Knowledge, Attitudes, and Beliefs Surveys to Identify Factors Associated with SARS-CoV-2 Vaccination in The General Population and Among Pregnant Women in the Vaccine Safety Datalink (VSD)

VSD Project #1348

Version 5.0
July 7, 2021

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Protocol Change History

Version	Date	Change
1.0	2/9/2021	N/A – Draft Protocol
2.0	3/16/2021	Revised Protocol based on CDC and VSD Sites' Feedback
3.0	3/18/2021	Revised precision estimates in Table 7 (precision previously reported as 2-sided corrected to reflect calculation of 1-sided)
4.0	5/11/21	Incorporated edits reflecting site and CDC preferences to move up 1st wave of survey to occur as soon as possible (estimated 8/1/21) and clarifying sampling strategy for pregnant women.
5.0	7/7/21	Incorporated final site and CDC preferences for survey administration (eliminating text message outreach and replacing with telephone call) and sampling strategy for pregnant women (including all women who had a pregnancy episode during sampling period and also received a vaccine during the sampling period).

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Glossary of Abbreviations

Abbreviation	Definition
AAPOR	American Association of Public Opinion Research
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus disease 2019
DDF	Dynamic data files
DH	Denver Health
DTD	Data transfer agreement
DUA	Data use agreement
EHR	Electronic Health Records
EUA	Emergency use authorization
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
ICD-10	International Classification of Disease, 10th Revision
IIS	Immunization information systems
IRB	Institutional review board
KPCO	Kaiser Permanente Colorado
LMP	Last Menstrual Period
NIS	National Influenza Survey, Child
NHIS	National Health Interview Survey, Adult
OOR	Denver Health Office of Research
PCORI	Patient-Centered Outcomes Research Institute
PEA	Pregnancy Episode Algorithm
PHI	Protected Health Information
PRAMS	Pregnancy Risk Assessment Monitoring System
REDCap	Research Electronic Data Capture
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
VSD	Vaccine Safety Datalink

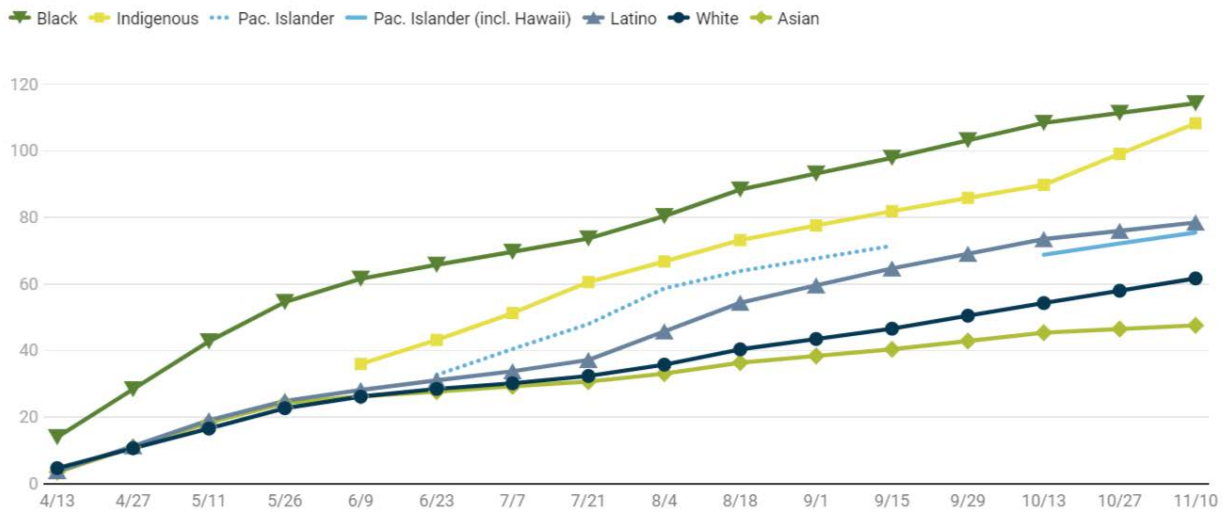
PROTOCOL SYNOPSIS

Title: Knowledge, Attitudes, and Beliefs Surveys to Identify Factors Associated with SARS-CoV-2 Vaccination in The General Population and Among Pregnant Women in the Vaccine Safety Datalink (VSD)	
Short Title: COVID-19 Vaccination KAB Survey	
Project Rationale	The cause of the COVID-19 pandemic, severe acute respiratory syndrome coronavirus 2, has infected 30 million Americans and caused over 530,000 deaths. Vaccines to combat the disease have been developed at an unprecedented pace, and it is critical to identify knowledge, attitudes, and beliefs associated with vaccination in (1) members of the general population and (2) pregnant women to inform public health promotion strategies.
Project Objectives	To conduct surveys among pregnant and non-pregnant members of the VSD who are vaccinated and unvaccinated, in English and Spanish, to (1) identify factors associated with COVID vaccination or non-vaccination, and (2) estimate the accuracy of VSD COVID-19 vaccination data.
Project Design	The design is retrospective, with surveys at the end of each study year for those who have already been vaccinated or are not currently vaccinated.
Population Characteristics	Both survey waves will include members of the VSD, a collaboration between CDC and 9 healthcare organizations; the VSD population is approximately 12 million people.
Project Duration	Survey planning began January 2021; surveys will commence as early as 8/2021 and finish by 2023. Analyses and data archival will occur by 2024.
Outcomes	Among the truly unvaccinated or truly vaccinated (assessed by self-report), our primary outcome will be knowledge, attitudes, beliefs, or demographics associated with vaccination status. Among unvaccinated and vaccinated adults and pregnant women (per VSD data), our outcomes of interest will be estimates of the PPV, NPV, specificity, and sensitivity of VSD data.
Analysis	Using subject report of vaccination as the criterion standard, we will calculate the sensitivity, specificity, positive predictive value, and negative predictive value for vaccination in VSD data for adults and pregnant women. Next, we will calculate survey response rates using published standards. Survey respondents will be compared to survey non-respondents on all available demographic characteristics, using Pearson's χ^2 test and the Student *t* test as appropriate. We will examine associations for measures of knowledge, attitudes, beliefs (e.g. government distrust, efficacy of SARS-CoV-2 vaccines, etc.), socio-demographic variables (e.g. race/ethnicity, age, gender, religion/spirituality) and the primary outcome (vaccination).

BACKGROUND AND SIGNIFICANCE

On December 31, 2019, a novel coronavirus infection associated with severe morbidity and mortality was reported in Wuhan, China.[1] In March 2020, the World Health Organization declared the novel coronavirus (SARS-CoV-2) outbreak a global pandemic.[2] As of March 11, 2021, there have been ~118,000,000 confirmed cases worldwide and over 2,600,000 deaths (https://coronavirus.jhu.edu/). To date, the US has suffered 30,000,000 reported cases and over 529,000 deaths.[3] Unfortunately, COVID-19 has exacerbated US health disparities, causing high mortality in US Black, Latino, and Indigenous communities.[4,5] Hospitalization rates and mortality rates for Black, Indigenous, and other minority communities have been and continue to be disproportionately higher, referent to non-Latino White and Asian communities.[6] Figure 1 presents one example of disparities in the cumulative COVID-19 mortality rates (per 100,000) by race and ethnicity over time, beginning April 13, 2020 and continuing through November 2020.[6]

Figure 1. Cumulative COVID-19 mortality rates (per 100,000) by race and ethnicity over time.



In response to this global pandemic and the significant burden on US citizens and healthcare systems, the U.S. government formed a novel public-private partnership – "Operation Warp Speed" – to rapidly develop, test, and prepare SARS-CoV-2 vaccines for use.[7] As of March 11, 2021, SARS-CoV-2 vaccines from three companies (Pfizer, Moderna, Johnson & Johnson) have completed Phase III clinical trials with efficacy results of between 72-95% and have received Emergency Use Authorizations (EUA) from the FDA.[8] To date, public health authorities and health systems have delivered nearly 100,000,000 SARS-CoV-2 vaccines to the general public.[3,7]

Since the beginning of the pandemic, several national[9–11] and global[12] surveys have assessed US adults' intentions of receiving SARS-CoV-2 vaccines and associations with demographic variables and other key factors (Table 1). For example, all three studies reporting race/ethnicity data in Table 1 found Black Americans were least likely to intend to receive (or least accepting of) SARS-CoV-2 vaccines.[9–11] Reasons for this appeared multifactorial, grounded in vaccine hesitancy associated with a rapid approval of SARS-CoV-2 vaccines, political affiliations, longstanding distrust of healthcare, and more. Additional demographic correlates of vaccination intention or acceptance included political party, age, family with COVID-19 infection, etc.[9–11]

Table 1. Designs and key findings of prior SARS-CoV-2 vaccine intention surveys in US adults.

Author	Site & Date	Sample Size (n)	Response Rate (%)	Age in years (%)	Demographics	Accept/Intend to get vaccine (%)
Kreps et al.[9]	US (7/2020)	1,971	53%	Median 43 (IQR 30-58)	51% female; 14% Black, 10% Latinx	79%
Lazarus et al.[12]	US + 18 Countries (6/2020)	773 (US)	Not reported	18-24 (15%) 25-54 (62%) 55+ (22%)	53% female; race/ethnicity not reported	75% (US)
Malik et al.[10]	US (5/2020)	672	72%	18-24 (11%) 25-54 (51%) 55+ (38%)	57% female; 10% Black, 14% Asian	67%
Fisher et al.[11]	US (4/2020)	1003	16.1%	Mean 48 (SD 18.1)	52% female; 12% Black, 16% Hispanic	58%

Specific vaccine characteristics and the processes by which vaccines were developed and recommended have been equally influential in reported intention to receive COVID-19 vaccines. For example, in Kreps' survey, vaccine efficacy was the most important characteristic associated with willingness to receive a vaccine. An increase in the efficacy from 50% to 90% was associated with an increase in willingness to get a vaccine from 51% to 61%.[9] If the vaccine was approved with an Emergency Use Authorization (EUA), it was associated with a 2% decrease in willingness to get a vaccine; those formally approved by the Centers for Disease Control and Prevention associated with the highest mean marginal willingness (59%) for vaccination.[9]

While providing important public health insights, these studies have had significant limitations. Arguably, the greatest limitation was the outcome itself: vaccine acceptance or intention, which may not correlate with behavior. Lack of clarity on pregnancy status, low proportions of non-White respondents, and response bias were also concerning, especially as surveys used primarily online survey platforms requiring member registration. Additional national surveys measuring vaccination receipt are critical to best describe factors associated with actual vaccination. It is equally important to describe the accuracy of data stored in large electronic health systems, such as the VSD provides, as many vaccines are being given at "pop-up" events at community sites.

STUDY POPULATION

The VSD[13–15] is an ideal setting for assessing the validity of electronic medical record data on COVID-19 vaccination status and for exploring how knowledge, attitudes, and beliefs – as well as race/ethnicity and vaccine characteristics – associate with SARS-CoV-2 vaccination behaviors among pregnant women and members of the general population. The VSD is a collaboration between the Centers for Disease Control and Prevention (CDC) and nine health care delivery organizations (referred to as "sites").[14,15] Seven VSD sites serve a majority White, insured population;[16] for the purposes of this study project, Denver Health serves uninsured as well as insured patients with a high proportion of non-White patients and nearly 25% Spanish-speaking-only families. Furthermore, Denver Health is expert in patient-oriented research with minority stakeholders,[17] assisted by state-of-the-art electronic health record systems. Otherwise, the VSD population is generally representative of the US population.[16]

Other advantages of studying knowledge, attitudes, and beliefs toward SARS-CoV-2 vaccines, with particular attention to racial/ethnic disparities, within the VSD include: (i) the population having a denominated population (by virtue of having data on health plan enrollment), (ii) the availability of electronic health record based vaccination data, and (iii) the ability to identify with a high degree of accuracy the sub-population in the VSD that is currently or recently pregnant. Furthermore, the quality of vaccination data in the VSD is generally high.[18,19] Vaccines given at VSD sites are ordered and recorded in EHR data. At some sites, this data is supplemented by administrative claims for vaccines given outside the VSD or by data from state immunization registries. Nonetheless, vaccination data can sometimes be missing, such as for vaccines given outside the VSD. **This could be substantial for COVID-19 vaccines and could vary by race/ethnicity and language, underscoring the need to confirm vaccination status among diverse VSD site members.**

PROJECT OBJECTIVES

Objective 1A (Cohort 1: Vaccinated Pregnant Women)

Among women, who according to VSD vaccination data *received* a SARS-CoV-2 vaccine and had a completed or ongoing pregnancy in 2021 & 2022, to assess by survey (1) knowledge, attitudes, and beliefs associated with vaccine uptake, and (2) accuracy of VSD SARS-CoV-2 vaccination data:

1. Assess whether SARS-CoV-2 vaccine was received within the VSD or elsewhere;
   1.1. Calculate positive predictive value and sensitivity of VSD data;
2. Among the NOT truly vaccinated, assess reasons for reported vaccination in the VSD;
3. Among the truly vaccinated, assess:
   3.1. Race/ethnicity and reasons (e.g. knowledge, attitudes, beliefs) for getting a vaccine;
   3.2. Site of SARS-CoV-2 vaccination (e.g. at VSD site, pharmacy, community site, etc.);

Objective 1B (Cohort 2: Unvaccinated Pregnant Women)

Among women, who according to VSD vaccination data *did NOT receive* a SARS-CoV-2 vaccine in 2021 & 2022 but had a completed or ongoing pregnancy episode in 2021 & 2022, to assess by survey (1) knowledge, attitudes, and beliefs associated with non-vaccination, and (2) accuracy of VSD SARS-CoV-2 vaccination data:

4. Assess whether SARS-CoV-2 vaccine was truly NOT received in the VSD or elsewhere;
   4.1. Calculate negative predictive value and specificity of VSD data;
5. Among the truly vaccinated, assess vaccination site (e.g. pharmacy, community center) and potential reasons vaccination was missed in the VSD;
6. Among the NOT truly vaccinated, assess:
   6.1. Race/ethnicity and reasons (e.g. knowledge, attitudes, beliefs) for vaccine refusal;
   6.2. Differences in race/ethnicity, knowledge, attitudes, and beliefs compared to women who were truly vaccinated (Objective 1A, Section 3.1.)

Objective 2A (Cohort 3: Vaccinated Adults in the General Population)

Among the general population, who according to VSD vaccination data *received* a SARS-CoV-2 during 2021 & 2022, to assess by survey (1) knowledge, attitudes, and beliefs associated with vaccine uptake, and (2) accuracy of VSD SARS-CoV-2 vaccination data:

7. Assess whether SARS-CoV-2 vaccine was received within the VSD or elsewhere;
   7.1. Calculate positive predictive value and sensitivity of VSD data;

8. Among the NOT truly vaccinated, assess reasons for reported vaccination in the VSD;
9. Among the truly vaccinated, assess:
   9.1. Race/ethnicity and reasons (e.g. knowledge, attitudes, beliefs) for getting a vaccine;
   9.2. Site of SARS-CoV-2 vaccination (e.g. at VSD site, pharmacy, community site, etc.);

Objective 2B (Cohort 4: Unvaccinated Adults in the General Population)
Among the general population, who according to VSD vaccination data *did NOT receive* a SARS-CoV-2 vaccine during 2021 & 2022, to assess by survey (1) knowledge, attitudes, and beliefs associated with non-vaccination, and (2) accuracy of VSD SARS-CoV-2 vaccination data:

10. Assess whether SARS-CoV-2 vaccine was truly NOT received in the VSD or elsewhere;
    10.1. Calculate negative predictive value and specificity of VSD data;
11. Among the truly vaccinated, assess vaccination site (e.g. pharmacy, community center) and potential reasons vaccination was missed in the VSD;
12. Among the NOT truly vaccinated, assess:
    12.1. Race/ethnicity and reasons (e.g. knowledge, attitudes, beliefs) for vaccine refusal;
    12.2. Differences in race/ethnicity, knowledge, attitudes, and beliefs compared to those in general population who were truly vaccinated (Objective 2A, Section 9.1)

RESEARCH STRATEGY: DESIGN AND METHODS
Within this section, we describe the details of cohort selection criteria, survey instrument development, survey administration, analyses, and sample size and power calculations. As noted elsewhere in this proposal, we will conduct each of two end-of-season surveys, one in late summer of 2021 (tentatively beginning August 1, 2021) and one at the end of 2022.

Focus on 4 cohorts: We will survey 4 cohorts: (1) women who completed or have an ongoing pregnancy since December 11th, 2020 and were vaccinated against SARS-CoV-2 during the sampling period, (2) women who completed or have an ongoing pregnancy since December 11th, 2020 and were unvaccinated against SARS-CoV-2 during the sampling period, (3) adults vaccinated against SARS-CoV-2, and (4) adults unvaccinated against SARS-CoV-2. Selecting these cohorts allows us to achieve the main study objectives. At this time, we have not included children in our cohort as the populations from which to sample are significantly larger for adults and pregnant women and children are generally at low risk of COVID-19 disease morbidity and mortality.

Study sites: We will invite all VSD infrastructure sites to participate in this survey.

Study cohort inclusion and exclusion criteria: In the first survey wave, we will randomly sample subjects continuously enrolled in their respective health plans from the time SARS-CoV-2 vaccines were first available (e.g. December 11th, 2020) through the time of survey administration (e.g., August 1st, 2021). For the second survey wave, we will randomly sample subjects continuously enrolled in their respective health plans from January 1st, 2022 through December 31st, 2022.

Health plan enrollment gaps less than 30 days duration will be ignored. We will not require health care utilization during the study period of interest. For Denver Health, we will use a proxy

for enrollment, modified for the purposes of this survey, as done with previous survey Task Orders. Subjects will be excluded from study participation for any of the following reasons: listed on site-specific "do not contact" or "no research" lists, deceased, or (e-)mailing address is unavailable. Subjects will also be excluded if they have a contraindication to SARS-COV-2 vaccination (e.g., anaphylaxis with prior vaccine administrations). Subjects will also be excluded if possible data quality errors are present (e.g. simultaneous administration of multiple different SARS-CoV-2 vaccines).

Identification of pregnant women: We will use new and existing VSD algorithms to identify women who are currently pregnant or completed a pregnancy episode during each of the two sampling periods. For example, we will use a modification of the VSD Dynamic Pregnancy Algorithm (DPA) to identify women who were pregnant and completed the pregnancy between 12/11/20 and 7/31/21. This will be executed against the Dynamic Data File (DDF) at each site. We will try to exclude those with a known pregnancy outcome of spontaneous or therapeutic abortion or other adverse outcomes (e.g. molar or ectopic pregnancy). However, some women with adverse pregnancy outcomes may not be identified before hand.

To assist in this process, we will use the new estimated date of delivery (EDD) and last menstrual period (LMP) files to identify pregnancy dates. We may also rely on a process we have developed internally for an unrelated study: two separate-day diagnoses of pregnancy (using defined ICD-10 codes) in the obstetrics-gynecology department, with an associated pregnancy outcome (i.e. delivery). We will use the most recent data available in these processes. However, because of the possibility of incompletely capturing all women with adverse pregnancy outcomes and the sensitivity around surveying a woman after an adverse pregnancy outcome (e.g. ectopic or molar pregnancy, spontaneous abortion), we will use carefully worded text within survey instrument cover letters (see below) when referring to women who are identified based on their recent pregnancy status.

Identification of subjects unvaccinated for SARS-CoV-2: After applying the study cohort selection criteria described above, we will search available vaccine data for any evidence of SARS-CoV-2 vaccination during the relevant season. We will include only individuals with no evidence of SARS-CoV-2 vaccination from December 11th, 2020 through the data extraction dates (July 31st 2021). This search will examine VSD vaccination data, including data from state immunization information systems (i.e. registries) when available.

Identification of subjects vaccinated for SARS-CoV-2: After applying the study cohort selection criteria described above, we will search all available data for any evidence of SARS-CoV-2 vaccination during the relevant season. We will include only individuals with evidence of SARS-CoV-2 vaccination (1 or 2 vaccine doses) from December 11th, 2020 through data extraction dates (July 31st 2021). This search will examine VSD vaccination data, including data from state registries if available. SARS-CoV-2 vaccines given prior to December 11th, 2020, the date of an EUA for the Pfizer vaccine), (e.g. possibly in a vaccine efficacy trial) will be ignored for the purposes of defining who is vaccinated during the 2021 season.

Data Extraction Process: We will write a data extraction program to identify cohorts for survey administration at all participating VSD sites. We will review with CDC colleagues and VSD data

managers, modify based upon the feedback received, and seek approval for this program by the CDC and participating VSD infrastructure sites. We anticipate a multi-step data extraction process. First, in early July 2021, we will identify a pregnant cohort unvaccinated for SARS-CoV-2 (and a separate pregnant cohort who appears vaccinated for SARS-CoV-2), and we will clean and perform data quality checks for these cohorts. Then, we will follow the same process for members the general VSD population. Next, immediately prior to starting survey administration in August 2021, we will request updated vaccination data for the cohorts selected for surveying. This will allow us to exclude, at the last possible moment, individuals whose pregnancy status or vaccination status has changed since initial data extraction (e.g. an individual who was vaccinated after the date of initial extraction). In this way, we will partner with all sites to confirm eligibility for cohort members prior to survey administration. We will follow a similar process with the second wave of surveys in 2022.

Development and revision of survey instrument, including cognitive interviews: The primary aim of the survey instrument will be to assess differences in vaccination between cohort members (pregnant and general population) by race/ethnicity, attitudes, knowledge, and beliefs. Another co-primary aim will be to determine the accuracy of SARS-CoV-2 vaccination data within the VSD. Among subjects who according to VSD vaccination data *have NOT received* a SARS-CoV-2 vaccine by the end of the relevant study season, we will assess: (1) whether a SARS-CoV-2 vaccine was received within the VSD site or elsewhere; (2) among those unvaccinated by self-report, the reasons for not receiving a SARS-CoV-2 vaccine; and (3) among those vaccinated by self-report, potential reasons vaccination was not captured in VSD data and where the individual received the SARS-CoV-2 vaccine (e.g. pharmacy, community center, other site).

Among subjects who according to VSD vaccination data *have received* a SARS-CoV-2 vaccine by the end of the relevant season, we will assess: (1) subjects' recall/report of having received a SARS-CoV-2 vaccine; (2) reasons for receiving a SARS-CoV-2 vaccine; and (3) whether subjects recall receiving a SARS-CoV-2 vaccine within a VSD site or elsewhere. The survey instrument will include: location of vaccination and clinical circumstances of vaccination. Thus, we will be able to construct 2x2 tables to better compare VSD SARS-CoV-2 vaccination data against self-report (Table 2).

Table 2. Method for classifying vaccination status by self-report and by available VSD data.

	VSD Vaccine Data = Vaccinated	**VSD Vaccine Data = Unvaccinated**
Self-report on survey: Vaccinated	**True positive**	• Vaccinated elsewhere (work; pharmacy; grocery; community site) • Not recorded in EHR • Social desirability bias • Mistaken (thinking about prior year)
Self-report on survey: Unvaccinated	• Vaccine recorded in EHR for wrong patient • Forgot/mistaken about vaccination • Intentional wrong answer	**True negative**

The wording of specific questions about vaccination self-report will be based upon existing survey instruments (Table 3) and published COVID-19 questions from national governmental or other research team surveys. Whenever possible, we will utilize the exact wording (or a very close approximation) of published wording from NIS, NHIS, or Internet panel surveys, which will help with the interpretation and generalizability of findings. Examples of specific wording from published national surveys of influenza vaccination are presented in Table 3 below. To capture important covariates in our analytical models, we will include attitudinal, knowledge, and belief questions specific to SARS-CoV-2 vaccine safety and efficacy previously published in national surveys of adults (see: Background & Significance). We will also include validated measures of vaccine hesitancy, such as those that have been used in national influenza surveys of Black and White pregnant and non-pregnant adults.[20] We will capture existing VSD data on race and ethnicity[16] but also provide respondents the opportunity to self-identify as one or more races and Latino or non-Latino ethnicity with standards for healthcare data quality and improvement.[21]

Table 3. Example questions and response options from national surveys; bracketed items are suggested substitutions or additions to the existing questions' wordings for this protocol.

Source	Question	Response options
NIS[a]	At what kind of place did [SC[b]] get [his/her] most recent [COVID-19] vaccination?	Doctor's office; Health department; Clinic/ health center; Hospital; Other medically-related place; Pharmacy or drug store; Workplace; Elementary/middle/high school; Other non-medically-related place; Mall outreach; Village outreach; Don't know; Refused
NHIS[c]	During the past 12 months, have you had a [COVID-19] vaccination?	Yes; No; Refused; Don't know
PRAMS[d]	During the 12 months before the delivery of your new baby, did you get a [COVID-19] shot?	No; Yes, before my pregnancy; Yes, during my pregnancy[; Yes, after my pregnancy]

[a]NIS-CIM: National Influenza Survey Child Influenza Module
[b]SC: Sampled Child
[c]NHIS: National Health Interview Survey, Adult
[d]PRAMS: Pregnancy Risk Assessment Monitoring System

In addition to querying race/ethnicity, we will also use validated questions to probe individuals' religious affiliations and levels of religiosity/spirituality.[22] Attention to religion/spirituality in this survey is important for two reasons. First, Dr. Williams has demonstrated significant associations between religion and religiosity and vaccination behavior (unpublished work by Williams et. al. presented at Pediatric Academic Societies, 2020). Second, public opinion surveys have suggested that individuals within certain religious traditions may be less likely to get SARS-CoV-2 vaccines, referent to individuals from other faith communities.[23] As faith-based organizations and clergy are key community leaders and essential partners in public health work and in current COVID-19 vaccination work,[24,25] it will be helpful to understand whether adherents within specific religions are unduly concerned about SARS-CoV-2 vaccines to inform public health work and clergy engagement. Finally, as SARS-CoV-2 variants are emerging,

some of which may evade currently authorized vaccines, we will probe intention to receive future SARS-CoV-2 booster vaccine doses.

Survey language related to pregnancy: We will make every attempt to avoid upsetting survey subjects, such as a woman who experienced an adverse pregnancy event. As noted elsewhere, we will attempt to exclude using diagnosis codes adverse pregnancy events such as those with a spontaneous abortion. Additionally, we will use sensitive language, such as "based on our medical records, you were identified as someone who may be expecting a child or who was recently pregnant." We will also add a disclaimer such as "We do our best to only contact study participants who are in good health and currently enrolled as Denver Health members. You may have been contacted by mistake because our information systems can sometimes be delayed or miss information. We apologize for any inconvenience and can be reached at (000) 000-0000 to answer any questions. If you believe you have received this survey in error, please contact us."

Translation of survey instrument into Spanish: To improve the representativeness and generalizability of survey findings, especially given the disproportionate impact of COVID-19 cases within Latino communities across the US (see: Background and Significance), we will translate the survey instrument into Spanish. This task will be accomplished through Denver Health's Language Services Department, with translation performed by certified translation experts. We also have the technological expertise to deliver materials in Spanish and will build the flexibility into our system to respond to requests for Spanish materials at any stage of the survey administration process. A Spanish-version survey can be sent to any subject with a "preferred language" listed as Spanish within the EHR. We will perform Spanish language only surveys at Denver Health and at Kaiser Permanente Southern California during the both survey years. Furthermore, in case EHR data does not accurately reflect primary language, we will mail surveys in both English and Spanish for participants at these sites and include easily-accessible links to REDCap surveys in English or Spanish. We will use available language information in the EHR to ensure that all other surveys, e-mails, and automated telephone reminders for study years 2 and 3 will be sent in English at other VSD sites.

Cognitive Interviews: To improve the quality of the survey instrument, we will conduct cognitive interviews with a sample of up to 10 unvaccinated and vaccinated adults at Denver Health, including pregnant women, of diverse self-reported races/ethnicities, in both English and in Spanish. A research assistant will elicit feedback on each question, focusing on question wording, tone, and comprehension. The results from these discussions will be used to further refine the survey by adding, eliminating, or changing the wording of questions accordingly.

Survey Administration: Surveys will be administered by postal mail as well as e-mail (when e-mail addresses are available), with one scheduled reminder by telephone if response rate remains below 60%. We provide the following justifications for this approach. First, best practices in survey administration emphasize the need for multiple modes of contact with staggering of contacts at set intervals.[26] Thus, if certain contact information is missing or incorrect (i.e. an individual's mailing address has changed), we will still reach the individual through other modes. Second, this approach has generated high survey response rates in prior Task Orders (59% in the Under-vaccination Task Order and 40-41% in the Influenza Vaccination Task Orders). Third, some individuals appear to prefer one mode (e.g. answering by e-mail) versus

another mode. In the Under-vaccination Task Order, the percentage of individuals responding by e-mail varied by 15-45% across sites. Fourth, using e-mail is low-cost and rapid for those with an accurate e-mail address. Once an individual has completed the survey, they will not receive additional contact. Survey administration will be centralized at Denver Health.

Administration of mail-based survey: We will administer surveys by standard US mail, with a return envelope and postage provided. The first contact with subjects will be by mail (as opposed to e-mail) to allow subjects to view the survey on paper in its entirety. We will send up to 4 mailed surveys, with at least 2 weeks in between each mailing. The final mailing will only occur if the overall study response rate remains below 60%.

Administration of surveys by e-mail: An e-mail will be sent to study participants who have not yet responded by mail, with a hyperlink to a web-based survey. The web-based survey will be on the Research Electronic Data Capture system (REDCap) platform, which is a secure web application for building and managing online surveys and databases in a HIPAA-compliant environment.[27] Each hyperlink will be unique, so that we will be able to track survey responses for each subject.

Telephone reminders: All subjects who have not completed a survey by week 8 will receive a telephone reminder from a bilingual research staff member at Denver Health. We will attempt to contact participants up to a maximum of 3 times before abandoning future phone calls.

Timing of survey administration: While the originally RFTOP proposed administering the first and second survey waves in February of 2022 and February of 2023, respectively, we will work with CDC and VSD colleagues to determine the optimal timing of survey administration. Surveys could go out as early as August 2021, and we will coordinate with CDC and partner sites to determine optimal administration times for the second wave in 2022. An overview of survey administration is provided in Table 4 below.

Table 4. Overview of survey administration.

Timeline	Contact	Notes
Week 1	Mailed survey contact #1	The cover letter will contain a link and individualized code if subjects wish to take the survey online
Week 2	E-mailed survey contact #1 (via hyperlink)	For those with e-mail addresses, an individualized hyperlink will be e-mailed for convenience to take online
Week 3	E-mailed survey contact #2 (via hyperlink)	For those with e-mail addresses, an individualized hyperlink will be e-mailed for convenience to take online
Week 4	Mailed survey contact #2	The cover letter will contain a link and individualized code if subjects wish to take the survey online
Week 5	E-mailed survey contact #3 (via hyperlink)	For those with e-mail addresses, an individualized hyperlink will be e-mailed for convenience to take online

Week 6	E-mailed survey contact #4 (via hyperlink)	For those with e-mail addresses, an individualized hyperlink will be e-mailed for convenience to take online
Week 7	Mailed survey contact #3	The cover letter will contain a link and individualized code if subjects wish to take the survey online
Week 8	Telephone reminder #1	A member of the Denver Health research team will call all non-respondents, attempting to contact them up to a maximum of three times (this method only if response rate is below 60%)..
Week 9	E-mailed survey contact #5 (via hyperlink)	For those with e-mail addresses, an individualized hyperlink will be e-mailed for convenience to take online (these methods only if response rate is below 60%)
Week 9	Mailed survey contact #4 (to those without an e-mail)	A survey will be mailed, and the cover letter will include a link and individualized code if subjects wish to take the survey online (these methods only if response rate is below 60%)
Week 10	Survey closes	Survey closes

Reimbursement for survey completion: It has become a standard of practice to reimburse participants for the completion of surveys. This reimbursement is a means of recognizing the value of the time and effort survey respondents bring to our research. This expectation has been articulated by organizations such as the Patient-Centered Outcomes Research Institute (PCORI), although the PCORI Framework on Compensation addresses the concept in general, not specifically with respect to surveys. Finally, the use of financial reimbursement for survey response has been shown in multiple studies to increase survey response rates.[28] For the current study, we propose to reimburse subjects who complete a survey with a $25 gift card.

Data entry of survey responses: All paper surveys will include a unique identifier on the survey that does not include personally identifiable information and will be linked to COVID-19 vaccination data in REDCap. When paper surveys are returned by mail, we will first enter the unique ID on the survey into our survey tracking database. This database will then be used to determine who does or does not need additional reminders to complete the survey. Next, our trained research assistant will enter survey responses into our REDCap database. We will perform double data entry on the first 50 returned surveys and analyze any discrepancies in entered data. We will also conduct quality audits of 10% of remaining surveys returned by mail and entered by study personnel. We will review these results as a means of assessing the quality of data entry, and will revise our data entry processes (such as revising the REDCap database, or providing feedback to the research assistant) to minimize any quality issues with data entry.

Primary study outcomes: Our primary outcome will be vaccination status, with our independent variables of interest being demographic, knowledge, attitudinal, and belief measures associated with vaccination status. For the cohorts (adults, pregnant women) who appear *unvaccinated* for SARS-CoV-2 vaccines in VSD data, we will define the primary outcome as the proportion who report NOT having received SARS-CoV-2 vaccines, with subject report being treated as the

criterion standard. For the cohorts (adults, pregnant women) who appear *vaccinated* for SARS-CoV-2 in VSD vaccination data, the primary outcome will be the proportion who confirm having received a SARS-CoV-2 vaccine, with VSD data being treated as the criterion standard.

Analytic methods: Survey response rates will be calculated using published standards, such as those advocated by the American Association of Public Opinion Research (AAPOR).[29] Subjects who answer question #1 (e.g. "Have you had a COVID-19 vaccine?") but did not finish the survey will be considered partial completes. Subjects who answered the entire survey will be considered full completes. Subjects who returned a survey without answering question #1 will be considered incomplete. The unadjusted survey response rate will be calculated as: (partial complete + full complete) ÷ total sampled. The adjusted survey response rate will be calculated as: (partial complete + full complete) ÷ (total sampled - total ineligible). Subjects may be determined as survey ineligible after surveying, but this should be a rare occurrence. Survey response rates will be calculated overall, and within each study cohort.

Survey responses will be analyzed as follows. Survey respondents will be compared to survey non-respondents on all available demographic characteristics, using Pearson's χ^2 test and the Student *t* test as appropriate. Descriptive statistics will be used to examine each survey question. We will use univariate statistics to examine associations between measures of knowledge, attitudes, beliefs (e.g. government distrust, efficacy of SARS-CoV-2 vaccines, etc.), socio-demographic variables (e.g. race/ethnicity, age, gender, religion/spirituality) and the primary outcome (vaccination). Using subject report of having received a SARS-CoV-2 vaccine as the criterion standard, we will calculate the sensitivity, specificity, positive predictive value, negative predictive value, and kappa for SARS-CoV-2 vaccination in VSD vaccination data.

We will also calculate end-of-season SARS-CoV-2 vaccination coverage estimates among the entire VSD population, including among adults and pregnant women, based on a combination of VSD vaccination data, data from regional IISs when available, and survey data. These estimates will account for the uncertainty around the estimates provided by the survey data.

Sample size & power calculations: We propose an overall sample size for survey administration of 3000, with the sample size stratified by vaccination status and pregnancy status. We expect the number of sampled pregnant women and non-pregnant adults to be relatively equal (~1500/group per year), although small differences may exist between groups based on our oversampling strategy (see below).

Oversampling and Sampling Strategy: We will oversample racial/ethnic minorities, Spanish-speaking patients, and unvaccinated patients, as we expect their response rates to be lower and we desire to have comparably-sized groups from which to conduct analyses (e.g. Black/Non-Black, English/Spanish, Pregnant/Non-Pregnant). Specifically, we will survey 2000 English-speaking individuals each year and 1000 Spanish-speaking individuals each year. 25% of the ~150,000 patients at Denver Health identify Spanish as their preferred language, and nearly 380,000 Kaiser Permanente Southern California members 18 years of age and older speak Spanish as a primary language (of which ~50,000 are women aged 18-45). This creates a unique opportunity to compare knowledge, attitudes, beliefs, and vaccination practices between subjects who identify as Latino and speak Spanish (versus other racial/ethnic groups). We plan to

administer the Spanish-speaking survey instruments at both Denver Health and Kaiser Permanente Southern California.

Tables 5 and 6 provide overviews of our sampling estimates, which assumes variable response rates by vaccination status and race/ethnicity with the goal of equally-sized groups. We will survey equal numbers of adults and pregnant women. If requested by CDC colleagues or other VSD sites, we can add additional cohorts (e.g. parents of young children, the elderly). We have also conducted exploratory power calculations to ensure our design will be adequately powered to detect relatively small differences in vaccination status by race/ethnicity between cohorts.

Table 5. Oversampling strategy in year one in English-speaking VSD members (n = 2000).

	Race/Ethn.	**Preg**		**Adult**		**Total**
Vaccinated	Black	263	417	189	358	**775**
	Non-Black	154		169		
Unvacc.	Black	383	595	389	631	**1226**
	Non- Black	212		242		
Total		**1012**		**989**		**2001**

Table 6. Oversampling strategy in year one in Spanish-speaking VSD members (n = 1000).

Spanish	**Preg**	**Adult**	**Totals**
Vaccinated	214	154	**368**
Unvaccinated	312	317	**629**
Totals	**626**	**471**	**997**

If response-rates for COVID-19 mirror those previously observed for influenza vaccines, this oversampling approach will yield equally-sized strata of English-speaking (n = 103) & Spanish-speaking (n = 84) vaccinated and unvaccinated adults and pregnant women from which to run analyses. It will also preserve precision in our estimates. For example, among pregnant women who speak English, we will have high precision for those confirming vaccination and reasonable 95% confidence intervals around those confirming they were unvaccinated (see: Table 7).

Table 7. Sample precision calculations for English-speaking pregnant women in year 1.

Cohort	**Sample**	**Resp.**	**Confirmed Status**	**1-sided CI Width**	**LCL**	**UCL**
Vaccinated, Black; English	263	103	0.99	0.019	0.97	1.00
Vaccinated, Non-Black; English	154	103	0.99	0.019	0.97	1.00
Unvaccinated, Black; English	383	103	0.83	0.073	0.75	0.90

Unvaccinated, Non-Black; English	212	103	0.78	0.080	0.70	0.86
Totals	1012	412				

Survey Wave Two: We will conduct surveys at the end of the second year in accordance with the design and procedures outlined for the first survey year. We will compare vaccination status and measures of SARS-CoV-2 vaccine knowledge, attitudes, and beliefs as previously described, and we will explore trends in knowledge, attitudes, and beliefs over time by race/ethnicity. We will update our response rate assumptions and sampling estimates prior to our second survey wave, as we are currently basing these estimates on assumptions from influenza survey work.
At the end of the second survey wave, we will also perform an exploratory analysis of individuals who were unvaccinated during the first survey wave who appear to be vaccinated in the VSD Data during the timeframe for the second survey wave. We will examine underlying demographic variables and knowledge, attitudes, and beliefs to discern if certain groups were more likely to follow-up and be vaccinated at a later date (e.g. pregnant women vs. adults).

Dissemination of Results: Upon completion of surveys and analyses, we will produce one or more manuscripts for publication. Given the rapidly changing public health environment, we expect to draft a manuscript describing our initial survey wave's findings by the end of 2021. Manuscripts will be shared with CDC and VSD co-Is and will be revised incorporating their feedback and comments. After submitting draft manuscripts for review and comment, we will incorporate comments into a final manuscript, which we will submit to CDC for clearance. We will respond to all comments prior to submission for publication. Once cleared, we will submit for publication in a peer-reviewed journal. We anticipate this work being relevant to: *Journal of the American Medical Association, American Journal of Public Health,* and *American Journal of Preventive Medicine.*

Data Archival: We will produce an archival data set, which will contain all data from VSD immunization data as well as survey results. This archival data set will adhere to all recommended standards for such data sets with respect to patient confidentiality and anonymity.

PROTECTION OF HUMAN SUBJECTS & DATA MANAGEMENT PLAN

Human Subjects Research Protections

We will coordinate all necessary administrative, regulatory, and compliance activities with participating VSD infrastructure sites and CDC. With respect to human subjects research, the proposed activities fall outside the VSD "umbrella" IRB-approved protocol, because activities involve direct patient contact and are not primarily focused on vaccine safety. Consequently, we will submit a new IRB application to the Colorado Multiple Institutional Review Board (COMIRB) and request all other VSD infrastructure sites to cede IRB oversight to COMIRB.

We will administer the survey centrally at Denver Health and will therefore need sites to share patient contact information with us. When sharing protected health information such as name and address, a data transfer agreement (DTA) is required rather than a data use agreement (DUA). We will complete DTAs with all infrastructure sites to permit the necessary data sharing, and we will coordinate survey administration activities with sites. This coordination will involve, for

example, obtaining site letterhead and logos for envelopes and letters as needed, confirming site-specific telephone numbers for patients with questions or complaints, and including additional site-specific instructions if needed. We will engage in clear and timely communication with all sites, which will be critical to successful coordination. For example, site investigators and project managers will need to know precisely when letters, e-mails, or telephone calls are made to their members. During active survey administration, we will send weekly updates to all sites.

The privacy and confidentiality of all study subjects will be strictly protected, according to standard VSD procedures. We anticipate using procedures like those in place for the Under-vaccination and Influenza Task Orders. We will submit our protocol for human subjects research review at COMIRB and request that participating VSD sites cede IRB oversight to COMIRB. This process is efficient, timely, and minimizes additional work for participating sites, such as when submitting study modifications. We will request a waiver of HIPAA authorization for study activities. Protected health information (PHI) such as name and address will be transferred to Denver Health so that survey administration can be centralized at Denver Health. To accommodate the transfer of PHI, we will request that sites complete a data transfer agreement (DTA) with Denver Health as noted above. Only minimum data necessary will be shared.

Data Security

This study will be conducted at Denver Health Offices of Research (OOR). The OOR has procedures in place to maximally protect the security of all data used for the purposes of this study. All OOR employees and investigators are required, as a condition of their employment, to complete training in HIPAA and IRB requirements. Any information provided by a study sponsor to the research site and to COMIRB is considered confidential. All research conducted from the OOR must comply with federal regulations regarding the privacy and confidentiality of study participants and their protected health information as specified in the Common Rule and the HIPAA Privacy Rule. The OOR at Denver Health has robust and redundant procedures to protect the security of its computing environment. All data used for this study will be kept in password-protected files on password-protected servers accessible only to study team members.

CHALLENGES AND LIMITATIONS

Two challenges for a survey-based study to identify factors associated with COVID-19 vaccination include response bias and sampling bias. First, as has been noted with prior VSD-wide survey task orders, we may have lower response rates from minority pregnant women or minority individuals within the VSD, referent to non-minority pregnant women or other members of the general population. This has also been true of those who are unvaccinated, referent to those who are vaccinated. These phenomena could introduce response bias if response rates differ significantly between minority and non-minority groups or vaccinees and those who have not yet been vaccinated per VSD Data. Additionally, sampling bias may be another limitation for this survey project, as the likelihood of being sampled across different VSD sites differs due to the internal demographics and sizes at each site. To account for these possible biases, we may pursue weighting and oversampling in partnership with VSD sites to improve our ability to provide precise estimates of vaccination data within the VSD population.

TIMELINE WITH KEY DELIVERABLE DATES

During the performance of this study, we will produce deliverables – in collaboration with our site Co-Investigators and CDC colleagues – a series of deliverables (Table 8). Table 8 and its timeline dates assume a start date of 1/25/2020.

Table 8. Deliverable item numbers, actions, and proposed dates.

Item	Action	Date
1	Provide a concept of the proposed project to CDC for review	March 2021
2	Provide draft protocol and survey instruments to CDC for review.	April 2021
3	Provide final protocol and survey instruments to CDC for approval.	May 2021
4	Provide documentation to CDC of IRB approval and DUA execution from participating sites for the survey.	June 2021
5	Initiate end of first year retrospective surveys at participating sites.	February 2022
6	Complete first year surveys at participating sites.	July 2022
7.a.	Provide annual report of first year's findings.	September 2022
7.b.	Consider drafting a manuscript for review by CDC and Co-Investigators.	October 2022
8	Initiate end of second year retrospective surveys at participating sites.	February 2023
9	Complete second year surveys at participating sites.	July 2023
10	Provide annual report of second year's findings.	September 2023
11	Draft manuscript #2 for review by CDC and Co-Investigators.	October 2023
12	Final manuscript for CDC clearance.	December 2023
13	Archival of final dataset.	January 2024
14	Meeting minutes from monthly meetings.	Within 7 days
15	Monthly reports to CDC.	10th of each calendar month

SITE RESPONSIBILITIES

This project will be co-led by investigators at Denver Health and Kaiser Permanente Colorado. Investigators at participating sites and the CDC will be invited to contribute to protocol development, survey development, analytical methods and design, and interpretation and reporting of results. Participating VSD sites will be responsible for the following tasks:

- Obtaining and providing documentation of IRB approval, including ceding to COMIRB
- Providing documentation of data transfer agreement (DTA) approval
- Reviewing and approving SAS data extraction programs
- Reviewing protocol and survey instrument drafts and providing feedback to study PIs

- Assisting with cohort creation for pregnant women and non-pregnant members of the general population in both survey waves (excluding Spanish-speaking surveys at DH and Kaiser Permanente Southern California)
- Confirming eligibility for selected cohorts immediately prior to survey administration
- Communicating with study PIs monthly via e-mail or through scheduled study meetings

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