Official Title: VAX-MOM COVID-19: Increasing Maternal COVID-19 Vaccination (Supplemental Award to "The VAX-MOM Study: Increasing Influenza and Tdap Vaccination of Pregnant Women")

NCT #: NCT05570630

Protocol Document Date: Version 2/4/25 (the most recently approved protocol version for the study)

PLEASE NOTE: This protocol has sentences/sections redacted to maintain the confidentiality of participating individuals and practice sites.

VAX-MOM COVID-19: Protocol for Phase 2

[redacted]

NOTE: The VAX-MOM COVID-19 study is divided into 2 main phases, baseline and intervention. The **baseline phase** [*STUDY00007624: VAX-MOM: COVID-19 (Phase 1)*] was previously submitted and approved independently through each participating health system's regulatory board.

The current protocol covers the **intervention phase** (Phase 2), which is being submitted for single IRB review, with the [redacted] acting as the IRB of record for all study sites.

1. PURPOSE OF STUDY

COVID-19 infection during pregnancy is associated with increased risk of pre-eclampsia, preterm birth and stillbirth.[1] Pregnant women with COVID-19 have a higher rate of ICU admission and intubation than those who are not pregnant.[2] COVID-19 vaccine is recommended before pregnancy and during pregnancy to decrease the risk of severe illness and death. Pregnant women should also receive a booster dose of COVID-19 vaccine after the original series. A 2022 study showed the effectiveness of maternal vaccination against hospitalization for COVID-19 among infants was 52% overall, 80% during the delta period, and 38% during the omicron period.[3] Importantly, studies show that the vaccine is safe and not associated with any negative maternal or infant outcomes.[4]

Despite the benefits of COVID-19 vaccination, only 71% of pregnant women were vaccinated for COVID-19 as of June 2022 (most prior to pregnancy), with a much lower rate of 58% among non-Hispanic Black women.[5] Additionally, only 56% of pregnant women overall have received a booster, but only 39% of Black pregnant women have received a COVID-19 booster vaccine. **An effective intervention is needed to improve COVID vaccination rates for pregnant women overall, and particularly for Black women**.

Using participating OB/GYN offices affiliated with 3 health systems in [redacted], the **VAX-MOM COVID-19 intervention phase will implement a quality improvement initiative aimed at increasing maternal COVID-19 vaccination rates at participating sites.**

2. BACKGROUND AND RATIONALE

Burden of COVID-19

Pregnant women are at risk of significant morbidity and mortality from COVID-19 infection, compared to the general population. Complications include increased need for ICU care, need for extracorporeal membrane oxygenation, prolonged ventilation, and death.[2]

Effectiveness of maternal COVID-19 vaccination

Maternal IgG raised by vaccination during pregnancy crosses the placenta to the infant, and remains detectable in more than half of infants at 6 months of age. Early estimates suggest that vaccinating pregnant women after 20 weeks is 80% effective, and before 20 weeks is 32% effective at preventing hospitalization of infants younger than 6 months with COVID-19.[6]

Barriers to Vaccination

There are many barriers to COVID-19 vaccination for pregnant women. *Patient Barriers* include vaccine hesitancy, lack of knowledge of the benefits and risks of COVID-19 vaccine or protection for the baby, concerns about vaccine safety generally and during pregnancy due to misinformation, and low perceived susceptibility to infection.[7,8] *Provider Barriers* likely include missed opportunities for vaccination, lack of a vaccine recommendation or weak endorsements by health providers[9-12] and various suboptimal practice operations.[13-15] Since most women vaccinated during pregnancy receive their immunizations from their OB/GYN,[16] it is critical for OBs to discuss, recommend, and offer immunizations. *System Barriers* include lack of audit and feedback, and lack of a standing orders as well as challenges with vaccine purchase and storage.[11,17]

The VAX-MOM COVID-19 study will ultimately address multiple components by focusing on provider and staff communication, workflow optimization and vaccine rate feedback to overcome these barriers.

3. ADMINISTRATIVE ORGANIZATION

PRINCIPAL INVESTIGATOR (PI) OVERSIGHT PLAN

[redacted] (PI) will oversee all project activities, which will be identical across the participating [redacted] study locations. All sites will utilize the same site communication methods, training materials, study measures, feedback tools, online dissemination platforms, etc. Additionally, all sites will follow the same study design, procedures and timeline.

Study staff will be grouped into distinct administrative teams, and each team will focus on defined project tasks. Team details and staff descriptions are presented below.

[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

*Team leader

[redacted]

[redacted]

[redacted], **study PI, will ensure study and regulatory compliance, by:**

- Participating in and/or remaining updated regarding routine prescheduled meetings with project investigators and project staff for the duration of the study, including:
    - *Weekly Core Leadership Team Meetings* (State-level investigators, study coordinator, study consultants, data specialist, support staff): discussion of global project goals, timeline, regulatory requirements and adherence, protocol requirements and adherence, measure development, e-learning content, data analysis, workflow details, etc.
    - *Weekly State-Level Team Meetings* (State-level investigator, study coordinator, support staff, data specialist and/or consultant as needed): discussion of day-to-day operations needed to support global study goals (including protocol and regulatory items).
    - *As-Needed Health System Liaison Meetings* (State-level investigator, study coordinator, OB/GYN site liaisons): discussion of provider/nurse/staff workflow, development of study measures specific to providers/nurses/staff, optimal measure dissemination procedures, identification of possible vaccine champions.
    - *As-Needed Data Development & Analysis Meetings* (State-level investigators, study coordinator, EHR report builders, data specialists, consultants as needed): discussion of data collection methods, EHR data extraction methods, data analysis, data storage/management.
- Keeping all study personnel abreast of *prearranged study changes* and subsequent regulatory determinations (e.g., changes to study measures, workflow procedures, study personnel, etc.) via a predetermined communication chain:
    - Core Leadership Team discusses necessary study change→Study coordinator submits amendment via sIRB→ IRB notifies Study PI and study coordinator of regulatory determination→ Study PI and coordinator notify Core Leadership Team→ As appropriate, study coordinator will further notify local IRBs and site-level personnel and/or data specialists
    - Communication with study site personnel will most often take place during prescheduled meeting times, but in more urgent cases, will take place as soon as needed.

- Communication will be both verbal (during or outside of weekly meetings depending upon level of urgency) and written as needed (via e-mail, e-mail attachments, or the secure shared Box folder).

- Keeping all study personnel abreast of *unforeseen study events* and subsequent regulatory determinations (e.g., protocol deviations, breaches in confidentiality, subject/site withdrawal, etc.) via a predetermined communication chain:
  - Study personnel reports study event to PI→ PI notifies study coordinator→ PI and study coordinator notify IRB, as well as other study personnel as appropriate→ any action requested by IRB is communicated to Core Leadership Team→ As appropriate, study coordinator will further notify site-level personnel and/or data specialists
  - As described above, communication will be both verbal and written.
  - Also see section #16 "Data & Safety Monitoring Plan"

4. STUDY DESIGN & PROCEDURES

Brief Overview of Phase 2:

Using a clustered RCT (randomizing practices), we will allocate half of the practices within each health system to the VAX-MOM COVID-19 intervention and the other half to standard of care (control). We will measure the impact of the intervention on vaccination rates (primary outcomes) as well as rates of vaccination by subgroup (secondary outcomes) (see Table 4). Finally, if VAX-MOM COVID-19 is successful, we will provide the control practices with core intervention materials (e.g., learning module, rate feedback template) at the conclusion of the study.

Design and Procedural Details of Phase 2: (also see Figure 1 for Timeline)

Step 1) Deliver VAX-MOM COVID-19 training to randomized practices:

Randomization Details:

Practices will be the unit of randomization. We will assign practices using a covariate constrained randomization strategy. Practices will be stratified by health system, as well as arm assignment in the primary VAX-MOM trial. Within strata, we will perform constrained randomization to allocate practices to intervention/control arms, and ensure each arm has similar baseline COVID vaccination rates, percent of patients covered by Medicaid, number of OB providers, and number of patients. Specifically, we will use these variables to construct and evaluate a balance criterion, which is the sum of the squared difference between standardized group means on these variables. We will generate all possible combinations of eligible practices in 2 arms (using a SAS macro), and define an acceptable set of randomizations that result in balanced variables (generally the lowest 10% on the balance criterion). From this set of randomizations, we will select one set at random, and then randomly assign each practice to intervention vs control group.

Intervention Details:

Once randomization has been completed, and "intervention group" practices have been identified, multiple quality improvement (QI) techniques will be aimed at practice providers, nurses, and staff.

- **Identification of a "vaccine champion" at each intervention site:** At each site, the affiliated medical director or health system liaison will select one "vaccine champion" for each practice. Each identified vaccine champion will be e-mailed an Information Sheet (see "*InfoSheet_VaccineChampion…"* document) by the study coordinator, outlining the basic study goals as well as their involvement in tasks throughout the training and intervention adoption phases of the study (see "Consent Process" section). The position of vaccine champion is voluntary, and if they do not wish to accept the role, they may decline and another individual will be identified as a replacement. The vaccine champion will play a lead role throughout the study intervention, including:
    - assisting with the dissemination of e-learning training modules and the scheduling of follow-up site-specific meetings
    - acting to ensure training content is being appropriately adopted into practice workflow procedures
    - fielding questions from site personnel regarding the logistics of study interventions
    - acting as an ongoing liaison between the site personnel and study staff
    - leading regular discussions regarding immunization rate feedback with site personnel (see step 2 for further detail)
    - planning for and completing monthly PDSA cycles (see step 2 for further detail)
    - monthly completion of the "Practice Time/Cost Survey" (see step 4 for further detail)
    - participating in monthly learning collaborative meetings with the study team

- **Delivery/discussion of an online training module**: Each site will receive training focused on four main areas of content: a) the importance of COVID-19 vaccination during pregnancy, b) vaccine communication, c) optimization of workflow and d) review and resources (see Table 3). This training will be delivered first via an online e-learning platform, and next via an in-person or virtual site meeting.

Table 3: Training Module Content

General Topic:	Training Lessons:
Importance of COVID-19 vaccination during pregnancy	1- How bad is COVID-19 disease during pregnancy?
	2- Why does ACOG recommend vaccination?
	3- What are ACOG's COVID-19 vaccination recommendations?
Streamlining vaccine communication	4- A range of patient concern levels
	5- For everyone: An evidence-based recommendation
	6- For hesitant patients: Motivational interviewing
	7- For patients who refuse at this visit
Optimizing workflow to increase vaccination	8- Strategies for increasing immunization rates
	9- Putting the strategies into action
Review and resources	10- Test your knowledge
	11- Provider & Patient Resources

- E-learning module dissemination: Module lessons will first be disseminated to practice site personnel via an e-mail link taking them to the Articulate/Rise 360 platform. The study coordinator will obtain e-mail addresses for the site personnel from either the health system liaison or the associated vaccine champion, and will then e-mail a training content link to all appropriate site providers, nurses, and staff. Attached to this initial e-mail will be an Information Sheet describing the study goals and training phase details, as well as their involvement throughout the duration of the 6-month QI intervention (see *"IntroEmail_TrainingPhase…"* and "*InfoSheet_TrainingPhase…*" documents; also see "Consent Process" section for more detail). After reviewing the Information Sheet and discussing any questions/concerns with study staff, site personnel will be asked to access and complete the training lessons prior to their scheduled site meeting.

  Embedded at the conclusion of the online training module, will be a link to a brief REDCap survey (see *"TrainingModuleCompletionSurvey…"* document) to obtain information regarding those who have fully

completed the training. A list of practice personnel who have successfully completed the online training will be stored in a password-protected Excel file by the study coordinator. The names will not be linked with any other study data. The list will be accessible only by study staff for the purposes of confirming those who should receive MOC/CME/CNE credit for their participation and to calculate overall completion rates for each site.

- Site meeting: Following the online training, all site personnel will meet with study staff either in-person or via a virtual Zoom meeting. The meetings (both virtual and in-person) will be audio and video recorded using a laptop or handheld recording device (in-person meetings) or via the Zoom recording option (virtual meetings) (see "Audio/Video Recording" and "Privacy and Confidentiality" sections for more detail). These archived video files will allow for the review of meeting content by site personnel who were unable to attend the meeting live, or by those who simply wish to review the meeting discussion for a second time.

  During the site meeting, study staff will briefly review online training content, allow time for the sharing of comments/questions from site personnel, and lead a discussion regarding the application of training content ideas specifically to that practice site. During this meeting, study staff will also present site personnel with their current immunization rates. Each designated vaccine champion will track meeting attendance or participation will be tracked via the Zoom "participant list." The study coordinator will store this roster in a password-protected Excel file. The names will not be linked with any other study data. This list will be accessed for the purposes of confirming those who should receive MOC credit for their participation in the project, and for calculating overall attendance rates for each site.

- MOC/CME/CNE credit: To encourage the completion of online trainings and attendance at site meetings, providers and nurses will be offered CME/CNE credit for completing the online learning module, and providers will be offered MOC/QI credit for attending office systems change meetings and reviewing practice rates.

Step 2) Implement intervention ideas and monitor progress at intervention practices:

To monitor the adoption of VAX-MOM COVID-19 training content (changes in communication techniques, workflow optimization, etc.) at each practice site, each vaccine champion will participate in the following activities:

1. *Lead a discussion regarding immunization rate feedback* with practice providers, nurses, and staff on a monthly basis. The site-specific vaccination information will be obtained from either: 1) the EHR report builders for each health system, or 2) manual chart review (i.e., accessing eRecord to look up patient charts and

entering information into a REDCap data entry template) completed by study staff or the site's vaccine champion. Obtained vaccination information will be uploaded to the secure [redacted] Box folder. The project's data analyst will plug this vaccination information into a template that will create visual graphs and tables, allowing practice personnel to better understand trends within their site. The study coordinator will then disseminate the visual vaccination rate feedback to each site for review and discussion (see *"RateFeedbackTemplate…"* document).

2. *Develop PDSA cycle goals* on a monthly basis utilizing knowledge about current workflow efficiency and data from vaccine rate reports. Vaccine champions will utilize the PDSA template (see *"PDSAandTimeCostSurvey…"* document) to guide progress with their respective teams. The template will help them decide upon specific intervention activities appropriate for their setting, track those involved with each activity, compare results from the activity to previous performance, and focus on changes that may need implementation during future cycles. PDSA cycle logs will be sent to vaccine champions for completion via a secure REDCap survey.

   For participating [redacted] practice sites, the 6-month intervention (entailing PDSA cycles described above) will be extended by 3-5 months (depending upon the original start date of the specific location) until April of 2024, to optimize vaccine intervention efforts and data collection during the peak of the COVID season.

   During the 6+-month intervention phase, a study team member may observe intervention sites in-person in order to collect qualitative data regarding workflow and communication techniques as described in the sites' submitted PDSA cycle logs. Specifically, the study team member will document the ways in which the targeted intervention techniques are implemented within the practice (see "*InPersonObservationNotes*…" document). Observation notes will then be compared with submitted PDSA cycle log information and analyzed for consistency.

   Of Note: Although study staff will observe OB/GYN practice personnel during patient encounters, practice patients will NOT be the target of the observation, and no identifying patient information will be collected. Rather, the focus of observation will be the select practice personnel only. Any patient-level information recorded during the observation will be done so in a generic manner such that the patient could not be identified on the basis of the notes (e.g., *"…when patient indicated that they did not want the COVID-19 vaccine, the nurse stated, 'The doctor may talk to you more about that when she comes in.'"*).

3. *Complete the "Practice Time/Cost Survey"* on a monthly basis (see step 4 for further detail). The vaccine champion will track site personnel attending each rate feedback and PDSA discussion as well as their role (e.g., Ob/Gyn, nurse, desk

staff, etc.) within the practice. They will then complete a monthly REDCap survey reporting aggregate information regarding total time spent on project-specific activity (see *"PDSAandTimeCostSurvey…"* document).

Additionally, to monitor study staff efforts during this phase (to parallel surveys completed by practice champions), study staff will participate in the completion of a weekly *"Study Staff Time Survey"* (see step 4 for further detail).

Again, for participating [redacted] practice sites, the 6-month intervention (including the Practice Time/Cost Survey and Study Staff Time Survey described above) will be extended by 3-5 months depending upon the specific location, to optimize vaccine intervention efforts and data collection during the peak of the COVID season.

4. *Participate in learning collaborative meetings* on a monthly basis with the study team. The vaccine champions from all participating intervention sites, along with the study team, will meet together as a group to discuss current COVID-19 information, intervention strategies/tips and overall project progress.

Step 3) Compare intervention vs. control practices:

Using the "RE-AIM" framework (see Table 4) we will compare intervention practices to control practices using multiple data sources. We will focus on one primary outcome and multiple secondary outcomes.

Primary Outcome: Following the conclusion of phase 2 (6-month duration), we will assess the "Effectiveness" of the intervention by comparing intervention group COVID-19 vaccination rates against control group COVID-19 vaccination rates.

Secondary Outcomes: Following the conclusion of phase 2 (6-month duration), we will assess the remaining "RE-AIM" domains including "Reach," "Adoption," "Implementation," and "Maintenance."

Table 4: Summary of Outcome Measures and Tools

RE-AIM Category	Outcome Measure(s)	Data Source
Reach	• Number of patients seen in the practice within study period. • Number of providers/nurses/staff completing the training modules.	EHR data & training attendance records

Effectiveness	• Primary Outcome: Rate of COVID-19 vaccination (intervention vs control) • Secondary Outcomes: • COVID-19 vaccination rates by subgroups including (i) insurance groups, (ii) race/ethnicity, (iii) number of pregnancy, (iv) vaccine in prior year • Flu and Tdap vaccination rates by subgroups including (i) insurance groups, (ii) race/ethnicity, (iii) number of pregnancy, (iv) vaccine in prior year	EHR data
Adoption	• Number and proportion of personnel involved in the VAX-MOM office changes (receiving MOC credit, attending in-office meetings)	Training attendance records
Implementation	• Provider and office staff perceptions of feasibility, acceptability, barriers and facilitators to implementation, adherence to intervention, perceived time and cost, and impact on patient flow. • Perceived strength of vaccine recommendations. • Perceived adherence to staff checking whether vaccine is due. • Costs of implementing interventions	Post-Intervention Survey & Time/Cost Survey
Maintenance	• Sustainability	Post-Intervention Survey

Details for EHR data extraction:

- **EHR Measure Description**: We will work with health system EHR report builders and our experienced analysts to build EHR reports which evaluate vaccination coverage at participating sites (see Table 5).

  Baseline data was previously gathered during STUDY00007624, STUDY00005115 and STUDY00004408. The remainder of this data (COVID intervention data), as well as any missing baseline data from the protocols listed above, will be gathered under the current protocol STUDY00007717.

Table 5. Data obtained from EHR for women with live births during intervention period (NOTE: any data missing from the baseline period may also be gathered during Phase 2)	
Primary Information	• COVID-19 vaccination status (both dates and type) • Flu vaccination status (dates) • Tdap vaccination status (dates)

Additional Information: Patient Demographics	• DOB • MRN • Date of Delivery • GA at delivery • Race/ethnicity	• Insurance • Language • Parity • High risk status • Other social determinants
Additional Information: Practice Demographics	• Site • Provider type (resident, midwife, MD)	

- **EHR Measure Procedures:** EHR data report builders for each health system will extract the requested information (data in Table 5, also see "*EHRData…*" document) using live births occurring from July 2022 until the conclusion of the study, and place into an excel file which will then be uploaded to a secure [redacted] Box "initial report" folder for the study team.

  The data will be extracted for intervention and control sites both **a)** on a monthly basis, for the purposes of providing monthly rate feedback reports to intervention sites, and **b)** if needed, at the conclusion of the study to obtain any missing data from sites not obtained in the previous months.

  Initial automated report files will go through an auditing process in which a small percentage of patient charts will be reviewed manually (i.e., charts accessed in eRecord) by study staff and compared to automated report findings. Study staff completing this process will have received the proper Epic/EHR training and clearance. During the auditing process, files will be placed temporarily in secure "SMDNAS Research Storage" folders, to reduce the risk of altering original report files, or confusing audited files for originals.

  Once the auditing process is complete, the finalized EHR reports will be uploaded back into a secure [redacted] Box "final report" folder for analysis and/or for creation of the monthly rate feedback form by the [redacted] data specialist. De-identified analyzed data and/or the rate feedback reports will then be placed in a "analyzed data/rate feedback reports" folder on [redacted] Box by the data specialist, accessible by the study team. For monthly rate feedback reports, the study coordinator will then disseminate the vaccination rate reports for each site to all corresponding vaccine champions via secure e-mail.

  In the event automated reports cannot be generated in a timely manner (i.e., as needed for monthly feedback or final analyses), study staff or vaccine champions will extract this same information by conducting manual chart reviews. A list of delivery MRNs will be passed from the health system liaison into [redacted] Box, to identify appropriate patient charts that should be reviewed. Study staff will then manually access patient charts in eRecord for the appropriate health system and enter the information indicated in Table 5 into a REDCap "Manual Chart Review Tool" (i.e., a form into which study staff can easily enter the information needed). Once manual data entry into REDCap has been completed, the information will be exported as an excel file and saved to the secure [redacted] Box "final report" folder (as auditing will not be needed).

Details for Post-Intervention Survey:

- **Survey Measure Description**: The Post-Intervention Survey (see *"VAXMOMCOVID_PostInterventionSurvey…"* document) is a survey consisting of Likert scale, multi-option and open-ended questions. The survey takes approximately 10 minutes to complete. The survey assesses opinions regarding COVID-19 infection and vaccination, patient vaccine refusal, barriers to vaccination, vaccine workflow, RSV vaccine, practice culture, and basic demographic information.

- **Survey Measure Procedures:** At the conclusion of phase 2, all providers (MD, residents, NPs, PAs and CNMs) and 1-2 select nurses from both the intervention and control sites will be asked to complete the survey. A notification e-mail (see "*NotificationEmail*…" document) may first be sent out by the health system liaison and/or Chair of Obstetrics and Gynecology affiliated with the appropriate health system.

  Surveys will be e-mailed to providers and select nurses by project staff using the secure web application REDCap (see *"IntroEmail_PostInterventionSurvey…"* document). E-mail addresses will have previously been obtained from the health system liaison or vaccine champion and uploaded to the REDCap platform. After initial survey distribution, if the subject does not click on the survey link embedded within the e-mail, the REDCap platform will automatically disseminate reminder e-mails to the subject (identical content as initial invite e-mail). Once clicked, the survey link will first take potential respondents to the Survey Information Sheet for review (see "Consent Process" section for more details), and if they agree, will then allow them to continue to the full survey. Surveys will be sent in 3 "waves" in order to allow subjects from each health system to view their own system-specific Information Sheet (e.g., [redacted] subjects will first see the [redacted] Info Sheet, followed by the full survey). Subjects may answer survey questions at their own pace and may stop and restart at any time. At the conclusion of the survey, they will receive an automated confirmation message to assure them that the process is complete.

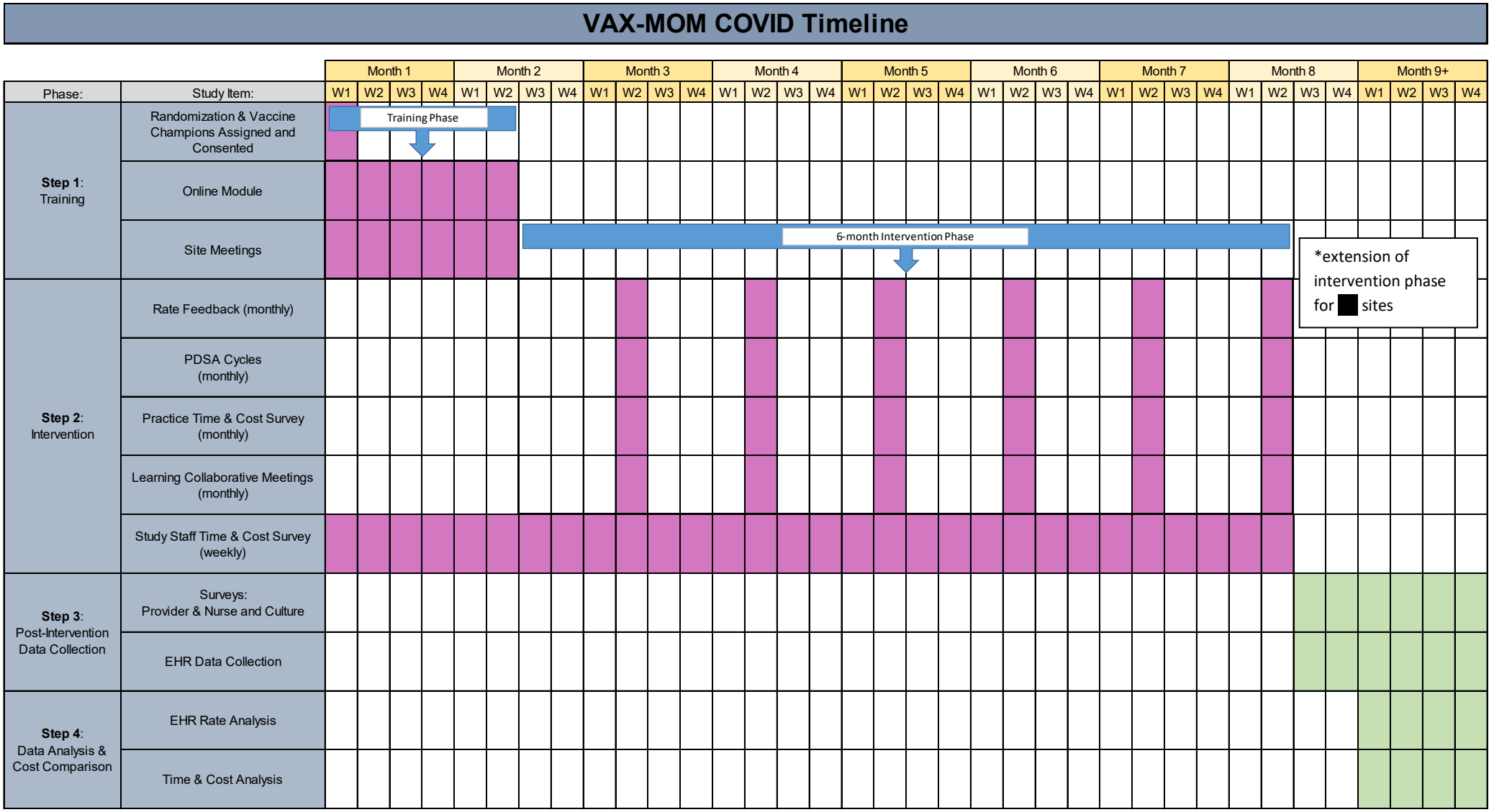
Step 4) Evaluate cost of the VAX-MOM COVID-19 intervention:

Practice Time & Cost Survey (see *"PDSAandTimeCostSurvey…"* document): A survey aimed at evaluating the amount of time and money devoted to VAX-MOM COVID-19 intervention activities will be sent by the study coordinators via REDCap to the vaccine champion for each site on a monthly basis. The survey will be completed by the vaccine champion using their best time/cost estimates pertaining to the month prior.

Study Staff Time Survey (see *"StudyStaffTimeSurvey…"* document): A survey aimed at evaluating the efforts of VAX-MOM COVID-19 study staff will be sent to study personnel on a weekly basis via REDCap.

Final Time & Cost Analysis:
Upon completion of phase 2 we will conduct a final time/cost analysis. Our two-fold cost measures are (a) total intervention cost to implement the VAX-MOM COVID-19 program aggregated at the three health-system level under a cost analysis and (b) cost per additional vaccination under a subsequent cost-effectiveness analysis.

Figure 1: Timeline of Intervention Phase Procedures



5. SUBJECT POPULATION

For the purposes of this study, the term "subject" refers to both a) the personnel at participating OB/GYN practice sites and b) practice patient information (pregnant women with a live birth on record) gathered via electronic health record (EHR) extraction. All participating practices, approximate subject pool totals, and corresponding demographic information is listed in Table 6. The breakdown of optimal subject numbers per measure per health system is listed in Table 7.

[redacted]

[redacted]

[redacted]

[redacted]

Inclusion of women and minorities

Every effort will be made within this project to ensure that women, racial and ethnic minorities will be included in all aspects of the research. Practices selected include a broad spectrum of size, regional location as well as public and private practices. These variables will ensure racial/ethnic diversity among study subjects that will mirror the state of [redacted] racial and ethnic distribution as shown in the enrollment table. An estimated 57% of practicing Obstetrician/Gynecologists (OB) and 85% of graduating OB residents are female. Therefore, we anticipate a higher percentage of females among the provider study subjects. Patient study subjects will all be female.

Inclusion of children

Pregnant patients receiving care at eligible practices will be considered part of the study population and will include pregnant patients that are aged less than 18 years of age.

Inclusion of Pregnant Women

Although the research project involves OB/GYN practice sites, study staff will have minimal contact with pregnant patients, and study efforts do not place the patients' pregnancy at risk. All pregnant patients, at both the intervention and control sites, will continue to receive their expected standard of care for the entirety of their pregnancy.

Inclusion of Employees

Employees of [redacted] will be included as subjects. All Information Sheets disseminated to study subjects during this study phase will emphasize that the decision to participate will have no impact upon: performance evaluations, job advancement, or the loss/gain of benefits (e.g., salary increases, time off).

6. INCLUSION/EXCLUSION CRITERIA & RECRUITMENT METHODS

All Participating Sites (Intervention & Control)

[redacted] sites that participated in the previous VAX-MOM studies (STUDY00007624, STUDY00005115 and STUDY00004408) were invited to participate in this study. Prior to the start of the current VAX-MOM COVID-19 project, Drs. [redacted] contacted leadership within each health system to confirm interest in continued participation.

Originally (for previous VAX-MOM studies), health systems ([redacted]) within each state were chosen because a) their size allowed for an ample sampling of patients and practitioners (i.e., large subject pool) and b) they allowed for a broad spectrum of geographic and socio-economic diversity (e.g., privately and publicly insured, ethnic multiplicity, rural and urban locations, etc.).

Intervention Sites

As described in the "Randomization" subsection of the "Study Design & Procedures" portion of the protocol, study sites from the larger pool will be selected to be part of the "intervention group" using specific constrained randomization procedures within each health system (see section 4 of protocol for more details). All remaining sites will be allocated to the "control group."

Practice-Level Personnel

Criteria/Recruitment Method for Vaccine Champion:

At each site, the affiliated medical director or health system liaison will select one "vaccine champion" for the practice. The vaccine champion will be selected due to their perceived ability to play a lead role throughout the study intervention, including their ability to complete all monthly tasks listed in "Step 1" of the "Study Design and Procedures" section. The position of vaccine champion is voluntary, and if they do not wish to accept the role, they may decline and another individual will be identified as a replacement.

Criteria/Recruitment Method for Remaining Site Personnel:

By default (and with the support of health system and practice site leaders) all remaining providers, nurses, and practice staff employed by the practice location, are able to participate in the quality improvement initiative.

Patient-Level Study Subjects

Criteria for EHR Data from Practice Patients (Pregnant Women):
Baseline vaccine rates (reported to each site during their site meeting) were established during the prior protocols (STUDY00007624, STUDY00005115 and STUDY00004408), and contained EHR information from practice patients who were identified as having a live birth within a 6 month time period prior to the start of the intervention.

To establish vaccine rates for the ongoing monthly feedback reports (July 2022 onward), EHR information will be collected every month from intervention sites during the entirety of the intervention phase (see timeline depicted in Figure 1). EHR information will reflect practice patients who are identified as having a live birth on record for that month. Again, all subjects will be female and may be <18 years of age.

To establish the final vaccine data reports (for intervention vs. control comparison), detailed EHR information (see Table 5) will be collected from both intervention and control sites for the entire intervention period, and additionally, any missing data from the baseline period will be collected at this time.

7. CONSENT PROCESS

Health System, Practice Site, & Site Personnel Level

Health System & Practice Site Consent:

Health system support, and subsequently site-level support, was previously obtained during phase 1 of this study (STUDY00007624), as well as during our original VAX-MOM studies (STUDY00005115 and STUDY00004408), and is described in the "Inclusion/Exclusion Criteria & Recruitment Methods" section of the protocol.

Site Personnel Consent:

Delivery of Training Content & Involvement in 6-Month QI Intervention
***(All site personnel**: completion of e-learning module, attendance of follow-up site meeting, and participation in monthly discussions of rate feedback and PDSA cycles)*

This study involves commonly accepted quality improvement efforts aimed to improve upon the standard of care in medical settings, such as the completion of e-learning modules and in-person trainings specifically related to practice goals, the review of practice metrics (vaccine rates) by site personnel, discussion of office workflow procedures/efficacy, and trainings in optimal communication techniques.

We are therefore seeking a *waiver of documentation of consent* for the training portion of the study. More specifically, we are requesting this waiver because: **a)** the training portion of the study is no greater than minimal risk, **b)** the purpose of

the study/intervention and a basic framework of the trainings will be clearly outlined for participants in the Information Sheet (see *"InfoSheet_TrainingPhase…"* document) e-mailed to them at the onset of the intervention phase, and **c)** ample time will be given to personnel to review the Information Sheet in full and ask questions of study staff regarding the quality improvement effort and/or specific tasks involved in the training phase.

We will attach an Information Sheet (cited above) to the first e-learning invite e-mail, describing the study goals and training phase details, as well as site personnel involvement throughout the duration of the 6-month QI intervention (e-mailed to site personnel just prior to the training phase). Study staff will field any and all questions from potential study subjects prior to their module training and subsequent site meeting.

Assessment of Intervention Adoption: Surveys & Rate Feedback
*(**Selected Vaccine Champions**: completion of monthly rate feedback discussions and monthly PDSA cycles and Practice Time & Cost Surveys; participation in monthly learning collaborative meetings)*

The assessment of intervention adoption by study sites involves commonly occurring procedures within a medical setting, including the ongoing review of practice metrics (vaccine rate feedback sessions), the development and assessment of practice goals (PDSA Cycles and learning collaborative meetings), and the evaluation of personnel efforts to achieve these goals (Time & Cost Survey).

We are therefore seeking a *waiver of documentation of consent* for the intervention adoption portion of the study. More specifically, we are requesting this waiver because: **a)** the assessment portion of the study is no greater than minimal risk, **b)** the purpose of the study/intervention and a description of the assessment tasks will be clearly outlined for vaccine champions in the Information Sheet (see *"InfoSheet_VaccineChampion…"* document) e-mailed to them at the onset of the assessment phase, and **c)** ample time will be given to each vaccine champion to review the Information Sheet in full and ask questions of study staff regarding the quality improvement effort and/or specific tasks involved in the assessment phase.

As soon as they are selected, each identified vaccine champion will be e-mailed (see *"IntroEmail_VaccineChampion…"* document) an Information Sheet by the study coordinator, outlining the basic study goals as well as their involvement in tasks throughout the training and intervention adoption portions of the study. After the Information Sheets have been disseminated, the study coordinator will conduct a follow-up phone/Zoom call with each vaccine champion, reviewing their role within the project and fielding any and all questions they may have. The position of vaccine champion is voluntary, and if they do not wish to accept the role, they may decline and another individual will be identified as a replacement.

Assessment of Intervention Adoption: In-Person Observation
*(**Select Personnel**: observation of workflow and communication techniques)*

The in-person observation of intervention adoption involves commonly occurring procedures within a medical setting, including the ongoing documentation and review of daily workflow and communication procedures.

We are therefore seeking a *waiver of documentation of consent* for the in-person observation portion of the study. More specifically, we are requesting this waiver because: **a)** the observation portion of the study is no greater than minimal risk, **b)** the purpose of the observation will be clearly outlined for practice personnel in the Information Sheet (see *"InfoSheet_InPersonObs…"* document) e-mailed to them prior to the scheduled observation, and **c)** ample time will be given to practice personnel to review the Information Sheet in full and ask questions of study staff regarding the observation.

Prior to in-person observation, the study coordinator will contact each site's vaccine champion to determine days that would be optimal for study staff to be onsite. Once the observation schedule has been determined, all personnel who are scheduled to work on the specified day(s) will be e-mailed an Information Sheet (see *"IntroEmail_InPersonObs…"* document) by the study coordinator, which they may review at their own pace prior to the observation date. They may e-mail the project coordinator with any questions, or bring questions to the attention of the study staff on the scheduled visit day prior to the start of any observation. The content of the Information Sheet will be reviewed again by study staff with practice personnel on the visit day prior to the start of any documented observation (any personnel not previously known to be working that day will be given a hard copy of the Information Sheet upon arrival by the study staff and given ample time to review).

As stated previously, although study staff will observe OB/GYN practice personnel during patient encounters, practice patients will NOT be the target of the observation, and no patient information (in either individual or aggregate form) will be collected. Rather, the focus of observation will be the select practice personnel only. Information recorded during the observation session will be written in a generic manner such that specific personnel/patients will not be identifiable. Notes will describe the general workflow processes and communication methods used, rather than specific unique behaviors or exact dialogue. For example, study staff may document *"…when patient declined to receive the COVID vaccine, the practice nurse gave them an informational handout and told them the doctor may speak with them further*." Although the patient is <u>not</u> the study subject, prior to each observation, practice personnel or the study staff will explain to the patient in simple language the purpose of the observation (i.e., to take notes regarding the nurse/staff work routine), and any patient that communicates discomfort or preference to not be observed, will not be observed.

Post-Intervention Survey Dissemination

We are seeking a *waiver of documentation of consent* for the Post-Intervention Survey portion of the study. We are doing so because: **a)** the survey is no greater than minimal risk (a brief online survey with unobtrusive questions), **b)** a detailed Information Sheet will be made available to each subject prior to the start of the survey (embedded within REDCap with subjects matched to the correct health-system Information Sheet), **c)** ample time will be given to each subject to consider participation (subjects are notified of the survey via e-mail and can review the information sheet and/or ask questions of study staff for as long as necessary before deciding about survey completion), and **d)** no identifiers will be included on the survey form (only subject IDs), and the separate document linking subject name to subject ID will only be made available to a limited number of study staff, will be kept under double-locked conditions, and will be destroyed three years after study completion.

Patient (EHR) Level

EHR Data Extraction: We are seeking a *waiver of consent and a waiver of HIPAA authorization* for the EHR data extraction portion of the study. We are doing so because: **a)** we believe that this research cannot be practicably conducted without such a waiver, as we cannot feasibly obtain consent and HIPAA authorization from all potential subjects (thousands in total subject pool), **b)** site liaisons and report builders have routine access to patient records, **c)** a minimal number of patient-level data fields will be extracted from the EHR (just enough to complete analysis) **d)** a plan to protect EHR data during all data transfers will be implemented (see "Privacy & Confidentiality" section for details), **e)** any individual-level data will be destroyed three years after study completion, and **f)** PHI will not be reused or disclosed to any other person or entity except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.

8. AUDIO/VIDEO RECORDINGS

All site meetings held during the training phase and all learning collaborative meetings held during the intervention adoption phase may be audio and/or video recorded using a laptop or handheld recording device (in-person meetings) or via the Zoom recording option (virtual meetings) (see "Privacy and Confidentiality" section for more detail). These archived audio/video files will allow for the review of meeting content by site personnel who were unable to attend the meetings live, or by those who simply wish to review the meeting discussion for a second time.

The archived meeting audio/video files will be stored on a secure Box platform, accessible only to study staff and site personnel from the corresponding practice site (each site will have their own Box folder ensuring meetings from other sites are not viewable to outside personnel). Invites to the secure Box folder will be e-mailed from study coordinators directly to site personnel. As soon as the video files have been uploaded to the secure Box platform,

they will be deleted from the laptop or handheld recording device. Once the study has been fully completed, all video files will be deleted from the shared Box folder.

9. RISKS TO SUBJECTS

Practice Level Risk: This project involves QI trainings/interventions which aim to improve upon the existing communication techniques and workflow procedures at each intervention practice site. Planned study trainings/interventions are widely accepted among medical practices (e.g., practice providers/nurses/staff attending an informational meeting regarding the risk of COVID-19 in the pregnant population), and do not involve any novel high-risk changes to practice structure or procedures. Practice sites in the control group will continue to utilize "best-practice" guidelines. Thus, at the practice level, anticipated overall study risk is very low.

Site Personnel & Patient Level Risk: The primary risk to site personnel and practice patients is the risk of a breach of confidentiality, though overall risk remains low.

To reduce risk, personal information being collected from site personnel or practice patients (EHR data) has been minimized, and when possible is being collected in aggregate form or using study IDs.

A number of policies, procedures, and technical safeguards (described in the "Privacy & Confidentiality" section of this protocol) will be in place to ensure that there is no breach of confidentiality as a result of this study.

10. POTENTIAL BENEFITS TO SUBJECTS

Practice personnel will receive targeted training related to: COVID-19 disease as it pertains to the pregnant population, communication, and optimization of office workflow as it relates to the improvement of immunization rates within their practice. As such, practice personnel who participate in both the training and ongoing QI portions of the study will have the opportunity to apply for MOC, CME, or CNE credit.

There are no anticipated benefits for practice patients beyond those inherent to the overarching study goals (i.e., an improvement in immunization rates).

11. COSTS FOR PARTICIPATION

There will be no costs incurred by participants.

12. PAYMENT FOR PARTICIPATION

For assisting with learning module dissemination/completion and site meeting scheduling/engagement, each vaccine champion will receive $50. For completing the monthly "PDSA Cycle" and "Practice Time & Cost" surveys for the full 6 month duration, each vaccine champion will receive $150. Payments will be in the form of an eGift card and will be e-mailed to the vaccine champion at the conclusion of the site meeting ($50) and conclusion of the 6 month intervention phase ($150). For [redacted] sites participating in the extended intervention period,

vaccine champions will be paid an additional $25 for each continued month.

Additionally, if manual chart review is necessary to obtain vaccine rates for any practice sites, each vaccine champion will receive $20 for each monthly review. Payments will be in the form of an eGift card and will be e-mailed to the vaccine champion at the conclusion of the 6 month intervention phase.

For completing the "Post-Intervention Survey" portion of the study, each subject will receive $50. Payment will be in the form of an eGift card and will be e-mailed to the subject within 6 weeks of survey completion.

13. SUBJECT WITHDRAWALS

During phase 1 of this study all health systems and affiliated practice sites agreed to participate in this quality improvement effort. While we do not anticipate a high level of subject/site withdrawals, any site wishing to end their involvement in the quality improvement initiative may do so at any time. Any practice personnel wishing to abstain from participation in quality improvement activities (trainings, ongoing meetings, adoption of new workflow procedures) are free to do so. Any vaccine champion who does not fully complete all monthly study activities during the 6 month intervention period, will still receive payment for all completed surveys prior to their withdrawal using a prorated amount. All subjects (practice personnel) are free to discontinue participation at any time, without consequence.

14. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

The following data collection and storage procedures will be implemented to ensure that subject privacy and confidentiality are maintained throughout the entirety of the research process:

Data obtained via e-mail and REDCap during the <u>training phase</u>:
(Site personnel names collected during the e-learning modules and site meetings)

The study coordinator will maintain a list of site personnel affiliated with all project locations, and those who have successfully completed their e-learning modules and who attended follow-up site meetings. These names will be obtained via e-mails from the vaccine champions and/or REDCap surveys. The lists will be stored in a password protected Excel file on a password protected computer for the purposes of confirming requests for MOC, CME and CNE credit and to track the overall level of active site participation. No additional study information (e.g., future survey responses) will be contained within this file. All files will be stored on a secure server hosted by the university. These individual-level training completion files will be deleted once they are no longer necessary (i.e., once all credit applications are in and the project has concluded). Only aggregate data, not individual names, will be stored long-term by study staff regarding the completion of online training content by site personnel (i.e., the total number of providers, nurses, and staff who did/didn't complete the training).

Data Obtained via REDCap during the intervention adoption & assessment phase:
(PDSA cycles, Time & Cost Surveys, Post-Intervention Survey)

For study measures completed via a REDCap survey, all subject names and corresponding e-mail addresses will first be collected by the study coordinator from either the health system liaisons or the assigned vaccine champions for each site. The names, e-mail addresses, site locations, role and an assigned subject ID for each person, will be stored in a password protected Excel file on a password protected computer. No additional study information (e.g., survey responses) will be contained within this file. All files will be stored on a secure server hosted by the university.

Once e-mail addresses have been obtained, the study coordinator will upload the e-mail addresses onto the secure REDCap platform. Surveys will automatically be disseminated to the appropriate subjects through REDCap programming completed by the study coordinator. Completed REDCap survey data will be exported in an Excel file and stored under double-locked conditions (password protected file) on the secure "SMDNAS Research Storage" folders, before transfer to the [redacted] Box platform for analysis by the project's [redacted] data specialists.

Data Obtained via EHRs:

EHR data reports will be generated only by the specified EHR report builder for each health system, or via manual chart review as described on page 12. A minimal number of patient-level data fields (only those needed for analyses) will be extracted from the EHRs. For data verification purposes, identified study staff will check a small percentage of patient eRecord files to ensure the accuracy of generated EHR reports. The identified individuals will have access to EHR files and will complete all appropriate eRecord training prior to conducting data verification. All individual level PHI data will be stored on either the secure [redacted] Box platform (original and final files) or the secure "SMDNAS Research Storage" folders (files currently being audited). Whenever possible, data will be stored in aggregate form.

All Research Data:

ORPA will be consulted and a Data Use Agreement (DUA) will be implemented as required between all participating health systems.

Please also see the "Human Subject Research Data Security Questionnaire" for all utilized methods of data collection/transfer/management/analyses for all study activities.

15. DATA / SAMPLE STORAGE FOR FUTURE USE

Hard copy data: Due to the online (e.g., REDCap and excel files) nature of data collection during phase 2 of the study, no hard-copy documents will be created or stored. As we are seeking a waiver of documentation of consent or waiver of consent for all portions of the study, there will be no need to store consent forms with subject names.

Electronic data:

Site Meeting Attendance:
Files containing site meeting attendance records will be stored in a password protected Excel file on a password protected computer. No additional study information (e.g., survey responses) will be contained within these files. All files will be stored on a secure server within the university system.

E-learning modules, PDSA cycles, Time & Cost Surveys, Post-Intervention Survey:
Survey data is stored immediately upon completion by the REDCap website. Study staff will then access the secure password-protected survey site to generate data reports when needed. These data reports (exported excel files) will be stored in "SMDNAS Research Storage" folders or [redacted] Box.

EHR data output:
All individual level PHI data will be stored on either the secure [redacted] Box platform (original and final files) or in the secure "SMDNAS Research Storage" folders (files currently being audited). Whenever possible, data will be stored in aggregate form. Analyzed data reports from the [redacted] data specialist will be sent in a de-identified form via secure e-mail to the project PI for review. All data will be stored 6 years beyond study completion.

16. DATA AND SAFETY MONITORING PLAN

This study presents no more than minimal risk, however there is still a risk to privacy and confidentiality. Prior to the start of phase 1, the research team from both [redacted] met to create a data safety monitoring plan. PIs, team members, and representatives from each study clinic regularly discuss communication and action plans in the unlikely event that an adverse event occurs. Information on how to contact the study team via phone, mail or email is readily apparent to all participating providers and care team members. Though adverse events are not anticipated, should any occur they will be reported to the site PI ("team leader") in each state and then to the IRB at the time of the event, and copies of all correspondence regarding the event with the IRB will be shared with the CDC, as needed.

17. DATA ANALYSIS PLAN

The primary outcome (receipt of 1+ COVID vaccine) is binary and our main explanatory variable will be an indicator for study arm. We will employ intent-to-treat analyses using generalized linear mixed models (GLMMs) with practice random effects, an approach recommended for group-randomized RCTs in which the goal is to estimate the causal effects of interventions on individuals, adjusted for clustering within groups. This method performs well in situations where the number of observations per cluster is large and for unequal cluster sizes. Models will assume a binomial distribution and a log link function in order to compare vaccination rates between study arms in terms of risk ratios. We will adjust for all practice-level variables included in the randomization balancing criterion, as well as patient-level race/ethnicity. Hypothesis tests will be two-sided with alpha = 0.05. Analyses will be performed

using SAS v. 9.4 (SAS Institute Inc., Cary, NC).

Power Analysis: We conservatively assume a control group vaccination rate of 50% (maximum variance). Adjusting for clustering of patients in practices, and assuming an intraclass correlation (ICC) of 1% (consistent with previous work), this sample size provides 80% power to detect an overall increase of 8.0 percentage point increase in vaccination rates between the QI intervention and control arms. This assumes a chi-squared test (a simplification of the planned mixed model analysis described above), an alpha of 0.05, and a sample size of 5,000 pregnant women organized into 16 practices per study arm.

Final Time/Cost Analysis:

Our two-fold cost measures are (a) total intervention cost to implement the VAX-MOM COVID program aggregated at the three health-system level under a cost analysis and (b) cost per additional COVID vaccination under a subsequent cost-effectiveness analysis. To derive a policy implication regarding the sustainability of programs, we will estimate costs and ICER estimates from the health system perspective.

Costs: To make these cost measures comparable to similar past interventions of reminders and educational programs, we will estimate cost with one-year time horizon, excluding the cost to purchase, store and administer vaccines. We will estimate the total intervention cost, summing non-personnel costs (e.g., EHR hardware, software, and materials) and personnel costs. The personnel costs will distinguish research costs from intervention costs (e.g., practice-level meeting and collecting EHR data). The dollar values of these personnel costs will be calculated by multiplying "time efforts" (weekly reported by study personnel using a REDCap email survey) with the nationally representative "hourly-wage rates" by occupation codes of study personnel, derived from the Bureau of Labor Statistics. We are using this method in an NIH-funded R01 study (the STOP-HPV study) which involves a practice-level intervention to raise HPV vaccination rates and in the original VAX-MOM study; surveys take <1 minute to complete.

Cost-Effectiveness: We will develop a standard decision model for our cost-effectiveness analyses as conducted in our past studies. The effectiveness measures are the rates of COVID vaccination estimated under Aim 2b. We will estimate incremental cost effectiveness ratios (ICERs) for the intervention defined as: $ICER\ (Study\ vs\ control) = (cost_{Study} - cost_{Control}) / (COVID\ vaccine\ rate_{Study} - COVID\ vaccine\ rate_{Control})$

In the numerator of the equation, the $cost_{Study}$ is standardized to be equal to average intervention cost per patient in a study arm to account for the potential sample size difference between study and control arms.

As explained above, this intervention cost will exclude the cost to purchase, store and administer vaccines, which is assumed to be identical among all practices. Applying the same assumption, the average cost for the control group ($cost_{Control}$) is zero. Using the developed standard decision model, we will conduct probabilistic analyses to generate point estimates and 95% CIs for ICERs and one-way sensitivity analyses to determine conditions for being lower than the thresholds of cost-effectiveness, e.g., healthcare-system based quality improvement

interventions to improve flu vaccination uptake targeting general populations (median ICER $51 among 23 interventions) and healthcare workers (median ICER $125 among 6 interventions) reported by a systematic review.

18. REFERENCES

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