay | 41, Cepheid - Xpert Omni | 42, Cepheid - Xpert Xpress SARS-CoV-2/Flu/RSV | 43,

Cepheid - Xpert Xpress SARS-CoV-2 test | 44, ChromaCode Inc. - HDPCR SARS-CoV-2 Assay | 45, C

ıboratory Medicine Institute - Cleveland Clinic SARS-CoV-2 Assay | 47, Clinical Enterprise, Inc. - Empov

werDX At-Home COVID-19 PCR Test Kit | 48, Clinical Reference Lab

COVID-19 Vaccine Breakthrough Case Investigation Form

Case Identification Numbers and Contacts

Vaccine breakthrough REDCap ID: _____

CDC case identification number: _____

State/local case identification number: _____

State health department contact name: _____

Email address: _____

Case-Patient Demographics

Age: _____

Sex:
- ○ Male
- ○ Female
- ○ Unknown

Race (Select all that apply):
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian/Other Pacific
- ☐ White

OR ☐ **Unknown**

Ethnicity:
- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Unknown

State of residence: _____

County of residence: _____

Type of residence [Select one]
- ○ House
- ○ Apartment
- ○ Hotel
- ○ Long-term care facility
- ○ Correctional facility
- ○ Mobile home
- ○ Group home
- ○ Shelter
- ○ Other
- ○ Unknown

COVID Laboratory Confirmation

Specimen Type :
- ○ Upper respiratory sample *(nasopharyngeal swab, nasal swab, nasal wash, oropharyngeal swab)*
- ○ Saliva
- ○ Sputum
- ○ Bronchoalveolar lavage fluid
- ○ Pleural fluid
- ○ Lung tissue

Date specimen was collected: _____

Location where testing performed:
- ○ Laboratory or medical facility
- ○ Home test only

Name of laboratory where testing was performed:

Test type:
- ○ RT-PCR or other NAAT
- ○ Antigen only

Test result:
- ○ Positive
- ○ Negative
- ○ Indeterminate

CT Value: _____

Available specimens from initial COVID-19 laboratory confirmation: (Select all that apply)
- ☐ SARS-CoV-2 sequence data
- ☐ Primary respiratory specimen
- ☐ None

SARS-CoV-2 sequencing performed: ○ Yes ○ No ○ Unknown

SARS-CoV-2 lineage: _____ **GISAID accession number:** _____ **GenBank accession number:** _____

COVID-19 Vaccination Information

DOSE # 1

Vaccine manufacturer and type: _____ ***or Other:*** _____

Date received: _____ **Vaccine lot number:** _____

Name of facility where vaccine was received: _____

City and state where vaccine was received: _____

DOSE # 2

Vaccine manufacturer and type: _____ ***or Other:*** _____

Date received: _____ **Vaccine lot number:** _____

Name of facility where vaccine was received: _____

City and state where vaccine was received: _____

Clinical Illness

Symptoms during the course of illness

- ○ Yes
- ○ No
- ○ Unknown

Clinical symptoms reported from 2 days before to 2 weeks after the positive test (Select any present):

- ☐ Fever
- ☐ Chills
- ☐ Rigors
- ☐ Myalgia
- ☐ Headache
- ☐ Sore throat
- ☐ Nausea or vomiting
- ☐ Diarrhea
- ☐ Fatigue
- ☐ Congestion or runny nose
- ☐ Cough
- ☐ Shortness of breath
- ☐ Difficulty breathing
- ☐ New olfactory disorder
- ☐ New taste disorder

OR ☐ **No COVID-19-like symptoms**

Underlying Medical Conditions

Underlying medical conditions: (Select all that apply)

- ☐ Pregnancy
- ☐ Diabetes mellitus
- ☐ Chronic kidney disease
- ☐ Chronic liver disease
- ☐ Autoimmune disease
- ☐ Immunocompromised
- ☐ HIV infection
- ☐ Active cancer
- ☐ Solid organ transplant
- ☐ Hematopoietic stem cell transplant
- ☐ Other immunosuppressive condition: *(specify)* _____

Systemic immunosuppressive therapy or medications (i.e., chemotherapy, corticosteroids, monoclonal antibodies, excludes topical agents and inhaled steroids)

- ○ Yes
- ○ No
- ○ Unknown

Clinical Course

Presented for outpatient medical care (e.g., telemedicine, clinic, urgent care, or emergency room) from 2 days before to 2 weeks after the positive test:

- ○ Yes
- ○ No
- ○ Unknown

Hospitalized for ≥1 night in an inpatient facility within 2 weeks after the positive test:

- ○ Yes
- ○ No
- ○ Unknown

If Yes

Admitted to an intensive care unit during the hospitalization:

- ○ Yes
- ○ No
- ○ Unknown

Required mechanical ventilation during the hospitalization:

- ○ Yes
- ○ No
- ○ Unknown

Hospitalization related to SARS-CoV-2 infection:

- ○ Yes
- ○ No
- ○ Unknown

Died:

- ○ Yes
- ○ No
- ○ Unknown

If Yes

Date died: _____

Death related to SARS-CoV-2 infection:

- ○ Yes
- ○ No
- ○ Unknown

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Wed, 7 Apr 2021 00:26:15 +0000
To: Pam Daily
Cc: Gretchen Rothrock;Chai, Shua (CDC cdph.ca.gov);Reingold, Arthur MD (CDC berkeley.edu)
Subject: RE: CA outline updated for Breakthrough study

Pam.

Thanks for the brief outline for the COVID-19 vaccine breakthrough project in the California EIP site.

Please let me know when you are ready and available for a site-specific call to discuss next steps and timeline for starting the project in California.

Best wishes,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

From: Pam Daily <pdaily@ceip.us>
Sent: Monday, April 5, 2021 5:06 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Gretchen Rothrock <grothrock@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>
Subject: CA outline updated for Breakthrough study

Hi Marc,
We have added a few clarifications to our Breakthrough Study outline that is more specific in detail (attached).
Please let me know if you have any questions- this is our final version ☺
Thanks, Pam

Pam Daily Kirley
California Emerging Infections Program
COVID-19, Influenza and RSV Surveillance Coordinator

From: Andrew Adams
Sent: Wed, 28 Jul 2021 17:46:19 +0000
To: Jain, Seema (CDC cdph.ca.gov);Silk, Benjamin J. (CDC/DDID/NCIRD/DVD)
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

Completely understand- the group knows this is a closed call, but it's always good to reinforce that!

Andrew M. Adams, MPH
Senior Program Analyst
aadams@cste.org

CSTE
Council of State and Territorial Epidemiologists
"Using the power of epidemiology to improve the public's health"
CSTE.org • Membership • Facebook • Twitter • Instagram
2635 Century Parkway NE, Suite 700, Atlanta, GA 30345
Tel: 770.458.3811 | Fax: 770.458.8516

From: Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Sent: Wednesday, July 28, 2021 1:37 PM
To: Andrew Adams <aadams@cste.org>; Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

I'm ok if internal purposes – sorry I haven't shared some of it with the powers that be though I got permission ☺ to speak.

Seema Jain, MD, FIDSA
Chief, Epidemiology, Surveillance and Modeling Section, COVID-19 Response
Chief, Disease Investigations Section, Infectious Diseases Branch
California Department of Public Health
Ph: (510)-620-3444
Email:Seema.Jain@cdph.ca.gov

From: Andrew Adams <aadams@cste.org>
Sent: Wednesday, July 28, 2021 10:35 AM
To: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>; Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

Thanks, Ben. Apologies for just now seeing this.

Seema, I can go into the recording and remove that portion, not an issue. I'll also note that while recorded, we only use the recording for internal notetaking, but removing your portion isn't a problem at all. happy to do it

Thanks,

Andrew

Andrew M. Adams, MPH
Senior Program Analyst
aadams@cste.org

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From: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>
Sent: Wednesday, July 28, 2021 1:29 PM
To: Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>
Cc: Andrew Adams <aadams@cste.org>
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

Adding Andrew to see what can be done

From: Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Sent: Wednesday, July 28, 2021 1:23 PM
To: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

Can I not be recorded by any chance on this meeting?

Seema Jain, MD, FIDSA
Chief, Epidemiology, Surveillance and Modeling Section, COVID-19 Response
Chief, Disease Investigations Section, Infectious Diseases Branch
California Department of Public Health
Ph: (510)-620-3444
Email:Seema.Jain@cdph.ca.gov

From: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>
Sent: Monday, July 26, 2021 2:18 PM
To: Layton, Marci (CDC health.nyc.gov) <mlayton@health.nyc.gov>; Herlihy, Rachel (CDC state.co.us) <rachel.herlihy@state.co.us>; Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Cc: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>; Scobie, Heather (CDC/DDPHSIS/CGH/GID)

<vih8@cdc.gov>; Taylor, Mackenzie (CDC/DDNID/NCIPC/DVP) <ouf1@cdc.gov>; Lemos, Pamela R. (CDC/DDNID/NCCDPHP/OSH) <xld8@cdc.gov>; Fuld, Jennifer (CDC/OD/OADPS) <ngt0@cdc.gov>; Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Ritchey, Matthew D. (CDC/DDPHSS/CSELS/DHIS) <hha7@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

Dear Marci, Rachel, and Seema,

Many thanks to you and/or your program colleagues for agreeing to present this Wednesday on breakthrough cases & surveillance.

We may still add a few other programs/speakers, but wanted to confirm with you all today that this is indeed happening.

Mackenzie and others with CSTE will be following up with a meeting invitation and more info soon…

Thanks again,
Ben

From: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>
Sent: Friday, July 23, 2021 11:32 AM
To: Balter, Sharon (CDC ph.lacounty.gov) <sbalter@ph.lacounty.gov>; Marcelle Layton <mlayton@health.nyc.gov>; Herlihy, Rachel (CDC state.co.us) <rachel.herlihy@state.co.us>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; jennifer.dillaha@arkansas.org; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>
Cc: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>; Scobie, Heather (CDC/DDPHSIS/CGH/GID) <vih8@cdc.gov>; Taylor, Mackenzie (CDC/DDNID/NCIPC/DVP) <ouf1@cdc.gov>; Lemos, Pamela R. (CDC/DDNID/NCCDPHP/OSH) <xld8@cdc.gov>; Fuld, Jennifer (CDC/OD/OADPS) <ngt0@cdc.gov>; Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Ritchey, Matthew D. (CDC/DDPHSS/CSELS/DHIS) <hha7@cdc.gov>; Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

PS Apologies, but I meant **July 28**.

From: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD)
Sent: Friday, July 23, 2021 11:12 AM
To: Balter, Sharon (CDC ph.lacounty.gov) <sbalter@ph.lacounty.gov>; Layton, Marci (CDC health.nyc.gov) <mlayton@health.nyc.gov>; Herlihy, Rachel (CDC state.co.us) <rachel.herlihy@state.co.us>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; jennifer.dillaha@arkansas.org; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>

Cc: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>; Scobie, Heather (CDC/DDPHSIS/CGH/GID) <vih8@cdc.gov>; Taylor, Mackenzie (CDC/DDNID/NCIPC/DVP) <ouf1@cdc.gov>; Lemos, Pamela R. (CDC/DDNID/NCCDPHP/OSH) <xld8@cdc.gov>; Fuld, Jennifer (CDC/OD/OADPS) <ngt0@cdc.gov>; Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Ritchey, Matthew D. (CDC/DDPHSS/CSELS/DHIS) <hha7@cdc.gov>; Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>
Subject: CDC/CSTE CORE call on breakthrough cases & surveillance
Importance: High

Dear colleagues,

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We're planning a series of short presentations on this topic ideally from each of your programs. The call is 90 minutes, so we would divide time among however many programs are able to accept this invitation (i.e., LA County, New York City, Colorado, Minnesota, Arkansas, and CDC's vaccine breakthrough SMEs).

We would appreciate it if each of you listed on the To line above could kindly confirm participation by **Monday, 12 PM Eastern**.

And we're happy to answer any questions.

Many thanks,
Ben

Benjamin Silk, PhD
Lead, Surveillance and Analytics
Epidemiology Task Force
CDC COVID-19 Response
bsilk@cdc.gov

From: Jain, Seema@CDPH
Sent: Fri, 23 Jul 2021 16:45:38 +0000
To: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD)
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

Yes, I am the best contact. Can you send me the invite?

Seema Jain, MD, FIDSA
Chief, Epidemiology, Surveillance and Modeling Section, COVID-19 Response
Chief, Disease Investigations Section, Infectious Diseases Branch
California Department of Public Health
Ph: (510)-620-3444
Email:Seema.Jain@cdph.ca.gov

From: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>
Sent: Friday, July 23, 2021 8:54 AM
To: Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Subject: Re: CDC/CSTE CORE call on breakthrough cases & surveillance

Too much multitasking! Would be great to have CA present as well if you agree… are you the best contact?

From: Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Sent: Friday, July 23, 2021 8:16 AM
To: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD)
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

I don't think you meant June 18? We also have all CA data….

Seema Jain, MD, FIDSA
Chief, Epidemiology, Surveillance and Modeling Section, COVID-19 Response
Chief, Disease Investigations Section, Infectious Diseases Branch
California Department of Public Health
Ph: (510)-620-3444
Email:Seema.Jain@cdph.ca.gov

From: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>
Sent: Friday, July 23, 2021 8:12 AM
To: Balter, Sharon@Los Angeles County <SBalter@ph.lacounty.gov>; Layton, Marci (CDC health.nyc.gov) <mlayton@health.nyc.gov>; Herlihy, Rachel (CDC state.co.us) <rachel.herlihy@state.co.us>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; jennifer.dillaha@arkansas.org; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>

Cc: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>; Scobie, Heather (CDC/DDPHSIS/CGH/GID) <vih8@cdc.gov>; Taylor, Mackenzie (CDC/DDNID/NCIPC/DVP) <ouf1@cdc.gov>; Lemos, Pamela R. (CDC/DDNID/NCCDPHP/OSH) <xld8@cdc.gov>; Fuld, Jennifer (CDC/OD/OADPS) <ngt0@cdc.gov>; Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Ritchey, Matthew D. (CDC/DDPHSS/CSELS/DHIS) <hha7@cdc.gov>; Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Subject: CDC/CSTE CORE call on breakthrough cases & surveillance
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Many thanks,
Ben

Benjamin Silk, PhD
Lead, Surveillance and Analytics
Epidemiology Task Force
CDC COVID-19 Response
bsilk@cdc.gov

From: Taylor, Mackenzie (CDC/DDNID/NCIPC/DVP)
Sent: Tue, 27 Jul 2021 01:07:07 +0000
To: Jain, Seema (CDC cdph.ca.gov);Silk, Benjamin J. (CDC/DDID/NCIRD/DVD);Layton, Marci (CDC health.nyc.gov);Herlihy, Rachel (CDC state.co.us)
Cc: Layden, Jennifer (CDC/DDPHSS/OS/OD);Scobie, Heather (CDC/DDPHSIS/CGH/GID);Lemos, Pamela R. (CDC/DDNID/NCCDPHP/OSH);Fuld, Jennifer (CDC/OD/OADPS);Lubar, Debra (CDC/DDID/NCEZID/OD);Ritchey, Matthew D. (CDC/DDPHSS/CSELS/DHIS);Fischer, Marc (CDC/DDID/NCEZID/DPEI);Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD)
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

Hi Seema,

I just sent the request to ask CSTE to add all of the contacts on this email chain to the call invite tongiht, so you should see the official information from CSTE by tomorrow morning sometime. I can add you all to CDC's internal hold now as well.

Thanks!
Mackenzie

Mackenzie Taylor, MPH
Partnerships Lead
STLT Task Force Policy and Public Health Partnership Unit
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
Phone: 404-498-3304 | Email: ouf1@cdc.gov | Pronouns: She / Her / Hers

---

From: Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Sent: Monday, July 26, 2021 8:55 PM
To: Silk, Benjamin J. (CDC/DDID/NCIRD/DVD) <ekj8@cdc.gov>; Layton, Marci (CDC health.nyc.gov) <mlayton@health.nyc.gov>; Herlihy, Rachel (CDC state.co.us) <rachel.herlihy@state.co.us>
Cc: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>; Scobie, Heather (CDC/DDPHSIS/CGH/GID) <vih8@cdc.gov>; Taylor, Mackenzie (CDC/DDNID/NCIPC/DVP) <ouf1@cdc.gov>; Lemos, Pamela R. (CDC/DDNID/NCCDPHP/OSH) <xld8@cdc.gov>; Fuld, Jennifer (CDC/OD/OADPS) <ngt0@cdc.gov>; Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Ritchey, Matthew D. (CDC/DDPHSS/CSELS/DHIS) <hha7@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>
Subject: RE: CDC/CSTE CORE call on breakthrough cases & surveillance

HI all- Can someone send me the invite to the meeting? I don't have it. Best, Seema

Seema Jain, MD, FIDSA
Chief, Epidemiology, Surveillance and Modeling Section, COVID-19 Response
Chief, Disease Investigations Section, Infectious Diseases Branch
California Department of Public Health
Ph: (510)-620-3444
Email:Seema.Jain@cdph.ca.gov

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Sent: Monday, July 26, 2021 2:18 PM
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Ben

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Sent: Friday, July 23, 2021 11:32 AM
To: Balter, Sharon (CDC ph.lacounty.gov) <sbalter@ph.lacounty.gov>; Marcelle Layton <mlayton@health.nyc.gov>; Herlihy, Rachel (CDC state.co.us) <rachel.herlihy@state.co.us>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; jennifer.dillaha@arkansas.org; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Kugeler, Kiersten (CDC/DDID/NCEZID/DVBD) <bio1@cdc.gov>
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Benjamin Silk, PhD
Lead, Surveillance and Analytics
Epidemiology Task Force
CDC COVID-19 Response
bsilk@cdc.gov

From: Art Reingold
Sent: Thu, 29 Apr 2021 17:26:13 -0600
To: Gretchen Rothrock
Cc: Fischer, Marc (CDC/DDID/NCEZID/DPEI);Pam Daily;Chai, Shua (CDC cdph.ca.gov);Joelle Nadle
Subject: Re: EIP vaccine breakthrough project multi-site call on May 4-7-CA availability

I think I am

Sent from my iPhone

On Apr 29, 2021, at 4:57 PM, Gretchen Rothrock <grothrock@ceip.us> wrote:

I've emailed Pam. She is in a meeting. I think some of us might be available at 10am (PT) on 5/6. I believe Shua is not available.

Art?

Gretchen

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Thursday, April 29, 2021 3:48 PM
To: Pam Daily <pdaily@ceip.us>
Cc: Gretchen Rothrock <grothrock@ceip.us>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Joelle Nadle <jnadle@ceip.us>
Subject: RE: EIP vaccine breakthrough project multi-site call on May 4-7-CA availability

Pam.

Is someone from the California EIP available to participate in a call on Thursday (May 6) at 1:00pm Eastern time (10:00am Pacific)?

That is by far the best time for the most number of sites.

Thanks,
Marc

From: Pam Daily <pdaily@ceip.us>
Sent: Wednesday, April 28, 2021 9:52 AM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Gretchen Rothrock <grothrock@ceip.us>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Joelle Nadle <jnadle@ceip.us>
Subject: RE: EIP vaccine breakthrough project multi-site call on May 4-7-CA availability

Hi Marc,
Below is the availability indicated for the CA site for an All-site study meeting next week.
Best, Pam

Eastern times	Tue, May 4	Wed, May 5	Thu, May 6	Fri, May 7
1:00-2:00pm (10-11)				
2:00-3:00pm (11-12)				CA site
3:00-4:00pm (12-1)				CA site
4:00-5:00pm (1-2)		CA site		CA Site

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Wednesday, April 28, 2021 10:02 AM
To: Allison Roebling <aroebling@gaeip.org>; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Schmoll, Emma (CDC state.co.us) <emma.schmoll@state.co.us>; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; kopeno@gaeip.org; Gretchen Rothrock <grothrock@ceip.us>; Pam Daily <pdaily@ceip.us>; Sosin, Daniel (CDC state.nm.us) <Daniel.Sosin@state.nm.us>; Joelle Nadle <jnadle@ceip.us>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; Como-Sabetti, Kathy (MDH) <kathy.como-sabetti@state.mn.us>; Alden, Nisha (CDC state.co.us) <nisha.alden@state.co.us>; isaac.armistead@state.co.us
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Gantt, Susan Conner (CDC/DDID/NCEZID/OD) (CTR) <ZKV0@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCEZID/DFWED) <fez7@cdc.gov>; Lee, Justin (CDC/DDID/NCEZID/DSR) <psd8@cdc.gov>; Armstrong, Gregory (CDC/DDID/NCEZID/OD) <gca3@cdc.gov>; Taylor, Christopher A. (CDC/DDID/NCIRD/DVD) <iyq3@cdc.gov>; Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) <xbe9@cdc.gov>
Subject: EIP vaccine breakthrough project multi-site call on May 4-7

EIP partners.

We would like to schedule another multi-site call for next week (May 4-7). Please provide times when at least one person from your site will be available to participate.

Please let me know your availability during the following days and times (**All Eastern times**):

Eastern times	Tue, May 4	Wed, May 5	Thu, May 6	Fri, May 7

1:00-2:00pm				
2:00-3:00pm				
3:00-4:00pm				
4:00-5:00pm				

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

From: Pam Daily
Sent: Thu, 20 May 2021 20:59:11 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Gantt, Susan Conner (CDC/DDID/NCEZID/OD) (CTR);Lee, Justin (CDC/DDID/NCEZID/DSR);Armstrong, Gregory (CDC/DDID/NCEZID/OD);Taylor, Christopher A. (CDC/DDID/NCIRD/DVD);Bressler, Sara S. (CDC/DDID/NCEZID/DPEI)
Subject: RE: EIP vaccine breakthrough project multi-site calls starting in June-CA availability

Hi Marc and Team,
Below are the dates that the CA site team will be available for a twice monthly call.
Just a thought- you may want to avoid regularly scheduled calls on Mondays, due to holidays.
Also, our group did not have a preference for specific weeks of the month for these calls.

Best, Pam

Eastern times	Monday	Tuesday	Wednesday	Thursday	Friday
1:00-2:00pm (10-11)					
2:00-3:00pm(11-12)		yes			
3:00-4:00pm(12-1)	YES	yes			yes
4:00-5:00pm(1-2)			yes		yes
5:00-6:00pm(2-3)			yes	yes	yes

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Tuesday, May 18, 2021 11:45 AM
To: Allison Roebling <aroebling@gaeip.org>; kopeno@gaeip.org; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Schmoll, Emma (CDC state.co.us) <emma.schmoll@state.co.us>; Alden, Nisha (CDC state.co.us) <nisha.alden@state.co.us>; isaac.armistead@state.co.us; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; Gretchen Rothrock <grothrock@ceip.us>; Pam Daily <pdaily@ceip.us>; Joelle Nadle <jnadle@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Reingold,

Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Sosin, Daniel (CDC state.nm.us) <Daniel.Sosin@state.nm.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; Como-Sabetti, Kathy (MDH) <kathy.como-sabetti@state.mn.us>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>; Clogher, Paula <paula.clogher@yale.edu>; Yousey-Hindes, Kimberly (CDC yale.edu) <kimberly.yousey-hindes@yale.edu>; Plano, Julie <julie.colburn@yale.edu>; Kevin_Popham@urmc.rochester.edu
Cc: Gantt, Susan Conner (CDC/DDID/NCEZID/OD) (CTR) <ZKV0@cdc.gov>; Lee, Justin (CDC/DDID/NCEZID/DSR) <psd8@cdc.gov>; Armstrong, Gregory (CDC/DDID/NCEZID/OD) <gca3@cdc.gov>; Taylor, Christopher A. (CDC/DDID/NCIRD/DVD) <iyq3@cdc.gov>; Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) <xbe9@cdc.gov>
Subject: EIP vaccine breakthrough project multi-site calls starting in June

EIP partners.

In June, we will begin regular twice monthly multi-site project calls.

Please send one response per EIP site regarding days/times when at least one representative can participate in the call. Let me know if you have a preference between 1st/3rd versus 2nd/4th weeks of the month

Please let me know your availability during the following days and times (**All Eastern times**):

Eastern times	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
1:00-2:00pm					
2:00-3:00pm					
3:00-4:00pm					
4:00-5:00pm					
5:00-6:00pm					

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

Attached please find a revised data dictionary that can be used to create the REDCap database for the EIP vaccine breakthrough project, and a spreadsheet defining the variables in the database.

With just a few exceptions, the variables will be defined and formatted as you are already doing for COVID-NET.

Please let us know if you have any questions.

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Pam Daily
Sent: Mon, 24 May 2021 22:52:47 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Gretchen Rothrock;Chai, Shua (CDC cdph.ca.gov);Reingold, Arthur MD (CDC berkeley.edu)
Subject: RE: EIP vaccine breakthrough project multi-site calls starting in June

Hi Marc,
Below is our availability and preference for meeting time and weeks.
Best, Pam

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Saturday, May 22, 2021 8:08 AM
To: Allison Roebling <aroebling@gaeip.org>; kopeno@gaeip.org; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Niccolai, Linda <linda.niccolai@yale.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; Pam Daily <pdaily@ceip.us>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>; Kevin_Popham@urmc.rochester.edu; White, Melinda <melinda.white@vumc.org>; bentley.m.akoko.1@vumc.org; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>
Subject: RE: EIP vaccine breakthrough project multi-site calls starting in June

The two times that look best for the most sites are Mondays at 3:00pm Eastern or Fridays at 3:00pm Eastern.

Please let me know which day will work for your site and if you prefer the 1st and 3rd or 2nd and 4th weeks of the month.

Days and dates	**3:00-4:00pm Eastern time**
1st and 3rd Monday (Jun 7 and 21, Jul 5 and 19, Aug 2 and 16)	
1st and 3rd Friday (Jun 4 and 18, Jul 2 and 16, Aug 6 and 20)	Ok .**Prefer Friday.**
2nd and 4th Monday (Jun 14 and 28, Jul 12 and 26, Aug 9 and 23)	Can attend but prefer Friday.
2nd and 4th Friday (Jun 11 and 25, Jul 9 and 23, Aug 13 and	****Ok , this is our highest preference!!**

27)	

Thanks,
Marc

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Tuesday, May 18, 2021 10:45 AM
To: Allison Roebling <aroebling@gaeip.org>; kopeno@gaeip.org; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Schmoll, Emma (CDC state.co.us) <emma.schmoll@state.co.us>; Alden - CDPHE, Nisha <nisha.alden@state.co.us>; isaac.armistead@state.co.us; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; Gretchen Rothrock <grothrock@ceip.us>; Pam Daily <pdaily@ceip.us>; Joelle Nadle <jnadle@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Sosin, Daniel, DOH <Daniel.Sosin@state.nm.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; Como-Sabetti, Kathy (MDH) <kathy.como-sabetti@state.mn.us>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>; Clogher, Paula <paula.clogher@yale.edu>; Yousey-Hindes, Kimberly (CDC yale.edu) <kimberly.yousey-hindes@yale.edu>; Plano, Julie <julie.colburn@yale.edu>; Kevin_Popham@urmc.rochester.edu
Cc: Gantt, Susan Conner (CDC/DDID/NCEZID/OD) (CTR) <ZKV0@cdc.gov>; Lee, Justin (CDC/DDID/NCEZID/DSR) <psd8@cdc.gov>; Armstrong, Gregory (CDC/DDID/NCEZID/OD) <gca3@cdc.gov>; Taylor, Christopher A. (CDC/DDID/NCIRD/DVD) <iyq3@cdc.gov>; Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) (xbe9@cdc.gov) <xbe9@cdc.gov>
Subject: EIP vaccine breakthrough project multi-site calls starting in June

EIP partners.

In June, we will begin regular twice monthly multi-site project calls.

Please send one response per EIP site regarding days/times when at least one representative can participate in the call. Let me know if you have a preference between 1st/3rd versus 2nd/4th weeks of the month

Please let me know your availability during the following days and times (**All Eastern times**):

Eastern times	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
1:00-2:00pm					
2:00-3:00pm					
3:00-4:00pm					
4:00-5:00pm					
5:00-6:00pm					

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

Attached please find a revised data dictionary that can be used to create the REDCap database for the EIP vaccine breakthrough project, and a spreadsheet defining the variables in the database.

With just a few exceptions, the variables will be defined and formatted as you are already doing for COVID-NET.

Please let us know if you have any questions.

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Joelle Nadle
Sent: Mon, 12 Apr 2021 18:17:23 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Gretchen Rothrock;Pam Daily
Subject: RE: EIP vaccine breakthrough protocol and proposed call

See below for Joelle Nadle, California

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Monday, April 12, 2021 10:34 AM
To: Allison Roebling <aroebling@gaeip.org>; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Schmoll, Emma (CDC state.co.us) <emma.schmoll@state.co.us>; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; kopeno@gaeip.org; Gretchen Rothrock <grothrock@ceip.us>; Pam Daily <pdaily@ceip.us>; Sosin, Daniel (CDC state.nm.us) <Daniel.Sosin@state.nm.us>; Joelle Nadle <jnadle@ceip.us>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Havers, Fiona (CDC/DDID/NCIRD/DVD) <wja7@cdc.gov>; Gantt, Susan Conner (CDC/DDID/NCEZID/OD) (CTR) <ZKV0@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCEZID/DFWED) <fez7@cdc.gov>
Subject: EIP vaccine breakthrough protocol and proposed call

EIP partners.

Attached please find the project protocol with the draft watermark removed in case it is needed for submission for research determination/exemption.

We would like to schedule a multi-site call for next week (April 20-23).

Please let me know your availability during the following days and times (**All Eastern times**):

Eastern times	Tue, Apr 20	Wed, Apr 21	Thu, Apr 22	Fri, Apr 23
1:00-2:00pm	If needed	No	Yes	If needed
2:00-3:00pm	Yes	If needed	Yes	No

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention

970 556 7514
mfischer@cdc.gov

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD)
Sent: Tue, 11 May 2021 17:33:08 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI);Harriman, Kathleen (CDC cdph.ca.gov)
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team;Siegel, Jane (CDC cdph.ca.gov);Jain, Seema (CDC cdph.ca.gov);Epson, Erin@CDPH;Stendel, Patrick@CDPH;Jernigan, John A. (CDC/DDID/NCEZID/DHQP);Kirking, Hannah L. (CDC/DDID/NCIRD/DVD);Nolen, Leisha (CDC/DDID/NCEZID/DPEI);Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD);HAI Outbreak - COVID-19 (CDC);Jacobs Slifka, Kara (CDC/DDID/NCEZID/DHQP);Smith, Jessica (CDC/DDID/NCIRD/DBD);Keaton, Amelia (CDC/DDID/NCEZID/DHQP)
Subject: RE: Outbreak with severe and fatal cases in vaccinated people
Attachments: Information for breakthrough clusters_2021-05-10.docx, Summary of outbreak for CDC consultation 5.10.21.docx

Hi Kathy, Seema, Erin, Jane, and Patrick,

Thank you for alerting us to this outbreak, which sounds like a very concerning situation. I am including a few others from the Vaccine Effectiveness Team (Jess Smith), the Division of Healthcare Quality Promotion (HAICOVID inbox, Kara Jacobs Slifka and Amelia Keaton) and Epi Task Force (Jackie Tate). We would be happy to help set up a call. This is a very helpful summary of the outbreak (attached for those who were added). If you have specific questions outside of vaccine effectiveness, breakthrough infections or infection prevention and control, please let us know so that we can make sure the right people are on the call to answer your questions.

We are trying collect the information on outbreaks with a high number of breakthrough infections in the attached form, to help inform next steps. If it is possible to complete the form before that call, that would help but it is not necessary. It looks like most of this information is in the summary, and if you don't have any of the requested information, that is fine.

If you can send us some times that work for your team, we can coordinate schedules on this end.

Thank you and we will look forward to talking with you soon.

Best,
Katherine

Katherine E. Fleming-Dutra, MD
Vaccine Effectiveness Team
Vaccine Evaluation Unit
Vaccine Task Force
COVID-19 Response
Centers for Disease Control and Prevention

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Sent: Tuesday, May 11, 2021 1:03 PM
To: Harriman, Kathleen (CDC cdph.ca.gov) <Kathleen.Harriman@cdph.ca.gov>
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Siegel, Jane (CDC cdph.ca.gov) <Jane.Siegel@cdph.ca.gov>; Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>; Stendel, Patrick@CDPH <Patrick.Stendel@cdph.ca.gov>; Jernigan, John A. (CDC/DDID/NCEZID/DHQP) <jqj9@cdc.gov>; Kirking, Hannah L. (CDC/DDID/NCIRD/DVD) <hrj7@cdc.gov>; Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>
Subject: RE: Outbreak with severe and fatal cases in vaccinated people

Kathy.

Thanks for sharing this information. There has been a small group from multiple teams at CDC assisting with consultations regarding outbreaks in long-term care facilities.

In general, John Jernigan's group from Healthcare-Associated Infections has taken the lead but also copying Leisha Nolen from our team, Katherine Fleming-Dutra from the Vaccine Effectiveness Team, and Hannah Kirking from the Epidemiology Special Studies Team.

Will see if they can coordinate a call with you to discuss this outbreak.

Best wishes,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Harriman, Kathleen@CDPH <Kathleen.Harriman@cdph.ca.gov>
Sent: Monday, May 10, 2021 10:40 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Siegel, Jane (CDC cdph.ca.gov) <Jane.Siegel@cdph.ca.gov>; Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>; Stendel, Patrick@CDPH <Patrick.Stendel@cdph.ca.gov>
Subject: Outbreak with severe and fatal cases in vaccinated people

Dear Dr. Fischer,
We have what we think is an unusual outbreak of COVID-19 cases, including hospitalized and fatal cases among fully vaccinated residents of an assisted living facility (summary attached). Is it possible to set up a call to talk with you and your team about this outbreak?

Thanks so much, Kathy

Kathleen Harriman
COVID-19 Response
California Department of Public Health

In order to assist in the evaluation of COVID-19 vaccine breakthrough case clusters in a facility, the breakthrough and vaccine effectiveness (VE) teams ask for the below basic data. This information will help understand if the cluster of cases your facility is observing is outside of the expected pattern. Please complete as best as possible, we understand this data may only be an estimate. CDC will use this data to understand if your cluster is unusual and if it may be a good situation to evaluate (VE). Regardless of whether this cluster is a good fit to evaluate VE, the CDC may be able to provide IPC technical assistance for facility outbreaks. While this information is being complied please report breakthrough cases as per the norm to CDC and hold any specimens from the cluster in case evaluation of viral sequence is appropriate.

Name of contact investigation this cluster:

Email for contact:

Name and type of facility (or way to identify if anonymity is preferred):

Date of first positive case in cluster:

Date of most recent positive case in cluster:

Date of report:

Date as of which information below was collected:

Please fill out numbers as best as possible for all fields below

- if only estimates are available, list numbers with a ~ symbol

	Residents	**Staff**
Total number in the facility (resident census and total staff working in cluster period)		
Number of people **fully vaccinated** on date that cluster began*		
Number of infections in symptomatic fully vaccinated people		
Number of infections in asymptomatic fully vaccinated people		
Number of people **partially vaccinated** on date that cluster began**		
Number of infections in symptomatic partially vaccinated people		
Number of infections in asymptomatic partially vaccinated people		
Number of people **unvaccinated** on date that cluster began***		
Number of infections in symptomatic unvaccinated people		
Number of infections asymptomatic unvaccinated people		

*Fourteen or more days after completing a primary series of an FDA-authorized vaccine (i.e., 2 doses of the Pfizer-BioNTech or Moderna vaccines or 1 dose of the Janssen vaccine) at the time of positive test or evaluation

**Received either 1 dose of the Pfizer-BioNTech or Moderna vaccine or completed a primary series of an FDA-authorized vaccine (i.e., 2 doses of the Pfizer-BioNTech or Moderna vaccines or 1 dose of the Janssen vaccine) less than 14 days prior at the time of positive test or evaluation

***Has not received any COVID-19 vaccine at the time of positive test or evaluation

Positive by either Antigen, PCR or other NAAT

For all the positive cases listed above please list the test type used:

	Antigen ONLY	NAAT* Confirmation
Number of cases		

*NAAT includes PCR and all other nucleic acid amplification tests

If any virus has been sequenced for this cluster please list below. Feel free to add additional lines if needed

	Number of isolates with sequence	Pangolin lineage*
Viral strain 1		
Viral strain 2		

*Pangolin lineage is the name for the viral strain. Some common ones are B.1.1.7 or B.1.2. This should come from the laboratory sequence data

Send back to the breakthrough team at eocevent531@cdc.gov and vaccine effectiveness team eocevent426@cdc.gov. For long-term care facility clusters, please also send to haicovid@cdc.gov

Summary of outbreak of SARS-CoV-2 infections in fully vaccinated residents in an Assisted Living Facility (ALF) with a Memory Care Unit in [redacted]

Facility: Total occupancy 64

- 58 bed capacity in ALF; current occupancy 50
  - All single person rooms except for one double room
- Additional 14 beds in Memory Care Unit
  - All double rooms
- Had opened up to communal dining, visitation, group activities
- Vaccination rate: 98% of residents, 50% of staff overall, but only 3 of 24 (12.5%) clinical staff
- All vaccinations except 2 were with Pfizer vaccine, date of second dose 2/18/21 (other 2 people received Moderna vaccine)

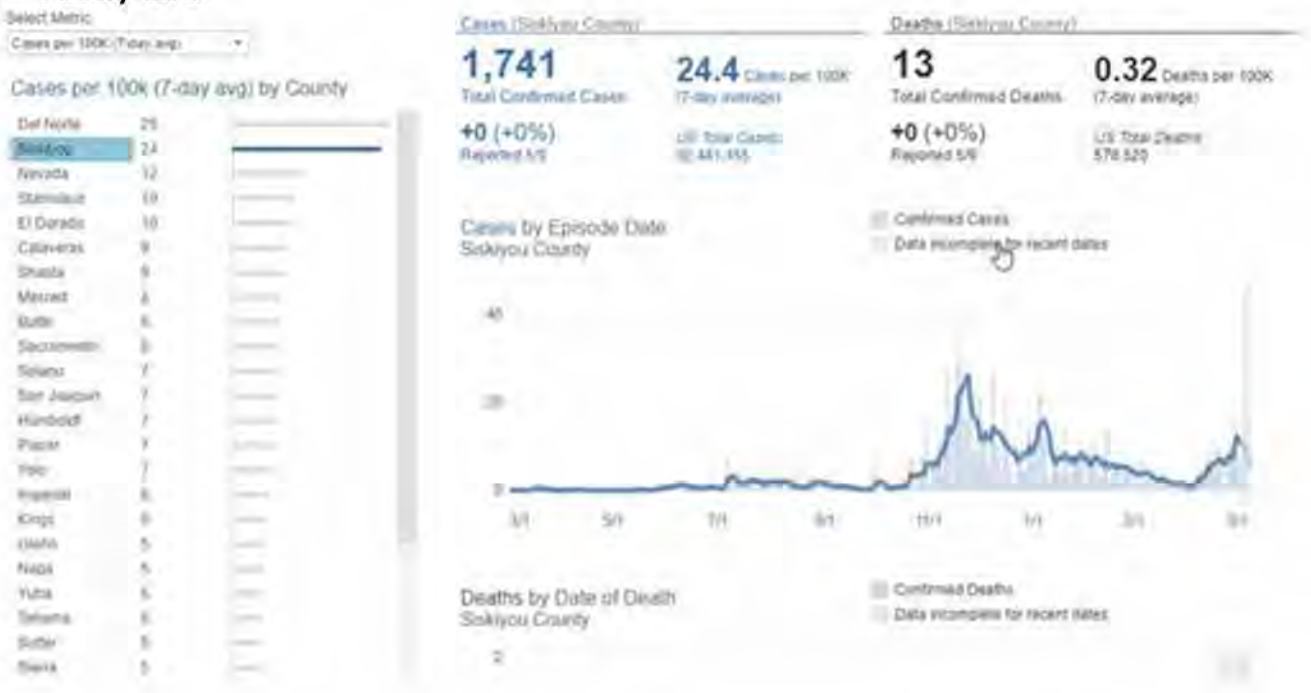
Outbreak:

- Index case: 83 y.o. woman in ALF developed SOB, respiratory symptoms on **4/21**, and G.I. symptoms on 4/23. Admitted to hospital 4/23, transferred to ICU, intubated, expired 5/5/21 with COVID-19 pneumonia.
  - Co-morbidities: COPD, obesity (90 kg), rheumatoid arthritis for which she had been taking Rituximab.
  - Reported to be "social butterfly" - interacted with everyone, loved by everyone.
  - Fully vaccinated with Pfizer vaccine; dose #2 on 2/18/2021.
  - 4/23: Binax Now positive, PCR positive with Ct value of 26.3.
- Investigation:
  - **4/19**: Med tech who is not vaccinated and works in ALF and Memory Care had a stuffy nose and worked all week
    - Reportedly wears a mask when managers are present, but removes mask when managers are not present
    - Contact with residents throughout facility
    - Symptoms worsened, last day of work 4/22, went to ED 4/24 and had positive PCR
  - **4/24-4/25**:
    - Binax now tests on all other **residents: 14 residents** positive (8 became symptomatic). All fully vaccinated, dose #2 on 2/18/21.
    - Binax now tests on all staff: 5 positive, 2 symptomatic. All staff worked with med tech
    - 1 visitor positive 4/25.
    - Returned to COVID policies of no communal dining, no group activities, no visitors
  - **4/29**: PCR sent on all pos. antigen tests and were positive
  - **4/30**: Call with LHD, Facility, CDPH HAI
    - Facility had no N95s or eye protection; PPE delivered 5/1 and staff instructed on seal check
    - Monoclonal antibody combinations had not been considered
  - **5/4:** All staff fit tested by LHD; reported not to be wearing N95s
    - HAI IP visit: Staffing needs and infection control breaches observed

    - Also visited 3 other ALFs in County and 1 SNF
  - **5/5:** HAI IP returns to facility
  - **5/6:** Second round of response testing; all Binax Now positives confirmed with PCR
    - Monoclonal antibody combination (Regeneron) administered to 20 people (?)
    - Specimens sent to VRDL for WGS

- **Current status (as of 5/10)**
  - **Residents:** 26 positive, PCR confirmed; 50-60% symptomatic
    - 25 fully vaccinated (24 Pfizer, 1 Moderna)
    - 5 hospitalizations; 2 admitted to ICU, both expired
    - 3 had 48 hr. stays, no ICU care required
  - **Staff**: 7 positive
    - 2 of 7 fully vaccinated; no hospitalizations; most symptomatic
  - **Visitors:** 1 positive, fully vaccinated
  - **Whole genome sequencing**
    - **5/7:** 17 specimens from residents; SNP screen showed EKE 484 mutation only in all
    - **5/10:** 8 of 17 adequate for WGS: all with EKE 484 and P681H mutations; insufficient to be VOC or VOI. Clade 20B B.1.1.318
  - **Serology**: pending
  - **County vaccination rate:** 26% of 43,000
  - **Attempting to obtain information from CVS about their storage and handling of vaccine;** 4 hour drive to facility

- **County data:**



B1.1.318 information from the UK (from March 31, 2021), which classifies this as a variant under investigation (VUI) -- for more details see:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/975742/Variants_of_Concern_VOC_Technical_Briefing_8_England.pdf

VUI-21FEB-04 (B.1.1.318)
The VUI-21FEB-04 is lineage B.1.1.318 and was identified in England in mid-February 2021 through routine horizon scanning for the development of new clusters of genomes containing E484K. This analysis identified an initial cluster of 6 cases containing E484K and other spike mutations, designated VUI-21FEB-04 (B.1.1.318) on 23 February 2021.

Epidemiological profile
As of 31 March 2021, there were 72 genomically confirmed cases of VUI-21FEB-04 (B.1.1.318). Cases have occurred in most regions of England, concentrated in London and the South East. Regional cases are shown in Table 14 and confirmed and probable cases by specimen date are shown in Figure 15. Figure 15 shows sporadic cases in several regions. The supplementary data for figures is available here. Of the 72 cases, 34 were travel associated countries and 2 were contacts of travelers. 13 cases had no known link to travel.

International Epidemiology
As of 31 March 2021 there are no cases reported internationally. GISAID (gisaid.org) includes data on sequences available internationally. As of the 31 March 2021, there are 2 international VUI-21FEB-04 sequences, excluding UK. (Germany 1, USA 1).

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD)
Sent: Thu, 20 May 2021 22:09:24 +0000
To: Siegel, Jane (CDC cdph.ca.gov);Fischer, Marc (CDC/DDID/NCEZID/DPEI);Harriman, Kathleen (CDC cdph.ca.gov)
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team;Jain, Seema (CDC cdph.ca.gov);Epson, Erin@CDPH;Stendel, Patrick@CDPH;Jernigan, John A. (CDC/DDID/NCEZID/DHQP);Kirking, Hannah L. (CDC/DDID/NCIRD/DVD);Nolen, Leisha (CDC/DDID/NCEZID/DPEI);Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD);HAI Outbreak - COVID-19 (CDC);Jacobs Slifka, Kara (CDC/DDID/NCEZID/DHQP);Smith, Jessica (CDC/DDID/NCIRD/DBD);Keaton, Amelia (CDC/DDID/NCEZID/DHQP);McMorrow, Meredith (CDC/DDID/NCIRD/DVD);Verani, Jennifer R. (CDC/DDID/NCIRD/DBD);Mbaeyi, Sarah (CDC/DDID/NCIRD/OD);Schiffer, Jarad (CDC/DDPHSIS/CPR/OD);Thornburg, Natalie (CDC/DDID/NCIRD/DVD);MacNeil, Jessica R. (CDC/DDID/NCIRD/OD);Hicks, Lauri (CDC/DDID/NCEZID/DHQP)
Subject: RE: Outbreak with severe and fatal cases in vaccinated people: update

Hi Jane and CDPH team,

I am sorry if my response was confusing. We did loop both the Lab TF and VTF Clinical team into this specific situation. Regarding the serology question, seeing the pending serology results stratified by vaccination and breakthrough infection status will inform the next steps. The serology results for those who are vaccinated and did not have a breakthrough case will hopefully give us an indication of whether something went wrong at the vaccine clinic or with this batch of vaccines.

Also, the clinical team conferred about this specific situation and said they would not want to base revaccination decisions on serology results. However, if the investigation around storage/handling of the vaccine raises any concerns (temperature excursion, etc), please let us know.

Lastly, regarding your question about Pfizer's changing guidance on the management of the COVID-19 vaccine and what constitutes a breach, my understanding is that is a question for the manufacturer (Pfizer). We ran into this situation for another state, and that was the guidance from our VTF colleagues in the Federal Pharmacy Partnership.

Jarad, Natalie, Sarah, Jessica, and Lauri, please feel free to weigh in on these questions. Specifically, do you have any further guidance on the changing handling instructions?

Best,
Katherine

From: Siegel, Jane@CDPH <Jane.Siegel@cdph.ca.gov>
Sent: Thursday, May 20, 2021 4:40 PM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Harriman, Kathleen (CDC cdph.ca.gov) <Kathleen.Harriman@cdph.ca.gov>
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>;

Stendel, Patrick@CDPH <Patrick.Stendel@cdph.ca.gov>; Jernigan, John A. (CDC/DDID/NCEZID/DHQP) <jqj9@cdc.gov>; Kirking, Hannah L. (CDC/DDID/NCIRD/DVD) <hrj7@cdc.gov>; Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <jqt8@cdc.gov>; HAI Outbreak - COVID-19 (CDC) <haicovid@cdc.gov>; Jacobs Slifka, Kara (CDC/DDID/NCEZID/DHQP) <ipf8@cdc.gov>; Smith, Jessica (CDC/DDID/NCIRD/DBD) <lyd7@cdc.gov>; Keaton, Amelia (CDC/DDID/NCEZID/DHQP) <nrx9@cdc.gov>; McMorrow, Meredith (CDC/DDID/NCIRD/DVD) <bwe3@cdc.gov>; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) <qzr7@cdc.gov>; Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>; Schiffer, Jarad (CDC/DDPHSIS/CPR/OD) <aku3@cdc.gov>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>; Hicks, Lauri (CDC/DDID/NCEZID/DHQP) <auq3@cdc.gov>
Subject: RE: Outbreak with severe and fatal cases in vaccinated people: update

Hi, Katherine.
As our team reviewed the response from the Lab Task Force and the VTF clinical team, it seems that their response was a generic response and not a response that takes into context the outbreak we presented to you. We found it helpful to have a recommendation from you on our call to pursue obtaining serology testing from other fully vaccinated residents who where not COVID-19 positive. We have done so and 19 specimens have arrived in our lab for testing.

I wanted to know if there are any other tests to run in this specific situation.
Perhaps these specimens will answer our question.

However, I do not think that the younger, fully vaccinated staff will be willing to have their blood drawn.

Jane

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From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Thursday, May 20, 2021 8:50 AM
To: Siegel, Jane@CDPH <Jane.Siegel@cdph.ca.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Harriman, Kathleen@CDPH <Kathleen.Harriman@cdph.ca.gov>
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>; Stendel, Patrick@CDPH <Patrick.Stendel@cdph.ca.gov>; Jernigan, John A. (CDC/DDID/NCEZID/DHQP) <jqj9@cdc.gov>; Kirking, Hannah L. (CDC/DDID/NCIRD/DVD) <hrj7@cdc.gov>; Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <jqt8@cdc.gov>; HAI Outbreak - COVID-19 (CDC) <haicovid@cdc.gov>; Jacobs Slifka, Kara (CDC/DDID/NCEZID/DHQP) <ipf8@cdc.gov>; Smith, Jessica (CDC/DDID/NCIRD/DBD) <lyd7@cdc.gov>;

Keaton, Amelia (CDC/DDID/NCEZID/DHQP) <nrx9@cdc.gov>; McMorrow, Meredith (CDC/DDID/NCIRD/DVD) <bwe3@cdc.gov>; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) <qzr7@cdc.gov>; Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>; Schiffer, Jarad (CDC/DDPHSIS/CPR/OD) <aku3@cdc.gov>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>; Hicks, Lauri (CDC/DDID/NCEZID/DHQP) <auq3@cdc.gov>
Subject: RE: Outbreak with severe and fatal cases in vaccinated people: update

Hi Jane and CDPH team,

Regarding your questions, I was able to connect with colleagues from the Lab Task Force (Jarad Schiffer and Natalie Thornberg) and VTF Clinical Team (Sarah Mbaeyi, Jessica MacNeil and Lauri Hicks). See below for their responses. I have also added them to this email chain.

Are there any other serology tests that should be done?
No additional serology tests are needed at this time, but it would be very helpful to see the serology results stratified by vaccination and breakthrough infection status. Can you share these with our teams?

We have been asked if those with neg. spike protein antibody should receive a booster dose of vaccine. What is your advice on that?
Regarding this question, are you asking this in general or in regards to either this outbreak or the situation with the cold chain failure?

We do not recommend using antibody testing to assess post-vaccination immunity or need for additional doses at this time. We also have not been recommending additional doses to anyone unless there was an administration error (including improper storage/handling that would potentially affect validity of the doses).

Here is the posted guidance: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#laboratory-testing
"Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination because the clinical utility of post-vaccination testing has not been established. Antibody tests currently authorized under an EUA have variable sensitivity, specificity, as well as positive and negative predictive values, and are not authorized for the assessment of immune response in vaccinated people. Furthermore, the serologic correlates of protection have not been established, and antibody testing does not evaluate the cellular immune response, which may also play a role in vaccine-mediated protection. Finally, antibody testing against nucleocapsid will not detect immune responses resulting from vaccination, but patients may not always know what type of antibody test was used. If antibody testing was performed following vaccination, additional doses of the same or different COVID-19 vaccines are not recommended based on antibody test results at this time. If antibody testing was done after the first dose of an mRNA vaccine, the vaccination series should be completed regardless of the antibody test result."

Please let us know if you have further questions and we will look forward to learning more about the serology results in this assisted living facility.

Best,
Katherine

Katherine E. Fleming-Dutra, MD
Vaccine Effectiveness Team
Vaccine Evaluation Unit
Vaccine Task Force
COVID-19 Response
Centers for Disease Control and Prevention

From: Siegel, Jane@CDPH <Jane.Siegel@cdph.ca.gov>
Sent: Wednesday, May 19, 2021 3:02 PM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Harriman, Kathleen (CDC cdph.ca.gov) <Kathleen.Harriman@cdph.ca.gov>
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>; Stendel, Patrick@CDPH <Patrick.Stendel@cdph.ca.gov>; Jernigan, John A. (CDC/DDID/NCEZID/DHQP) <jqj9@cdc.gov>; Kirking, Hannah L. (CDC/DDID/NCIRD/DVD) <hrj7@cdc.gov>; Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <jqt8@cdc.gov>; HAI Outbreak - COVID-19 (CDC) <haicovid@cdc.gov>; Jacobs Slifka, Kara (CDC/DDID/NCEZID/DHQP) <ipf8@cdc.gov>; Smith, Jessica (CDC/DDID/NCIRD/DBD) <lyd7@cdc.gov>; Keaton, Amelia (CDC/DDID/NCEZID/DHQP) <nrx9@cdc.gov>
Subject: RE: Outbreak with severe and fatal cases in vaccinated people: update
Importance: High

Hi, all.
Thank you very much for meeting with us about our vaccine breakthrough cluster last week on 5/13.
We received serology results of the patients who were infected and vaccinated. The tests that were run are:

1. Bio-Rad/Platelia SARS CoV-2 Total Antobody EIA (EUA); Analyte: Anti-Nucleocapsid Total Antibody
2. UBI SARS CoV-2 ELISA (EUA); Analyte: Anti-Nucleocapsid, Matrix and Spike IgG Antibody

There were various combinations of results, including negatives on spike protein antibody in those who received vaccine.
We are supposed to receive serology on those who are not infected with SARS-CoV-2.
I have confidence in our state lab to be running these tests correctly. Are there any other serology tests that should be done?

We have another situation where there was definitely a cold chain problem.

We have been asked if those with neg. spike spike protein antibody should receive a booster dose of vaccine.

What is your advice on that?
Should this be a question that goes to the Vaccine Task force?

Thanks very much for your assistance. These are challenging problems for us to navigate.

Jane

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From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Tuesday, May 11, 2021 10:33 AM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>; Harriman, Kathleen@CDPH <Kathleen.Harriman@cdph.ca.gov>
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Siegel, Jane@CDPH <Jane.Siegel@cdph.ca.gov>; Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>; Stendel, Patrick@CDPH <Patrick.Stendel@cdph.ca.gov>; Jernigan, John A. (CDC/DDID/NCEZID/DHQP) <jqj9@cdc.gov>; Kirking, Hannah L. (CDC/DDID/NCIRD/DVD) <hrj7@cdc.gov>; Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <jqt8@cdc.gov>; HAI Outbreak - COVID-19 (CDC) <haicovid@cdc.gov>; Jacobs Slifka, Kara (CDC/DDID/NCEZID/DHQP) <ipf8@cdc.gov>; Smith, Jessica (CDC/DDID/NCIRD/DBD) <lyd7@cdc.gov>; Keaton, Amelia (CDC/DDID/NCEZID/DHQP) <nrx9@cdc.gov>
Subject: RE: Outbreak with severe and fatal cases in vaccinated people

Hi Kathy, Seema, Erin, Jane, and Patrick,

Thank you for alerting us to this outbreak, which sounds like a very concerning situation. I am including a few others from the Vaccine Effectiveness Team (Jess Smith), the Division of Healthcare Quality Promotion (HAICOVID inbox, Kara Jacobs Slifka and Amelia Keaton) and Epi Task Force (Jackie Tate). We would be happy to help set up a call. This is a very helpful summary of the outbreak (attached for those who were added). If you have specific questions outside of vaccine effectiveness, breakthrough infections or infection prevention and control, please let us know so that we can make sure the right people are on the call to answer your questions.

We are trying collect the information on outbreaks with a high number of breakthrough infections in the attached form, to help inform next steps. If it is possible to complete the form before that call, that would help but it is not necessary. It looks like most of this information is in the summary, and if you don't have any of the requested information, that is fine.

If you can send us some times that work for your team, we can coordinate schedules on this end.

Thank you and we will look forward to talking with you soon.

Best,
Katherine

Katherine E. Fleming-Dutra, MD
Vaccine Effectiveness Team
Vaccine Evaluation Unit
Vaccine Task Force
COVID-19 Response
Centers for Disease Control and Prevention

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Sent: Tuesday, May 11, 2021 1:03 PM
To: Harriman, Kathleen (CDC cdph.ca.gov) <Kathleen.Harriman@cdph.ca.gov>
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Siegel, Jane (CDC cdph.ca.gov) <Jane.Siegel@cdph.ca.gov>; Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>; Stendel, Patrick@CDPH <Patrick.Stendel@cdph.ca.gov>; Jernigan, John A. (CDC/DDID/NCEZID/DHQP) <jqj9@cdc.gov>; Kirking, Hannah L. (CDC/DDID/NCIRD/DVD) <hrj7@cdc.gov>; Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>
Subject: RE: Outbreak with severe and fatal cases in vaccinated people

Kathy.

Thanks for sharing this information. There has been a small group from multiple teams at CDC assisting with consultations regarding outbreaks in long-term care facilities.

In general, John Jernigan's group from Healthcare-Associated Infections has taken the lead but also copying Leisha Nolen from our team, Katherine Fleming-Dutra from the Vaccine Effectiveness Team, and Hannah Kirking from the Epidemiology Special Studies Team.

Will see if they can coordinate a call with you to discuss this outbreak.

Best wishes,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Harriman, Kathleen@CDPH <Kathleen.Harriman@cdph.ca.gov>
Sent: Monday, May 10, 2021 10:40 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Siegel, Jane (CDC cdph.ca.gov) <Jane.Siegel@cdph.ca.gov>; Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>; Stendel, Patrick@CDPH <Patrick.Stendel@cdph.ca.gov>
Subject: Outbreak with severe and fatal cases in vaccinated people

Dear Dr. Fischer,
We have what we think is an unusual outbreak of COVID-19 cases, including hospitalized and fatal cases among fully vaccinated residents of an assisted living facility (summary attached). Is it possible to set up a call to talk with you and your team about this outbreak?
Thanks so much, Kathy

Kathleen Harriman
COVID-19 Response
California Department of Public Health

From: Gretchen Rothrock
Sent: Thu, 25 Mar 2021 22:36:45 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Reingold, Arthur MD (CDC berkeley.edu);Pam Daily;Chai, Shua (CDC cdph.ca.gov);Joelle Nadle
Subject: RE: Primary contact for EIP protocol to evaluate COVID-19 vaccine breakthrough cases

Hi Marc,
Could you please add me to the mailing list for Breakthrough WG calls **along with Joelle Nadle**, cc'd?
We are both deeply entrenched in budgeting and protocols and need to make sure we are on all calls.

Thanks a million!

Gretchen

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Tuesday, March 9, 2021 5:00 PM
To: Gretchen Rothrock <grothrock@ceip.us>
Cc: Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Pam Daily <pdaily@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>
Subject: RE: Primary contact for EIP protocol to evaluate COVID-19 vaccine breakthrough cases

Gretchen.

Thanks for the interest and willingness to participate. I will work with Shua and representatives from the other EIP sites to revise the protocol.

Will also add Pam to the distribution list for further communications regarding this project.

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
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970 556 7514
mfischer@cdc.gov

From: Gretchen Rothrock <grothrock@ceip.us>
Sent: Tuesday, March 9, 2021 3:34 PM

To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Pam Daily <pdaily@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>
Subject: RE: Primary contact for EIP protocol to evaluate COVID-19 vaccine breakthrough cases

Hi Marc,

The Project Coordinator for COVID, Pam Daily, is not on this email. Please add her to the group .

We plan to participate and we are putting together a project budget as requested by the COVID team on last Friday's call.

Pam, Art, Shua and I are CA team. For this study, **Shua Chai, cc'd, will be the POC**.

Thank you,

Gretchen

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Tuesday, March 9, 2021 12:47 PM
To: Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Gretchen Rothrock <grothrock@ceip.us>; Herlihy, Rachel (CDC state.co.us) <rachel.herlihy@state.co.us>; Quyen.Phan@ct.gov; linda.niccolai@yale.edu; Melissa.Tobin-DAngelo@dph.ga.gov; mfarley@emory.edu; Patricia.Ryan@Maryland.gov; richard.danila@health.state.mn.us; ruth.lynfield@health.state.mn.us; slathrop@salud.unm.edu; alison.muse@health.ny.gov; Ghinwa_Dumyati@URMC.Rochester.edu; Melissa.Sutton@dhsoha.state.or.us; Cieslak, Paul (CDC dhsoha.state.or.us) <paul.r.cieslak@dhsoha.state.or.us>; william.schaffner@vumc.org; keipp.talbot@vumc.org; Alden - CDPHE, Nisha <nisha.alden@state.co.us>; Como-Sabetti, Kathy (MDH) <kathy.como-sabetti@state.mn.us>; Fridkin, Scott <sfridki@emory.edu>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>
Subject: Primary contact for EIP protocol to evaluate COVID-19 vaccine breakthrough cases

EIP partners.

If your site is interested in possibly participating in the project to compare the frequency of SARS-CoV-2 variants of concern among vaccinated and unvaccinated COVID-19 cases, please provide a primary point of contact who will work with me on revising the draft protocol.

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Fri, 4 Jun 2021 21:42:02 +0000
To: Pam Daily
Cc: Kyle Openo;Yousey-Hindes, Kimberly (CDC yale.edu)
Subject: RE: Question about Breakthrough study matching

Pam.

That is correct and all sounds good. Let me know if you have additional questions or would like to discuss further.

Have a good weekend,
Marc

From: Pam Daily <pdaily@ceip.us>
Sent: Friday, June 4, 2021 1:39 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Kyle Openo <kopeno@gaeip.org>; Yousey-Hindes, Kimberly (CDC yale.edu) <kimberly.yousey-hindes@yale.edu>
Subject: RE: Question about Breakthrough study matching

Thank you Marc for your quick response- this all makes sense.

I understand that the matching will be done in the analysis by frequency matching, so we won't need to identify specific case to control matches upon data collection, is that correct?

So we will plan to include in our site specific PHI database the inclusion of up to 3 randomly selected controls for the case calendar week of specimen collection .

Also, I will consult with our HCP vaccine study staff to identify how we can best use this model for control identification and documentation.

Thanks, Pam

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Friday, June 4, 2021 12:21 PM
To: Pam Daily <pdaily@ceip.us>
Cc: Kyle Openo <kopeno@gaeip.org>; Yousey-Hindes, Kimberly (CDC yale.edu) <kimberly.yousey-hindes@yale.edu>
Subject: RE: Question about Breakthrough study matching

Pam.

Vaccinated and unvaccinated cases should be frequency matched based on week of positive test. For each vaccinated case identified, you will randomly select three unvaccinated cases from the same testing laboratory and with a specimen collection date within that same calendar week. If

three unvaccinated cases are not identified with specimens collection dates within that calendar week, enroll the one or two cases that are identified.

The vaccinated and unvaccinated cases are being frequency matched, not pair matched. For example, if two vaccinated cases are identified within a calendar week, you are randomly selecting up to six unvaccinated cases from that same testing laboratory and week. Since the vaccinated and unvaccinated cases are not pair matched, we do not need to link the identification numbers.

These should be the same procedures that have been used for the EIP COVID vaccine effectiveness study among healthcare providers.

Please let me know if you have additional questions.

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Epi Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Pam Daily <pdaily@ceip.us>
Sent: Friday, June 4, 2021 9:18 AM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Kyle Openo <kopeno@gaeip.org>; Yousey-Hindes, Kimberly (CDC yale.edu) <kimberly.yousey-hindes@yale.edu>
Subject: Question about Breakthrough study matching

Hi Marc,
I am working with an analyst setting up parameters for the specimen collection and I have a few questions about matching controls to cases and documenting the linkage for the study.

I had a discussion with a few people who also have this question, and it may help to clarify for the entire study group:

Since we are matching controls with cases by week of specimen collection, if we use the specimen date of the case as the reference, would controls have

1. **a specimen collection date (+) or (–) 7 days from the case specimen date**, [eg case=march 15 then control date would be March 8 - 21] or
2. **would the controls have dates in the same week (eg MMWR week**) [eg case=march 15, then control date would be same week March 14-20]

Also it may help to have a standardized field (standardized format) to document linking of cases to controls for the "local_id" field :

	Study identification	
local_id	number	number

Within the study group we have lots of combined experience conducting case control studies, and if you can bring this up for discussion, I'm sure an efficient format can be used by all.
For instance one way we have documented linking cases to controls in previous studies, is to have the case be something like: **CA**VB001 then the controls would be CAVB001-1, CAVB001-2, CAVB001-3, etc.

This will make a big difference when selecting matched controls and documenting the matching, and I think it would help to do these step consistently among sites!

Thanks for considering,
Pam

Pam Daily Kirley
California Emerging Infections Program
COVID-19, Influenza and RSV Surveillance Coordinator

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Thu, 6 May 2021 16:36:50 +0000
To: Harriman, Kathleen@CDPH;Mbaeyi, Sarah (CDC/DDID/NCIRD/OD);Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Cc: CDC IMS 2019 NCOV Response VTF Vaccine Breakthrough Team
Subject: RE: Quick question
Attachments: Pfizer mRNA healthcare provider fact sheet.pdf

Kathy.

Until states are able to report vaccination history for COVID cases through routine case-based surveillance (i.e., NNDSS/DCIPHER), we have asked them to voluntarily report vaccine breakthrough cases to the national vaccine breakthrough REDCap database.

As expected, when the number of people vaccinated increased substantially so did the number of vaccine breakthrough cases. This became a large burden for reporting, especially when you include asymptomatic or mild infections that are detected through routine screening. Therefore, as of May 1, we transitioned from monitoring all reported vaccine breakthrough cases to focus on identifying and investigating only vaccine breakthrough infections that result in hospitalization or death. We hope this shift will help maximize the quality of the data collected on cases of greatest clinical and public health importance

Under the EUA, the vaccination provider is responsible for mandatory reporting COVID-9 vaccine breakthrough cases that result in hospitalization or death to VAERS. See page 8 of the attached provider fact sheet for the Pfizer vaccine.

More information about vaccine breakthrough surveillance is at https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html.

Let me know if you have questions.

Best wishes,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Harriman, Kathleen@CDPH <Kathleen.Harriman@cdph.ca.gov>
Sent: Thursday, May 6, 2021 8:14 AM
To: Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>; Oliver, Sara Elizabeth

(CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Cc: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Subject: Re: Quick question

Thank you - but not ALL breakthrough cases, right? Once we stop screening testing of asymptomatic fully vaccinated HCP we will stop getting PCR positives with high Cts who are very unlikely to be current cases or infectious. We have had many...

From: Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>
Sent: Thursday, May 6, 2021 8:57:27 AM
To: Harriman, Kathleen@CDPH <Kathleen.Harriman@cdph.ca.gov>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Cc: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Subject: RE: Quick question

Hi Kathy,
I think it's still necessary to report COVID-19 cases that are hospitalized or die to VAERS because it's a requirement under the EUA, but I'm cc'ing Marc who leads the breakthrough case work in case there are additional conversations I may not be aware.
Best,
Sarah

From: Harriman, Kathleen@CDPH <Kathleen.Harriman@cdph.ca.gov>
Sent: Thursday, May 6, 2021 11:32 AM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>; Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>
Subject: Quick question

CDC guidance requests reporting of vaccine breakthrough cases in VAERS. However, states are doing separate surveillance for breakthrough cases, particularly hospitalized and fatal cases.

How necessary is it for us to ask providers to report these cases through VAERS?
Thanks, Kathy

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **Pfizer-BioNTech COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 16 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF). Vials must be kept frozen between -80ºC to -60ºC (-112ºF to -76ºF) and protected from light until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

Dosing and Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

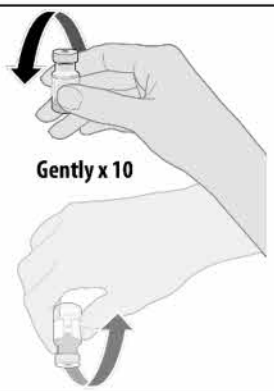
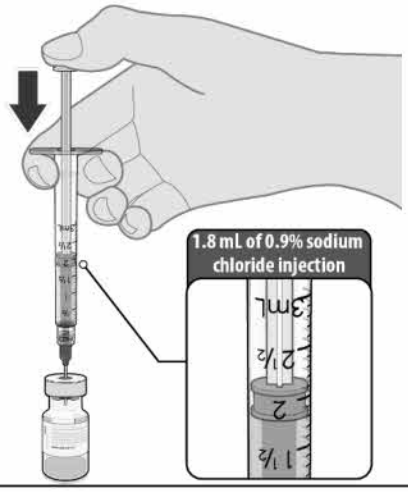
Prior to Dilution

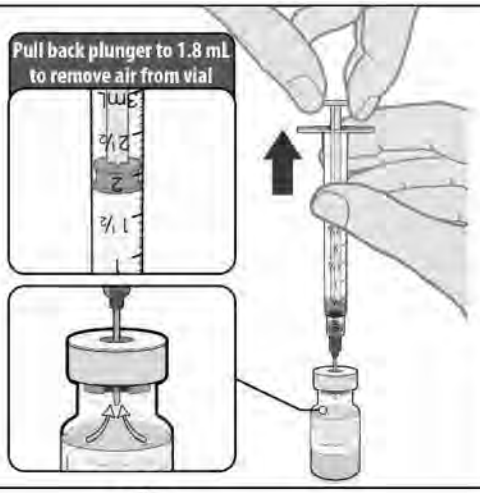
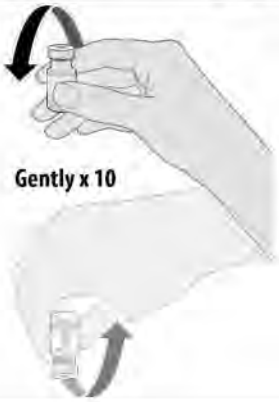
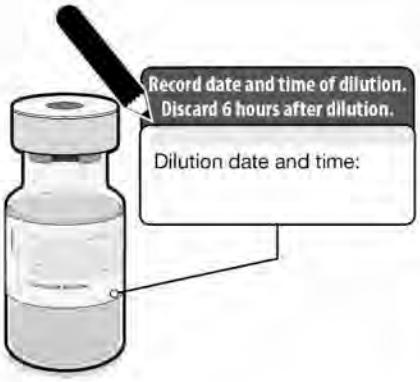
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)] *(see Storage and Handling)*.
- Refer to thawing instructions in the panels below.

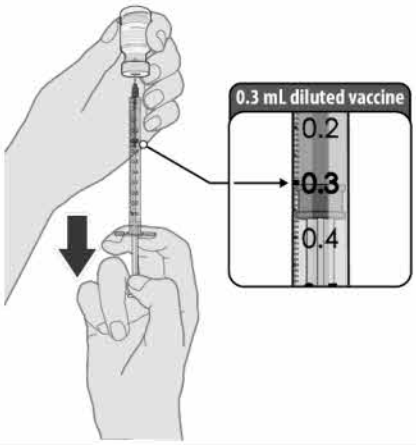
Dilution

Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: ○ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). ○ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	• Before dilution invert vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Warnings

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy *(see Full EUA Prescribing Information)*.

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Fact Sheet) prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 16 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
   - vaccine administration errors whether or not associated with an adverse event,
   - serious adverse events* (irrespective of attribution to vaccination),
   - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
   - cases of COVID-19 that result in hospitalization or death.

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;

- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 16 years of age and older.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1450-1.0

Revised: December 2020

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

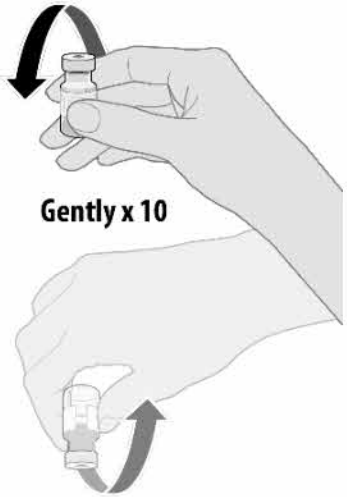
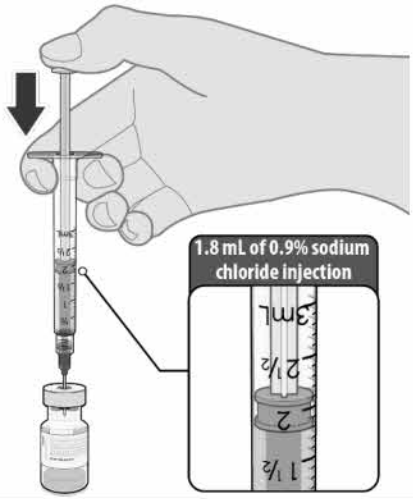
2.1 Preparation for Administration

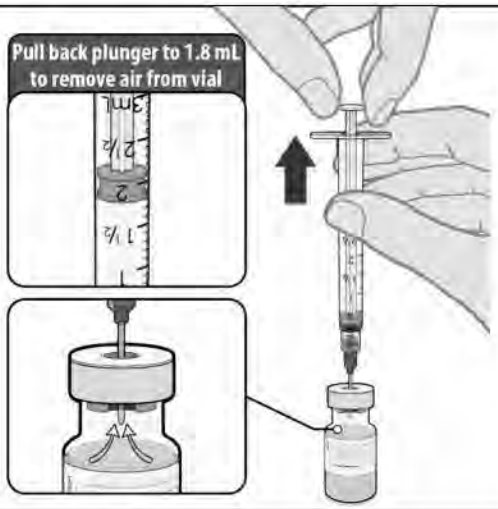
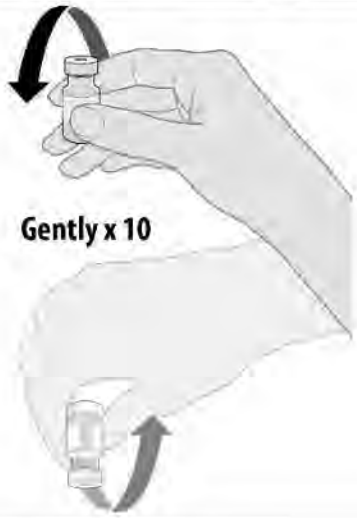
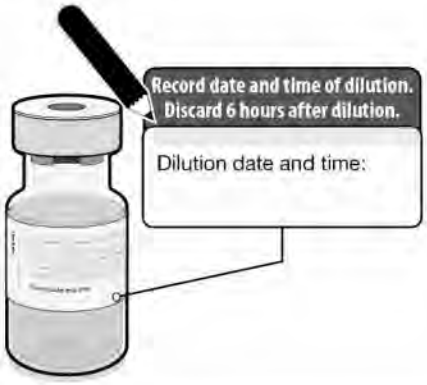
Prior to Dilution

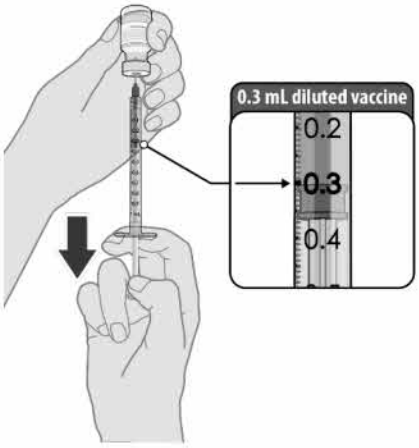
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)] *[see How Supplied/Storage and Handling (19)]*.
- Refer to thawing instructions in the panels below.

Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). o Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	• Before dilution invert vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine. • Administer immediately.

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

2.3 Vaccination Schedule for Individuals 16 Years of Age and Older

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

5.3 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 16 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 44,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively).

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older have been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020. Participants 18 years and older in the reactogenicity subset are monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination].

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Local and Systemic Adverse Reactions Solicited in the Study 2

Table 1 and Table 2 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo in the subset of participants 18 to 55 years of age included in the EUA safety population who were monitored for reactogenicity with an electronic diary.

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo for participants 56 years of age and older.

Across both age groups, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Redness[c]				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling[c]				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
Pain at the injection site[d]				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age‡ – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue[c]				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Headache[c]				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills[c]				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Vomiting[d]				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea[e]				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain[c]				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication[f]	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Redness[c]				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Swelling[c]				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Headache[c]				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills[c]				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting[d]				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea[e]				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain[c]				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 to 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7960, placebo = 7934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Overall in Study 2 in which 10,841 participants 16 to 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. The higher frequency of reported unsolicited non-serious adverse events among Pfizer BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.

3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 16 and 17 years of age is based on extrapolation of safety and effectiveness from adults 18 years of age and older. Emergency Use Authorization of Pfizer BioNTech COVID-19 Vaccine does not include use in individuals younger than 16 years of age.

11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy *[see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)]*. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 5 presents the specific demographic characteristics in the studied population.

Table 5: Demographics (population for the primary efficacy endpoint)[a]

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	**Placebo (N=18,379) n (%)**
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other[b]	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities[c]		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.

b. Includes multiracial and not reported.

c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease
- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index ≥ 30 kg/m^2)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

Efficacy Against COVID-19

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 to 55 years of age and 56 years of age and older began enrollment from July 27,2020, 16 to 17 years of age began enrollment from September 16, 2020 and 12 to 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 6.

Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)[f]
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)[g]
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)[g]
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=19,965 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=20,172 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3)[f]
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7)[g]
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9)[g]

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.
e. No confirmed cases were identified in participants 12 to 15 years of age.
f. Credible interval for VE was calculated using a beta-binomial model with a beta (0.700102, 1) prior for θ=r(1-VE)/(1+r(1-VE)), where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2).

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF). Vials must be kept frozen between -80ºC to -60ºC (-112ºF to -76ºF) and protected from light, in the original cartons, until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.cvdvaccine.com.

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1457-1.0

Revised: December 2020

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Fri, 2 Apr 2021 01:53:00 +0000
To: Pam Daily
Cc: Chai, Shua (CDC cdph.ca.gov);Gretchen Rothrock
Subject: RE: Revised draft protocol for EIP COVID-19 vaccine breakthrough project

Pam.

All of the EIP sites have expressed some interest and have received funding to participate in this or other COVID projects. Five sites have submitted project outlines thus far.

We may have a better idea after tomorrow's call which sites plan to participate.

It is a somewhat risky project and I understand if you are concerned that the overall project may not be able to meet the overall estimated sample. However, there will not be a specific number of expected cases to enroll at each site.

The focus of the project is on SARS-CoV-2 variants of concern which have variable distribution across the country. Therefore, it will be better to have sites that are geographically spread to increase the likelihood of identifying strains that may be circulating in some areas but not others.

I hope to begin having calls next week with individual sites and will try to move the project forward as soon as possible in those sites that are ready to proceed.

If you are interested, I am happy to discuss further.

Best wishes,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

From: Pam Daily <pdaily@ceip.us>
Sent: Thursday, April 1, 2021 5:40 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Gretchen Rothrock <grothrock@ceip.us>
Subject: RE: Revised draft protocol for EIP COVID-19 vaccine breakthrough project

Hi Marc,

Thank you for the update. It would be really helpful to know how many sites are participating, as that will determine the sample size our site will be expected to enroll for the study. We are currently working with a Kaiser investigator and figuring out our goal sample size is important for him to put together a budget.

Do you have an idea of how many sites are planning to participate?

Thanks, Pam

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Thursday, April 1, 2021 5:47 PM
To: Allison Roebling <aroebling@gaeip.org>; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Emma Schmoll - CDPHE <emma.schmoll@state.co.us>; Fridkin, Scott <sfridki@emory.edu>; kopeno@gaeip.org; Pam Daily <pdaily@ceip.us>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; Gretchen Rothrock <grothrock@ceip.us>; Joelle Nadle <jnadle@ceip.us>
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Havers, Fiona (CDC/DDID/NCIRD/DVD) <wja7@cdc.gov>; Gantt, Susan Conner (CDC/DDID/NCEZID/OD) (CTR) <ZKV0@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCEZID/DFWED) <fez7@cdc.gov>; Pinner, Robert W. (CDC/DDID/NCEZID/OD) <rwp1@cdc.gov>
Subject: Revised draft protocol for EIP COVID-19 vaccine breakthrough project

EIP COVID vaccine breakthrough project workgroup,

Attached please find the revised draft protocol, "Comparing the frequency of SARS-CoV-2 variants of concern among vaccinated and unvaccinated COVID-19 cases".

The protocol has been cleared by the CDC COVID-19 Vaccine Taskforce and has been submitted for CDC project determination.

I received project outlines from five sites. If you plan to participate and have not already done so, please submit your project outline as soon as possible.

I look forward to tomorrow's call and further follow-up on this project next week.

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce

Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

From: Pam Daily
Sent: Mon, 3 May 2021 03:20:49 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI)
Subject: RE: Revised EIP vaccine breakthrough project database
Attachments: COVID19_LabSurvey_Round 2.pdf, COVID19LaboratorySurvey202021_DataDictionary_2020-09-09.csv

Hi Marc,
Last fall COVID-Net conducted a laboratory survey for all labs in our catchment. I am attaching the survey pdf and the data dictionary. In the data dictionary #12 lists all of the molecular tests that were available at the time. There are likely more tests than this, but many of us conducted the survey and have used this REDCap form for data entry- this could be one way to standardize the nomenclature for the tests.
In CA we have asked our labs about test methods recently in preparation for the study and launching the COVID-Net sequencing project.

Best, Pam

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Friday, April 30, 2021 7:05 PM
To: Allison Roebling <aroebling@gaeip.org>; kopeno@gaeip.org; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Schmoll, Emma (CDC state.co.us) <emma.schmoll@state.co.us>; Alden, Nisha (CDC state.co.us) <nisha.alden@state.co.us>; isaac.armistead@state.co.us; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; Gretchen Rothrock <grothrock@ceip.us>; Pam Daily <pdaily@ceip.us>; Joelle Nadle <jnadle@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Sosin, Daniel (CDC state.nm.us) <Daniel.Sosin@state.nm.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; Como-Sabetti, Kathy (MDH) <kathy.como-sabetti@state.mn.us>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Gantt, Susan Conner (CDC/DDID/NCEZID/OD) (CTR) <ZKV0@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCEZID/DFWED) <fez7@cdc.gov>; Lee, Justin (CDC/DDID/NCEZID/DSR) <psd8@cdc.gov>; Armstrong, Gregory (CDC/DDID/NCEZID/OD) <gca3@cdc.gov>; Taylor, Christopher A. (CDC/DDID/NCIRD/DVD) <iyq3@cdc.gov>; Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) <xbe9@cdc.gov>
Subject: Revised EIP vaccine breakthrough project database

Attached please find an updated data dictionary and data elements for the EIP vaccine breakthrough project REDCap database. Please review prior to Thursday's call.

We also request the following information from each site to help complete the database:

1. Confirm whether you plan to create a local instance of the REDCap database that will be periodically uploaded and synched with the combined database at CDC.

2. Provide a list of the RT-PCR or NAAT assays that are performed at the clinical laboratory (or laboratories) and that will be used to identify cases for the project. We will use this information to populate the database drop-down menu for that variable.
    a. Please try to use the name as listed on the EUA so we can standardize between sites. A list of FDA-authorized molecular diagnostic tests is available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2.
    b. Let me know if this is too difficult a task and we will reconsider the approach.

Thanks,
Marc

Testing Facility Name: _____ **Testing Facility ID** *(COVID-NET use only)*: _____

Name of person completing form: _____ **Date:** _____

COVID-19-Associated Hospitalization Laboratory Testing Survey – Round 2

Survey Instructions (This survey should take 5 minutes to complete)

- Administer this survey to all labs that serve COVID-NET hospitals.
- The questions in this survey refer to **diagnostic testing** ordered by healthcare providers for routine clinical care of **hospitalized and emergency department (ED) patients only**.
- All questions relate to testing performed **on-site** within the lab facility unless otherwise specified. If a COVID-NET hospital lab sends specimens to one or more labs (other than commercial or state public health labs) for clinical testing, please have each lab complete this survey.
- Do NOT administer this survey to commercial labs or to state public health labs
- Do NOT administer this survey to labs that are not affiliated with COVID-NET hospitals
- Do NOT include information on testing for the purposes of surveillance
- Do NOT include information on testing for outpatients

---

1. Who is the person completing this survey?

   ☐ Lab Staff at Testing Facility ☐ COVID-NET Staff ☐ Other, specify _____

2. Does your laboratory perform testing for SARS-CoV-2 on-site?

   ☐ Yes ☐ No (if no, go to Q5)

3. If your laboratory tests for SARS-CoV-2, what date did testing for SARS-COV-2 begin on-site?

   Month: _____ Date: _____ ☐ Year _____ ☐ Unknown

4. What test(s) is (are) used for SARS-CoV-2 (Select all that apply)? See following link for updated tests that have received EUA for SARS-CoV-2 testing: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

   ☐ Abbott Real*Time* SARS-CoV-2 assay (Abbott Molecular)
   ☐ Alinity m SARS-CoV-2 assay (Abbott Molecular Inc.)
   ☐ Allplex 2019-nCoV Assay (SeeGene, Inc.)
   ☐ BD SARS-CoV-2Reagents for BD MAX System (Becton, Dickinson & Company)
   ☐ BioFire COVID-19 Test (BioFire Defense, LLC)
   ☐ BioGX SARS-CoV-2 Reagents for BD MAX System (Becton, Dickinson & Company)
   ☐ CDC real-time RT-PCR Assay
   ☐ Cobas SARS-CoV-2 (Roche Molecular Systems, Inc.)
   ☐ COVID-19 RT-PCR Test (Laboratory Corporation of America)
   ☐ ePlex SARS-CoV-2 Test (GenMark Diagnostics, Inc.)
   ☐ Lyra SARS-CoV-2 Assay (Quidel Corp.)
   ☐ New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (Wadsworth Center, NYSDOH)
   ☐ Panther Fusion SARS-CoV-2 (Hologic, Inc.)
   ☐ PerkinElmer New Coronavirus Nucleic Acid Detection Kit (PerkinElmer, Inc.)
   ☐ Primerdesign Ltd COVID-19 genesig Real-Time PCR assay (Primerdesign Ltd)
   ☐ QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN GmbH)

☐ Quest SARS-CoV-2 rRT-PCR (Quest Diagnostics Infectious Disease, Inc.)
☐ RealStar SARS-CoV02 RT-PCR Kits U.S. (altona Diagnostics GmbH)
☐ Simplexa COVID-19 Direct (DiaSorin Molecular LLC)
☐ TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific, Inc.)
☐ Xpert Xpress SARS-CoV-2 test (Cepheid)

☐ Other, specify: _____

5. Does your laboratory send specimens, or did they previously send specimens for SARS-CoV-2 testing off-site?

☐ Yes, the lab currently sends specimens off-site for SARS-CoV-2 testing (insert start date)

☐ The lab previously sent specimens off-site for testing but stopped (insert stop date)

☐ No (if no, go to Q7)

6. If yes, where does/has your laboratory send specimens for SARS-CoV-2 testing?

☐ Hospital Network Central lab (specify lab ID) _____
☐ State or local public health lab
☐ Commercial lab, specify: _____
☐ Other, specify: _____

7. If you do not currently have capability to test for SARS-CoV-2 on-site or off-site, when do you anticipate that your lab will have the capability to test for SARS-CoV-2 on- or off-site?

Month: _____ Date: _____ ☐ Year _____ ☐ Unknown

List COVID-NET hospital ID(s)* associated with this laboratory:

_____ _____ _____

_____ _____ _____

_____ _____ _____

*COVID-NET IDs should be the same as FluSurv-NET and RSV-NET IDs. If there are new COVID-NET hospitals that do not yet have an ID, please contact CDC so that an ID can be assigned. Thank you for taking time to complete this survey!

END OF SURVEY

Variable / Field Name	Form Name
labnm_r2	covid19_lab_survey_round_2
labcomplete_dt_r2	covid19_lab_survey_round_2
survey_r2	covid19_lab_survey_round_2
survey_oth_r2	covid19_lab_survey_round_2
labtest_r2	covid19_lab_survey_round_2
labtest_label_r2	covid19_lab_survey_round_2
labtest_month_r2	covid19_lab_survey_round_2
labtest_date_r2	covid19_lab_survey_round_2
labtest_year_r2	covid19_lab_survey_round_2
labtest_stdt_unk_r2	covid19_lab_survey_round_2
labtesttyp_r2	covid19_lab_survey_round_2
labtest_oth_r2	covid19_lab_survey_round_2
labtest_offsite_r2	covid19_lab_survey_round_2
offsite_stdt_r2	covid19_lab_survey_round_2
offsite_enddt_r2	covid19_lab_survey_round_2
labtest_offsitenm_r2	covid19_lab_survey_round_2
labtest_hospnm_r2	covid19_lab_survey_round_2
labtest_comnm_r2	covid19_lab_survey_round_2
labtest_othnm_r2	covid19_lab_survey_round_2
labtest_futurelabel_r2	covid19_lab_survey_round_2
labtest_futuremonth_r2	covid19_lab_survey_round_2
labtest_futuredt_r2	covid19_lab_survey_round_2
labtest_futureyear_r2	covid19_lab_survey_round_2
labtest_futuredt_unk_r2	covid19_lab_survey_round_2
ignore_formstatus_r2	covid19_lab_survey_round_2
ignore_svmsg_r2	covid19_lab_survey_round_2
hosp_tx1_r2	hospital_ids_round_2
hosp_txoth1_r2	hospital_ids_round_2
hosp_tx2_r2	hospital_ids_round_2
hosp_txoth2_r2	hospital_ids_round_2
hosp_tx3_r2	hospital_ids_round_2
hosp_txoth3_r2	hospital_ids_round_2
hosp_tx4_r2	hospital_ids_round_2
hosp_txoth4_r2	hospital_ids_round_2
hosp_tx5_r2	hospital_ids_round_2
hosp_txoth5_r2	hospital_ids_round_2
hosp_tx6_r2	hospital_ids_round_2
hosp_txoth6_r2	hospital_ids_round_2
hosp_tx7_r2	hospital_ids_round_2
hosp_txoth7_r2	hospital_ids_round_2
hosp_tx8_r2	hospital_ids_round_2
hosp_txoth8_r2	hospital_ids_round_2
hosp_tx9_r2	hospital_ids_round_2
hosp_txoth9_r2	hospital_ids_round_2
hosp_tx10_r2	hospital_ids_round_2
hosp_txoth10_r2	hospital_ids_round_2
hosp_tx11_r2	hospital_ids_round_2
hosp_txoth11_r2	hospital_ids_round_2
hosp_tx12_r2	hospital_ids_round_2
hosp_txoth12_r2	hospital_ids_round_2
hosp_tx13_r2	hospital_ids_round_2

hosp_txoth13_r2	hospital_ids_round_2
hosp_tx14_r2	hospital_ids_round_2
hosp_txoth14_r2	hospital_ids_round_2
hosp_tx15_r2	hospital_ids_round_2
hosp_txoth15_r2	hospital_ids_round_2
ignore_formstatus2_r2	hospital_ids_round_2
ignore_end_r2	hospital_ids_round_2

Section Header
<p style="padding-left: 30px;">Instructions (This survey should take 5 minutes

This section should be completed by the COVID-NET Surveillance Officer.Please list COVID-NET hospital ID(s) as

Field Type
text
text
radio
text
yesno
descriptive
dropdown
dropdown
dropdown
checkbox
checkbox
text
radio
text
text
checkbox
text
text
text
descriptive
dropdown
dropdown
dropdown
checkbox
descriptive
descriptive
dropdown
text
dropdown
text
dropdown
text
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dropdown
text
dropdown
text
dropdown
text
dropdown
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text
dropdown
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dropdown
text
descriptive
descriptive

Field Label
Testing Facility Name
Date of Survey Completion
1. Who is the person completing this survey?
Specify:
2. Does your laboratory perform testing for SARS-CoV-2 on-site?
3. What date did testing for SARS-COV-2 begin on-site?
Month:
Date:
Year:

4. What test(s) is (are) used for SARS-CoV-2 (Select all that apply)?
Specify Other Test:
5. Does your laboratory send specimens, or did they previously send specimens for SARS-CoV-2 testing off-site?
Specify Start Date:
Specify End Date:
6. Where does/has your laboratory send/sent specimens for SARS-CoV-2 testing?
Specify Hospital Network Central Lab ID:
Specify Commercial Lab:
Specify Other Lab:
7. If you do not currently have capability to test for SARS-CoV-2 on-site or off-site, when do you anticipate that you
Month:
Date:
Year:

<h5 style="text-align:left;"><u>FORM STATUS INSTRUCTIONS
<h5 style="text-align:center;"><u>You must continue to the Hospita
Hospital ID 1:
Specify Other COVID-NET hospital ID:
Hospital ID 2:
Specify Other COVID-NET hospital ID:
Hospital ID 3:
Specify Other COVID-NET hospital ID:
Hospital ID 4:
Specify Other COVID-NET hospital ID:
Hospital ID 5:
Specify Other COVID-NET hospital ID:
Hospital ID 6:
Specify Other COVID-NET hospital ID:
Hospital ID 7:
Specify Other COVID-NET hospital ID:
Hospital ID 8:
Specify Other COVID-NET hospital ID:
Hospital ID 9:
Specify Other COVID-NET hospital ID:
Hospital ID 10:
Specify Other COVID-NET hospital ID:
Hospital ID 11:
Specify Other COVID-NET hospital ID:
Hospital ID 12:
Specify Other COVID-NET hospital ID:
Hospital ID 13:

Specify Other COVID-NET hospital ID:
Hospital ID 14:
Specify Other COVID-NET hospital ID:
Hospital ID 15:
Specify Other COVID-NET hospital ID:
<h5 style="text-align:left;"><u>FORM STATUS INSTRUCTIONS<
<h4 style="text-align:center;">End of survey. Thank you for participating in this survey!

Choices, Calculations, OR Slider Labels

1, Lab staff at testing facility | 2, COVID-NET staff | 3, Other, specify:

1, 01- January | 2, 02- February | 3, 03- March | 4, 04- April | 5, 05- May | 6, 06- June | 7, 07- July | 8, 08- August |
1, 1 | 2, 2 | 3, 3 | 4, 4 | 5, 5 | 6, 6 | 7, 7 | 8, 8 | 9, 9 | 10, 10 | 11, 11 | 12, 12 | 13, 13 | 14, 14 | 15, 15 | 16, 16 | 17, 17
1, 2020 | 2, 2021
1, Unknown start date for SARS-COV-2 testing
1, Abbott RealTime SARS-CoV-2 assay (Abbott Molecular) | 2, Alinity m SARS-CoV-2 assay (Abbott Molecular Inc

1, Yes, the lab currently sends specimens off-site for SARS-CoV-2 testing (specify start date) | 2, The lab previous

4, Hospital Network Central lab, specify lab ID: | 1, State or public health lab | 2, Commercial lab, specify: | 3, Othe
>

ır lab will have the capability to test for SARS-CoV-2 on- or off-site?
1, 01- January | 2, 02- February | 3, 03- March | 4, 04- April | 5, 05- May | 6, 06- June | 7, 07- July | 8, 08- August |
1, 1 | 2, 2 | 3, 3 | 4, 4 | 5, 5 | 6, 6 | 7, 7 | 8, 8 | 9, 9 | 10, 10 | 11, 11 | 12, 12 | 13, 13 | 14, 14 | 15, 15 | 16, 16 | 17, 17
1, 2020 | 2, 2021
1, Unknown anticipated start date for SARS-CoV-2 testing
</u><font color="red">If the Lab Survey is not yet complete, select <u>Incomplete</u> below. This is the default.</f
al ID form to list all Hospital IDs associated with this testing facility.</u>

To continue to the Hospital ID
177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

177, 177 | 187, 187 | 259, 259 | 393, 393 | 401, 401 | 705, 705 | 710, 710 | 711, 711 | 712, 712 | 713, 713 | 716, 71

</u>If the Lab Survey is not yet complete, select <u>Incomplete</u> below. This is the default.</f

Field Note	Text Validation Type OR Show Slider Number	Text Validation Min	Text Validation Max
	date_mdy		

9, 09- September | 10, 10- October | 11, 11- November | 12, 12- December
| 18, 18 | 19, 19 | 20, 20 | 21, 21 | 22, 22 | 23, 23 | 24, 24 | 25, 25 | 26, 26 | 27, 27 | 28, 28 | 29, 29 | 30, 3(

:.) | 3, Allplex 2019-nCoV Assay (SeeGene, Inc.) | 4, BD SARS-CoV-2Reagents for BD MAX System (Bec

ly sent specimens off-site for SARS-CoV-2 testing (specify stop date) | 0, No
date_mdy
date_mdy
r, specify:

9, 09- September | 10, 10- October | 11, 11- November | 12, 12- December
| 18, 18 | 19, 19 | 20, 20 | 21, 21 | 22, 22 | 23, 23 | 24, 24 | 25, 25 | 26, 26 | 27, 27 | 28, 28 | 29, 29 | 30, 3(

ont>If the Lab Survey is complete, select <u>Complete</u> below.
D Form, press the <u>Save & Go To Next Form</u> button, as shown below. The Hospital ID Fo
6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

6 | 718, 718 | 720, 720 | 726, 726 | 727, 727 | 731, 731 | 732, 732 | 737, 737 | 738, 738 | 740, 740 | 742, 7

ont>If the Lab Survey is complete, select <u>Complete</u> below.

Identifier?

ɔ | 31, 31

ɔton, Dickins

ɔ | 31, 31

rm can also
'42 | 749, 74

'42 | 749, 74

'42 | 749, 74

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'42 | 749, 74

'42 | 749, 74

'42 | 749, 74

'42 | 749, 7⁴

'42 | 749, 7⁴

Branching Logic (Show field only if...)

[survey_r2] = '3'

[labtest_r2]='1'
[labtest_r2] = '1'
[labtest_r2] = '1'
[labtest_r2] = '1'
[labtest_r2]='1' and [labtest_month_r2]='' and [labtest_date_r2]='' and [labtest_year_r2]=''
[labtest_r2] = '1'
[labtesttyp_r2(14)] = '1' and [labtest_r2]='1'

[labtest_offsite_r2]='1'
[labtest_offsite_r2]='2'
[labtest_offsite_r2] ='1' or [labtest_offsite_r2] = '2'
[labtest_offsitenm_r2(4)] = '1' and [labtest_offsite_r2] <> '3' and [labtest_offsite_r2] <> ''
[labtest_offsitenm_r2(2)] = '1' and [labtest_offsite_r2] <> '3' and [labtest_offsite_r2] <> ''
[labtest_offsitenm_r2(3)] = '1' and [labtest_offsite_r2] <> '3' and [labtest_offsite_r2] <> ''
[labtest_r2]='0'
[labtest_offsite_r2] = '3' or [labtest_r2]='0'
[labtest_offsite_r2] = '3' or [labtest_r2]='0'
[labtest_offsite_r2] = '3' or [labtest_r2]='0'
[labtest_futuredt_r2] = '' and [labtest_futuremonth_r2] = '' and [labtest_futureyear_r2] = '' and [labtest_r2]='0'

› be found under the "Data Collection Instruments" section in the left hand navigation menu.
49 | 759, 759 | 766, 766 | 767, 767 | 849, 849 | 851, 851 | 855, 855 | 2057, 2057 | 8888, 8888 | 9063, 9063 | 0240
[hosp_tx1_r2] = 'Other'
[hosp_tx1_r2] <> ' '
[hosp_tx2_r2] = 'Other'
[hosp_tx2_r2] <> ' '
[hosp_tx3_r2] = 'Other'
[hosp_tx3_r2] <> ' '
[hosp_tx4_r2] = 'Other'
[hosp_tx4_r2] <> ' '
[hosp_tx5_r2] = 'Other'
[hosp_tx5_r2] <> ' '
[hosp_tx6_r2] = 'Other'
[hosp_tx6_r2] <> ' '
[hosp_tx7_r2] = 'Other'
[hosp_tx7_r2] <> ' '
[hosp_tx8_r2] = 'Other'
[hosp_tx8_r2] <> ' '
[hosp_tx9_r2] = 'Other'
[hosp_tx9_r2] <> ' '
[hosp_tx10_r2] = 'Other'
[hosp_tx10_r2] <> ' '
[hosp_tx11_r2] = 'Other'
[hosp_tx11_r2] <> ' '
[hosp_tx12_r2] = 'Other'
[hosp_tx12_r2] <> ' '

[hosp_tx13_r2] = 'Other'
[hosp_tx13_r2] <> ' '
[hosp_tx14_r2] = 'Other'
[hosp_tx14_r2] <> ' '
[hosp_tx15_r2] = 'Other'

Required Field?	Custom Alignment	Question Number (surveys only)	Matrix Group Name	Matrix Ranking?
	RH			
		)3, 02403 | 13323, 13323 | 00301, 00301 | 00302, 00302 | 00303, 00303 | 00304, 00304 | 02603, 02603 | 02604, 0		

Field Annotation

@DEFAULT='99'

@DEFAULT='99'

@DEFAULT='99'

@DEFAULT='99'

@DEFAULT='99'

@DEFAULT='99'

@DEFAULT='99'

@DEFAULT='99'

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From: Pam Daily
Sent: Mon, 3 May 2021 03:28:06 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI);Nolen, Leisha (CDC/DDID/NCEZID/DPEI)
Cc: Gretchen Rothrock;Reingold, Arthur MD (CDC berkeley.edu);Chai, Shua (CDC cdph.ca.gov)
Subject: RE: Revised EIP vaccine breakthrough project database

Hi Marc,

We will most likely be working with only one large hospital system regional laboratory, and this lab conducts the following tests:

1. Cobas SARS-CoV-2 (Roche Molecular Systems, Inc.)
2. Panther Fusion SARS-CoV-2 (Hologic, Inc.)
3. Xpert Xpress SARS-CoV-2 test (Cepheid)

We have not yet determined if we will use the main database (CDC instance of REDCap – with a site specific Access db to hold our PHI) or if we will use a CA site specific REDCap data base and import into the main CDC REDCap database. We will be working with an analyst at the hospital system and that person has not yet been assigned to this project, not available to discuss data base issues yet.

Thanks, Pam

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) [mailto:mxf2@cdc.gov]
Sent: Friday, April 30, 2021 7:05 PM
To: Allison Roebling <aroebling@gaeip.org>; kopeno@gaeip.org; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; Schmoll, Emma (CDC state.co.us) <emma.schmoll@state.co.us>; Alden, Nisha (CDC state.co.us) <nisha.alden@state.co.us>; isaac.armistead@state.co.us; Sutton Melissa <Melissa.Sutton@dhsoha.state.or.us>; Talbot, H. Keipp <keipp.talbot@vumc.org>; Markus, Tiffanie M <tiffanie.m.markus@vumc.org>; Meek, James <james.meek@yale.edu>; Niccolai, Linda <linda.niccolai@yale.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Felsen, Christina <Christina_Felsen@URMC.Rochester.edu>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>; Crum, David (CDC maryland.gov) <david.crum@maryland.gov>; Gretchen Rothrock <grothrock@ceip.us>; Pam Daily <pdaily@ceip.us>; Joelle Nadle <jnadle@ceip.us>; Chai, Shua (CDC cdph.ca.gov) <shua.chai@cdph.ca.gov>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Sosin, Daniel (CDC state.nm.us) <Daniel.Sosin@state.nm.us>; Lathrop, Sarah <slathrop@salud.unm.edu>; Lynfield, Ruth (CDC state.mn.us) <Ruth.Lynfield@state.mn.us>; Como-Sabetti, Kathy (MDH) <kathy.como-sabetti@state.mn.us>; Eikmeier, Dana (MDH) <dana.eikmeier@state.mn.us>
Cc: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>; Gantt, Susan Conner (CDC/DDID/NCEZID/OD) (CTR) <ZKV0@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCEZID/DFWED) <fez7@cdc.gov>; Lee, Justin (CDC/DDID/NCEZID/DSR) <psd8@cdc.gov>; Armstrong, Gregory (CDC/DDID/NCEZID/OD) <gca3@cdc.gov>; Taylor, Christopher A. (CDC/DDID/NCIRD/DVD) <iyq3@cdc.gov>; Bressler, Sara S. (CDC/DDID/NCEZID/DPEI) <xbe9@cdc.gov>
Subject: Revised EIP vaccine breakthrough project database

Attached please find an updated data dictionary and data elements for the EIP vaccine breakthrough project REDCap database. Please review prior to Thursday's call.

We also request the following information from each site to help complete the database:

1. Confirm whether you plan to create a local instance of the REDCap database that will be periodically uploaded and synched with the combined database at CDC.

2. Provide a list of the RT-PCR or NAAT assays that are performed at the clinical laboratory (or laboratories) and that will be used to identify cases for the project. We will use this information to populate the database drop-down menu for that variable.
    a. Please try to use the name as listed on the EUA so we can standardize between sites. A list of FDA-authorized molecular diagnostic tests is available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2.
    b. Let me know if this is too difficult a task and we will reconsider the approach.

Thanks,
Marc

From: Chai, Shua@CDPH
Sent: Mon, 15 Mar 2021 16:02:01 +0000
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Subject: RE: Scheduling next calls to discuss revised protocol for EIP vaccine breakthrough project

I look forward to it. Please see below.

Shua Chai, MD, MPH
Science and Policy Advisor
Division of Communicable Disease Control
California Department of Public Health
(470) 553-4078
Shua.Chai@cdph.ca.gov

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Sent: Saturday, March 13, 2021 7:15 PM
To: linda.niccolai@yale.edu; Melissa.Sutton@dhsoha.state.or.us; keipp.talbot@vumc.org; Chai, Shua@CDPH <Shua.Chai@cdph.ca.gov>; Bamberg, Wendy (CDC state.co.us) <Wendy.Bamberg@state.co.us>; aroebling@gaeip.org; dana.eikmeier@state.mn.us; tiffanie.m.markus@vumc.org; Meek, James <james.meek@yale.edu>; Lathrop, Sarah <slathrop@salud.unm.edu>; Dumyati, Ghinwa <Ghinwa_Dumyati@URMC.Rochester.edu>; Muse, Alison T (HEALTH) <alison.muse@health.ny.gov>; Patricia Ryan -MDH- <patricia.ryan@maryland.gov>
Subject: Scheduling next calls to discuss revised protocol for EIP vaccine breakthrough project

EIP vaccine breakthrough project working group.

I would like to schedule one call each of the next 2 weeks (March 16-18 and March 23-25) to continue our discussions about the protocol and project.

Please let me know your availability during the following days and times (**All Eastern times**):

Eastern times	Tue, Mar 16	Wed, Mar 17	Thu, Mar 18	Tue, Mar 23	Wed, Mar 24	Thu, Mar 25
1:00-2:00pm			Y	Y	Y	Y
2:00-3:00pm						
3:00-4:00pm	Y			Y	Y	Y

4:00-5:00pm	Y		Y	Y	Y	Y

Thanks,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
970 556 7514
mfischer@cdc.gov

From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Wed, 12 May 2021 02:22:18 +0000
To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP);Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Cc: Cetron, Marty (CDC/DDID/NCEZID/DGMQ);Clark, Thomas A. (CDC/DDID/NCIRD/DVD)
Subject: Re: URGENT MATTER

Thanks Marc, Seems like a repeat test as next step is consensus
From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Sent: Tuesday, May 11, 2021 8:58:49 PM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>
Cc: Cetron, Marty (CDC/DDID/NCEZID/DGMQ) <mzc4@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>
Subject: RE: URGENT MATTER

Henry.

(b)(5)

Of the >10,000 vaccine breakthrough infections reported to CDC, 25-30% are reported as "asymptomatic" and were detected due to routine screening or testing for other reasons (e.g., travel, work, or unrelated healthcare visit like surgery or delivery). There is limited evidence to suggest these people may have lower Ct values and may be less likely to transmit but that is still speculation and currently does not change management.

Reinfection after both previous wild-type infection and full vaccination has been reported not uncommonly from long-term care facilities. For surveillance purposes, we exclude vaccine breakthrough infections among people who had a positive NAAT or antigen test in the 45 days prior to the positive test obtained post-vaccination. There are published reports of vaccine breakthrough infections occurring at longer intervals after the previous positive test but for those it was not possible to tell if they were new infections (i.e., reinfections) or detection of persistent RNA. In this case, the person reportedly had multiple negative tests between the two positives.

For the most recent positive test on May 9, it only says "positive rapid COVID test". If that is an antigen test, a false positive test is a possibility. If it is an RT-PCR or other NAAT, false positive is still possible but seems much less likely.

(b)(5)

Marc

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Tuesday, May 11, 2021 4:28 PM
To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>; Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Cetron, Marty (CDC/DDID/NCEZID/DGMQ) <mzc4@cdc.gov>
Subject: RE: URGENT MATTER

Marc, any comments on highlights below?

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>
Sent: Tuesday, May 11, 2021 8:24 PM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Cc: Cetron, Marty (CDC/DDID/NCEZID/DGMQ) <mzc4@cdc.gov>
Subject: RE: URGENT MATTER

He's had three events that would offer immunity:

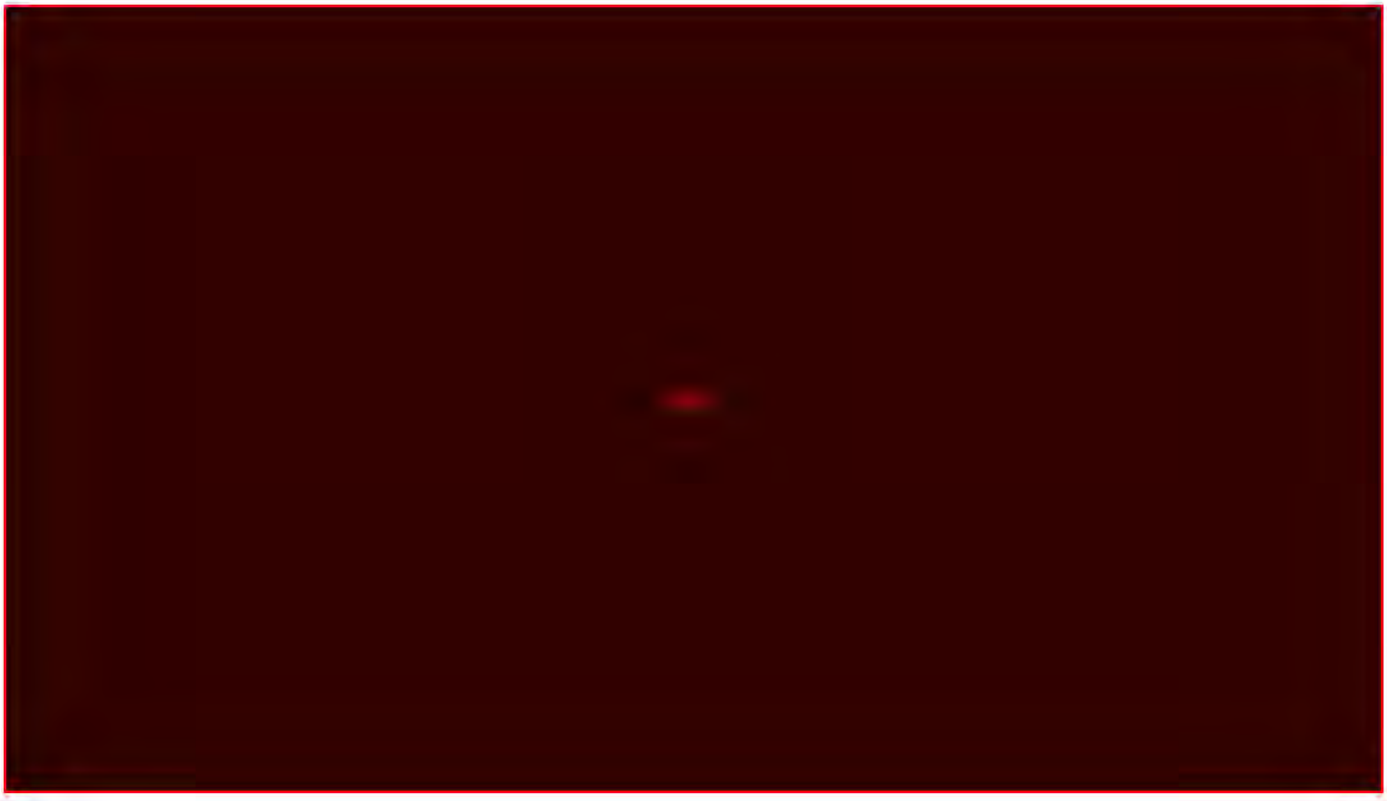
- JAN 2021:
  - Natural infection
- JAN 2021:
  - Monoclonal antibodies (he got bamlanivimab so some possibility his virus may have been resistant but unlikely in January 2021)
- MAR 2021:
  - Vaccination series completed about 60 days after infection and monoclonal administration, so their *theoretical* effects on suppressing vaccine inducible immunity likely waning (CDC recommendation is to wait 90 days after monoclonals but recent unpublished data suggest they be cleared by 8 weeks)

He had several negative tests including before entering the foreign country, thus unlikely to be shedding RNA from prior infection.

At his final in-country destination he has a positive “rapid test”.

Possibilities in order of likelihood:

- Falsely positive rapid test
- Vaccine breakthrough and asymptomatic reinfection



[redacted]

We could also query Marc Fischer to see if there have been *any* documented vaccine breakthroughs that also would be reinfections (vaccine failure in a recovered person).

Hope this help,

-john

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Tuesday, May 11, 2021 7:44 PM
To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>
Cc: Cetron, Marty (CDC/DDID/NCEZID/DGMQ) <mzc4@cdc.gov>
Subject: FW: URGENT MATTER

John, what do you think of this, putting aside the question of whether we should send a letter.

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Tuesday, May 11, 2021 7:22 PM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Cetron, Marty (CDC/DDID/NCEZID/DGMQ) <mzc4@cdc.gov>
Subject: Fwd: URGENT MATTER

Get Outlook for iOS

From: Lance Howell <[redacted]
Sent: Tuesday, May 11, 2021 6:14 PM
To: Schuchat, Anne MD (CDC/OD)
Subject: URGENT MATTER

Good afternoon Dr. Schuchat,

My employer, [redacted] has requested that I contact you because he is in a very urgent situation that requires guidance from an government-employed expert on COVID issues.

[redacted] is currently being held in a military medical facility out of the country on a 10 day quarantine/isolation due to a positive rapid COVID test. However, [redacted] believes that this a false positive according to the following history:

12 Jan 21: Moderna Vaccine #1.

16 Jan 21: I became symptomatic for Covid.

18 Jan 21: Positive PCR

19 Jan 21: I became seriously ill.

21 Jan 21: Regeneron monoclonal antibody infusion with Bam.

20 Feb 21: Recovery from Covid.

13 Mar 21: Moderna vaccine #2.

13 Mar - 1 May: Several negative tests for Covid.

1 May 21: Negative rapid COVID test for travel to Spain.

4 May 21: Arrival in Madrid.

8 May 21: Travel to Rota.

9 May 21: Positive rapid COVID test.

On behalf of [redacted], we request that you please write a letter of exception to travel based on the information from the chronology, current CDC guidelines and [redacted]s input as to why he believes his PCR result is a false positive. In 2020 [redacted] worked in a Covid field hospital and is a member of the [redacted]. It has been 112 days since his first positive test in January and there is research concluding one can test positive 120 to 150 days subsequent to being infected. **He has a positive PCR with NO SYMPTOMS. The unvaccinated people he was around for five days have tested negative even though he was around them in close quarters for 8-9 hours per day.** Hence, he believes this is an issue of science driven by an outdated policy. The base has never even seen a person who had the Regeneron antibody infusion.

[redacted]believes, as does the Navy doctor he spoke with yesterday, that the PCR test most likely picked up on viral particles from when he was seriously ill with Covid from 16 January 21 to 20 February 21. Based upon the chronology, his medical history, the science, CDC guidelines and information, his experience as a medical professional, his consultation with infectious disease experts, and irregularities in the testing and lab processing of his PCR test, he believes there is a very high probability that he does not have Covid. Once again, he doesn't have a single symptom.

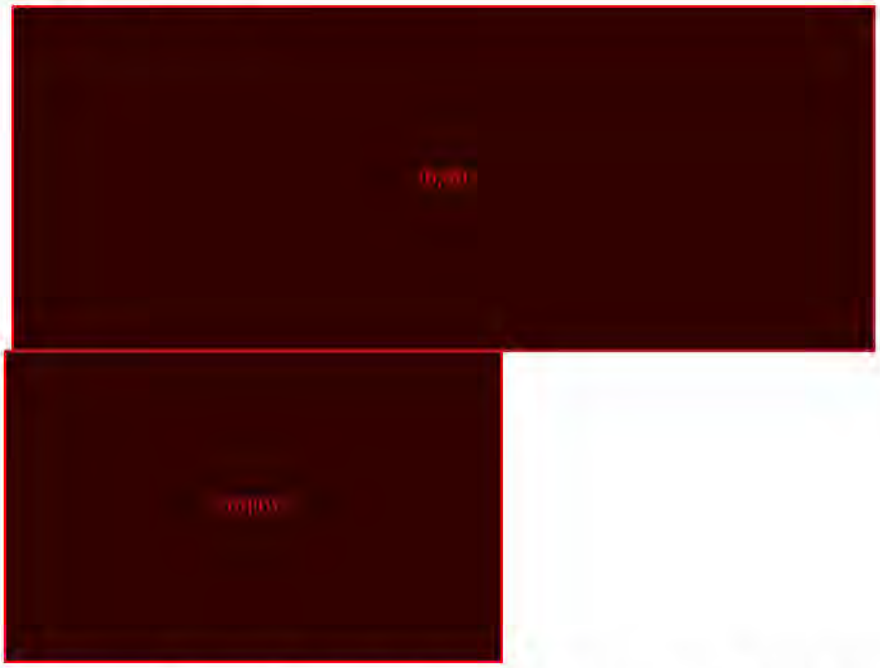
We initially thought it was a PCR test, but we just found out it was a rapid test. It is our understanding that the rapid test is unreliable and should not be used for a person with [redacted] history of serious infection in January and February of this year.

Once again, on behalf of [redacted] we request that you please write a letter stating a positive result on a rapid test would be expected given [redacted] history and that this does not point to a new infection, especially in the absence of symptoms. This, along with his doctor's letter indicating his symptoms cleared in late February will allow him to secure a Fit to Fly Letter. Otherwise, he is stranded in a dangerous situation with limited access to the medical care he needs, the medicine he needs and the need to return home. Without a single symptom doesn't it appear to be highly unlikely this is a new infection?

Please help. It is urgent.

--

Very Respectfully,



From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Mon, 7 Jun 2021 17:02:17 +0000
To: Prabhu Gounder
Cc: CDC IMS 2019 NCOV Response EPI TF Vaccine Breakthrough Team;Nolen, Leisha (CDC/DDID/NCEZID/DPEI)
Subject: RE: vaccine breakthrough cases

Prabhu.

Appreciate the effort and flexibility. It would be great to receive those data from LA County but, as you know, gets complicated when we receive information from additional entities below the state level.

Think receiving data from LA County would require three conditions: 1) CDPH agrees to LA County reporting directly to the CDC national database; 2) LA County and CDPH ensure there is de-duplication of cases that may be reported form the two entities; LA County stops direct reporting to CDC once CDPH begins report vaccine history with their COVID case data reported to NNDSS.

My understanding is these discussions have been going on for a while. If you still want to pursue, let me know if you have had further discussions and clarifications with CDPH.

Best wishes,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Epi Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Prabhu Gounder <PGounder@ph.lacounty.gov>
Sent: Sunday, June 6, 2021 12:27 PM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: CDC IMS 2019 NCOV Response EPI TF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>
Subject: RE: vaccine breakthrough cases

Hi Marc

Thanks for the clarification. We initially heard about this project as a call for breakthrough cases through one of the ELC projects. We thought we had good quality data and were willing to support the project because we thought it was important to understand who was not adequately protected by the current

vaccines so we know who still needs to take additional precautions. But we are happy to stand down if CDC does not feel comfortable receiving data directly from LA County.

Prabhu

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Sent: Friday, June 4, 2021 10:11 AM
To: Prabhu Gounder <PGounder@ph.lacounty.gov>
Cc: CDC IMS 2019 NCOV Response EPI TF Vaccine Breakthrough Team <eocevent531@cdc.gov>; Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>
Subject: RE: vaccine breakthrough cases

Prabhu.

Nice to hear from you. As you may have heard, Leisha has accepted the position as Utah State Epidemiologist. Today is her last day working on the Vaccine Breakthrough Team and at CDC.

I am not aware of any plans to make vaccine breakthrough cases a nationally notifiable condition. Reporting from state health departments is and will remain voluntary. However, as states are able to report vaccination history with their case-based surveillance reports of all COVID cases we will transition to identifying vaccine breakthrough cases through that mechanism.

At this time, only five states have that capacity. Other state and territorial health departments continue to voluntarily submit or upload cases directly into the national vaccine breakthrough REDCap database. As you know, as of May 1, we are focusing on reports of hospitalized and fatal cases; however, some states are continuing to report all vaccine breakthrough infections.

No other county or local health departments are reporting directly to us. It would be best if LA County could report through CDPH. However, if there is agreement with CDPH that LA County will be the only reporting entity from California, we can probably make that work but need to make sure there is no duplicated reporting.

Let me know if this requires further discussion.

Thanks,

Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Epi Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Prabhu Gounder <PGounder@ph.lacounty.gov>
Sent: Thursday, June 3, 2021 10:17 PM
To: CDC IMS 2019 NCOV Response EPI TF Vaccine Breakthrough Team <eocevent531@cdc.gov>
Subject: FW: vaccine breakthrough cases

Hello

We had been working with Leisha over the last few weeks to contribute LA County surveillance data on post-vaccination positive cases. The main issue we were trying to determine is whether CDC plans to make breakthrough cases nationally notifiable – or if it will continue to be voluntary, as it is now. If voluntary, then we at LA County would like to contribute data to this database. But if there is a possibility that this might become nationally notifiable, we wanted to make sure that it does not complicate reporting through the state. Specifically, the way we classify cases and manage our data is slightly different than how it is done by CDPH. Meaning if breakthroughs do become nationally notifiable retroactively, CDPH might not be able to easily remove LA County cases. But if the reporting will be done prospectively at the time it becomes notifiable, then we can stop reporting and work through the state as we do for our other diseases.
On a related note, does CDC plan to start reporting this data at the state level? If so, it raises the same issues as above about deduplicating LAC cases when CDPH eventually starts to report.
Would you be able to clarify for us CDC's plans for reporting breakthrough cases? Does CDC consider this effort routine surveillance? Will it become notifiable? IF not notifiable, will CDC eventually start making public data at the state level?

Thank you,
Prabhu

From: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>
Sent: Thursday, June 3, 2021 12:40 PM
To: Jain, Seema (CDC cdph.ca.gov) <Seema.Jain@cdph.ca.gov>
Cc: Prabhu Gounder <PGounder@ph.lacounty.gov>; Sharon Balter <SBalter@ph.lacounty.gov>; Dawn Terashita <dterashita@ph.lacounty.gov>
Subject: RE: vaccine breakthrough cases

No, I don't believe they are. The COVID positive case should be reported as you have been no matter if breakthrough or not.

I should let you know that tomorrow is my last day working at CDC. I recently took the Utah State Epidemiologist position and will be transitioning over to that position in the coming weeks. It has been very enjoyable working with all of you and I hope to have further opportunities to work with you in the future.

As you go forward, I would recommend reaching out to the breakthrough teams box for questions: CDC IMS 2019 NCOV Response EPI TF Vaccine Breakthrough Team eocevent531@cdc.gov.

Best wishes and hope to see you in Salt Lake City!

Leisha

From: Jain, Seema@CDPH <Seema.Jain@cdph.ca.gov>
Sent: Thursday, June 3, 2021 11:21 AM
To: Nolen, Leisha (CDC/DDID/NCEZID/DPEI) <xdf8@cdc.gov>
Cc: Prabhu Gounder <PGounder@ph.lacounty.gov>; Balter, Sharon (CDC ph.lacounty.gov) <sbalter@ph.lacounty.gov>; Terashita, Dawn (CDC ph.lacounty.gov) <dterashita@ph.lacounty.gov>
Subject: vaccine breakthrough cases

Hi Leisha-

Are vaccine breakthrough cases considered nationally notifiable?

Thanks,
Seema

Seema Jain, MD, FIDSA
Chief, Epidemiology, Surveillance and Modeling Section, COVID-19 Response
Chief, Disease Investigations Section, Infectious Diseases Branch
California Department of Public Health
Ph: (510)-620-3444
Email:Seema.Jain@cdph.ca.gov

From: Fischer, Marc (CDC/DDID/NCEZID/DPEI)
Sent: Wed, 5 May 2021 21:59:12 +0000
To: Sharon Balter
Cc: Schrag, Stephanie (CDC/DDID/NCIRD/DBD);Prabhu Gounder
Subject: RE: Vaccine Breakthrough

Sharon.

Nice to hear from you. I hope you are doing well. I received a similar email yesterday from Prabhu, so am copying him on this response.

We have a draft paper on modeling to estimate the numbers of expected symptomatic vaccine breakthrough cases based on vaccine efficacy from phase 3 clinical trials, vaccine coverage, and disease incidence. It was initially developed as a simple Excel-based tool that CDC and public health departments could use to estimate and message the numbers of expected cases. The modelers got involved and made it a more robust and sophisticated tool but no longer clear if it can be easily shared for partners to use with their own data. We are working on that and I will get back to you with any additional information.

Of note, the tool is to estimate numbers of expected symptomatic vaccine breakthrough infections. It does not address your specific questions of estimating the number of expected vaccine breakthrough infections that would result in hospitalization or death.

Let me know if you have questions or would like to discuss further.

Best wishes,
Marc

Marc Fischer, MD, MPH
Lead, Vaccine Breakthrough Case Investigation Team
COVID-19 Vaccine Taskforce
Centers for Disease Control and Prevention
907 201 5223
mfischer@cdc.gov

From: Sharon Balter <SBalter@ph.lacounty.gov>
Sent: Wednesday, May 5, 2021 11:59 AM
To: Fischer, Marc (CDC/DDID/NCEZID/DPEI) <mxf2@cdc.gov>
Cc: Schrag, Stephanie (CDC/DDID/NCIRD/DBD) <zha6@cdc.gov>
Subject: Vaccine Breakthrough

Marc,

Greetings from the LA County Department of Public Health. I heard from Stephanie that you have a calculator that could allow us to get an estimate of what to expect in terms of breakthrough

hospitalizations and deaths under current conditions. Was wondering if you can share the calculator or at least tell us what your estimate is.

I think that the numbers we have are very low and represent people for who we would expect bad outcomes with breakthrough, those s/p organ transplant who are severely immunosuppressed or with severe coronary disease so that even a mild case could lead to a massive MI. These populations were not represented or well represented in the trials in any case but based on the trials and the data on the CDC website there is some sense that our numbers are high so we are interested in your calculator. Do you have time to share/discuss?

Sharon

Sharon Balter, MD
Director Division of Communicable Disease Control and Prevention
Los Angeles County Department of Public Health
313 N. Figueroa St, Rm 212
Los Angeles, CA 90012
Office 213-240-7941
Cell [redacted]

"Public Health is Purchasable. Within a few natural and important limitations any community can determine its own health."
Hermann Biggs, 1914