DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

June 28, 2022

Aaron Siri
Siri & Glimstad LLP
200 Park Ave
17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Mr. Siri:

This letter is regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 11, 2021, assigned #22-00326-FOIA, and subsequently assigned #22-00078-APP upon appeal which was filed May 17, 2022. The request was for:

> A copy of the analysis plan, including any drafts, amendments, and the final version, for the study titled "COVID-19 Vaccination and Non–COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021" published in the Morbidity and Mortality Weekly Report dated October 22, 2021, available at https://www.cdc.gov/mmwr/volumes/70/wr/mm7043e2.htm?fbclid=IwAR3GY1TZSMAOdyNuqwbjlNuGsCdw-R8PafRkeegvqMUtVOYg_nElzAWI2zo# and attached hereto as Exhibit A.

Upon a subsequent search on appeal, we located 258 pages of responsive records (36 pages released in full, 24 pages disclosed in part, and 198 pages withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption(s) (b)(5). The foreseeable harm standard was considered when applying these redactions.

Please note that the analytic plan is located within the protocol on page 4 of the responsive records. The protocol can also be accessed at the following public link: https://www.cdc.gov/vaccinesafety/pdf/SCK_COVID_Vaccine_Mortality-508.pdf

EXEMPTION 5

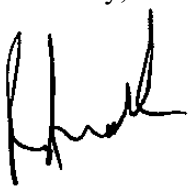
Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include draft versions of the report and pre-decisional and deliberative clearance forms that discussed edits to said document.

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services

they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at http://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by September 26, 2022.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
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Enclosures

22-00078-APP

Title: Mortality and Vaccination with COVID-19 Vaccines (VSD#1343)

Protocol Version 1.2

May 26, 2021

Lead site: Kaiser Permanente Southern California

Investigators: Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Michael Jackson, Gabriela Vasquez-Benitez, Jason Glanz, David McClure, Nicola Klein, Beth Liles, Eric Weintraub

Aim: To assess mortality risk after receiving COVID-19 vaccines among members enrolled in VSD sites

1. BACKGROUND

COVID-19 disease, caused by the novel coronavirus (SARS-CoV-2), has infected 13 million and killed over 260,000 Americans as of November 27, 2020 (Johns Hopkins University, 2020). While social distancing, wearing face masks and improved hygiene education/procedures have helped to slow the disease transmission, they are impermanent and not curative. Effective and safe therapeutics and COVID-19 vaccines will eventually be required to contain the disease. Since the early pandemic in March 2020, scientists worldwide have been racing to find effective and safe vaccines for COVID-19. On November 18, 2020, Pfizer announced that Pfizer and BioNTech's vaccine BNT162 had a vaccine efficacy rate of 95% in participants without prior SARS-CoV-2 infection. Two days later, they submitted an application to the US Food and Drug Administration for an emergency use authorization for their COVID-19 vaccine. On December 11, 2020, FDA granted an Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older (FDA-1, 2020). Another US pharmaceutical company, Moderna, also reported 95% vaccine efficacy for their COVID-19 vaccine. Moderna was granted an EUA for their COVID-19 vaccine on December 18, 2020 (FDA-2, 2020). These two mRNA-based vaccines require two shots, 21 days apart for Pfizer-BioNTech COVID-19 vaccine and 28 days apart for Moderna's vaccine. Janssen COVID-19 vaccine is a replication incompetent adenovirus vector vaccine that is administered as a single dose. It was granted an EUA on February 27, 2021 (FDA-3, 2021). It demonstrated 66% overall efficacy against symptomatic, laboratory-confirmed COVID-19, and 85% efficacy against moderate-to-severe COVID-19 occurring at least 28 days after vaccination. There are several other COVID-19 vaccine candidates that are in Phase 3 of their clinical development program.

Although clinical trials showed that the two mRNA COVID-19 vaccines and the adenoviral vector vaccine were well tolerated with no serious safety concerns observed to date (Polack et al., 2020; Baden et al., 2021; FDA-3, 2021), serious rare adverse events may not be revealed in clinical trials even with more than 30,000 participants. Of all adverse events, death is the most severe form.

Despite the existence of rare cases of plausible risk of death following vaccination, very few studies had showed the association between modern vaccines and death (Miller et al., 2015). McCarthy et al (2013) showed that mortality rates among a VSD population were lower than that in the general U.S. population. McCarthy et al (2016) investigated the association between vaccination and death among individuals 9 to 26 years of age and found that the risk of death was not increased during the 30 days after vaccination. COVID-19 vaccines are new, and their risk profiles are unknown; thus, it is important to study their safety including possible association with elevated mortality risk not due to the novel coronavirus infection.

2. METHODS

2.1 Study population: Kaiser Permanente Southern California (KPSC) will lead this study. All VSD sites will be invited. We will clarify with sites what data sources they have available and how complete the data are from the various sources over time. Membership on the vaccination date or index date will be required. Our primary analysis will include adults 18 and above. On May 10, 2021, the FDA authorized the Pfizer-BioNTech COVID-19 vaccine for emergency use in adolescents 12-15 years old. We will include adolescents in the analyses.

2.2 Outcome: The outcome of this safety study is mortality except COVID-19 related death. The rationale for excluding COVID-19 related death is that mortality increased substantially during the pandemic due to COVID-19. Without excluding COVID-19 related death, any potential safety concerns associated with COVID-19 vaccine and mortality would be masked by the protective effect of COVID-19 vaccine against COVID-19 related death.

We will identify death primarily using the inpatient/outpatient files. VSD sites are in the process of adding a new variable to the inpatient/outpatient files to capture deaths occurring in the hospitals and Emergency Department (ED). Inpatient/outpatient files capture date of death and discharge diagnoses. These data files are updated weekly. Because usually it takes about 10 weeks for data to settle due to hospital length of stay and claims, we will describe death data monthly during the first 3-6 months and quarterly thereafter. We will conduct interim analyses every six months. However, death data from inpatient/outpatient files may miss deaths occurring in other settings and/or outside of the health care system.

Our preliminary investigation of historical data from KPSC showed that inpatient and ED deaths only accounted for about 30% of all deaths among active members and those members who died within 90 days after disenrollment. We propose to ask participating VSD sites to create a death ancillary file to collect more death data from patients' records in the electronic medical records (EMR) and membership files which capture reported deaths outside of medical settings and are more timely than the annual state death file. At KPSC, among deaths of active members occurring in 2018 reported in the C2019 Mort file, the deaths identified through inpatient/ED encounters and the ancillary file (i.e., deaths reported to member services) accounted for 94% of the total deaths. Thus, these sources capture a substantial portion of deaths without relying on the annual state death files. This death ancillary file will be updated monthly. We will combine this ancillary file with the inpatient/outpatient files monthly. In addition, we will also consider other death data sources including VSD mortality files. VSD mortality files include cause and date of

death among all members. Because the VSD mortality files are updated annually, we will merge the VSD mortality files with inpatient/outpatient files on an annual basis to capture additional death data. However, because the death data from the VSD mortality files are lagged by almost two years, they won't be used until the third year of the study. KPSC will explore the possibility of obtaining monthly updates of California's state death records and evaluate their data quality and data lag. We will assess whether other VSD sites have access to state death data and how frequently these data are updated.

2.3 Exposure and risk windows: The emerging COVID-19 vaccines in the US include two mRNA-based vaccines, Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine, and the adenoviral vector Janssen COVID-19 vaccine. There are other COVID-19 vaccine candidates in clinical development. Separate analyses will be conducted for each authorized/licensed COVID-19 vaccine, provided there is sufficient uptake at VSD sites.

We will not pre-specify the risk window for this study. We will employ a flexible analytic approach that allows for assessing mortality risk for certain days after exposure such as 21, 30 days or 42 days. The maximum follow-up is 3 years in this study. For details, please see our analytic plan below.

2.4 Comparators: Two concurrent comparison groups will be used depending on stages of surveillance. At early and middle stages of surveillance (e.g., less than 60% of the population is vaccinated with COVID-19 vaccine), our primary comparison group will be those who were not vaccinated with a COVID-19 vaccine prior to the date of an interim analysis (for details about the interim analyses, please see below). Those who received a COVID-19 vaccine will be in the exposed group in analyses. To make the unexposed comparator group like the exposed group, we will consider the following members: those who did not receive any COVID-19 vaccine but had ≥1 dose of influenza vaccine within the two years prior. Confounder adjustment is critical in using unvaccinated comparators. For details about how to adjust for confounders, please see our analytic plan.

At later stages of surveillance (e.g., more than 60% of the population is vaccinated with COVID-19 vaccine), we will consider using those early vaccinees who received a COVID-19 vaccine at least 6 months prior to an interim analysis date. The reasons for using this comparison group are 1) fewer comparable unvaccinated individuals will be available as most of the population will have received a COVID-19 vaccine; 2) it will help to increase the sample size of the comparison group over time. In this design, those who received a COVID-19 vaccine recently will be in the exposed group while early vaccinees will be comparators. Early vaccinees can contribute person time to both the risk window and the comparison window. The limitations of this approach are 1) given the prioritization scheme, early vaccinees may be systematically different from those who are vaccinated later, and thus, this comparison group may not be comparable to the exposed group; 2) the loss to follow-up will differ between recent vaccinees and early vaccinees because increasing time since vaccination will increase the likelihood of disenrolling from health plans; 3) if the elevated mortality risk of a COVID-19 vaccine is constant over several years after vaccination, this method would not detect the risk because it compares the recent risk versus long term risk; 4) the comparison window must occur after the risk window; however, the exact risk

window for these new vaccines are unknown; 5) potentially, immortal time bias may be introduced because one has to survive up to an interim analysis to be included in that interim analysis.

The design using either of these two concurrent comparison groups will be influenced by data lag. However, if the data lag is non-differential between the exposed group and the comparison group, the point estimate of vaccination association with mortality will be unbiased, but with wider 95% confidence intervals because the number of deaths will be undercounted.

We will not consider historical comparison approach because we anticipate that this design will be impacted by data lag significantly. Historical death data will be more complete than the death data for the current population; thus, point estimate of vaccination association with mortality will be underestimated, potentially resulting in a false negative signal.

The self-controlled case series (SCCS) design is not appropriate here because the outcome (death) prevents one from future exposure and the outcome is not a recurrent event (Farrington 1995). Data lag also has impact on estimating the association between vaccination and death, because deaths in the comparison window are more likely to be undercounted than deaths in the preceding risk window. In addition, a SCCS design requires a pre-specified risk window for death which is unknown.

2.5 Analytic plan

We plan to provide quarterly mortality reports by vaccine type, dose number, age, sex, and race/ethnicity using two approaches: a matched cohort analysis and a cohort analysis with a time-varying exposure. In the matched cohort analysis, follow-up will start at a vaccination date for vaccinees or at an index date for comparators. A frequency matching approach will be employed to use the distribution of vaccination week of the first dose among vaccinees to assign the index date to unvaccinated comparators who had ≥1 dose of influenza vaccine within the two years prior to the reporting month; follow-up for the first dose will be censored upon the receipt of the second dose. Follow-up will end if patients die, disenroll, receive a COVID-19 vaccine for unvaccinated individuals, or at the end of the current report. Mortality rates per 100 person-years will be calculated after the first and the second doses among vaccinees and after the index date among comparators. In a cohort analysis with a time-varying exposure, a patient's follow-up up to the current month is partitioned into three intervals: a comparison interval before the first vaccination, an interval after the first dose and before the second dose if the second dose is received, and an interval after the second dose. Those who have not received COVID-19 vaccines will only contribute to the comparison interval. Mortality rates per 100 person-years will be calculated for these three intervals. We will report the number of deaths, mortality rates, and relative risks cumulatively up to the reporting month. Due to data lag in deaths from other settings (e.g., from claims and outside utilization of VSD sites) and in COVID-19 vaccination outside of VSD sites, we will include those who were vaccinated at least two months prior to the reporting month. Those comparators who were vaccinated during the subsequent two months will be censored upon receipt of their first dose of COVID-19 vaccine. In a sensitivity analysis

using the matched cohort design, we will calculate mortality at 30 days after the index date among comparators, and 30 days after the first and second doses among vaccinees.

We will conduct interim analyses every six months for a total of 6 interim analyses over 3 years. Although we will not establish and apply stopping rules as in a formal sequential analysis, we will adjust for multiple testing using the Pocock approach for controlling overall type I error rate (Pocock, 1982). Compared to O'Brien-Fleming approach, with constant significance levels, the Pocock approach allows for early signal detection if there exists an association between the vaccination and mortality. A diagram for the interim analyses is displayed in Figure 1.

In our primary analyses, we will include all deaths except COVID-19 related deaths. We will use cause of death, if available, to identify COVID-19 related deaths. When cause of death is not available in the early stage of surveillance, a death will be designated as a COVID-19 related death if it is identified from inpatient or ED settings with a COVID-19 diagnosis code or a positive lab test within 30 days of death. We will conduct two secondary analyses. First, we will include all-cause deaths. In this secondary analysis, the association between COVID-19 vaccines and mortality will be affected by both any potential adverse effect of the vaccine on mortality and any protective effect of the vaccine against mortality by reducing SARS-CoV-2 infection and severity of COVID-19 disease. Second, we will exclude deaths due to external causes such as accident and homicide in addition to excluding COVID-19 related deaths (McCarthy et al, 2016).

Survival analyses will be carried out to assess the mortality risk of COVID-19 vaccines. The start time (index date) for the exposed group is the date that one received the first dose of COVID-19 vaccine. We will assign an index date to each comparator according to the frequencies of COVID-19 vaccination dates in each month of the six months of an interim analysis. To reduce selection bias, we will employ a propensity score approach to adjust for the potential imbalance in confounders between the exposed and the comparison groups. Our primary analyses will use an improved inverse propensity weighting: stabilized weights (SW) (Robins et al, 2000). The stabilized weights not only reduce the impact of some extreme weights but also preserve the original sample size (Xu et al, 2010).

Let t_k denote the calendar time for the kth interim analysis, t_k =6, 12, 18, 24, 30, and 36 months after start of surveillance for k=1 to 6. At the kth interim analysis, two steps will be taken. When the pool of the first comparison group becomes limited, we will consider those who are vaccinated more than 6 months prior to the kth interim analyses to be comparators in the kth interim analysis.

Step 1: We will use logistic regression models to calculate propensity scores for those who are newly identified in the exposed and the comparison groups. We will identify those who were vaccinated with a COVID-19 vaccine between $t_{(k-1)}$ and t_k and those comparators whose index dates were between $t_{(k-1)}$ and t_k but had never been vaccinated with a COVID-19 vaccine. Let n_{1k} represent the sample size of the exposed group and n_{0k} represent the sample size of the comparison group, $N_k = n_{1k} + n_{0k}$ is the sample size at the kth interim analysis. A propensity score model will be built with the exposure variable as the dependent variable. We will include the

following confounders in our propensity score models: seasonality, age, gender, race/ethnicity, socioeconomic status (SES) variables such as Medicaid status and neighborhood level income and education, comorbidities, pregnancy status, health care utilization (e.g. number of outpatient, ED and inpatient visits) in prior year, receipt of other vaccines, VSD site, and etc. We will also collect the information whether a patient has ED and inpatient visits one week prior to the index date. Comorbidities are important confounders. It is likely that the exposed and the comparison group will differ in comorbidities. We will explore three ways to use comorbidities as predictors for vaccination in the propensity score models: 1) using each individual comorbidity; 2) using Charlson comorbidity index (CCI); and 3) using the more sophisticated Elixhauser Comorbidity Index (ECI). We will choose the one that is the best predictor in propensity score models and is balanced between the exposed and comparison groups after stabilized weights are applied.

We will then use the results from the propensity score model to calculate SW for each individual. Individuals in the exposed group will carry their SWs for future interim analyses. Those in the comparison group will carry their SWs for future interim analyses until they become vaccinated with COVID-19 upon which they will be in the exposed group. We will examine whether the SWs help balance confounders among treatment groups. If necessary, we will trim data to optimize SWs.

Step 2: We will employ a cumulative estimation approach to assess the mortality risk of the vaccines using all data up to t_k, the time for the kth interim analysis (Xu et al 2016). The sample size for the kth interim analysis will be sum of $N_1,\ldots, N_k$. Those in $N_{(k-1)}$ will be allowed to extend their follow-up into t_k. For vaccines that require only one dose such as Johnson & Johnson's JNJ-78436735, a proportional hazard model will be fit to assess the association between COVID-19 vaccines with mortality (Cox 1972; Cox 1975). The assumption of proportional hazard will be tested using statistical tests and graphical diagnostics based on the scaled Schoenfeld residuals (Schoenfeld 1982; Harrell and Lee, 1986). If the assumption does not hold, we will include an interaction term between the exposure variable and time in the Cox model to allow the exposure effect to vary over time (Cox and Oakes 1984; Allison 1995).

For the two mRNA-based vaccines that require two doses, the counting process approach will be used with a new observation period when the second dose starts (Andersen and Gill, 1982; Andersen et al, 1992). The index date is still the date of receipt of the first dose. Different indicator variables will be used for the first and the second doses. This counting process approach can be used to test if the mortality risk after receiving the second dose differs from the risk after receiving the first dose. In these survival analyses, SW will be applied to adjust for imbalance of confounders between the exposed and the comparison groups (Xu et al 2012; Xu et al 2014).

As we mentioned previously, we won't pre-specify the risk window for these new vaccines. However, our approach can assess the mortality risk by different risk windows. For example, when we censor follow-up at 42 days after vaccination, we will be able to assess mortality risk within 42 days after vaccination. This is equivalent to assessing a vaccination effect with a risk window of 42 days using either SCCS design or a risk-interval design (Glanz et al 2006).

In addition to conducting separate analyses for each COVID-19 vaccine, we will also consider comparing different vaccines to each other when uptake of two or more vaccines is sufficient to allow for such a comparison. We will use the analytic approaches described above for this purpose. On the other hand, since mortality is expected to be a rare adverse event, at the initial phase of vaccination rollout, we may combine the two mRNA vaccines to increase the sample size and statistical power.

3. STUDY LIMITATIONS

There are some potential limitations in our proposed approach. First, important confounders may not be available. The validity of this observational study may be threatened without adjusting for these unmeasured confounders. Second, this study does not address if the mortality risk of COVID-19 vaccines differs by gender, age, race/ethnicity, and/or clinical conditions although these risk factors will be adjusted for in propensity score models. Third, to some degree, the validity of our results depends on the completeness and accuracy of ascertainment of deaths in our death data. Some patients who appear alive in VSD data may have died while some patients who appear to have died in VSD data may be still alive. In addition, we observed that a small proportion of patients who appear to have died in VSD data had medical visits after death. Fourth, using a COVID-19 diagnosis code or a positive lab test within 30 days of death to identify and exclude COVID-19 related death may result in misclassification; however, this approach is needed because data on the true underlying causes of death are not available in a timely fashion. We recognize the potential for misclassification of COVID-19 related death, and as such will include all-cause deaths in the secondary analysis approach.

4. DATA SOURCES

We will use the VSD Dynamic Data Files (DDF) and cycle files from all participating sites. We will also be requesting that sites generate an ancillary death file. The data files will be updated monthly with death data from patients' records in the electronic medical records (EMR) and membership files. Necessary files include the Constant File, Enroll File, Vaccine File, Inpatient File, Outpatient File, Procedure file, Mort and MortCOD Files, Medicaid and Geocode files, Pregnancy Episode Algorithm (PEA), Dynamic Pregnancy Algorithm (DPA), and Pregnancy files, and COVID-19 DXID and lab files. The files will include but are not limited to the following variables: age, sex, race/ethnicity, SES variables, VSD site, comorbidities, pregnancy status, health care utilization, receipt of influenza and other vaccines, and vital status.

5. DATA MANAGEMENT

SCK will be responsible for overall data management activities. SCK will oversee study documentation and archiving. Data will be
exchanged using the secure Distributed Data Model (DDM). Participating sites will be responsible for exploring and sharing information about availability of their death data, investigating any data quality issues, and incorporating additional data sources or data elements. SCK will create a data dictionary and instructions for ancillary files as needed, and sites will write and test the programs that will be used to create these files according to the data dictionary and instructions. SCK programmers/analysts will write and test the programs that will be used to

capture the data from the DDF and ancillary files at the participating sites. Individual level data will be collected to calculate propensity score weights and conduct survival analyses.

6. CHART REVIEW

Manual review of medical records will be performed to assess cause of deaths that occurred in the health care systems of participating sites. This information will be used to determine if a death is due to external causes such as accident and homicide. Clinician input may be required to assess biological plausibility of identified cause of death being vaccine related. All deaths within 42 days after vaccination will be chart reviewed. When the number of deaths in the comparison group is large, a random sample will be selected for chart review.

We will also conduct manual reviews of a random sample of medical records to evaluate the quality of death data. For example, deaths identified from claims with encounters after the death date, or death dates occurring prior to vaccination, are suspect and warrant further chart review. Because the proportion of deaths from various sources and their accuracy may differ by site, each site will conduct reviews of a random sample of medical records and site-specific confirmation rates will be obtained. The confirmation rates of deaths may be used in a sensitivity analysis.

We plan to adapt and utilize the chart abstraction forms and manuals used in previous VSD studies as needed for this project. Participating sites will have the opportunity to review the tools. We will send the abstraction forms to CDC for review and comment before the documents are finalized. We will coordinate the collection, analysis, and interpretation of chart abstraction data. Chart review data will be collected from participating sites in Excel or REDCap.

7. SITE RESPONSIBILITIES

We hope that all sites with appropriate data will participate. Participating VSD sites are responsible for obtaining site-specific IRB approval and data use agreements, if applicable. Data managers at each site may be asked to create ancillary files and review the SAS program(s) prior to submission to the DDM. CDC will be responsible for submitting programs to the DDM. Participating sites and CDC will be invited to provide feedback on study results, manuscripts, and presentations.

8. HUMAN SUBJECTS

The privacy and confidentiality of all study subjects will be strictly protected, according to standard VSD procedures. We will seek IRB review and approval at each individual participating VSD site. We will also request a waiver of HIPAA authorization, as this study will involve only a limited dataset of protected health information (PHI). Data use agreements will be signed with all participating sites.

PROJECTED TIMELINE

Date	Description
December 2020	Present protocol on VSD Project Call
January 2021	Provide a final protocol to CDC for approval
January 2021	Invite sites to participate and obtain necessary IRB approvals and DUAs
January 2021 - March 2021	Ancillary death file development by participating sites. DDM SAS program development by KPSC and distribution to participating sites for review and approval.
March 2021	Preliminary data extraction
March 2021	Begin monthly updates of ancillary death file
October 2021	Present findings from first interim analysis
April 2022	Present findings from second interim analysis
October2022	Present findings from third interim analysis
April 2023	Present findings from fourth interim analysis
October 2023	Present findings from fifth interim analysis
April 2024	Present findings from final analysis
TBD	Manuscript development

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Xu S, Shetterly S, Powers D, Raebel M, Tsai T, Ho M, Magid D. Extension of Kaplan-Meier Methods in observational studies with time-varying treatment. Value in Health. 2012;15:167-174.

Xu S, Shetterly S, Raebel MA, Ho PM, Tsai TT, Magid D. Estimating the effects of time-varying exposures in observational studies using Cox models with stabilized weights adjustment. Pharmacoepidemiology and Drug Safety 2014; 23: 812–818.

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Number represents subject;
letter **v** denotes vaccination with a COVID vaccine;
letter **p** denotes having a preventive care but not COVID vaccines;
PS: propensity score model

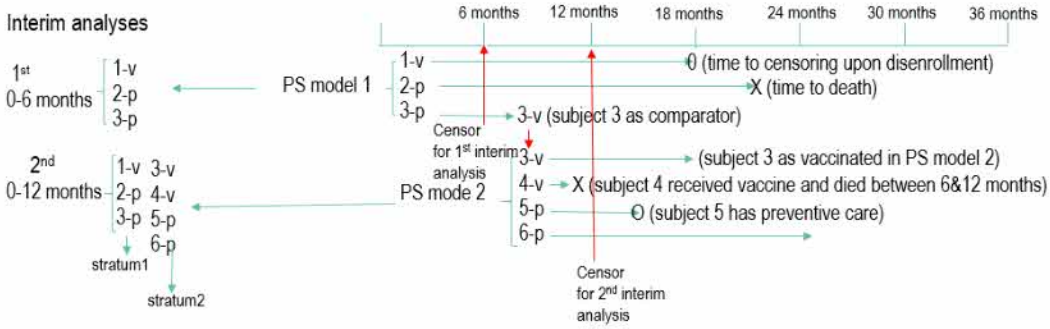

Figure 1. Overview of interim analyses

Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

June 8, 2021

Title of Document	**COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021**
Point of Contact	Eric Weintraub (eiw8@cdc.gov)
Task Force *If you are submitting from outside the response, please list your CIO.*	Vaccine Task Force
Author	Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California) Gabriela Vasquez-Benitez (HealthPartners Institute) Jason Glanz (Kaiser Permanente Colorado) Michael Jackson (Kaiser Permanente Washington) David McClure (Marshfield Clinic Research Institute) Nicola Klein (Kaiser Permanente Northern California) Elizabeth Liles (Kaiser Permanente Northwest) David Shay, Eric Weintraub (CDC)
Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	Letter or a short report – MMWR – approved for tier 1
New document or updated? *Please use tracked changes to clearly indicate what has changed from the current version (e.g., the current webpage). Documents submitted with highlighted changes, instead of tracked changes, will be returned.* **If web content, please include URL**	☒ **New** ☐ **Updated** **URL:**
Summary paragraph describing document • *For new resources, describe its purpose, why it is needed, and what is included in it.* • *For updates to existing resource, summarize changes and the reasons for making them.*	(b)(5)

	(b)(5)
Intended audience(s) *Please be as specific as possible.*	Public Health Workers, Physicians, Nurses, General Public
Was this document cleared by your Task Force? Please list the reviewer name & title (TF ADS, TF lead, etc.) *If you are submitting from outside the response, provide the name and title of the most senior CIO reviewer who cleared the document.*	☒ **Yes** ☐ **No** **Reviewer name & title:** Cleared by VTF CMO John Piacentino, VTF ADS – Carolyn Bridges
Was this cross-cleared by other Task Forces or CIOs? ☐ **Yes** ☒ **No** If yes, please list the Task Forces and CIOs that cleared force as an fyi	**Task Forces and CIOs:** Was sent to the Epi task
New and updated web content for non-technical audiences must be cross-cleared with the JIC Deputy for Content before submission for response clearance. **Has the JIC Deputy for Content cross-cleared the document?** ☐ **Yes** ☒ **No**	
Does this document include any of the following? Previously unpublished scientific information, new science-based recommendations, or new scientific conclusions.	☒ **Yes** ☐ **No**
Does the document contain data and information about any of the following? Race/ethnicity, people experiencing poverty, congregate settings (e.g., correctional facilities, homeless shelters, meat packing plants, long-term care facilities), people experiencing homelessness, people who use drugs, rural populations, people with disabilities, non-U.S.-born persons, justice-involved persons, discussion of health disparities or health equity. ☒ **Yes** ☐ **No**	
For new or updated guidance documents: Updates to existing guidance and new guidance documents must be approved through the Guidance Clearance Portal. Has that happened? ☐ **Yes** ☐ **No** What is the ID number for your approved guidance proposal?	
For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens *Documents can include abstracts, manuscripts, and MMWRs.* Provide STARS Project Determination Number for the described activities or investigation? 032521AJ ☐ **N/A** If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.	
For presentations: *COVID-19 presentations must be in the response presentation template.* Presentation date: Presentation venue: Have you provided URLs or citations for all content (on the slides, when appropriate, or in notes)? ☐ **Yes** ☐ **No**	

For abstracts, journal manuscripts, and *MMWRs:*

Has your manuscript or MMWR been submitted and approved using the Publication Proposal Form? ☒ **Yes** ☐ **No**

What is the concept proposal ID number for your approved manuscript or *MMWR* submission? 1685

For abstracts: List the meeting, submission deadline, and word count limit

For journal manuscripts: Priority status assigned during concept approval: ☒ **High** ☒ **Standard**

Intended journal TBS, submission deadline August 30, 2021, and word count limit 850

For *MMWRs*: Tier status assigned during concept approval: ☒ **Tier 1** ☐ **Tier 2**

For *MMWRs only:*

After drafting the report, it must be pre-cleared by the MMWR editors before clearance submission.

List the date you received pre-clearance review from the *MMWR* editors? 9/24/2021

After MMWR pre-clearance, all MMWRs must *be reviewed by CHEO (eocevent444@cdc.gov) and SSU (eocevent538@cdc.gov) before submission for response clearance. MMWRs can be reviewed by CHEO and SSU simultaneously.*

Has CHEO cross-cleared? ☒ **Yes** ☐ **No** **Has SSU cross-cleared?** ☒ **Yes** ☐ **No**

Deadline for response clearance (date and time)	**Date:** 9/29/2021 **Time:** 4:00 PM
All clearance submissions will be processed according to standard response clearance timelines unless your document is a Tier 1 MMWR or high priority manuscript or has been approved for expedited review. *Priority status for journal manuscripts is assigned as part of the concept clearance process. Manuscripts not assigned priority status at that time will be processed as standard clearance submissions.*	**If urgent, which DIM approved:** **Justification for urgent clearance (if requested):** **Was approved for tier 1 clearance**

Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

August 19, 2021

Title of Document	**COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021**
Point of Contact	Eric Weintraub (eiw8@cdc.gov)
Task Force *If you are submitting from outside the response, please list your CIO.*	Vaccine Task Force
Author	Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California) Gabriela Vasquez-Benitez (HealthPartners Institute) Jason Glanz (Kaiser Permanente Colorado) Michael Jackson (Kaiser Permanente Washington) David McClure (Marshfield Clinic Research Institute) Nicola Klein (Kaiser Permanente Northern California) Elizabeth Liles (Kaiser Permanente Northwest) David Shay, Eric Weintraub (CDC)
Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	MMWR – approved for tier 1
New document or updated? *Please use tracked changes to clearly indicate what has changed from the current version (e.g., the current webpage). Documents submitted with highlighted changes instead of tracked changes will be returned.* **If web content, please include URL**	☒ **New** ☐ **Updated** **URL:**
Summary paragraph describing document • *For new resources, describe its purpose, why it is needed, and what is included in it.* • *For updates to existing resource, summarize changes and the reasons for making them.*	(b)(5)

	(b)(5)
Intended audience(s) *Please be as specific as possible.*	Public Health Workers, Physicians, Nurses, General Public
Was this document cleared by your Task Force? Please list the reviewer name & title (TF ADS, TF lead, etc.) *If you are submitting from outside the response, provide the name and title of the most senior CIO reviewer who cleared the document.*	☒ **Yes** ☐ **No** **Reviewer name & title:** Cleared by VTF CMO John Piacentino, VTF ADS – Carolyn Bridges
Was this cross-cleared by other Task Forces or CIOs? ☐ **Yes** ☒ **No** If yes, please list the Task Forces and CIOs that cleared force as an FYI	**Task Forces and CIOs:** Was sent to Epi task
New and updated web content for non-technical audiences must be cross-cleared with the JIC Deputy for Content before submission for response clearance. **Has the JIC Deputy for Content cross-cleared the document?** ☐ **Yes** ☒ **No**	
Does this document include any of the following? Previously unpublished scientific information, new science-based recommendations, or new scientific conclusions.	☒ **Yes** ☐ **No**
Does the document contain data and information about any of the following? Race/ethnicity, people experiencing poverty, congregate settings (e.g., correctional facilities, homeless shelters, meat packing plants, long-term care facilities), people experiencing homelessness, people who use drugs, rural populations, people with disabilities, non-U.S.-born persons, justice-involved persons, discussion of health disparities or health equity. ☒ **Yes** ☐ **No**	
For new or updated guidance documents: Updates to existing guidance and new guidance documents must be approved through the Guidance Clearance Portal. Has that happened? ☐ **Yes** ☐ **No** What is the ID number for your approved guidance proposal?	
For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens *Documents can include, but are not limited to, abstracts, manuscripts, and MMWRs.* Provide STARS Project Determination Number for the described activities or investigation? 032521AJ ☐ **N/A** If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.	
For presentations: *COVID-19 presentations must be in the response presentation template.* Presentation **Date** Click to enter a date **Time:** Presentation venue: Have you provided URLs or citations for all content (on the slides, when appropriate, or in notes)? ☐ **Yes** ☐ **No**	

For abstracts, journal manuscripts, and *MMWRs:*

Has your manuscript or MMWR been submitted and approved using the Publication Proposal Form? ☒ **Yes** ☐ **No**

What is the concept proposal ID number for your approved manuscript or *MMWR* submission? 1685

For abstracts: List the meeting , submission deadline , and word count limit

For journal manuscripts: Tier status assigned during concept approval: ☐ **Tier 1** ☐ **Tier 2** ☐ **Tier 3**

Intended journal , submission deadline , and word count limit

For *MMWRs*: Tier status assigned during concept approval: ☒ **Tier 1** ☐ **Tier 2**

For *MMWRs only:*

After drafting the report, it must be pre-cleared by the MMWR editors before clearance submission.

List the date you received pre-clearance review from the *MMWR* editors? 9/24/2021

After MMWR pre-clearance, all MMWRs must *be reviewed by CHEO (eocevent444@cdc.gov) and SSU (eocevent538@cdc.gov) before submission for response clearance. MMWRs can be reviewed by CHEO and SSU simultaneously.*

Has CHEO cross-cleared? ☒ **Yes** ☐ **No** **Has SSU cross-cleared?** ☒ **Yes** ☐ **No**

Deadline for response clearance (date and time)	**Date:** 9/30/2021 **Time:** 4:00 pm
All clearance submissions will be processed according to standard response clearance timelines unless your document is a Tier 1 MMWR or Tier 1 journal manuscript or has been approved for expedited review. *Authors are responsible for submitting presentations and abstracts in time to meet the due date. Due dates will not drive the review timeline unless a compelling reason is provided.*	**If expedited, which DIM approved:** **Justification for expedited clearance (if requested):** **Was approved for tier 1 clearance**

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COVID-19 Publication Proposal Form Template

****EFFECTIVE DATE/TIME: APRIL 5, 2021, 4 PM EST**

*This template may be used by Task Forces to prepare MMWR and manuscript concepts for submission through the electronic form: **COVID-19 Publication Proposal Form***

1. **Proposed title of *MMWR* or manuscript:**
   COVID-19 Vaccines Were Not Associated with Increased Risk of Mortality among Members Enrolled in Seven Integrated Health Care Organization, United States, December 14, 2020-May 31, 2021

2. **Responsible author name/POC for submission:** Eric Weintraub

3. **Responsible author/POC email:** eiw8@cdc.gov

1. **Other authors** (name, organization):
   Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California)
   Gabriela Vasquez-Benitez (HealthPartners Institute)
   Jason Glanz (Kaiser Permanente Colorado)
   Michael Jackson (Kaiser Permanente Washington)
   David McClure (Marshfield Clinic Research Institute)
   Nicola Klein (Kaiser Permanente Northern California)
   Elizabeth Liles (Kaiser Permanente Northwest)
   David Shay, Eric Weintraub (CDC)

2. **CDC first or senior author** (Yes or No): No

3. **Category *(MMWR* or Journal Manuscript)**: Journal manuscript (short report) MMWR

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- *All proposals must be submitted by an author or point of contact (POC) with a CDC user ID.*
- *Proposals submitted electronically by 4:00pm on Monday will be reviewed by response leadership on Wednesday and receive a decision on Thursday.*
- ** For urgent submissions the Task Force Lead should send an email to Response MMWR and Publications (EOCevent172@cdc.gov) and the Response ADS (EOCevent264@cdc.gov) confirming approval of an urgent submission.*
- *Questions may be sent to Response MMWR and Publications (EOCevent172@cdc.gov) and the Response ADS (EOCevent264@cdc.gov).*

COVID-19 Publication Proposal Form Template

****EFFECTIVE DATE/TIME: APRIL 5, 2021, 4 PM EST**

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1. **Proposed title of *MMWR* or manuscript:**
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2. **Responsible author name/POC for submission:** Eric Weintraub

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   David Shay, Eric Weintraub (CDC)

2. **CDC first or senior author** (Yes or No): No

(b)(5)

3. **Category *(MMWR* or Journal Manuscript)**: Journal manuscript (short report) MMWR

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Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

August 19, 2021

Title of Document	COVID-19 Vaccines Were Not Associated with Increased Risk of Mortality among Members Enrolled in Seven Integrated Health Care Organization, United States, December 14, 2020-May 31, 2021
Point of Contact	Eric Weintraub
Task Force *If you are submitting from outside the response, please list your CIO.*	VTF
Author	Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California) Gabriela Vasquez-Benitez (HealthPartners Institute) Jason Glanz (Kaiser Permanente Colorado) Michael Jackson (Kaiser Permanente Washington) David McClure (Marshfield Clinic Research Institute) Nicola Klein (Kaiser Permanente Northern California) Elizabeth Liles (Kaiser Permanente Northwest) David Shay, Eric Weintraub (CDCC)
Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	MMWR
New document or updated? *Please use tracked changes to clearly indicate what has changed from the current version (e.g., the current webpage). Documents submitted with highlighted changes instead of tracked changes will be returned.* **If web content, please include URL**	☒ **New** ☐ **Updated** **URL:**
Summary paragraph describing document • *For new resources, describe its purpose, why it is needed, and what is included in it.* • *For updates to existing resource, summarize changes and the reasons for making them.*	(b)(5)

Intended audience(s) *Please be as specific as possible.*	Readers of MMWR
Was this document cleared by your Task Force? Please list the reviewer name & title (TF ADS, TF lead, etc.) *If you are submitting from outside the response, provide the name and title of the most senior CIO reviewer who cleared the document.*	☒ **Yes** ☐ **No** **Reviewer name & title:** VTF ADS Jacek Mazurek and VTF ADS2 Carolyn Bridges, and CMO of VTF

Was this cross-cleared by other Task Forces or CIOs? ☒ **Yes** ☐ **No**

If yes, please list the Task Forces and CIOs that cleared Kamb

Task Forces and CIOs: Epi Task Force, Mary

New and updated web content for non-technical audiences must be cross-cleared with the JIC Deputy for Content before submission for response clearance.

Has the JIC Deputy for Content cross-cleared the document? ☐ **Yes** ☒ **No**

Does this document include any of the following? Previously unpublished scientific information, new science-based recommendations, or new scientific conclusions.	☒ **Yes** ☐ **No**

Does the document contain data and information about any of the following?

Race/ethnicity, people experiencing poverty, congregate settings (e.g., correctional facilities, homeless shelters, meat packing plants, long-term care facilities), people experiencing homelessness, people who use drugs, rural populations, people with disabilities, non-U.S.-born persons, justice-involved persons, discussion of health disparities or health equity. ☒ **Yes** ☐ **No**

For new or updated guidance documents:

Updates to existing guidance and new guidance documents must be approved through the Guidance Clearance Portal.

Has that happened? ☐ **Yes** ☐ **No**

What is the ID number for your approved guidance proposal?

For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens

Documents can include, but are not limited to, abstracts, manuscripts, and MMWRs.

Provide STARS Project Determination Number for the described activities or investigation? 032521AJ ☐ **N/A**

If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.

For presentations:

COVID-19 presentations must be in the response presentation template.

Presentation **Date** Click to enter a date **Time:** Presentation venue:

Have you provided URLs or citations for all content (on the slides, when appropriate, or in notes)? ☐ **Yes** ☐ **No**

For abstracts, journal manuscripts, and *MMWRs:*

Has your manuscript or MMWR been submitted and approved using the Publication Proposal Form? ☐ **Yes** ☒ **No**

What is the concept proposal ID number for your approved manuscript or *MMWR* submission?

For abstracts: List the meeting , submission deadline , and word count limit

For journal manuscripts: Tier status assigned during concept approval: ☐ **Tier 1** ☐ **Tier 2** ☐ **Tier 3**

Intended journal , submission deadline , and word count limit

For *MMWRs*: Tier status assigned during concept approval: ☐ **Tier 1** ☐ **Tier 2**

For *MMWRs only:*

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List the date you received pre-clearance review from the *MMWR* editors? Click to enter a date

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Has CHEO cross-cleared? ☐ **Yes** ☐ **No** **Has SSU cross-cleared?** ☐ **Yes** ☐ **No**

Deadline for response clearance (date and time)	**Date:** 9/21/2021 **Time:** 11:45 am
All clearance submissions will be processed according to standard response clearance timelines unless your document is a Tier 1 MMWR or Tier 1 journal manuscript or has been approved for expedited review. *Authors are responsible for submitting presentations and abstracts in time to meet the due date. Due dates will not drive the review timeline unless a compelling reason is provided.*	**If expedited, which DIM approved:** **Justification for expedited clearance (if requested):**

Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

June 8, 2021

Title of Document	**COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021**
Point of Contact	Eric Weintraub (eiw8@cdc.gov)
Task Force *If you are submitting from outside the response, please list your CIO.*	Vaccine Task Force
Author	Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California) Gabriela Vasquez-Benitez (HealthPartners Institute) Jason Glanz (Kaiser Permanente Colorado) Michael Jackson (Kaiser Permanente Washington) David McClure (Marshfield Clinic Research Institute) Nicola Klein (Kaiser Permanente Northern California) Elizabeth Liles (Kaiser Permanente Northwest) David Shay, Eric Weintraub (CDC)
Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	Letter or a short report – MMWR – approved for tier 1
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	(b)(5)
Intended audience(s) *Please be as specific as possible.*	Public Health Workers, Physicians, Nurses, General Public
Was this document cleared by your Task Force? Please list the reviewer name & title (TF ADS, TF lead, etc.) *If you are submitting from outside the response, provide the name and title of the most senior CIO reviewer who cleared the document.*	☐ **Yes** ☒ **No** **Reviewer name & title:**
Was this cross-cleared by other Task Forces or CIOs? ☐ **Yes** ☒ **No** If yes, please list the Task Forces and CIOs that cleared **Task Forces and CIOs:** *New and updated web content for non-technical audiences must be cross-cleared with the JIC Deputy for Content before submission for response clearance.* **Has the JIC Deputy for Content cross-cleared the document?** ☐ **Yes** ☐ **No**	
Does this document include any of the following? Previously unpublished scientific information, new science-based recommendations, or new scientific conclusions.	☒ **Yes** ☐ **No**
Does the document contain data and information about any of the following? Race/ethnicity, people experiencing poverty, congregate settings (e.g., correctional facilities, homeless shelters, meat packing plants, long-term care facilities), people experiencing homelessness, people who use drugs, rural populations, people with disabilities, non-U.S.-born persons, justice-involved persons, discussion of health disparities or health equity. ☒ **Yes** ☐ **No**	
For new or updated guidance documents: Updates to existing guidance and new guidance documents must be approved through the Guidance Clearance Portal. Has that happened? ☐ **Yes** ☐ **No** What is the ID number for your approved guidance proposal?	
For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens *Documents can include abstracts, manuscripts, and MMWRs.* Provide STARS Project Determination Number for the described activities or investigation? 032521AJ ☐ **N/A** If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.	
For presentations: *COVID-19 presentations must be in the response presentation template.* Presentation date: Presentation venue: Have you provided URLs or citations for all content (on the slides, when appropriate, or in notes)? ☐ **Yes** ☐ **No**	

For abstracts, journal manuscripts, and *MMWRs:*
Has your manuscript or MMWR been submitted and approved using the Publication Proposal Form? ☒ **Yes** ☐ **No**

What is the concept proposal ID number for your approved manuscript or *MMWR* submission? 1685

For abstracts: List the meeting, submission deadline, and word count limit

For journal manuscripts: Priority status assigned during concept approval: ☒ **High** ☒ **Standard**

Intended journal TBS, submission deadline August 30, 2021, and word count limit 850

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For *MMWRs only:*
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Has CHEO cross-cleared? ☐ **Yes** ☐ **No** **Has SSU cross-cleared?** ☐ **Yes** ☐ **No**

Deadline for response clearance (date and time)	**Date:** 9/22/2021 **Time:** 4:00 PM
All clearance submissions will be processed according to standard response clearance timelines unless your document is a Tier 1 MMWR or high priority manuscript or has been approved for expedited review. *Priority status for journal manuscripts is assigned as part of the concept clearance process. Manuscripts not assigned priority status at that time will be processed as standard clearance submissions.*	**If urgent, which DIM approved:** **Justification for urgent clearance (if requested):** **Was approved for tier 1 clearance, and needs to be submitted to the MMWR pre clearance by Thursday, Sept 23rd.**

Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

June 8, 2021

Title of Document	**COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021**
Point of Contact	Eric Weintraub (eiw8@cdc.gov)
Task Force *If you are submitting from outside the response, please list your CIO.*	Vaccine Task Force
Author	Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California) Gabriela Vasquez-Benitez (HealthPartners Institute) Jason Glanz (Kaiser Permanente Colorado) Michael Jackson (Kaiser Permanente Washington) David McClure (Marshfield Clinic Research Institute) Nicola Klein (Kaiser Permanente Northern California) Elizabeth Liles (Kaiser Permanente Northwest) David Shay, Eric Weintraub (CDC)
Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	Letter or a short report – MMWR – approved for tier 1
New document or updated? *Please use tracked changes to clearly indicate what has changed from the current version (e.g., the current webpage). Documents submitted with highlighted changes, instead of tracked changes, will be returned.* **If web content, please include URL**	☒ **New** ☐ **Updated** **URL:**
Summary paragraph describing document • *For new resources, describe its purpose, why it is needed, and what is included in it.* • *For updates to existing resource, summarize changes and the reasons for making them.*	(b)(5)

	(b)(5)
Intended audience(s) *Please be as specific as possible.*	Public Health Workers, Physicians, Nurses, General Public
Was this document cleared by your Task Force? Please list the reviewer name & title (TF ADS, TF lead, etc.) *If you are submitting from outside the response, provide the name and title of the most senior CIO reviewer who cleared the document.*	☒ **Yes** ☐ **No** **Reviewer name & title:** Cleared by VTF CMO John Piacentino, VTF ADS – Carolyn Bridges
Was this cross-cleared by other Task Forces or CIOs? ☐ **Yes** ☒ **No** If yes, please list the Task Forces and CIOs that cleared **Task Forces and CIOs:** *New and updated web content for non-technical audiences must be cross-cleared with the JIC Deputy for Content before submission for response clearance.* **Has the JIC Deputy for Content cross-cleared the document?** ☐ **Yes** ☒ **No**	
Does this document include any of the following? Previously unpublished scientific information, new science-based recommendations, or new scientific conclusions.	☒ **Yes** ☐ **No**
Does the document contain data and information about any of the following? Race/ethnicity, people experiencing poverty, congregate settings (e.g., correctional facilities, homeless shelters, meat packing plants, long-term care facilities), people experiencing homelessness, people who use drugs, rural populations, people with disabilities, non-U.S.-born persons, justice-involved persons, discussion of health disparities or health equity. ☒ **Yes** ☐ **No**	
For new or updated guidance documents: Updates to existing guidance and new guidance documents must be approved through the Guidance Clearance Portal. Has that happened? ☐ **Yes** ☐ **No** What is the ID number for your approved guidance proposal?	
For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens *Documents can include abstracts, manuscripts, and MMWRs.* Provide STARS Project Determination Number for the described activities or investigation? 032521AJ ☐ **N/A** If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.	
For presentations: *COVID-19 presentations must be in the response presentation template.* Presentation date: Presentation venue: Have you provided URLs or citations for all content (on the slides, when appropriate, or in notes)? ☐ **Yes** ☐ **No**	

For abstracts, journal manuscripts, and *MMWRs:*

Has your manuscript or MMWR been submitted and approved using the Publication Proposal Form? ☒ **Yes** ☐ **No**

What is the concept proposal ID number for your approved manuscript or *MMWR* submission? 1685

For abstracts: List the meeting, submission deadline, and word count limit

For journal manuscripts: Priority status assigned during concept approval: ☒ **High** ☒ **Standard**

Intended journal TBS, submission deadline August 30, 2021, and word count limit 850

For *MMWRs*: Tier status assigned during concept approval: ☒ **Tier 1** ☐ **Tier 2**

For *MMWRs only:*

After drafting the report, it must be pre-cleared by the MMWR editors before clearance submission.

List the date you received pre-clearance review from the *MMWR* editors? Click to enter a date

After MMWR pre-clearance, all MMWRs must *be reviewed by CHEO (eocevent444@cdc.gov) and SSU (eocevent538@cdc.gov) before submission for response clearance. MMWRs can be reviewed by CHEO and SSU simultaneously.*

Has CHEO cross-cleared? ☐ **Yes** ☒ **No** **Has SSU cross-cleared?** ☐ **Yes** ☒ **No**

Deadline for response clearance (date and time)	**Date:** 9/26/2021 **Time:** 4:00 PM
All clearance submissions will be processed according to standard response clearance timelines unless your document is a Tier 1 MMWR or high priority manuscript or has been approved for expedited review. *Priority status for journal manuscripts is assigned as part of the concept clearance process. Manuscripts not assigned priority status at that time will be processed as standard clearance submissions.*	**If urgent, which DIM approved:** **Justification for urgent clearance (if requested):** **Was approved for tier 1 clearance, and needs to be submitted to the MMWR pre clearance by Thursday, Sept 23rd.**

From:	CDC IMS 2019 NCOV Response VTF Clearance
To:	Weintraub, Eric (CDC/DDID/NCEZID/DHQP)
Cc:	Piacentino, John D. (CDC/NIOSH/OD); Mazurek, Jacek (CDC/NIOSH/RHD/SB); Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR); Shefer, Abigail (CDC/DDPHSIS/CGH/GID); Whittaker, Christine (CDC/NIOSH/DSI/REB); Holmes, David (CDC/OCOO/OSSAM/OHC)
Subject:	Cleared with comments/edits (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021
Date:	Wednesday, October 13, 2021 11:48:45 AM
Attachments:	Xu_1685_2021-10-10_clean (IMPDIM)_For OS cleared.docx Table 3 Xu_1685_2021-10-10_For OS cleared.docx Table 2 Xu_1685_2021-10-10_For OS cleared.docx Table 1 Xu_1685_2021-10-10_For OS cleared.docx

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Hi all,

Please see below from JIC.

Attached document cleared with comments. At your convenience, we will need a clean and final copy for our records.

Thank you,
Kimberly Sende
VTF Clearance Coordinator
VTF Clearance Hours of Operation:
Monday-Friday, 8:30am – 5:30pm EST
Saturday- Sunday, 11:00am – 1:00 pm EST

From: CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>
Sent: Wednesday, October 13, 2021 7:41 AM
To: CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>
Cc: CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>; CDC IMS 2019 NCOV Response MMWR and Publications <eocevent172@cdc.gov>; Gindler, Jacqueline (CDC/DDPHSS/CSELS/OD) <jsg5@cdc.gov>; Kent, Charlotte (CDC/DDPHSS/CSELS/OD) <cgk3@cdc.gov>; Reynolds, Mary (CDC/DDPHSS/OS/OSQ) <nzr6@cdc.gov>
Subject: Cleared with comments/edits (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021

VTF,

Attached document cleared with comments. At your convenience, we will need a clean and final copy for our records.

Thank you,
Kaliyah Hunter
JIC Emergency Clearance: eocjicclear3@cdc.gov
COVID-19 Response Joint Information Center (JIC)

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Response Clearance Hours (ET): Mon-Fri (9am-6pm), Sat/Sun (10am-3pm)

JIC Emergency Clearance Coordinators
Lisa Lynch | Jeanita Porter | Kaliyah Hunter | Joya Faruque | Eurkita Ford | Jamie Davis | Ken Durden | Brian Panasuk

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From: CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>
Sent: Tuesday, October 12, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>
Cc: CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>
Subject: Status Update: (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021

Good Morning,

The MMWR has been entered into eClearance for OS review.

Thank you,
Jeanita Porter
JIC Emergency Clearance: eocjicclear3@cdc.gov
COVID-19 Response Joint Information Center (JIC)
Response Clearance Hours (ET): Mon-Fri (9am-6pm), Sat/Sun (10am-3pm)

JIC Emergency Clearance Coordinators
Lisa Lynch | Jeanita Porter | Kaliyah Hunter | Joya Faruque | Eurkita Ford | Jamie Davis | Ken Durden | Brian Panasuk

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From: CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>
Sent: Tuesday, October 12, 2021 9:23 AM
To: CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>
Subject: Fw: for OS Review: Returning for JIC Clearance (not cleared): (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021

JIC...

Returning attached for OS Review.

Dany Hall
qij7@cdc.gov
VTF Clearance Coordinator
VTF Clearance Hours of Operation:
Monday-Friday, 8:30am – 5:30pm EST
Saturday- Sunday, 11:00am – 1:00 pm EST

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Tuesday, October 12, 2021 8:52 AM
To: Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR) <ctb1@cdc.gov>; CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>; CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>
Cc: Piacentino, John D. (CDC/NIOSH/OD) <gjt4@cdc.gov>; Shefer, Abigail (CDC/DDPHSIS/CGH/GID) <ams7@cdc.gov>; Mazurek, Jacek (CDC/NIOSH/RHD/SB) <acq8@cdc.gov>; Whittaker, Christine (CDC/NIOSH/DSI/REB) <cts6@cdc.gov>
Subject: for OS Review: Returning for JIC Clearance (not cleared): (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021

Thank you, attached is the tier 1 (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021 **for OS review**.

I have attached:

- a clean and track changes copy of the MMWR.
- Clean copies of table 1 – table 3
- Updated Clearance request from

Thank you,

Eric Weintraub
Vaccine Safety Datalink
Immunization Safety Office

From: Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR) <ctb1@cdc.gov>
Sent: Monday, October 11, 2021 11:11 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Cc: Piacentino, John D. (CDC/NIOSH/OD) <gjt4@cdc.gov>; CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer

<eocevent516@cdc.gov>; Shefer, Abigail (CDC/DDPHSIS/CGH/GID) <ams7@cdc.gov>; Mazurek, Jacek (CDC/NIOSH/RHD/SB) <acq8@cdc.gov>; Whittaker, Christine (CDC/NIOSH/DSI/REB) <cts6@cdc.gov>
Subject: FW: Returning for JIC Clearance (not cleared): (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021

Hi Eric!

I hope you are well! I am helping on the VTF ADS team this month. VTF Clearance coordinators are on leave today so I am forwarding directly to you, copying others for their record-keeping.

In case you are working over the holiday, please find attached comments from JIC clearance in case this did not reach you over the holiday weekend.

A revision can be resent to VTF clearance mailbox plus eocjicclear3@cdc.gov for OS review. Please also include those copied above for everyone's awareness.

Thanks, Eric!

Carolyn

Carolyn B. Bridges, MD

Sr. Vaccine Administration SME assigned to
COVID-19 Response/Vaccine Task Force ADS Team

General Dynamics Information Technology (GDIT) sub-contractor
Influenza Coordination Unit (ICU)
National Center for Immunization and Respiratory Diseases (NCIRD)
Centers for Disease Control and Prevention (CDC)
404-964-8691 (mobile)
cbridges@cdc.gov

From: CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>
Sent: Monday, October 11, 2021 10:59 AM
To: Mazurek, Jacek (CDC/NIOSH/RHD/SB) <acq8@cdc.gov>; Piacentino, John D. (CDC/NIOSH/OD) <gjt4@cdc.gov>; Whittaker, Christine (CDC/NIOSH/DSI/REB) <cts6@cdc.gov>; Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR) <ctb1@cdc.gov>; Shefer, Abigail (CDC/DDPHSIS/CGH/GID) <ams7@cdc.gov>
Cc: CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>; CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>; CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>
Subject: Re: Returning for JIC Clearance (not cleared): (ID #1685) MMWR - COVID-19 Vaccination

and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021

Hi all,

This was returned to VTF Clearance on Sunday evening around 7:20pm. The IM/PDIM approved with some additional comments that need to be addressed. Once we receive a clean revision, we will send up to CDC OS for final review. This will be the final step in response clearance. Once CDC OS approves, the authors will be able to submit to ScholarOne.

Thank you,

Brian Panasuk
JIC Emergency Clearance: eocjicclear3@cdc.gov
COVID-19 Response Joint Information Center (JIC)
Response Clearance Hours (ET): Mon-Fri (9am-6pm), Sat/Sun (10am-3pm)

JIC Emergency Clearance Coordinators
Lisa Lynch | Jeanita Porter | Kaliyah Hunter | Joya Faruque | Eurkita Ford | Jamie Davis | Ken Durden | Brian Panasuk

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From: Mazurek, Jacek (CDC/NIOSH/RHD/SB) <acq8@cdc.gov>
Sent: Monday, October 11, 2021 8:01 AM
To: Piacentino, John D. (CDC/NIOSH/OD) <gjt4@cdc.gov>; Whittaker, Christine (CDC/NIOSH/DSI/REB) <cts6@cdc.gov>; Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR) <ctb1@cdc.gov>; Shefer, Abigail (CDC/DDPHSIS/CGH/GID) <ams7@cdc.gov>; CDC IMS JIC Emergency Clearance-3 <eocjicclear3@cdc.gov>
Cc: CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>; CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>
Subject: Re: Returning for JIC Clearance (not cleared): (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021

Hi John,
According to the Daily Wrap Up the "**5122** (ID #1685) MMWR - COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021" is currently with JIC.

Dear JIC staff, please confirm receipt.

Kind regards,

Jacek
VTF ADS Team

Get Outlook for iOS

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Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

August 19, 2021

Title of Document	An Interim Analysis of COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021
Point of Contact	Eric Weintraub (eiw8@cdc.gov)
Task Force *If you are submitting from outside the response, please list your CIO.*	Vaccine Task Force
Author	Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California) Gabriela Vasquez-Benitez (HealthPartners Institute) Jason Glanz (Kaiser Permanente Colorado) Michael Jackson (Kaiser Permanente Washington) David McClure (Marshfield Clinic Research Institute) Nicola Klein (Kaiser Permanente Northern California) Elizabeth Liles (Kaiser Permanente Northwest) David Shay, Eric Weintraub (CDC)
Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	MMWR – approved for tier 1
New document or updated? *Please use tracked changes to clearly indicate what has changed from the current version (e.g., the current webpage). Documents submitted with highlighted changes instead of tracked changes will be returned.* **If web content, please include URL**	☒ **New** ☐ **Updated** **URL:**
Summary paragraph describing document • *For new resources, describe its purpose, why it is needed, and what is included in it.* • *For updates to existing resource, summarize changes and the reasons for making them.*	(b)(5)

	(b)(5)
Intended audience(s) *Please be as specific as possible.*	Public Health Workers, Physicians, Nurses, General Public
Was this document cleared by your Task Force? Please list the reviewer name & title (TF ADS, TF lead, etc.) *If you are submitting from outside the response, provide the name and title of the most senior CIO reviewer who cleared the document.*	☒ **Yes** ☐ **No** **Reviewer name & title:** Cleared by VTF CMO John Piacentino, VTF ADS – Carolyn Bridges
Was this cross-cleared by other Task Forces or CIOs? ☐ **Yes** ☒ **No** If yes, please list the Task Forces and CIOs that cleared force as an FYI	**Task Forces and CIOs:** Was sent to Epi task
New and updated web content for non-technical audiences must be cross-cleared with the JIC Deputy for Content before submission for response clearance. **Has the JIC Deputy for Content cross-cleared the document?** ☒ **Yes** ☐ **No**	
Does this document include any of the following? Previously unpublished scientific information, new science-based recommendations, or new scientific conclusions.	☒ **Yes** ☐ **No**
Does the document contain data and information about any of the following? Race/ethnicity, people experiencing poverty, congregate settings (e.g., correctional facilities, homeless shelters, meat packing plants, long-term care facilities), people experiencing homelessness, people who use drugs, rural populations, people with disabilities, non-U.S.-born persons, justice-involved persons, discussion of health disparities or health equity. ☒ **Yes** ☐ **No**	
For new or updated guidance documents: Updates to existing guidance and new guidance documents must be approved through the Guidance Clearance Portal. Has that happened? ☐ **Yes** ☐ **No** What is the ID number for your approved guidance proposal?	
For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens *Documents can include, but are not limited to, abstracts, manuscripts, and MMWRs.* Provide STARS Project Determination Number for the described activities or investigation? 032521AJ ☐ **N/A** If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.	
For presentations: *COVID-19 presentations must be in the response presentation template.* Presentation **Date** Click to enter a date **Time:** Presentation venue: Have you provided URLs or citations for all content (on the slides, when appropriate, or in notes)? ☐ **Yes** ☐ **No**	

For abstracts, journal manuscripts, and *MMWRs:*

Has your manuscript or MMWR been submitted and approved using the Publication Proposal Form? ☒ **Yes** ☐ **No**

What is the concept proposal ID number for your approved manuscript or *MMWR* submission? 1685

For abstracts: List the meeting , submission deadline , and word count limit

For journal manuscripts: Tier status assigned during concept approval: ☐ **Tier 1** ☐ **Tier 2** ☐ **Tier 3**

Intended journal , submission deadline , and word count limit

For *MMWRs*: Tier status assigned during concept approval: ☒ **Tier 1** ☐ **Tier 2**

For *MMWRs only:*

After drafting the report, it must be pre-cleared by the MMWR editors before clearance submission.

List the date you received pre-clearance review from the *MMWR* editors? 9/24/2021

After MMWR pre-clearance, all MMWRs must *be reviewed by CHEO (eocevent444@cdc.gov) and SSU (eocevent538@cdc.gov) before submission for response clearance. MMWRs can be reviewed by CHEO and SSU simultaneously.*

Has CHEO cross-cleared? ☒ **Yes** ☐ **No** **Has SSU cross-cleared?** ☒ **Yes** ☐ **No**

Deadline for response clearance (date and time)	**Date:** 10/6/2021 **Time:** 7:45 pm
All clearance submissions will be processed according to standard response clearance timelines unless your document is a Tier 1 MMWR or Tier 1 journal manuscript or has been approved for expedited review. *Authors are responsible for submitting presentations and abstracts in time to meet the due date. Due dates will not drive the review timeline unless a compelling reason is provided.*	**If expedited, which DIM approved:** **Justification for expedited clearance (if requested):** **Was approved for tier 1 clearance**

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From: Piacentino, John D. (CDC/NIOSH/OD)
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)
Cc: CDC IMS 2019 NCOV Response VTF Clearance; CDC IMS 2019 NCOV Response VTF Chief Medical Officer
Subject: FW: 5122 URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination
Date: Tuesday, September 21, 2021 12:35:53 PM

Hello Eric:

VTF ADS has cleared the manuscript with comments, see
VSD - SCK_COVID Vacc Mortality_MMWR_ID1685_Manuscript_2021-09-20 clean CMOv2.docx VSD - MMWR COVID-19 vaccination and Mortality - clearance request form Sept 20 2021.docx

Please submit the revised manuscript and clearance request form for MMWR preclearance, at eocevent172@cdc.gov. Please be sure to copy the VTF ADS (eocevent454@cdc.gov) and VTF CMO (eocevent516@cdc.gov) functional email boxes when submitting for preclearance. Once you have completed the preclearance review, we can submit the revised manuscript and updated clearance request form to VTF ADS for JIC and SSU/CHEO review.

Let me know if you have any questions.

Thank you,

John Piacentino, MD, MPH
Associate Director for Science
Vaccine Task Force, Chief Medical Officer Section
CDC COVID-19 Response

From: CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>
Sent: Tuesday, September 21, 2021 12:33 PM
To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>
Subject: 5122 URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

Hi CMO,

The below document has been cleared by VTF and forwarded to EPI TF for their awareness. Please address comments in the below link and return a clean copy and updated request form for JIC.

VSD - SCK_COVID Vacc Mortality_MMWR_ID1685_Manuscript_2021-09-20 clean CMOv2.docx VSD - MMWR COVID-19 vaccination and Mortality - clearance request form Sept 20 2021.docx

Thanks,
DeAngelo

Clearance Coordinator | Vaccine Task Force

COVID-19 Response
eocevent454@cdc.gov

VTF Clearance Coordinators:
Dany Hall: qij7@cdc.gov
DeAngelo Bryant: lwk9@cdc.gov
Hours of Operation: 8:30am-5:30pm EST Monday - Friday
11am-1pm EST Saturday & Sunday

From: Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR) <ctb1@cdc.gov>
Sent: Tuesday, September 21, 2021 11:31 AM
To: Piacentino, John D. (CDC/NIOSH/OD) <gjt4@cdc.gov>; CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>; Mazurek, Jacek (CDC/NIOSH/RHD/SB) <acq8@cdc.gov>; Shefer, Abigail (CDC/DDPHSIS/CGH/GID) <ams7@cdc.gov>
Cc: Albert, Alison P. (CDC/DDID/NCIRD/DBD) <aqp0@cdc.gov>; Julian, Anne (CDC/DDNID/NCCDPHP/DCPC) <qwq8@cdc.gov>; Holman, Dawn (CDC/DDNID/NCCDPHP/DCPC) <isc6@cdc.gov>
Subject: RE: 5122 URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

I have seen things done a couple of ways…

John – will you or the author walk this article through the process (with copy to VTF Clearance box) or should the VTF Clearance coordinators do so?

Carolyn B. Bridges, MD

Sr. Vaccine Administration SME assigned to
COVID-19 Response/Vaccine Task Force ADS Team

General Dynamics Information Technology (GDIT) sub-contractor

Influenza Coordination Unit (ICU)
National Center for Immunization and Respiratory Diseases (NCIRD)
Centers for Disease Control and Prevention (CDC)
404-964-8691 (mobile)
cbridges@cdc.gov

From: Piacentino, John D. (CDC/NIOSH/OD) <git4@cdc.gov>
Sent: Tuesday, September 21, 2021 11:29 AM
To: Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR) <ctb1@cdc.gov>; CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>; Mazurek, Jacek (CDC/NIOSH/RHD/SB) <acq8@cdc.gov>; Shefer, Abigail (CDC/DDPHSIS/CGH/GID) <ams7@cdc.gov>
Cc: Albert, Alison P. (CDC/DDID/NCIRD/DBD) <aqp0@cdc.gov>; Julian, Anne (CDC/DDNID/NCCDPHP/DCPC) <qwq8@cdc.gov>; Holman, Dawn (CDC/DDNID/NCCDPHP/DCPC) <isc6@cdc.gov>
Subject: RE: 5122 URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

Carolyn: thanks for the speedy review. The next step is for Pre-clearance. (see below). JP

Day 1	9am	VTF CMO & VTF-ADS concurrent	VTF-ADS functional box: eocevent454@cdc.gov	CMO clearance: eocevent516@cdc.gov ADS clearance: eocevent454@cdc.gov
Day 2	9am	MMWR Pre-clearance	Charlotte Kent (cgk3@cdc.gov) Jaqueline Gindler (jsg5@cdc.gov)	eocevent172@cdc.gov
Day 3	9am	CHEO/SSU concurrent review	SSU: (see below) CHEO: Jeffrey Hall (dzu4@cdc.gov)	CHEO: eocevent559@cdc.gov SSU: eocevent538@cdc.gov w/copy to MMWR functional box: eocevent172@cdc.gov
Day 4	9am	rADS and PDIM concurrent review - via JIC	CSO (on behalf of rADS, PDIM, and SSU): Brian King (iyn3@cdc.gov) JIC: Brian Panasuk (fwf2@cdc.gov)	eocjicclear3@cdc.gov
Day 5	9am	OS and GRA concurrent review - via JIC	Mary Ari (mkb9@cdc.gov) Shambavi Subbarao (sfs2@cdc.gov)	eocjicclear3@cdc.gov
Day 6	9am	Scholar One		ScholarOne Manuscripts (manuscriptcentral.com)
Day 7	9am	Proof 1 and senior CDC leadership comments		
Day 8	9am	Proof 2 and final comments		
Day 9	9am	Publication		

From: Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR) <ctb1@cdc.gov>
Sent: Tuesday, September 21, 2021 11:26 AM
To: CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>; Mazurek, Jacek (CDC/NIOSH/RHD/SB) <acq8@cdc.gov>; Shefer, Abigail (CDC/DDPHSIS/CGH/GID) <ams7@cdc.gov>; Piacentino, John D. (CDC/NIOSH/OD) <git4@cdc.gov>
Cc: Albert, Alison P. (CDC/DDID/NCIRD/DBD) <aqp0@cdc.gov>; Julian, Anne (CDC/DDNID/NCCDPHP/DCPC) <qwq8@cdc.gov>; Holman, Dawn (CDC/DDNID/NCCDPHP/DCPC) <isc6@cdc.gov>
Subject: RE: 5122 URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

This is cleared by VTF with comments. Please share with Epi Task Force as an FYI.

John P. – at this point I believe JIC is still the next step or do you think this needs to go now to the MMWR office for pre-clearance first?

Thanks!

Carolyn

Carolyn B. Bridges, MD

Sr. Vaccine Administration SME assigned to
COVID-19 Response/Vaccine Task Force ADS Team

General Dynamics Information Technology (GDIT) sub-contractor
Influenza Coordination Unit (ICU)
National Center for Immunization and Respiratory Diseases (NCIRD)
Centers for Disease Control and Prevention (CDC)
404-964-8691 (mobile)
cbridges@cdc.gov

From: CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>
Sent: Tuesday, September 21, 2021 9:45 AM
To: Mazurek, Jacek (CDC/NIOSH/RHD/SB) <acq8@cdc.gov>; Bridges, Carolyn (CDC/DDID/NCIRD/OD) (CTR) <ctb1@cdc.gov>; Shefer, Abigail (CDC/DDPHSIS/CGH/GID) <ams7@cdc.gov>
Cc: Albert, Alison P. (CDC/DDID/NCIRD/DBD) <aqp0@cdc.gov>; Julian, Anne (CDC/DDNID/NCCDPHP/DCPC) <qwq8@cdc.gov>; Holman, Dawn (CDC/DDNID/NCCDPHP/DCPC) <isc6@cdc.gov>
Subject: 5122 URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

Hi all,

We received the below document from CMO for clearance. Please review by **9/22 4:00pm**

VSD - SCK_COVID Vacc Mortality_MMWR_ID1685_Manuscript_2021-09-20 clean CMOv2.docx VSD - MMWR COVID-19 vaccination and Mortality - clearance request form Sept 20 2021.docx

Thanks,
DeAngelo

Clearance Coordinator | Vaccine Task Force

COVID-19 Response
eocevent454@cdc.gov

VTF Clearance Coordinators:
Dany Hall: qij7@cdc.gov
DeAngelo Bryant: lwk9@cdc.gov
Hours of Operation: 8:30am-5:30pm EST Monday - Friday
11am-1pm EST Saturday & Sunday

From: Piacentino, John D. (CDC/NIOSH/OD) <git4@cdc.gov>
Sent: Monday, September 20, 2021 7:26 PM
To: CDC IMS 2019 NCOV Response VTF Clearance <eocevent454@cdc.gov>
Cc: CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Subject: FW: URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

Hello VTF ADS:

Please see attached MMWR and request for review and clearance.

Thank you,

John Piacentino, MD, MPH
Associate Director for Science
Vaccine Task Force, Chief Medical Officer Section
CDC COVID-19 Response

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Monday, September 20, 2021 7:19 PM
To: Piacentino, John D. (CDC/NIOSH/OD) <git4@cdc.gov>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>
Subject: RE: URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

Thanks, attached is a clean copy addressing the earlier comments.
You handle sending this for VTF clearance correct?

Thanks,
Eric Weintraub

From: Piacentino, John D. (CDC/NIOSH/OD) <git4@cdc.gov>
Sent: Monday, September 20, 2021 5:39 PM
To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>
Cc: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Subject: RE: URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

Hello Arnita:

CMO clears this manuscript with consideration of comments.

Thank you,

John Piacentino, MD, MPH
Associate Director for Science
Vaccine Task Force, Chief Medical Officer Section
CDC COVID-19 Response

From: CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>
Sent: Monday, September 20, 2021 1:18 PM
To: Piacentino, John D. (CDC/NIOSH/OD) <git4@cdc.gov>
Subject: Fw: URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination
Importance: High

Hi CMO ADS, John,

Please review attached documents and provide an approval and/or added comments.

Thank you,
Arnita

Arnita Hires|Clearance Coordinator

Chief Medical Officer

Vaccine Task Force | COVID-19 Response

***Email**: eocevent516@cdc.gov*

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Monday, September 20, 2021 1:13 PM
To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>; Hires, Arnita L. (CDC/DDID/NCIRD/OD) (CTR) <auh6@cdc.gov>
Cc: Piacentino, John D. (CDC/NIOSH/OD) <gjt4@cdc.gov>
Subject: URGENT CMO clearance request: MMWR on Mortality and COVID-19 vaccination

Good afternoon,

The VSD's proposal submission **ID:1685**- "COVID-19 Vaccines Were Not Associated with Increased Risk of Mortality among Members Enrolled in Seven Integrated Health Care Organization, United States, December 14, 2020-May 31, 2021" was approved last Thursday as a Tier 1 MMWR report and has an accelerated review and publication schedule. Our timeline from last Thursday is as follows

- MMWR development (writing, Task Force Clearance, Task Force Cross-Clearance): 7 days

The mmwr has been cleared by the Vaccine Safety Team lead – Tom Shimabukuro, and the ISO director Frank Destefano

Attached is the developed mmwr report for VTF and CMO clearance and the clearance request form.

Thanks,
Eric Weintraub

From:	Piacentino, John D. (CDC/NIOSH/OD)
To:	CDC IMS 2019 NCOV Response VTF Clearance
Cc:	CDC IMS 2019 NCOV Response VTF Chief Medical Officer; Weintraub, Eric (CDC/DDID/NCEZID/DHQP)
Subject:	FW: MMWR report 1685 for JIC clearance
Date:	Monday, September 27, 2021 6:56:36 PM
Attachments:	TABLE 1_JG_Clean_SSU1_Clean_CHEO_Clean.docx TABLE 2_JG_Clean_SSU1_Clean_CHEO_Clean.docx TABLE 3_JG_Clean_SSU1_Clean_CHEO_Clean.docx Xu_1685_JG_Clean_SSU1_Clean_CHEO_Clean.docx VSD - MMWR COVID-19 vaccination and Mortality - clearance request form Sept 27 2021.docx
Importance:	High

Hello VTF ADS:

Our authors have revised the MMWR manuscript in response to comments from SSU and CHEO. Please facilitate review by the Office of Science.

Thanks,

JP

John Piacentino, MD, MPH
Associate Director for Science
Vaccine Task Force, Chief Medical Officer Section
CDC COVID-19 Response

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Monday, September 27, 2021 6:55 PM
To: Piacentino, John D. (CDC/NIOSH/OD) <gjt4@cdc.gov>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>
Subject: MMWR report 1685 for JIC clearance
Importance: High

John, attached is the VSD mortality and vaccination mmwr report 1685 for JIC clearance.
The manuscript has received VTF, mmwr pre-clearance, SSU and CHEO approval. (and shared with the epi task force as an fyi)

Thanks, let me know if I missed anything that needs to be sent to ensure the mmwr continue to moves forward. I've attached the tables, the clean manuscript and the updated clearance request form.

Thanks,

Eric

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Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

June 8, 2021

Title of Document	**COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020 – July 31, 2021**
Point of Contact	Eric Weintraub (eiw8@cdc.gov)
Task Force *If you are submitting from outside the response, please list your CIO.*	Vaccine Task Force
Author	Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California) Gabriela Vasquez-Benitez (HealthPartners Institute) Jason Glanz (Kaiser Permanente Colorado) Michael Jackson (Kaiser Permanente Washington) David McClure (Marshfield Clinic Research Institute) Nicola Klein (Kaiser Permanente Northern California) Elizabeth Liles (Kaiser Permanente Northwest) David Shay, Eric Weintraub (CDC)
Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	Letter or a short report – MMWR – approved for tier 1
New document or updated? *Please use tracked changes to clearly indicate what has changed from the current version (e.g., the current webpage). Documents submitted with highlighted changes, instead of tracked changes, will be returned.* **If web content, please include URL**	☒ **New** ☐ **Updated** **URL:**
Summary paragraph describing document • *For new resources, describe its purpose, why it is needed, and what is included in it.* • *For updates to existing resource, summarize changes and the reasons for making them.*	(b)(5)

	(b)(5)
Intended audience(s) *Please be as specific as possible.*	Public Health Workers, Physicians, Nurses, General Public
Was this document cleared by your Task Force? Please list the reviewer name & title (TF ADS, TF lead, etc.) *If you are submitting from outside the response, provide the name and title of the most senior CIO reviewer who cleared the document.*	☒ **Yes** ☐ **No** **Reviewer name & title:** Cleared by VTF CMO John Piacentino, VTF ADS – Carolyn Bridges
Was this cross-cleared by other Task Forces or CIOs? If yes, please list the Task Forces and CIOs that cleared force as an fyi *New and updated web content for non-technical audiences must be cross-cleared with the JIC Deputy for Content before submission for response clearance.* **Has the JIC Deputy for Content cross-cleared the document?**	☐ **Yes** ☒ **No** **Task Forces and CIOs:** Was sent to the Epi task ☐ **Yes** ☒ **No**
Does this document include any of the following? Previously unpublished scientific information, new science-based recommendations, or new scientific conclusions.	☒ **Yes** ☐ **No**
Does the document contain data and information about any of the following? Race/ethnicity, people experiencing poverty, congregate settings (e.g., correctional facilities, homeless shelters, meat packing plants, long-term care facilities), people experiencing homelessness, people who use drugs, rural populations, people with disabilities, non-U.S.-born persons, justice-involved persons, discussion of health disparities or health equity.	☒ **Yes** ☐ **No**
For new or updated guidance documents: Updates to existing guidance and new guidance documents must be approved through the Guidance Clearance Portal. Has that happened? What is the ID number for your approved guidance proposal?	☐ **Yes** ☐ **No**
For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens *Documents can include abstracts, manuscripts, and MMWRs.* Provide STARS Project Determination Number for the described activities or investigation? **N/A** If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.	032521AJ ☐
For presentations: *COVID-19 presentations must be in the response presentation template.* Presentation date: Have you provided URLs or citations for all content (on the slides, when appropriate, or in notes)?	Presentation venue: ☐ **Yes** ☐ **No**

For abstracts, journal manuscripts, and *MMWRs:*

Has your manuscript or MMWR been submitted and approved using the Publication Proposal Form? ☒ **Yes** ☐ **No**

What is the concept proposal ID number for your approved manuscript or *MMWR* submission? 1685

For abstracts: List the meeting, submission deadline, and word count limit

For journal manuscripts: Priority status assigned during concept approval: ☒ **High** ☒ **Standard**

Intended journal TBS, submission deadline August 30, 2021, and word count limit 850

For *MMWRs*: Tier status assigned during concept approval: ☒ **Tier 1** ☐ **Tier 2**

For *MMWRs only:*

After drafting the report, it must be pre-cleared by the MMWR editors before clearance submission.

List the date you received pre-clearance review from the *MMWR* editors? 9/24/2021

After MMWR pre-clearance, all MMWRs must *be reviewed by CHEO (eocevent444@cdc.gov) and SSU (eocevent538@cdc.gov) before submission for response clearance. MMWRs can be reviewed by CHEO and SSU simultaneously.*

Has CHEO cross-cleared? ☒ **Yes** ☐ **No** **Has SSU cross-cleared?** ☒ **Yes** ☐ **No**

Deadline for response clearance (date and time)	**Date:** 9/29/2021 **Time:** 4:00 PM
All clearance submissions will be processed according to standard response clearance timelines unless your document is a Tier 1 MMWR or high priority manuscript or has been approved for expedited review. *Priority status for journal manuscripts is assigned as part of the concept clearance process. Manuscripts not assigned priority status at that time will be processed as standard clearance submissions.*	**If urgent, which DIM approved:** **Justification for urgent clearance (if requested):** **Was approved for tier 1 clearance**

From: Stan Xu <Stan.Xu@kp.org>
Sent: Monday, September 27, 2021 6:31 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Denison S Ryan <Denison.S.Ryan@kp.org>; Cheryl M. Carlson <Cheryl.M.Carlson@kp.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>
Subject: Re: MMWR report 1685
Importance: High

Hi Eric, Dr. Ladva approved the report. He recommended that you submit the report to JIC for clearance.

Here are the clean versions of the report and three tables.

Thanks,
Stan

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Monday, September 27, 2021 7:04 AM
To: Stan Xu <Stan.Xu@kp.org>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Denison S Ryan <Denison.S.Ryan@kp.org>; Cheryl M. Carlson <Cheryl.M.Carlson@kp.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; dzg2@cdc.gov <dzg2@cdc.gov>
Subject: RE: MMWR report 1685

Thanks!

From: Stan Xu <Stan.Xu@kp.org>
Sent: Monday, September 27, 2021 9:59 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Denison S Ryan <Denison.S.Ryan@kp.org>; Cheryl M. Carlson <Cheryl.M.Carlson@kp.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>
Subject: Re: MMWR report 1685

Thanks, Eric for the update.

FYI: over the weekend, the report was revised based on comments from SSU and cleared by SSU. I also addressed CHEO's comments and sent the revision back to Dr. Ladva yesterday afternoon. I am waiting for his final approval. I was told the next clearance will be JIC; after that we will submit the manuscript to MMWR via ScholarOne.

Stan

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Monday, September 27, 2021 5:49 AM
To: Stan Xu <Stan.Xu@kp.org>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Denison S Ryan <Denison.S.Ryan@kp.org>; Cheryl M. Carlson <Cheryl.M.Carlson@kp.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; dzg2@cdc.gov <dzg2@cdc.gov>
Subject: RE: MMWR report 1685

Stan and team – I'm chatting with our Vaccine Task force medical officer now and he is going to reach out to the mmwr team for an estimate date of publication.
We still expecting to have a few more rounds of comments coming, he said it's possible the publication date could be next Tuesday, but is verifying with Charlotte Kent (mmwr editor) --- But once we get a pub date or are given a commitment to a date, we will get a 24 hour turn around to respond to last comments etc.

Eric

From: Stan Xu <Stan.Xu@kp.org>
Sent: Friday, September 24, 2021 2:29 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Denison S Ryan <Denison.S.Ryan@kp.org>; Cheryl M. Carlson <Cheryl.M.Carlson@kp.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>
Subject: Re: MMWR report 1685

Hi all,
Dr. Gindler's comments were helpful and straightforward. (b)(5)

(b)(5)

Thanks,

Stan

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Friday, September 24, 2021 11:19 AM
To: Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Stan Xu <Stan.Xu@kp.org>; Denison S Ryan <Denison.S.Ryan@kp.org>; Cheryl M. Carlson <Cheryl.M.Carlson@kp.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; dzg2@cdc.gov <dzg2@cdc.gov>
Subject: Re: MMWR report 1685

Thanks! I actually had just received an email asking if I had heard an update from clearance.

Thanks!!
Eric

From: Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>
Sent: Friday, September 24, 2021 1:59:27 PM
To: Stan Xu <Stan.Xu@kp.org>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Denison S Ryan <Denison.S.Ryan@kp.org>; Cheryl M. Carlson <Cheryl.M.Carlson@kp.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>
Subject: RE: MMWR report 1685

Thank you for the update Stan.

From: Stan Xu <Stan.Xu@kp.org>
Sent: Friday, September 24, 2021 1:52 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Denison S Ryan <Denison.S.Ryan@kp.org>; Cheryl M. Carlson <Cheryl.M.Carlson@kp.org>
Subject: Fw: MMWR report 1685

FYI

From: Stan Xu
Sent: Friday, September 24, 2021 8:42 AM
To: eocevent538@cdc.gov <eocevent538@cdc.gov>; eocevent559@cdc.gov <eocevent559@cdc.gov>
Cc: eocevent172@cdc.gov <eocevent172@cdc.gov>; Stan Xu <Stan.Xu@kp.org>
Subject: MMWR report 1685

Dear SSU and CHEO,

This is Stanley Xu, the corresponding author of an MMWR report titled "An Interim Analysis of COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021".

Dr. Gindler reviewed and approved our manuscript. She directed me to send the attachments to you for clearance. If you have any questions, please let me know.

Thank you,

Stan

(b)(5)

(b)(5)

(b)(5)

Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

August 19, 2021

Title of Document	An Interim Analysis of COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021
Point of Contact	Eric Weintraub (eiw8@cdc.gov)
Task Force *If you are submitting from outside the response, please list your CIO.*	Vaccine Task Force
Author	Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Sungching Glenn, Runxin Huang, Denison Ryan, Kerresa Morrissette (Kaiser Permanente Southern California) Gabriela Vasquez-Benitez (HealthPartners Institute) Jason Glanz (Kaiser Permanente Colorado) Michael Jackson (Kaiser Permanente Washington) David McClure (Marshfield Clinic Research Institute) Nicola Klein (Kaiser Permanente Northern California) Elizabeth Liles (Kaiser Permanente Northwest) David Shay, Eric Weintraub (CDC)
Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	MMWR – approved for tier 1
New document or updated? *Please use tracked changes to clearly indicate what has changed from the current version (e.g., the current webpage). Documents submitted with highlighted changes instead of tracked changes will be returned.* **If web content, please include URL**	☒ **New** ☐ **Updated** **URL:**
Summary paragraph describing document • *For new resources, describe its purpose, why it is needed, and what is included in it.* • *For updates to existing resource, summarize changes and the reasons for making them.*	(b)(5)

	(b)(5)
Intended audience(s) *Please be as specific as possible.*	Public Health Workers, Physicians, Nurses, General Public
Was this document cleared by your Task Force? Please list the reviewer name & title (TF ADS, TF lead, etc.) *If you are submitting from outside the response, provide the name and title of the most senior CIO reviewer who cleared the document.*	☒ **Yes** ☐ **No** **Reviewer name & title:** Cleared by VTF CMO John Piacentino, VTF ADS – Carolyn Bridges
Was this cross-cleared by other Task Forces or CIOs? ☐ **Yes** ☒ **No** If yes, please list the Task Forces and CIOs that cleared force as an FYI	**Task Forces and CIOs:** Was sent to Epi task
New and updated web content for non-technical audiences must be cross-cleared with the JIC Deputy for Content before submission for response clearance. **Has the JIC Deputy for Content cross-cleared the document?** ☒ **Yes** ☐ **No**	
Does this document include any of the following? Previously unpublished scientific information, new science-based recommendations, or new scientific conclusions.	☒ **Yes** ☐ **No**
Does the document contain data and information about any of the following? Race/ethnicity, people experiencing poverty, congregate settings (e.g., correctional facilities, homeless shelters, meat packing plants, long-term care facilities), people experiencing homelessness, people who use drugs, rural populations, people with disabilities, non-U.S.-born persons, justice-involved persons, discussion of health disparities or health equity. ☒ **Yes** ☐ **No**	
For new or updated guidance documents: Updates to existing guidance and new guidance documents must be approved through the Guidance Clearance Portal. Has that happened? ☐ **Yes** ☐ **No** What is the ID number for your approved guidance proposal?	
For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens *Documents can include, but are not limited to, abstracts, manuscripts, and MMWRs.* Provide STARS Project Determination Number for the described activities or investigation? 032521AJ ☐ **N/A** If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.	
For presentations: *COVID-19 presentations must be in the response presentation template.* Presentation **Date** Click to enter a date **Time:** Presentation venue: Have you provided URLs or citations for all content (on the slides, when appropriate, or in notes)? ☐ **Yes** ☐ **No**	

For abstracts, journal manuscripts, and *MMWRs:*

Has your manuscript or MMWR been submitted and approved using the Publication Proposal Form? ☒ **Yes** ☐ **No**

What is the concept proposal ID number for your approved manuscript or *MMWR* submission? 1685

For abstracts: List the meeting , submission deadline , and word count limit

For journal manuscripts: Tier status assigned during concept approval: ☐ **Tier 1** ☐ **Tier 2** ☐ **Tier 3**

Intended journal , submission deadline , and word count limit

For *MMWRs*: Tier status assigned during concept approval: ☒ **Tier 1** ☐ **Tier 2**

For *MMWRs only:*

After drafting the report, it must be pre-cleared by the MMWR editors before clearance submission.

List the date you received pre-clearance review from the *MMWR* editors? 9/24/2021

After MMWR pre-clearance, all MMWRs must *be reviewed by CHEO (eocevent444@cdc.gov) and SSU (eocevent538@cdc.gov) before submission for response clearance. MMWRs can be reviewed by CHEO and SSU simultaneously.*

Has CHEO cross-cleared? ☒ **Yes** ☐ **No** **Has SSU cross-cleared?** ☒ **Yes** ☐ **No**

Deadline for response clearance (date and time)	**Date:** 10/12/2021 **Time: 8:00** am
All clearance submissions will be processed according to standard response clearance timelines unless your document is a Tier 1 MMWR or Tier 1 journal manuscript or has been approved for expedited review. *Authors are responsible for submitting presentations and abstracts in time to meet the due date. Due dates will not drive the review timeline unless a compelling reason is provided.*	**If expedited, which DIM approved:** **Justification for expedited clearance (if requested):** **Was approved for tier 1 clearance**

Clearance Request Form

Coronavirus Disease 2019 (COVID-19) Response

August 19, 2021

Title of Document	An Interim Analysis of COVID-19 Vaccination and Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021
Point of Contact	Eric Weintraub (eiw8@cdc.gov)
Task Force *If you are submitting from outside the response, please list your CIO.*	Vaccine Task Force
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Type of document (HAN, *MMWR*, Presentation, Abstract, Social Media, FAQ, Guidance, Journal Manuscript, etc.)	MMWR – approved for tier 1
New document or updated? *Please use tracked changes to clearly indicate what has changed from the current version (e.g., the current webpage). Documents submitted with highlighted changes instead of tracked changes will be returned.* **If web content, please include URL**	☒ **New** ☐ **Updated** **URL:**
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For documents describing collecting, obtaining, analyzing, or transferring information, data, samples, or specimens *Documents can include, but are not limited to, abstracts, manuscripts, and MMWRs.* Provide STARS Project Determination Number for the described activities or investigation? 032521AJ If N/A, attach correspondence from COVID-19 human subjects contact indicating STARS determination not required.	☐ **N/A**
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What is the concept proposal ID number for your approved manuscript or *MMWR* submission? 1685

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Intended journal , submission deadline , and word count limit

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Title: Mortality and Vaccination with COVID-19 Vaccines (VSD#1343)

Protocol Version 1.2

May 26, 2021

Lead site: Kaiser Permanente Southern California

Investigators: Stan Xu, Hung Fu Tseng, Lei Qian, Lina Sy, Michael Jackson, Gabriela Vasquez-Benitez, Jason Glanz, David McClure, Nicola Klein, Beth Liles, Eric Weintraub

Aim: To assess mortality risk after receiving COVID-19 vaccines among members enrolled in VSD sites

1. BACKGROUND

COVID-19 disease, caused by the novel coronavirus (SARS-CoV-2), has infected 13 million and killed over 260,000 Americans as of November 27, 2020 (Johns Hopkins University, 2020). While social distancing, wearing face masks and improved hygiene education/procedures have helped to slow the disease transmission, they are impermanent and not curative. Effective and safe therapeutics and COVID-19 vaccines will eventually be required to contain the disease. Since the early pandemic in March 2020, scientists worldwide have been racing to find effective and safe vaccines for COVID-19. On November 18, 2020, Pfizer announced that Pfizer and BioNTech's vaccine BNT162 had a vaccine efficacy rate of 95% in participants without prior SARS-CoV-2 infection. Two days later, they submitted an application to the US Food and Drug Administration for an emergency use authorization for their COVID-19 vaccine. On December 11, 2020, FDA granted an Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older (FDA-1, 2020). Another US pharmaceutical company, Moderna, also reported 95% vaccine efficacy for their COVID-19 vaccine. Moderna was granted an EUA for their COVID-19 vaccine on December 18, 2020 (FDA-2, 2020). These two mRNA-based vaccines require two shots, 21 days apart for Pfizer-BioNTech COVID-19 vaccine and 28 days apart for Moderna's vaccine. Janssen COVID-19 vaccine is a replication incompetent adenovirus vector vaccine that is administered as a single dose. It was granted an EUA on February 27, 2021 (FDA-3, 2021). It demonstrated 66% overall efficacy against symptomatic, laboratory-confirmed COVID-19, and 85% efficacy against moderate-to-severe COVID-19 occurring at least 28 days after vaccination. There are several other COVID-19 vaccine candidates that are in Phase 3 of their clinical development program.

Although clinical trials showed that the two mRNA COVID-19 vaccines and the adenoviral vector vaccine were well tolerated with no serious safety concerns observed to date (Polack et al., 2020; Baden et al., 2021; FDA-3, 2021), serious rare adverse events may not be revealed in clinical trials even with more than 30,000 participants. Of all adverse events, death is the most severe form.

Despite the existence of rare cases of plausible risk of death following vaccination, very few studies had showed the association between modern vaccines and death (Miller et al., 2015). McCarthy et al (2013) showed that mortality rates among a VSD population were lower than that in the general U.S. population. McCarthy et al (2016) investigated the association between vaccination and death among individuals 9 to 26 years of age and found that the risk of death was not increased during the 30 days after vaccination. COVID-19 vaccines are new, and their risk profiles are unknown; thus, it is important to study their safety including possible association with elevated mortality risk not due to the novel coronavirus infection.

2. METHODS

2.1 Study population: Kaiser Permanente Southern California (KPSC) will lead this study. All VSD sites will be invited. We will clarify with sites what data sources they have available and how complete the data are from the various sources over time. Membership on the vaccination date or index date will be required. Our primary analysis will include adults 18 and above. On May 10, 2021, the FDA authorized the Pfizer-BioNTech COVID-19 vaccine for emergency use in adolescents 12-15 years old. We will include adolescents in the analyses.

2.2 Outcome: The outcome of this safety study is mortality except COVID-19 related death. The rationale for excluding COVID-19 related death is that mortality increased substantially during the pandemic due to COVID-19. Without excluding COVID-19 related death, any potential safety concerns associated with COVID-19 vaccine and mortality would be masked by the protective effect of COVID-19 vaccine against COVID-19 related death.

We will identify death primarily using the inpatient/outpatient files. VSD sites are in the process of adding a new variable to the inpatient/outpatient files to capture deaths occurring in the hospitals and Emergency Department (ED). Inpatient/outpatient files capture date of death and discharge diagnoses. These data files are updated weekly. Because usually it takes about 10 weeks for data to settle due to hospital length of stay and claims, we will describe death data monthly during the first 3-6 months and quarterly thereafter. We will conduct interim analyses every six months. However, death data from inpatient/outpatient files may miss deaths occurring in other settings and/or outside of the health care system.

Our preliminary investigation of historical data from KPSC showed that inpatient and ED deaths only accounted for about 30% of all deaths among active members and those members who died within 90 days after disenrollment. We propose to ask participating VSD sites to create a death ancillary file to collect more death data from patients' records in the electronic medical records (EMR) and membership files which capture reported deaths outside of medical settings and are more timely than the annual state death file. At KPSC, among deaths of active members occurring in 2018 reported in the C2019 Mort file, the deaths identified through inpatient/ED encounters and the ancillary file (i.e., deaths reported to member services) accounted for 94% of the total deaths. Thus, these sources capture a substantial portion of deaths without relying on the annual state death files. This death ancillary file will be updated monthly. We will combine this ancillary file with the inpatient/outpatient files monthly. In addition, we will also consider other death data sources including VSD mortality files. VSD mortality files include cause and date of

death among all members. Because the VSD mortality files are updated annually, we will merge the VSD mortality files with inpatient/outpatient files on an annual basis to capture additional death data. However, because the death data from the VSD mortality files are lagged by almost two years, they won't be used until the third year of the study. KPSC will explore the possibility of obtaining monthly updates of California's state death records and evaluate their data quality and data lag. We will assess whether other VSD sites have access to state death data and how frequently these data are updated.

2.3 Exposure and risk windows: The emerging COVID-19 vaccines in the US include two mRNA-based vaccines, Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine, and the adenoviral vector Janssen COVID-19 vaccine. There are other COVID-19 vaccine candidates in clinical development. Separate analyses will be conducted for each authorized/licensed COVID-19 vaccine, provided there is sufficient uptake at VSD sites.

We will not pre-specify the risk window for this study. We will employ a flexible analytic approach that allows for assessing mortality risk for certain days after exposure such as 21, 30 days or 42 days. The maximum follow-up is 3 years in this study. For details, please see our analytic plan below.

2.4 Comparators: Two concurrent comparison groups will be used depending on stages of surveillance. At early and middle stages of surveillance (e.g., less than 60% of the population is vaccinated with COVID-19 vaccine), our primary comparison group will be those who were not vaccinated with a COVID-19 vaccine prior to the date of an interim analysis (for details about the interim analyses, please see below). Those who received a COVID-19 vaccine will be in the exposed group in analyses. To make the unexposed comparator group like the exposed group, we will consider the following members: those who did not receive any COVID-19 vaccine but had ≥1 dose of influenza vaccine within the two years prior. Confounder adjustment is critical in using unvaccinated comparators. For details about how to adjust for confounders, please see our analytic plan.

At later stages of surveillance (e.g., more than 60% of the population is vaccinated with COVID-19 vaccine), we will consider using those early vaccinees who received a COVID-19 vaccine at least 6 months prior to an interim analysis date. The reasons for using this comparison group are 1) fewer comparable unvaccinated individuals will be available as most of the population will have received a COVID-19 vaccine; 2) it will help to increase the sample size of the comparison group over time. In this design, those who received a COVID-19 vaccine recently will be in the exposed group while early vaccinees will be comparators. Early vaccinees can contribute person time to both the risk window and the comparison window. The limitations of this approach are 1) given the prioritization scheme, early vaccinees may be systematically different from those who are vaccinated later, and thus, this comparison group may not be comparable to the exposed group; 2) the loss to follow-up will differ between recent vaccinees and early vaccinees because increasing time since vaccination will increase the likelihood of disenrolling from health plans; 3) if the elevated mortality risk of a COVID-19 vaccine is constant over several years after vaccination, this method would not detect the risk because it compares the recent risk versus long term risk; 4) the comparison window must occur after the risk window; however, the exact risk

window for these new vaccines are unknown; 5) potentially, immortal time bias may be introduced because one has to survive up to an interim analysis to be included in that interim analysis.

The design using either of these two concurrent comparison groups will be influenced by data lag. However, if the data lag is non-differential between the exposed group and the comparison group, the point estimate of vaccination association with mortality will be unbiased, but with wider 95% confidence intervals because the number of deaths will be undercounted.

We will not consider historical comparison approach because we anticipate that this design will be impacted by data lag significantly. Historical death data will be more complete than the death data for the current population; thus, point estimate of vaccination association with mortality will be underestimated, potentially resulting in a false negative signal.

The self-controlled case series (SCCS) design is not appropriate here because the outcome (death) prevents one from future exposure and the outcome is not a recurrent event (Farrington 1995). Data lag also has impact on estimating the association between vaccination and death, because deaths in the comparison window are more likely to be undercounted than deaths in the preceding risk window. In addition, a SCCS design requires a pre-specified risk window for death which is unknown.

2.5 Analytic plan

We plan to provide quarterly mortality reports by vaccine type, dose number, age, sex, and race/ethnicity using two approaches: a matched cohort analysis and a cohort analysis with a time-varying exposure. In the matched cohort analysis, follow-up will start at a vaccination date for vaccinees or at an index date for comparators. A frequency matching approach will be employed to use the distribution of vaccination week of the first dose among vaccinees to assign the index date to unvaccinated comparators who had ≥1 dose of influenza vaccine within the two years prior to the reporting month; follow-up for the first dose will be censored upon the receipt of the second dose. Follow-up will end if patients die, disenroll, receive a COVID-19 vaccine for unvaccinated individuals, or at the end of the current report. Mortality rates per 100 person-years will be calculated after the first and the second doses among vaccinees and after the index date among comparators. In a cohort analysis with a time-varying exposure, a patient's follow-up up to the current month is partitioned into three intervals: a comparison interval before the first vaccination, an interval after the first dose and before the second dose if the second dose is received, and an interval after the second dose. Those who have not received COVID-19 vaccines will only contribute to the comparison interval. Mortality rates per 100 person-years will be calculated for these three intervals. We will report the number of deaths, mortality rates, and relative risks cumulatively up to the reporting month. Due to data lag in deaths from other settings (e.g., from claims and outside utilization of VSD sites) and in COVID-19 vaccination outside of VSD sites, we will include those who were vaccinated at least two months prior to the reporting month. Those comparators who were vaccinated during the subsequent two months will be censored upon receipt of their first dose of COVID-19 vaccine. In a sensitivity analysis

using the matched cohort design, we will calculate mortality at 30 days after the index date among comparators, and 30 days after the first and second doses among vaccinees.

We will conduct interim analyses every six months for a total of 6 interim analyses over 3 years. Although we will not establish and apply stopping rules as in a formal sequential analysis, we will adjust for multiple testing using the Pocock approach for controlling overall type I error rate (Pocock, 1982). Compared to O'Brien-Fleming approach, with constant significance levels, the Pocock approach allows for early signal detection if there exists an association between the vaccination and mortality. A diagram for the interim analyses is displayed in Figure 1.

In our primary analyses, we will include all deaths except COVID-19 related deaths. We will use cause of death, if available, to identify COVID-19 related deaths. When cause of death is not available in the early stage of surveillance, a death will be designated as a COVID-19 related death if it is identified from inpatient or ED settings with a COVID-19 diagnosis code or a positive lab test within 30 days of death. We will conduct two secondary analyses. First, we will include all-cause deaths. In this secondary analysis, the association between COVID-19 vaccines and mortality will be affected by both any potential adverse effect of the vaccine on mortality and any protective effect of the vaccine against mortality by reducing SARS-CoV-2 infection and severity of COVID-19 disease. Second, we will exclude deaths due to external causes such as accident and homicide in addition to excluding COVID-19 related deaths (McCarthy et al, 2016).

Survival analyses will be carried out to assess the mortality risk of COVID-19 vaccines. The start time (index date) for the exposed group is the date that one received the first dose of COVID-19 vaccine. We will assign an index date to each comparator according to the frequencies of COVID-19 vaccination dates in each month of the six months of an interim analysis. To reduce selection bias, we will employ a propensity score approach to adjust for the potential imbalance in confounders between the exposed and the comparison groups. Our primary analyses will use an improved inverse propensity weighting: stabilized weights (SW) (Robins et al, 2000). The stabilized weights not only reduce the impact of some extreme weights but also preserve the original sample size (Xu et al, 2010).

Let t_k denote the calendar time for the kth interim analysis, t_k =6, 12, 18, 24, 30, and 36 months after start of surveillance for k=1 to 6. At the kth interim analysis, two steps will be taken. When the pool of the first comparison group becomes limited, we will consider those who are vaccinated more than 6 months prior to the kth interim analyses to be comparators in the kth interim analysis.

Step 1: We will use logistic regression models to calculate propensity scores for those who are newly identified in the exposed and the comparison groups. We will identify those who were vaccinated with a COVID-19 vaccine between $t_{(k-1)}$ and t_k and those comparators whose index dates were between $t_{(k-1)}$ and t_k but had never been vaccinated with a COVID-19 vaccine. Let n_{1k} represent the sample size of the exposed group and n_{0k} represent the sample size of the comparison group, $N_k = n_{1k} + n_{0k}$ is the sample size at the kth interim analysis. A propensity score model will be built with the exposure variable as the dependent variable. We will include the

following confounders in our propensity score models: seasonality, age, gender, race/ethnicity, socioeconomic status (SES) variables such as Medicaid status and neighborhood level income and education, comorbidities, pregnancy status, health care utilization (e.g. number of outpatient, ED and inpatient visits) in prior year, receipt of other vaccines, VSD site, and etc. We will also collect the information whether a patient has ED and inpatient visits one week prior to the index date. Comorbidities are important confounders. It is likely that the exposed and the comparison group will differ in comorbidities. We will explore three ways to use comorbidities as predictors for vaccination in the propensity score models: 1) using each individual comorbidity; 2) using Charlson comorbidity index (CCI); and 3) using the more sophisticated Elixhauser Comorbidity Index (ECI). We will choose the one that is the best predictor in propensity score models and is balanced between the exposed and comparison groups after stabilized weights are applied.

We will then use the results from the propensity score model to calculate SW for each individual. Individuals in the exposed group will carry their SWs for future interim analyses. Those in the comparison group will carry their SWs for future interim analyses until they become vaccinated with COVID-19 upon which they will be in the exposed group. We will examine whether the SWs help balance confounders among treatment groups. If necessary, we will trim data to optimize SWs.

Step 2: We will employ a cumulative estimation approach to assess the mortality risk of the vaccines using all data up to t_k, the time for the kth interim analysis (Xu et al 2016). The sample size for the kth interim analysis will be sum of $N_1,\ldots, N_k$. Those in $N_{(k-1)}$ will be allowed to extend their follow-up into t_k. For vaccines that require only one dose such as Johnson & Johnson's JNJ-78436735, a proportional hazard model will be fit to assess the association between COVID-19 vaccines with mortality (Cox 1972; Cox 1975). The assumption of proportional hazard will be tested using statistical tests and graphical diagnostics based on the scaled Schoenfeld residuals (Schoenfeld 1982; Harrell and Lee, 1986). If the assumption does not hold, we will include an interaction term between the exposure variable and time in the Cox model to allow the exposure effect to vary over time (Cox and Oakes 1984; Allison 1995).

For the two mRNA-based vaccines that require two doses, the counting process approach will be used with a new observation period when the second dose starts (Andersen and Gill, 1982; Andersen et al, 1992). The index date is still the date of receipt of the first dose. Different indicator variables will be used for the first and the second doses. This counting process approach can be used to test if the mortality risk after receiving the second dose differs from the risk after receiving the first dose. In these survival analyses, SW will be applied to adjust for imbalance of confounders between the exposed and the comparison groups (Xu et al 2012; Xu et al 2014).

As we mentioned previously, we won't pre-specify the risk window for these new vaccines. However, our approach can assess the mortality risk by different risk windows. For example, when we censor follow-up at 42 days after vaccination, we will be able to assess mortality risk within 42 days after vaccination. This is equivalent to assessing a vaccination effect with a risk window of 42 days using either SCCS design or a risk-interval design (Glanz et al 2006).

In addition to conducting separate analyses for each COVID-19 vaccine, we will also consider comparing different vaccines to each other when uptake of two or more vaccines is sufficient to allow for such a comparison. We will use the analytic approaches described above for this purpose. On the other hand, since mortality is expected to be a rare adverse event, at the initial phase of vaccination rollout, we may combine the two mRNA vaccines to increase the sample size and statistical power.

3. STUDY LIMITATIONS

There are some potential limitations in our proposed approach. First, important confounders may not be available. The validity of this observational study may be threatened without adjusting for these unmeasured confounders. Second, this study does not address if the mortality risk of COVID-19 vaccines differs by gender, age, race/ethnicity, and/or clinical conditions although these risk factors will be adjusted for in propensity score models. Third, to some degree, the validity of our results depends on the completeness and accuracy of ascertainment of deaths in our death data. Some patients who appear alive in VSD data may have died while some patients who appear to have died in VSD data may be still alive. In addition, we observed that a small proportion of patients who appear to have died in VSD data had medical visits after death. Fourth, using a COVID-19 diagnosis code or a positive lab test within 30 days of death to identify and exclude COVID-19 related death may result in misclassification; however, this approach is needed because data on the true underlying causes of death are not available in a timely fashion. We recognize the potential for misclassification of COVID-19 related death, and as such will include all-cause deaths in the secondary analysis approach.

4. DATA SOURCES

We will use the VSD Dynamic Data Files (DDF) and cycle files from all participating sites. We will also be requesting that sites generate an ancillary death file. The data files will be updated monthly with death data from patients' records in the electronic medical records (EMR) and membership files. Necessary files include the Constant File, Enroll File, Vaccine File, Inpatient File, Outpatient File, Procedure file, Mort and MortCOD Files, Medicaid and Geocode files, Pregnancy Episode Algorithm (PEA), Dynamic Pregnancy Algorithm (DPA), and Pregnancy files, and COVID-19 DXID and lab files. The files will include but are not limited to the following variables: age, sex, race/ethnicity, SES variables, VSD site, comorbidities, pregnancy status, health care utilization, receipt of influenza and other vaccines, and vital status.

5. DATA MANAGEMENT

SCK will be responsible for overall data management activities. SCK will oversee study documentation and archiving. Data will be
exchanged using the secure Distributed Data Model (DDM). Participating sites will be responsible for exploring and sharing information about availability of their death data, investigating any data quality issues, and incorporating additional data sources or data elements. SCK will create a data dictionary and instructions for ancillary files as needed, and sites will write and test the programs that will be used to create these files according to the data dictionary and instructions. SCK programmers/analysts will write and test the programs that will be used to

capture the data from the DDF and ancillary files at the participating sites. Individual level data will be collected to calculate propensity score weights and conduct survival analyses.

6. CHART REVIEW

Manual review of medical records will be performed to assess cause of deaths that occurred in the health care systems of participating sites. This information will be used to determine if a death is due to external causes such as accident and homicide. Clinician input may be required to assess biological plausibility of identified cause of death being vaccine related. All deaths within 42 days after vaccination will be chart reviewed. When the number of deaths in the comparison group is large, a random sample will be selected for chart review.

We will also conduct manual reviews of a random sample of medical records to evaluate the quality of death data. For example, deaths identified from claims with encounters after the death date, or death dates occurring prior to vaccination, are suspect and warrant further chart review. Because the proportion of deaths from various sources and their accuracy may differ by site, each site will conduct reviews of a random sample of medical records and site-specific confirmation rates will be obtained. The confirmation rates of deaths may be used in a sensitivity analysis.

We plan to adapt and utilize the chart abstraction forms and manuals used in previous VSD studies as needed for this project. Participating sites will have the opportunity to review the tools. We will send the abstraction forms to CDC for review and comment before the documents are finalized. We will coordinate the collection, analysis, and interpretation of chart abstraction data. Chart review data will be collected from participating sites in Excel or REDCap.

7. SITE RESPONSIBILITIES

We hope that all sites with appropriate data will participate. Participating VSD sites are responsible for obtaining site-specific IRB approval and data use agreements, if applicable. Data managers at each site may be asked to create ancillary files and review the SAS program(s) prior to submission to the DDM. CDC will be responsible for submitting programs to the DDM. Participating sites and CDC will be invited to provide feedback on study results, manuscripts, and presentations.

8. HUMAN SUBJECTS

The privacy and confidentiality of all study subjects will be strictly protected, according to standard VSD procedures. We will seek IRB review and approval at each individual participating VSD site. We will also request a waiver of HIPAA authorization, as this study will involve only a limited dataset of protected health information (PHI). Data use agreements will be signed with all participating sites.

PROJECTED TIMELINE

Date	Description
December 2020	Present protocol on VSD Project Call
January 2021	Provide a final protocol to CDC for approval
January 2021	Invite sites to participate and obtain necessary IRB approvals and DUAs
January 2021 - March 2021	Ancillary death file development by participating sites. DDM SAS program development by KPSC and distribution to participating sites for review and approval.
March 2021	Preliminary data extraction
March 2021	Begin monthly updates of ancillary death file
October 2021	Present findings from first interim analysis
April 2022	Present findings from second interim analysis
October2022	Present findings from third interim analysis
April 2023	Present findings from fourth interim analysis
October 2023	Present findings from fifth interim analysis
April 2024	Present findings from final analysis
TBD	Manuscript development

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Number represents subject;
letter **v** denotes vaccination with a COVID vaccine;
letter **p** denotes having a preventive care but not COVID vaccines;
PS: propensity score model

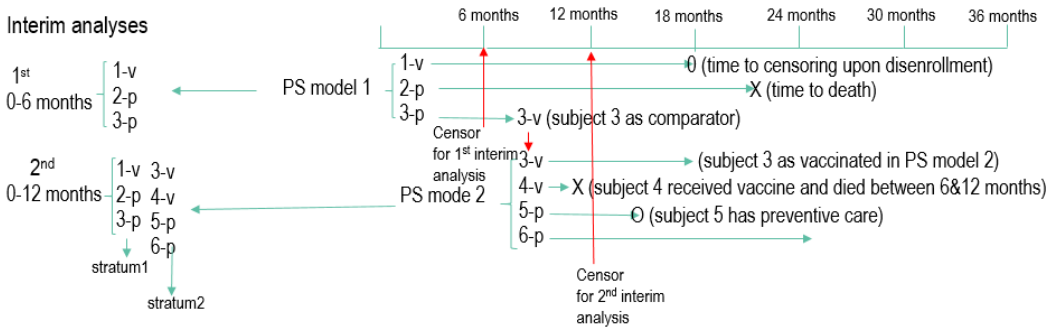

Figure 1. Overview of interim analyses