Biomedical Recommendations

KEY FINDINGS: BIOMEDICAL WORKING GROUP

The Biomedical PASC/Vaccine Working Group set out to create a set of CDEs that would collectively help researchers understand the clinical course of PASC, as well as vaccine hesitancy and outcomes and its effects on pregnant/postpartum individuals and their neonates (e.g., maternal and neonatal outcomes). This aims to build on PASC CDEs once developed and focuses specifically on the pregnant/postpartum population.

Summary of Biomedical Recommendations

The Biomedical Working Group prioritized four total domains (bolded below) to guide recommendations. Each domain is made up of between one and three individual CDEs. The summaries below describe why each domain was chosen and why their underlying CDEs are important to better understanding the effects of PASC and vaccination for COVID-19 on pregnant and lactating individuals and their neonates.

COVID-19 Vaccination History: This domain, which collects information on current and past COVID-19 vaccination, gives researchers an opportunity to understand details about the administered vaccine and reasons and/or factors that contributed to vaccine hesitancy.

Vaccine Attitudes: This domain aims to understand the vaccine attitudes of pregnant/postpartum/lactating people who, especially due to limited data on the safety of COVID-19 vaccines in pregnant people from clinical trials, may have different attitudes towards vaccination than the rest of the population.

Pregnant/Postpartum: This section includes elements related to PASC, menstruation, and sexual activity to help researchers to understand the long-term effects of infection or vaccination.

Family Planning: This domain aims to provide a set of elements that can help researchers understand potential changes to menstruation and fertility.

Vaccination History

Recommended Biomedical CDEs: Post-Acute Sequelae of SARS-CoV-2 in Pregnancy and Postpartum

A subset of measures included here are designated as "Tier 2." Those without this designation-i.e., "Tier 1" measures, are recommended for all studies that may include participants of reproductive age and pregnant individuals. Tier 2 measures are suggested additional measures for studies focused exclusively on COVID-19 in pregnancy and/or for any study interested in taking a "deeper dive" in certain domains.

COVID-19 Vaccination History

Have [you/the participant] received a vaccination for COVID-19?

◯ Yes ◯ No

Have [you/the participant] completed the vaccination for COVID-19 (dose or doses)?

◯ Yes ◯ No

Enter the brand name of the COVID-19 vaccine you received (if known)

◯ AstraZeneca
◯ Janssen (Johnson & Johnson)
◯ Moderna
◯ Novavax
◯ Pfizer
◯ Other, Specify
◯ Unknown

Specify Other

____

On what date did the patient receive the first dose of the vaccine?

____

On what date did the patient receive the second dose of the vaccine?

____

[Tier 2] Did [you/the participant] receive a COVID-19 vaccine 90 days after treatment with monoclonal antibodies or 30 days after an active COVID-19 infection?

◯ Yes ◯ No ◯ Unknown ◯ Prefer not to answer

Did you experience any side effects within 2 weeks after the FIRST vaccine dose?

◯ Yes ◯ No ◯ I do not know

What side effect(s) did you experience?
(Select all that apply)

☐ Pain where shot was given
☐ Fever ?100.4F
☐ Fatigue/tiredness
☐ Headache
☐ Muscle pain in parts of your body beyond where shot was given
☐ Immediate, severe allergic reaction (including difficulty breathing and feeling faint, nausea and/or vomiting)
☐ Skin rash
☐ Facial swelling
☐ Other (please describe)

Describe other side effect(s)

Did you experience any side effects within 2 weeks after the SECOND vaccine dose?

◯ Yes ◯ No ◯ I do not know

What side effect(s) did you experience?
(Select all that apply)

☐ Pain where shot was given
☐ Fever ?100.4F
☐ Fatigue/tiredness
☐ Headache
☐ Muscle pain in parts of your body beyond where shot was given
☐ Immediate, severe allergic reaction (including difficulty breathing and feeling faint, nausea and/or vomiting)
☐ Skin rash
☐ Facial swelling
☐ Other (please describe)

Describe other side effect(s)

[Tier 2] Medications taken to treat symptoms post-vaccine
(select all that apply)

☐ Ibuprofen
☐ Acetaminophen
☐ Aspirin
☐ Antihistamines
☐ Other, specify
☐ None

Specify other medication

____

If not vaccinated, Why? (Select ONE best reason)

◯ The vaccine is not available to me
◯ Doctor did not recommend it
◯ My family did not want me to take it
◯ It was not well tested in ethnically diverse people
◯ It was not well tested among pregnant individuals
◯ I cannot afford the vaccine
◯ I have not had time to get it
◯ I'm at low risk and do not need it
◯ It is riskier to go get the vaccine than staying at home
◯ Worried about side effects
◯ The vaccine's technology hasn't been tested enough
◯ Vaccine was approved too fast
◯ No long-term safety data available
◯ Concerned about vaccine storage
◯ Already had COVID-19
◯ Other, specify

Specify other reason

____

Do you intend to receive a coronavirus (COVID-19) vaccine?

◯ I intend to get it as soon as possible
◯ I intend to wait to see how it affects others in the community before I get it
◯ I do not intend on getting it soon, but might sometime in the future
◯ I do not intend to ever get the vaccine

[Tier 2] Is there anything that might convince you to change your mind about getting vaccinated?

(Based on those who would definitely not get the COVID-19 vaccine)

◯ No/Nothing
◯ More research
◯ If it were mandatory/required
◯ Other
◯ Do not know

Vaccination Attitudes Examination Vax Scale

[Tier 2] Please select how much you agree or disagree with the following statements about vaccines in general

	Strongly Agree	Agree	Slightly Agree	Slightly Disagree	Disagree	Strongly Disagree
1. I feel safe after being vaccinated.	○	○	○	○	○	○
2. Natural immunity lasts longer than a vaccination.	○	○	○	○	○	○
3. Vaccines can cause unforeseen problems.	○	○	○	○	○	○
4. Vaccines make a lot of money for pharmaceutical companies, but do not do much for regular people.	○	○	○	○	○	○
5. I worry about the unknown effects of vaccines in the future.	○	○	○	○	○	○
6. I feel protected after getting vaccinated.	○	○	○	○	○	○
7. Natural exposure to viruses and germs gives the safest protection.	○	○	○	○	○	○
8. Although most vaccines appear to be safe, there may be problems that we have not yet discovered.	○	○	○	○	○	○
9. Being exposed to diseases naturally is safer for the immune system than being exposed through vaccination.	○	○	○	○	○	○
10. Vaccination programs are a big con.	○	○	○	○	○	○
11. I can rely on vaccines to stop serious infectious diseases.	○	○	○	○	○	○
12. Authorities promote vaccination for financial gain, not for people's health.	○	○	○	○	○	○

Do you personally know someone who has been vaccinated for COVID-19? ◯ Yes ◯ No ◯ Do not know

[Tier 2] How much of a threat, if any, is the coronavirus outbreak for...

	A major threat	A minor threat	Not a threat
United States economy?	◯	◯	◯
Your personal health?	◯	◯	◯
Your personal financial situation?	◯	◯	◯

	Very concerned	Somewhat concerned	Not too concerned	Not at all concerned
[Tier 2] How concerned are you that you might spread the virus without knowing you have it?	◯	◯	◯	◯

[Tier 2] Do you personally know someone who has been hospitalized or died as a result of having COVID-19 (coronavirus)? ◯ Yes ◯ No

[Tier 2] Given the current situation with the coronavirus outbreak, would you feel comfortable or uncomfortable doing each of the following?

	Totally comfortable	Mostly comfortable	Slightly uncomfortable	Very uncomfortable
Visiting with a close friend or family member inside their home	◯	◯	◯	◯
Going to the grocery store	◯	◯	◯	◯
Eating out in a restaurant	◯	◯	◯	◯
Taking a flight	◯	◯	◯	◯
Attending an indoor sporting event or concert	◯	◯	◯	◯
Attending a crowded party	◯	◯	◯	◯
Going to a hair salon	◯	◯	◯	◯
Going to the gym or indoor recreation?	◯	◯	◯	◯

[Tier 2] How often do you wear a mask in public buildings?

◯ All or most of the time
◯ Some of the time
◯ Hardly ever
◯ Never

[Tier 2] Have you asked your health care provider about the vaccine?

◯ Yes ◯ No ◯ Do not know

Having gotten your COVID-19 vaccine, do you think you will now......?
(Based on those who have gotten at least one dose of the COVID-19 vaccine)

◯ Strictly follow social distancing guidelines
◯ Probably follow most social distancing guidelines
◯ No longer follow social distancing guidelines
◯ Don't know

[Tier 2] Which of the following applies to your plans about the COVID-19 vaccine for your child(ren)?

◯ I plan on getting the COVID-19 vaccine for my child(ren) as soon as it is available
◯ I plan on getting the COVID-19 vaccine for my child(ren) eventually
◯ I do not plan on getting the COVID-19 vaccine for my child(ren)
◯ I am unsure

How concerned are you, if at all, that...

	Very concerned	Somewhat concerned	Not too concerned	Not at all concerned	Don't know
The COVID-19 vaccines are not as safe as they are said to be	◯	◯	◯	◯	◯
You might experience serious side effects from the COVID-19 vaccine	◯	◯	◯	◯	◯

Do you feel you have enough information about...

	Have enough information	Do not have enough information	Don't know
The potential side effects of the COVID-19 vaccine	◯	◯	◯
Where you will be able to get a COVID-19 vaccine	◯	◯	◯
When you will be able to get the COVID-19 vaccine	◯	◯	◯

Pregnant Postpartum

Note: for researchers studying COVID-19 in pregnancy or any study enrolling participants of reproductive age, please note the elements below should be considered in addition to the biomedical and psychosocial elements for pregnant individuals which can be found here: Promoting Data Harmonization to Accelerate COVID -19 Pregnancy Research report.

Long COVID
Post-acute readmission
Note: If the following questions are included in the PASC Adult Questionnaire, please skip the following two questions.

Were [you/the participant] admitted to the hospital for a possible complication of COVID-19 after the acute illness? ○ Yes ○ No

If yes, date of (re)admission __________________________

☐ Unknown date of (re)admission

New diagnosis of illness or complication related to COVID-19

Were [you/the participant] newly diagnosed with any illness or complication related to COVID-19?

☐ Cardiovascular
☐ Dermatological
☐ Endocrine
☐ Gastro-intestinal
☐ Other Generic
☐ Musculoskeletal
☐ Mental Health
☐ Neurological
☐ Pulmonary
☐ Renal

Menses Menstruation Changes

Have you had any periods (menstrual cycles) in the last 3 months?

(We mean bleeding for which you needed a tampon or sanitary pad, NOT discharge (spotting) for which you needed a panty liner only)

◯ Yes ◯ No

If you have NOT had periods in the last 3 months:

What was the reason for not having periods?

☐ Taking hormones continuously (e.g. the Pill, injections, Mirena, HRT)
☐ Pregnant/breastfeeding
☐ Unsure
☐ Other (Please describe)

Describe other reason

____

The figure below shows examples of the amount of bleeding you can experience every four hours during your period (menstrual cycle).

Please describe the amount of bleeding you typically experience at its heaviest, and on average.

At its heaviest?

______

______

On average?

______

We are interested in what your period (menstrual cycle) was like when you were NOT using hormonal contraception (the Pill, patch, ring, injection or hormonal IUD).

For each time period, please tell us if you had periods and what they were like. If you did not have periods or were using hormonal contraception the whole time, please enter the code for "no" or "used hormonal contraception" in the first row and then skip the rest of the column.

Please answer each question in the appropriate column [3 Months] Pre-COVID diagnosis (skip if you have not been diagnosed) Post-COVID diagnosis (skip if you have not been diagnosed)

Did you have natural periods during this time period? (not on hormonal contraception) ______

If 1 entered above, please complete questions below

______

If 1 entered above, please complete questions below

Were your periods regular when not using hormonal contraception? ______ ______

How many days of bleeding did you usually have each period when not using hormonal contraception? (Not counting discharge or spotting for which you needed a panty liner only) ______

______

______

______

How heavy was your menstrual flow at its heaviest and on average, when not using hormonal contraception?

Please use the figure on the previous page to describe the amount of bleeding that you typically experienced every four hours.

At its heaviest:

______

At its heaviest:

______

On average:

______

On average:

______

On average, how many days were there between the start of one period and the start of the next, when not using hormonal contraception? ______ ______

Please answer each question in the appropriate column [3 Months] Pre-Vaccine (skip if you have not been vaccinated) Post-Vaccine (skip if you have not been vaccinated)
Did you have natural periods during this time period? (not on hormonal contraception) ______

If 1 entered above, please complete questions below

______

If 1 entered above, please complete questions below

Were your periods regular when not using hormonal contraception? ______ ______
How many days of bleeding did you usually have each period when not using hormonal contraception?

(Not counting discharge or spotting for which you needed a panty liner only)

______

______

______

______

How heavy was your menstrual flow at its heaviest and on average, when not using hormonal contraception?

Please use the figure on the previous page to describe the amount of bleeding that you typically experienced every four hours.

At its heaviest:______

At its heaviest:______

On average:______

On average:______

On average, how many days were there between the start of one period and the start of the next, when not using hormonal contraception? ______ ______

Has there been a time in your life pre-COVID 19 vaccine or COVID-19 diagnosis when you typically had pelvic pain during your periods?	◯ No pain ◯ Mild cramps (medication never or rarely needed) ◯ Moderate cramps (medication usually needed) ◯ Severe cramps (medication and bed rest needed)
At what age did you start having period pain?	______________________________
Has there been a time in your life post-COVID 19 vaccine when you typically had pelvic pain during your periods?	◯ No pain ◯ Mild cramps (medication never or rarely needed) ◯ Moderate cramps (medication usually needed) ◯ Severe cramps (medication and bed rest needed)

Family Planning

For each time period, please answer the questions below

Please think about the following questions... [3 months] Pre-COVID diagnosis (skip if you have not been diagnosed) Post-COVID diagnosis (skip if you have not been diagnosed)
Have you had vaginal sex, even once? ______ ______
How many times have you had vaginal sex?

Your best guess is okay

______

______

______

______

In the past 3 months, have you had vaginal sex without you or your partner using any methods of birth control?

Types of birth control listed in drop-down below.

______ ______
How many times have you had vaginal sex without you or your partner using any of these methods of birth control?

______

______

______

______

Please think about the following questions... [3 months] Pre-Vaccine (skip if you have not been vaccinated) Post-Vaccine (skip if you have not been vaccinated)
Have you had vaginal sex, even once? ______ ______
How many times have you had vaginal sex?

Your best guess is okay

______

______

______

______

In the past 3 months, have you had vaginal sex without you or your partner using any methods of birth control?

Types of birth control listed in drop-down below.

______ ______
How many times have you had vaginal sex without you or your partner using any of these methods of birth control?

______

______

______

Types of Birth Control

Types of birth control

- ◯ Birth control pills
- ◯ Condom
- ◯ Partner's vasectomy
- ◯ Female sterilizing operation, such as tubal sterilization and hysterectomy
- ◯ Withdrawal, pulling out
- ◯ Depo-Provera, injectables
- ◯ Hormonal implant (Norplant , Implanon, or Nexplanon)
- ◯ Calendar rhythm, Standard Days, or Cycle Beads method
- ◯ Safe period by temperature or cervical mucus test (Two Day, Billings Ovulation, or Sympto-thermal Method)
- ◯ Diaphragm
- ◯ Female condom, vaginal pouch
- ◯ Foam
- ◯ Jelly or cream
- ◯ Cervical cap
- ◯ Suppository, insert
- ◯ Today sponge
- ◯ Intrauterine device (IUD), coil, loop (Mirena, Paraguard)
- ◯ Emergency Contraception
- ◯ Respondent was sterile
- ◯ Respondent's partner was sterile
- ◯ Lunelle injectable (monthly shot)
- ◯ Contraceptive patch
- ◯ Vaginal contraceptive ring
- ◯ Other method (please specify)

Please specify ______________________________

START Time to Pregnancy Assessment

Think about the 12 months before you were diagnosed with COVID-19:

Were you pregnant during that time? ◯ Yes ◯ No

Were you trying to become pregnant during that time? ◯ Yes ◯ No

How many months of trying did it take you to get pregnant? ______________________________ (months)

How many months did you try but not get pregnant? ______________________________ (months)

Now think about the 12 months after you were diagnosed with COVID-19:

Were you pregnant during that time? ◯ Yes ◯ No

Were you trying to become pregnant? ◯ Yes ◯ No

How many months of trying did it take you to get pregnant? ____________ (months)

How many months did you try but not get pregnant? ____________ (months)

Think about the 12 months before you received the COVID-19 vaccine:

Were you pregnant during that time? ◯ Yes ◯ No

Were you trying to become pregnant during that time? ◯ Yes ◯ No

How many months of trying did it take you to get pregnant? ____________ (months)

How many months did you try but not get pregnant? ____________ (months)

Now think about the 12 months after you received the COVID-19 vaccine:

Were you pregnant during that time? ◯ Yes ◯ No

Were you trying to become pregnant during that time? ◯ Yes ◯ No

How many months of trying did it take you to get pregnant? ____________ (months)

How many months did you try but not get pregnant? ____________ (months)

To view all of the recommended measures below, download the PDF here:

[Attachment: "PASC Biospecimans Recommended Measures.pdf"]

Tier 1 Biospecimens (Neonate)

Neonate

______

Collection

______

Timing

______

Storage

______

Sample Analyses

______

Neonatal Respiratory Specimens

______

Collection

______

Timing

______

Storage

______

Analyses

______

Tier 1 Biospecimens (Maternal)

Maternal Blood

______

Collection

______

Timing

______

Storage

______

Sample Analyses

______

Cord Blood

______

Collection

______

Timing

______

Storage

______

Sample Analyses

______

Placenta

______

Collection

______

______

Fixed Tissue Collection

Timing

Storage

Sample Analyses

Maternal Side Biopsy and Fetal Side Biopsy

Timing

Storage

Sample Analyses

Colostrum and/or mature milk

Collection

Timing

Storage

Sample Analyses

Tier 2 Expanded Specimen Collection (Maternal)

Maternal Respiratory Specimens

Collection

Timing

Storage

Sample Analyses

Maternal Blood

Collection

Plasma, Buffy Coat, PBMC, Serum

Timing

Storage

Sample Analyses

PaxGene tube

Timing

Storage

Sample Analyses

Cord Blood

Collection

PBMC

Timing

Storage

Sample Analyses

PaxGene tube

Timing

Storage

Sample Analyses

Placenta

Collection

Maternal side placental biopsy and Fetal side placental biopsy

Timing

Storage

Sample Analyses

Full thickness biopsies or Remaining whole placenta

Timing

Storage

Sample Analyses

Breastmilk

Collection

Timing

Storage

Sample Analyses

Tier 3 (Maternal)

Saliva (Tier 3)

Collection Method

Timing

Storage

Sample Analyses

Placenta

Collection Method

Maternal biopsy and Fetal side biopsy

Timing

Storage

Sample Analyses

Full thickness biopsies or Remaining whole placenta

Timing

Storage

Sample Analyses

Membrane or decidua basalis

Timing

Storage

Sample Analyses

Recommended Psychosocial Cdes

Important Postpartum Pre-Questions:

Many of the recommended elements below are specific to the postpartum period and are framed in a way that assumes there is a surviving newborn living with the birthing person.

If either or both of the two questions below is answered "No" the items marked with "*" below should not be asked out of sensitivity to the participant.**

Is your baby alive now?
- ◯ Yes
- ◯ No - We are very sorry for your loss

Is your baby living with you now?
◯ Yes ◯ No

Pregnancy and Postpartum Function

Pregnancy - Physical Function

The following questions ask about how much you have experienced some feelings about your current pregnancy.

During the last two weeks:

	Not at all	A little	A moderate amount	Very much	An extreme amount
To what extent have you felt that your physical changes associated with this pregnancy do not allow you to do what you need?	◯	◯	◯	◯	◯
How worried have you been about not being able to perform activities around the house?	◯	◯	◯	◯	◯
How worried have you been about carrying out the pregnancy successfully?	◯	◯	◯	◯	◯
How worried have you been about not being able to handle labor and delivery?	◯	◯	◯	◯	◯
Have you been forced to cut down on your physical activity?	◯	◯	◯	◯	◯

Pregnancy - Psychological Function

The following questions focus on your feelings about some areas of life in the last two weeks.

	Not at all	A little	A moderate amount	Very much	An extreme amount
To what extent have you felt that your psychological changes associated with this pregnancy do not allow you to do what you need?	○	○	○	○	○

	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
How satisfied are you with how you have managed to adapt to this pregnancy ?	○	○	○	○	○

Postpartum Function - Infant Care Responsibilities

Please select the item that indicates to what extent you can perform the following aspects of your new baby's care:

	Not at all	Some days	Most days	All the time
Daytime feedings	○	○	○	○
Night feedings	○	○	○	○
Bathe the baby	○	○	○	○
Change diapers	○	○	○	○
Change the baby's clothes	○	○	○	○
Play with the baby	○	○	○	○

During the past 2 weeks, have you had any health conditions that made it hard or impossible to take care of your baby? ○ Yes ○ No

Postpartum Function - Household Activities

Please select the item that indicates to what extent you can perform the following household activities even if you don't routinely do them:

	Not at all	Some days	Most days	All the time
Care of family/household members	○	○	○	○
Cleaning the house	○	○	○	○
Tidying the house (making beds, picking up things, etc.)	○	○	○	○

Laundry	○	○	○	○
Doing dishes	○	○	○	○
Cooking	○	○	○	○
Household business (paying bills, banking, etc.)	○	○	○	○
Grocery shopping	○	○	○	○
Shopping, other than groceries. Doing errands	○	○	○	○
Heavy housework and maintenance work (seasonal cleaning, painting, etc.)	○	○	○	○

Infant Care Practices

Healthcare (infant)

Do you have health insurance or Medicaid for your new baby? ○ Yes ○ No

Has your new baby gone as many times as you wanted for a well-baby checkup? ○ Yes ○ No

Did any of these things keep your baby from having a well-baby checkup? Check ALL that apply.

☐ I didn't have enough money or health insurance to pay for the visit(s)
☐ I had no way to get my baby to the clinic or doctor's office
☐ I didn't have anyone to take care of my other children
☐ I couldn't get an appointment
☐ My baby was too sick to go for a well-baby checkup
☐ I was too sick to take my baby for a well-baby checkup
☐ I was too tired to take my baby for a well-baby checkup
☐ Other. Please tell us:

Specify other ______________________________

Has your new baby gone for care when he or she was sick (not including well-baby checkups)?
○ Yes
○ No
○ My baby has not been sick
○ My baby is still in the hospital

Enter number of times ______________________________

Has your new baby gone for care as many times as you wanted when he or she was sick? ○ Yes ○ No

Did any of these things keep you from taking your baby for care when he or she was sick?

Check ALL that apply.

☐ I didn't have enough money or health insurance to pay for the visit
☐ I couldn't get an appointment
☐ I didn't have a regular doctor for my baby
☐ I had no way to get my baby to the clinic or doctor's office
☐ I didn't have anyone to take care of my other children
☐ I was too sick to take my baby for care
☐ I was too tired to take my baby for care
☐ Other - please tell us ________

Specify other ______________________________

Breastfeeding

Did you ever breastfeed or pump breast milk to feed your new baby, even for a short period of time?
◯ No [skip remaining breastfeeding questions]
◯ Yes

Are you currently breastfeeding or feeding pumped milk to your new baby?
◯ No
◯ Yes [skip remaining breastfeeding questions]

Did you breastfeed as long as you wanted to? ◯ Yes ◯ No

What were your reasons for stopping breastfeeding?

Check ALL that apply.

☐ My baby had difficulty latching or nursing
☐ Breast milk alone did not satisfy my baby
☐ I thought my baby was not gaining enough weight
☐ My nipples were sore, cracked, or bleeding or it was too painful
☐ I thought I was not producing enough milk, or my milk dried up
☐ I had too many other household duties
☐ I felt it was the right time to stop breastfeeding
☐ I got sick or I had to stop for medical reasons
☐ I was too tired
☐ I did not want to breastfeed anymore
☐ I went back to work
☐ I went back to school
☐ My husband or partner did not support breastfeeding
☐ My baby was jaundiced (yellowing of the skin or whites of the eyes)
☐ Other. Please tell us:

Specify other ______________________________

Infant Sleeping Habits

In the last 2 weeks, what is the typical amount of time your baby sleeps at night without waking up?

- ◯ 2 hours or less
- ◯ 3 - 4 hours
- ◯ 5 - 6 hours
- ◯ 7 - 8 hours
- ◯ 8 hours or more

START Brief Infant Sleep Questionnaire (BISQ)

[Tier 2] The following questions relate to how your baby [youngest child] sleeps.

Infant/child DOB

____

Biological Sex at Birth

- ◯ Male
- ◯ Female
- ◯ Don't know

Sleeping arrangement

- ◯ Infant crib in a separate room
- ◯ Infant crib in parents' room
- ◯ In parents' bed
- ◯ Infant crib in room with sibling
- ◯ Other, Specify:

Specify Other

____

In what position does your baby sleep most of the time?

- ◯ On his/her belly
- ◯ On his/her side
- ◯ On his/her back

How much time does your baby spend in sleep during the NIGHT (between 7 in the evening and 7 in the morning)?

Hours:

____

Minutes

____

How much time does your baby spend in sleep during the DAY (between 7 in the morning and 7 in the evening)?

Hours

____

Minutes

____

Average number of night wakings per night:

____

How much time during the night does your baby spend in wakefulness (from 10 in the evening to 6 in the morning)?

Hours

____

Minutes

____

How long does it take to put your baby to sleep in the evening?

Hours

____

Minutes

____

How does your baby fall asleep?

- ◯ While feeding
- ◯ Being rocked
- ◯ Being held
- ◯ In bed alone
- ◯ In bed near parent

When does your baby usually fall asleep for the night:

Hour

____

Minute

____

Do you consider your baby's sleep as a problem?

- ◯ A very serious problem
- ◯ A moderate problem
- ◯ A small problem
- ◯ A very small problem
- ◯ Not a problem at all

[Tier 2] Feelings of Attachment to Newborn
Postpartum Only

This is the Impaired Bonding subscale (Factor/Scale 1) of the full Postpartum Bonding Questionnaire (PBQ). Please indicate how often the following are true for you. There are no 'right' or 'wrong' answers. Choose the answer which seems right in your recent experience

	Always	Very often	Quite often	Sometimes	Rarely	Never
I feel close to my baby	◯	◯	◯	◯	◯	◯
I wish the old days when I had no baby would come back	◯	◯	◯	◯	◯	◯
The baby doesn't seem to be mine	◯	◯	◯	◯	◯	◯
My baby winds me up	◯	◯	◯	◯	◯	◯
I love my baby to bits	◯	◯	◯	◯	◯	◯
I feel happy when my baby smiles or laughs	◯	◯	◯	◯	◯	◯

My baby irritates me	○	○	○	○	○	○
My baby cries too much	○	○	○	○	○	○
I feel trapped as a mother	○	○	○	○	○	○
I resent my baby	○	○	○	○	○	○
My baby is the most beautiful baby in the world	○	○	○	○	○	○
I wish my baby would somehow go away	○	○	○	○	○	○

Childcare and Education

Number of household members

How many total people live in your household now including yourself?

Please indicate the number of people living in your household:

____

Please indicate the number of people under 18 years-old living in your household:

____

Impact of Pandemic on Childcare

How has the COVID-19 outbreak affected your regular childcare? (Mark all that apply)

- ☐ I had difficulty arranging for childcare
- ☐ I had to pay more for childcare
- ☐ My spouse/partner or I had to change our work schedule to care for our children ourselves
- ☐ My regular childcare has not been affected by the COVID-19 outbreak
- ☐ I do not have a child in childcare

[Tier 2] Impact of Pandemic on Children's Education

What is your household's current situation for childcare and/or schooling? (select all that apply)

- ☐ I or someone in my household care for my child(ren) full-time
- ☐ I or someone in my household care for my child(ren) part-time
- ☐ I or someone in my household try to balance childcare/home schooling and work/telework responsibilities at home
- ☐ Someone from outside my household (friend, family, nanny) cares for my child(ren) in my home
- ☐ My child(ren) goes to a childcare center or someone else's home for childcare
- ☐ My child(ren) does not need childcare; they take care of themselves
- ☐ My child(ren) goes to school in-person
- ☐ My child(ren) goes to school virtually (online)

Attribution of Symptoms

Listed below are conditions you may or may not have ever experienced.

For each condition, please select 'Not at all', 'Somewhat', 'Quite a bit', or 'A great deal' next to each reason that corresponds to how much that might explain your condition.

In addition, please answer whether you have had the condition in the last 3 months.

Please answer all questions.

If I had a prolonged headache, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I am emotionally upset	○	○	○	○
There is something wrong with muscles nerves or brain	○	○	○	○
A loud noise, bright light or something else has irritated me	○	○	○	○
It's an effect of living during a pandemic	○	○	○	○
It's part of being pregnant	○	○	○	○
It's part of being postpartum	○	○	○	○
I have acute COVID-19	○	○	○	○
I have "long COVID"	○	○	○	○

Have you had a prolonged headache in the last 3 months? ○ Yes ○ No

If I was sweating a lot, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I must have a fever or infection	○	○	○	○
I'm anxious or nervous	○	○	○	○
The room is too warm, I'm overdressed or working too hard	○	○	○	○
It's an effect of living during a pandemic	○	○	○	○
It's part of being pregnant	○	○	○	○
It's part of being postpartum	○	○	○	○
I have acute COVID-19	○	○	○	○
I have "long COVID"	○	○	○	○

Have you noticed yourself sweating a lot in the last 3 months? ○ Yes ○ No

If I got dizzy all of a sudden, I would probably think it is because:

	Not at all	Somewhat	Quite a bit	A great deal
There is something wrong with my heart or blood pressure	◯	◯	◯	◯
I am not eating enough or I got up too quickly	◯	◯	◯	◯
I must be under a lot of stress	◯	◯	◯	◯
It's an effect of living during a pandemic	◯	◯	◯	◯
It's part of being pregnant	◯	◯	◯	◯
It's part of being postpartum	◯	◯	◯	◯
I have acute COVID -19	◯	◯	◯	◯
I have "long COVID"	◯	◯	◯	◯

Have you felt dizzy in the last 3 months? ◯ Yes ◯ No

If I noticed my mouth was dry, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I must be scared or anxious about something	◯	◯	◯	◯
I need to drink more liquids	◯	◯	◯	◯
There is something wrong with my salivary glands	◯	◯	◯	◯
It's an effect of living during a pandemic	◯	◯	◯	◯
It's part of being pregnant	◯	◯	◯	◯
It's part of being postpartum	◯	◯	◯	◯
I have acute COVID -19	◯	◯	◯	◯
I have "long COVID"	◯	◯	◯	◯

Have you had a dry mouth in the last 3 months? ◯ Yes ◯ No

If I felt my heart pounding in my chest, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I've exerted myself or drunk a lot of coffee	◯	◯	◯	◯
I must be excited or afraid	◯	◯	◯	◯
There must be something wrong with my heart	◯	◯	◯	◯
It's an effect of living during a pandemic	◯	◯	◯	◯

It's part of being pregnant	◯	◯	◯	◯
It's part of being postpartum	◯	◯	◯	◯
I have acute COVID -19	◯	◯	◯	◯
I have "long COVID"	◯	◯	◯	◯

Have you noticed your heart pounding in the last 3 months? ◯ Yes ◯ No

If I feel fatigued, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I'm emotionally exhausted or discouraged	◯	◯	◯	◯
I've been over-exerted myself or not exercising enough	◯	◯	◯	◯
I'm anemic or my blood is weak	◯	◯	◯	◯
It's an effect of living during a pandemic	◯	◯	◯	◯
It's part of being pregnant	◯	◯	◯	◯
It's part of being postpartum	◯	◯	◯	◯
I have acute COVID -19	◯	◯	◯	◯
I have "long COVID"	◯	◯	◯	◯

Have you felt fatigued in the last 3 months? ◯ Yes ◯ No

If I noticed my hand trembling, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I must have some sort of neurological problem	◯	◯	◯	◯
I'm very nervous	◯	◯	◯	◯
The muscles in my hand are tired	◯	◯	◯	◯
It's an effect of living during a pandemic	◯	◯	◯	◯
It's part of being pregnant	◯	◯	◯	◯
It's part of being postpartum	◯	◯	◯	◯
I have acute COVID -19	◯	◯	◯	◯
I have "long COVID"	◯	◯	◯	◯

Have you noticed your hands trembling in the last 3 months? ◯ Yes ◯ No

If I had trouble sleeping, I would probably think that is it because:

	Not at all	Somewhat	Quite a bit	A great deal
Some kind of pain or physical discomfort is keeping me awake	◯	◯	◯	◯
I'm not tired or I had too much coffee	◯	◯	◯	◯
I'm worrying too much or I must be nervous about something	◯	◯	◯	◯
It's an effect of living during a pandemic	◯	◯	◯	◯
It's part of being pregnant	◯	◯	◯	◯
It's part of being postpartum	◯	◯	◯	◯
I have acute COVID -19	◯	◯	◯	◯
I have "long COVID"	◯	◯	◯	◯

Have you had trouble sleeping in the last 3 months? ◯ Yes ◯ No

If my stomach was upset, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I've worried myself sick	◯	◯	◯	◯
I have the flu or stomach irritation	◯	◯	◯	◯
I've had something to eat that did not agree with me	◯	◯	◯	◯
It's an effect of living during a pandemic	◯	◯	◯	◯
It's part of being pregnant	◯	◯	◯	◯
It's part of being postpartum	◯	◯	◯	◯
I have acute COVID -19	◯	◯	◯	◯
I have "long COVID"	◯	◯	◯	◯

Have you had an upset stomach in the last 3 months? ◯ Yes ◯ No

If I lost my appetite, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I've been eating too much or my body doesn't need as much food as before	◯	◯	◯	◯
I'm worrying so much that food doesn't taste good any more	◯	◯	◯	◯
I have some stomach or intestinal problem	◯	◯	◯	◯

It's an effect of living during a pandemic	○	○	○	○
It's part of being pregnant	○	○	○	○
It's part of being postpartum	○	○	○	○
I have acute COVID -19	○	○	○	○
I have "long COVID"	○	○	○	○

Have you lost your appetite in the last 3 months? ○ Yes ○ No

If I had a hard time catching my breath, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
My lungs are congested from infection, irritation, or heart trouble	○	○	○	○
The room is stuffy or there is too much pollution in the air	○	○	○	○
I'm over excited or anxious	○	○	○	○
It's an effect of living during a pandemic	○	○	○	○
It's part of being pregnant	○	○	○	○
It's part of being postpartum	○	○	○	○
I have acute COVID -19	○	○	○	○
I have "long COVID"	○	○	○	○

Have you had a hard time catching your breath in the last 3 months? ○ Yes ○ No

If I noticed numbness or tingling in my hands or feet, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
I'm under emotional stress	○	○	○	○
There is something wrong with my nerves or blood circulation	○	○	○	○
I am cold or my hand or foot went to sleep	○	○	○	○
It's an effect of living during a pandemic	○	○	○	○
It's part of being pregnant	○	○	○	○
It's part of being postpartum	○	○	○	○
I have acute COVID -19	○	○	○	○
I have "long COVID"	○	○	○	○

Have you had numbness or tingling in your hands or feet in the last 3 months? ○ Yes ○ No

If I was constipated or irregular, I would probably think that it is because:

	Not at all	Somewhat	Quite a bit	A great deal
There is not enough fruit or fiber in my diet	○	○	○	○
Nervous tension is keeping me from being regular	○	○	○	○
There is something wrong with my bowels or intestines	○	○	○	○
It's an effect of living during a pandemic	○	○	○	○
It's part of being pregnant	○	○	○	○
It's part of being postpartum	○	○	○	○
I have acute COVID-19	○	○	○	○
I have "long COVID"	○	○	○	○

Have you been constipated or irregular in the last 3 months? ○ Yes ○ No

Domestic Violence

In the last 12 months, how often has a partner or spouse...

	Never	Almost never	Sometimes	Fairly often	Very often
Yelled at you or said things to you that made you feel bad about yourself, embarrassed you in front of others, or frightened you?	○	○	○	○	○
Done things like push, grab, hit, slap, kick, or throw things at you during an argument or because they were angry with you?	○	○	○	○	○

Access to Care

Prenatal Care

Did you get prenatal care as early in your pregnancy as you wanted? ○ Yes ○ No

Did any of these things keep you from getting prenatal care when you wanted it? For each item, check No or Yes

a. I couldn't get an appointment when I wanted one	◯ Yes	◯ No
b. I didn't have enough money or insurance to pay for my visits	◯ Yes	◯ No
c. I didn't have any transportation to get to the clinic or doctor's office	◯ Yes	◯ No
d. The doctor or my health plan would not start care as early as I wanted	◯ Yes	◯ No
e. I had too many other things going on	◯ Yes	◯ No
f. I couldn't take time off from work or school	◯ Yes	◯ No
g. I didn't have my Medicaid < or state Medicaid name> card	◯ Yes	◯ No
h. I didn't have anyone to take care of my children	◯ Yes	◯ No
i. I didn't know that I was pregnant	◯ Yes	◯ No
j. I didn't want anyone else to know I was pregnant	◯ Yes	◯ No
k. I didn't want prenatal care	◯ Yes	◯ No
l. I did not feel well enough to go to the appointment	◯ Yes	◯ No
m. I was too tired to keep the appointment	◯ Yes	◯ No

Postpartum Care

Since your pregnancy ended, have you had a postpartum checkup for yourself? A postpartum checkup is the regular checkup a person has about 4-6 weeks after giving birth — ◯ Yes ◯ No

Did any of these things keep you from having a postpartum checkup? Check ALL that apply.

- ☐ I didn't have health insurance to cover the cost of the visit
- ☐ I felt fine and did not think I needed to have a visit
- ☐ I couldn't get an appointment when I wanted one
- ☐ I didn't have any transportation to get to the clinic or doctor's office
- ☐ I had too many things going on
- ☐ I couldn't take time off from work
- ☐ I arrived late at my appointment and they cancelled it
- ☐ I was too sick to go for a checkup
- ☐ I was too tired to go for a checkup
- ☐ My baby was too sick to go for a checkup
- ☐ Other - Please tell us:

Specify other ______________________________