International Journal of Vaccine Theory, Practice, and Research
IJVTPR

# *Menstrual Abnormalities Strongly Associated with Proximity to COVID-19 Vaccinated Individuals*

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## Abstract

In Spring 2021, MyCycleStory[SM] launched a secure online survey to which 92.3% of 6049 respondents self-reported menstrual irregularities occurring after the rollout of the COVID-19 injectables. Each respondent served as her own control because prior to the rollout of COVID-19 vaccination, the vast majority had regular menstrual cycles. A subgroup of 3390 respondents were only *indirectly exposed* to COVID-19 vaccines or the SARS-CoV-2 virus. This subgroup reported 1) being unvaccinated for COVID-19; 2) having had no COVID-19 symptoms; and 3) no positive test for COVID-19, yet a substantial majority of these women, who were only *indirectly exposed* to COVID-19 injectables or COVID-19 infections still had many of the same menstrual abnormalities as the 2659 women who were *directly exposed* to a COVID-19 injection (798), or had COVID-19 symptoms (1347), or tested positive for COVID-19 (514). Generalized linear mixed modeling was used to examine the association

(not assuming causation) between abnormal menses experienced after the COVID-19 vaccine rollout by respondents who were only *indirectly exposed* by some degree of proximity to persons. Chi-Square, Student's *t*, Kruskal-Wallis or ANOVA tests were used to assess the statistical significance of the similarities of menstrual irregularities reported by the *directly exposed* and *indirectly exposed* groups. The mean age of the entire cohort was 37.8 ± 0.1 years. The percentage of the indirectly exposed participants who reported being within 6 feet of a COVID-19 vaccinated person was 85.5%. Of these, 71.7% had irregular menstrual symptoms within one week and 50.1% had irregular menstrual symptoms within ≤3 days after exposure. When comparing daily proximity to a vaccinated person, the categories of "daily within 6 feet outside the household" versus "seldom/sometimes/daily outside 6 feet" had the highest relative risk at 1.34 ($p$<0.01) for heavier menstrual bleeding, early menses at more than 7 days early with a relative risk at 1.28 ($p$=0.03), and extended bleeding for more than 7 days with relative risk at 1.26 ($p$=0.04). Indirect exposure to COVID-19 vaccinated persons was significantly associated with the likelihood of the onset of menstrual irregularities. This study provides additional data to complement a growing body of evidence raising concerns regarding the safety of mRNA vaccines.

**Keywords:** *abnormal menses, COVID-19 shedding, COVID-19 transmission, COVID-19 vaccines, menses irregularities, menstrual abnormalities, menstrual bleeding, mRNA spike protein, mRNA vaccines*

## Introduction

### *The mRNA "Vaccines"*

Administration of SARS CoV-2 mRNA vaccines began in the United States (US) on December 14, 2020, reaching 75.1 million doses administered by the end of February 2021 (Our World In Data 2023). These novel gene-based therapies were developed as countermeasures under the umbrella of Operation Warp Speed (OWS), a conglomerate of governmental health, security and defense agencies (HHS,2020). As described by the US FDA and industry, the countermeasures were designed, tested, and produced using emergency use authorization (EUA) policies in less than nine months and were branded as "safe and effective" even though limited clinical studies were performed on them (Pfizer Inc. 2020, FDA, 2020, FDA, 2020b, FDA, 2020c). These mRNA countermeasure technologies are categorized as gene therapies by the Food and Drug Administration (FDA, 2015), the manufacturer descriptions (Sahin, Karikó et al. 2014, Moderna Inc. 2018, Moderna Inc. 2020, Banoun 2023), and in the scientific literature (Abu Abed 2021). The FDA defines gene therapy products as "all products that mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and that are administered as nucleic acids, viruses, or genetically engineered microorganisms" (FDA, 2015). This distinction from "classic vaccines" is important because regulatory agencies in the US and Europe strongly recommend pre- and post-clinical pharmacokinetic studies of gene therapy products to assess their safety prior to approval (CHMP EMA, 2006, CBER FDA, 2013, NIH, 2019). The FDA provides detailed guidance for the "design and analyses of shedding studies for virus or bacteria-based gene therapy" (FDA, 2015).

### *Shedding Phenomena*

In addition, as described by Banoun (Banoun 2023), pharmacokinetic studies should include the study of the absorption, distribution, and biotransformation of the vaccine ingredients, the excretion (i.e. shedding) of mRNA containing lipid nanoparticles (LNPs), modified spike-encoding free mRNA, the resultant spike protein product manufactured by the human body, the residual DNA

from the manufacturing process (Speicher, Rose et al. 2023), and other chemical components (Diblasi, Monteverde et al. 2024). Unfortunately, there is no evidence that such shedding studies were implemented; however, in the Pfizer clinical trial documents, participants were advised to report any potential gene therapy exposure by way of inhalation or skin contact with a pregnant woman or the woman's sexual partner, prior to the time of conception (Pfizer Inc. 2020).

### *Biodistribution of Spike Protein and other Vaccine Components in Humans*

In an effort to promote vaccine acceptance, the Centers for Disease Control (CDC) stated on its website that the components of the COVID-19 mRNA do not last long in the body. This claim was presented in different iterations from December 2020 to December 2022 including: "The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions"(CDC, 2021), which was the basis used to educate the public with the statement that the vaccine "stays in the arm". This statement was quietly removed from the CDC website without explanation approximately two years after the vaccine rollout in the United States. However, the first animal biodistribution study was brought to public awareness in June of 2021 (Pfizer Inc. 2021). There have been numerous studies on human biodistribution of vaccine components since the initial vaccine rollout. COVID-19 mRNA vaccine fragments have been found in the blood up to at least 28 days post-vaccination (Fertig, Chitoiu et al. 2022, Castruita, Schneider et al. 2023), and recombinant spike protein has been reported in the blood of recipients more than 6 months post-injection (Patterson, Francisco et al. 2022, Brogna, Cristoni et al. 2023). COVID-19 mRNA vaccine fragments have also been found in breastmilk up to at least 7 days after injection (Hanna, Heffes-Doon et al. 2022, Yeo, Chia et al. 2022, Hanna, Manzano De Majia et al. 2023). In a study of axillary lymph nodes of vaccinated individuals, spike antigens and mRNA were found in the lymph nodes up to at least 60 days post-vaccination (Röltgen, Nielsen et al. 2022). Vaccine components were also detected in the myocardium (heart tissue) of individuals who were deceased up to at least 30 days post-vaccination (Krauson 2023).

### *Relevance to Menstrual Irregularities*

None of the clinical trials for the COVID-19 mRNA vaccines reported on significant health effects specific to women, including possible reproductive harm and/or menstrual disorders (Pfizer Inc. 2020, Moderna Inc. 2022), nor were they included as pre-specified symptoms in the Centers for Disease Control (CDC) active surveillance system (Wong, Heilig et al. 2022). However, as reported by Flam and others, within months of the widespread vaccine availability, women began to report menstrual irregularities occurring shortly after receiving a COVID-19 injection (Flam 2021). In response to increasing numbers of menstrual irregularity reports, several retrospective (Baena-García, Aparicio et al. 2022, Khan, Shilen et al. 2022, Lagana, Veronesi et al. 2022, Lessans, Rottenstreich et al. 2022, Muhaidat, Alshrouf et al. 2022, Parotto, Thorp et al. 2022, Blix, Laake et al. 2023, Kajiwara, Akiyama et al. 2023) and prospective (Wang, Mortazavi et al. 2022, Wong, Heilig et al. 2022) clinical studies have been performed, resulting in a general acceptance of a link between COVID-19 vaccination and menstrual irregularities.

The MyCycleStory℠(MCS) research collaborative is an assemblage of experienced research scientists, data management specialists, and obstetricians/gynaecologists from several regions of the United States. The MCS research collaborative created an online survey in 2021 to gather data to better understand this phenomenon with a long-term goal of uncovering both the cause and treatment solutions. The surveyed participants in this study included both vaccinated and unvaccinated individuals. Our primary analyses focused on an unvaccinated cohort with no direct

exposure to COVID-19 vaccine ingredients, or infection by the SARS-CoV-2 virus, prior to coming into proximity with a vaccinated person. To our knowledge, this is the first human research study to report on associations between proximity to a vaccinated person in daily activities and menstrual irregularities as well as the timing of the onset of menstrual abnormalities after being in close proximity to a vaccinated person. The group in focus consisted of unvaccinated individuals with no known direct exposure to COVID-19 vaccine or infection by SARS-CoV-2 virus. The primary objective of this study was to examine possible excretion and transmission (shedding) of COVID-19 vaccine components and/or products by the vaccinated population that may be contributing to a significant increase in menstrual irregularities in unvaccinated women a few months after the onset of the national COVID-19 vaccination roll-out.

## Methods

### *Study Design*

In May 2021, MCS designed and launched a secure online survey to capture demographic, lifestyle, and clinical data from women 18 years of age and older, COVID-19 vaccinated and unvaccinated, who were experiencing menstrual anomalies. This study was approved by the Simpson University Institutional Review Board per US Federal regulations.

In the spring of 2021, many women experiencing menstrual abnormalities, both minor and severe, became concerned about the cause of their sudden anomalies and were seeking information and giving testimonials on social media. One such Facebook page, which gained a following of over 18,000 in a few short weeks in April 2021, was abruptly shut down by Facebook with no explanation. The MCS online survey, fielded shortly thereafter, gave women a censorship-free outlet to report their menstrual irregularities.

We obtained survey responses by sharing the survey information via crowdsourcing to female participants on social media beginning on May 16, 2021. We closed the collection of data for this initial study on December 31, 2021. No financial incentives were given to participants and other than age, there were no screening criteria for respondents.

The survey contained 91 questions and focused on SARS-CoV-2 or COVID-19 exposure through infection or vaccination, as well as demographic information, medications, menstrual history, clinical characteristics, past diagnoses, supplement use, stress levels, exposure to hazardous agents, and other possible physical or environmental characteristics that could be associated with sudden menstrual irregularities. A subset of relevant questions is detailed here and the complete list of 91 questions is available upon request.

### *Participants*

Participants had to be at least 18 years of age and spanned to 85 years old. This study contains responses from 6049 women who consented to the study, with 89.1% of the participants responding within the first 3.5 months. A peer-reviewed study on decidual cast shedding in this population was previously published (Parotto, Thorp et al. 2022).

### *Sample Subgroups*

The analysis plan included examining the study sample overall ($n$ = 6049) and two subgroups: (1) women only exposed indirectly to a COVID-19 vaccine by proximity to COVID-19 vaccinated individuals ($n$ = 3390), and (2) women directly exposed to a COVID-19 vaccine injection, or to

infection by SARS-CoV-2, or who had a positive test for the COVID-19 virus ($n$ = 2659). A "yes" to any of the following survey questions would classify the participant as having been directly exposed to the COVID-19 vaccine ingredients, or to SARS-CoV-2 virus: 1) Have you received any vaccinations for COVID-19? 2) Do you believe you had COVID-19 (had symptoms) but not been tested? 3) Did you ever test positive for COVID-19? As the consort diagram below indicates (Figure 1), the portion of the sample that answered yes to any of the above questions were, in order and stepwise, removed from the total sample ($n$ = 6049) to produce a subset of participants for whom there was no known exposure to a COVID-19 vaccine injection, or to infection by SARS-CoV-2 ($n$ = 3390; 56% of the total sample).

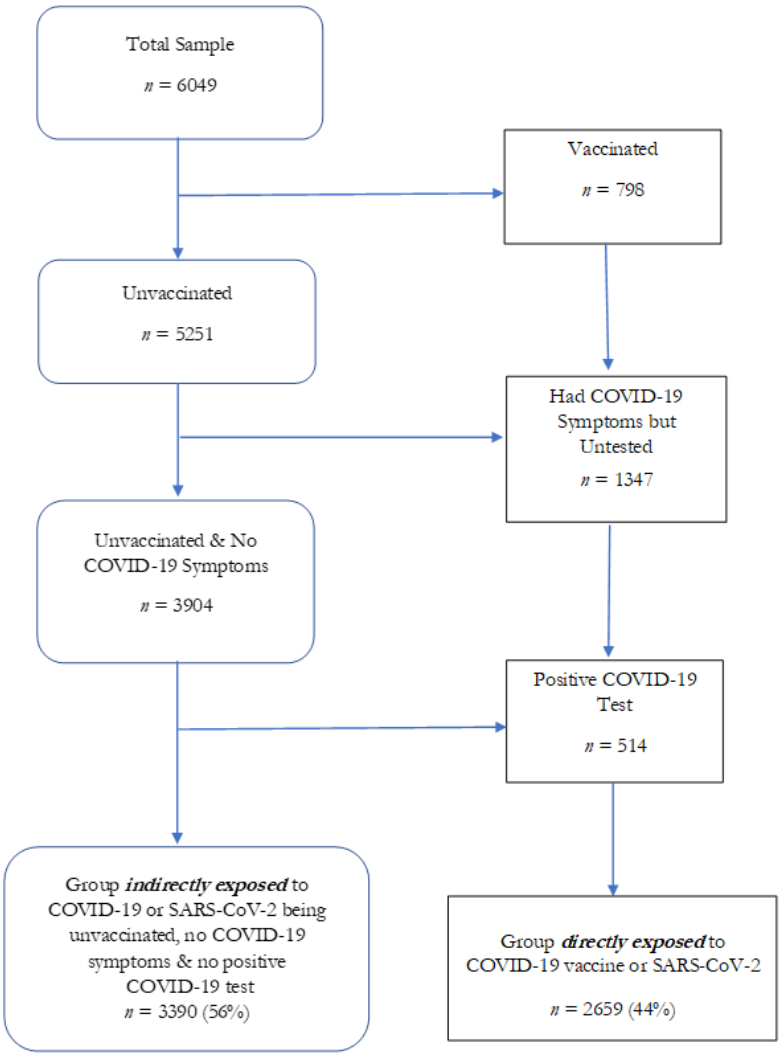


Figure 1. A consort diagram showin how the **Indirectly Exposed Group** ($n$ = 3390) consisting of women who did not receive a COVID-19 vaccine, had no symptoms of COVID-19, and did not test positive for COVID-19 were differentiated from the **Directly Exposed Group** ($n$ = 2659).

The subgroup of focal interest referred to as "having no known direct exposure to a COVID-19 vaccine or to a SARS-CoV-2 infection" and defined above as unvaccinated ($n$ = 3390) were analyzed as a whole and by age subgroups of 18-34 years (41.4%), 35-45 years (37.5%), 46-54 years (16.9%), and 55+ years (4.3%).

### *Demographic and Lifestyle Measures*

The user-centered MCS survey collected demographic and lifestyle characteristics, including age, race/ethnicity, country, employment, tobacco and alcohol use in the past 6 months, supplement intake, health status, stress level, and average number of hours of sleep per night.

### *Key Measures of Interest*

In order to assess the proximity of study participants to vaccinated individuals, data were collected on two key survey questions that were reported for the entire study population and by direct or indirect exposure status. The first question was: "How often are you in close proximity with individuals who have been vaccinated?" Seven response categories ranged from distant "seldom around maybe vaccinated people (<4x/month)" to close "have a vaccinated partner with whom I share a bed, have skin contact, intimacy and food sharing". The second key proximity question was: "Do you know how many days between being close to someone vaccinated and when you began showing symptoms?" Response categories included "unknown", "no symptoms", or "does not apply", "more than 2 weeks", "7-14 days", "3-7 days", "within 3 days", and "same day".

### *Clinical Measures*

#### *Abnormal Symptoms*

Participants were asked if they were experiencing one or more of 39 "symptoms seen for the first time that are abnormal for you"; they were also asked in a separate set of questions using the same 39 symptoms about "abnormal symptoms that you have experienced at least one time before". If the participant reported having experienced a symptom previously, then the symptom was removed from the analysis data set so that only symptoms that the respondent was experiencing for the first time ever were reported in these results. The Kuder-Richardson Coefficient (KR-20), a measure of the internal consistency or reliability, for this list of symptoms was 0.74 which is considered acceptable (Salkind 2010). Respondents were also asked if their abnormal health reactions or menstrual irregularities started after January 2021. Two data measures were created to assess if a participant reported at least one of the most prevalent six abnormal or irregular first-time symptoms and the median number of first-time symptoms.

#### *Menstrual History and Related Characteristics*

Survey questions covered menstrual history, including the age of first menstrual period, past miscarriages, typical regularity, length, flow of periods, peri/post-menopausal status, history of past pregnancies and births, breastfeeding status, and "trying to conceive" data. Detailed questions were included about current medications, including contraception, and hormone therapy use (e.g., hormonal contraception, intrauterine device use, and other hormonal therapies), as well as if the participant was ever diagnosed with seven primarily gynecological conditions or disorders, autoimmune disorders, or allergies, and if they were currently being treated for cancer. Other queried hormone therapies included hyper/hypothyroidism, gender-affirming hormones, hormone replacement therapy and pelvic organ prolapse treatment.

### *Statistical Analysis*

Descriptive statistics for the study sample were reported as frequencies and percentages, means and standard errors or medians and interquartile ranges, as appropriate. Survey procedures were used to analyze the data. Demographic and lifestyle characteristics were reported overall and by direct and indirect exposure group. Data for key proximity measures of interest were similarly reported using Chi-Square tests of association. Differences by exposure were tested using a Chi-Square test or

Student's *t*-test, and *p*-values were reported for all comparisons. Descriptive summary statistics were generated for clinical characteristics such as frequencies and percentages, means and standard errors, medians, and interquartile ranges. Chi-Square tests, Kruskal-Wallis tests, or ANOVAs were used, as appropriate, to examine differences between age groups. A Kuder-Richardson Coefficient (KR-20) was calculated for the complete list of first-time symptoms. Since the analysis plan included a subgroup analysis by age, multiple imputation was performed on the age variable to correct for 19.8% missingness of certain data points. The missing data were determined to be not missing at random. Therefore, the data was imputed using the mean by race/ethnicity category.

In separate models, generalized linear mixed (GLMM) was conducted to examine the association between abnormal symptoms experienced for the first time and the key proximity measures of interest. GLMMs were chosen to account for random and fixed effects, and they allow for a response variable from different distributions, such as binary responses. Three categories of proximity inside 6 feet, "partner/live with the vaccinated person(s)", "daily within 6 feet outside household", and "sometimes within 6ft". were each compared to the reference category of "seldom/sometimes/daily outside 6 feet", only for the indirect exposure group. Unadjusted relative risk estimates were reported, as well as 95% confidence intervals and *p*-values. The a priori alpha level of significance for all analyses was set at the standard scientific acceptance level of $<0.05$, and all analyses were conducted using SAS version 9.4 (Cary, NC, USA).

## Results

Table 1 displays descriptive statistics for the total sample, partitioned by indirect or direct COVID-19 vaccine exposure. The predominantly non-Hispanic white sample (86.7%) had a mean age overall of $37.8 \pm 0.1$ years. Most respondents were from the United States (81.2%). There was no statistically significant difference in direct versus indirect vaccine exposure for age, race/ethnicity, or country. Tobacco use in the past 6 months was higher for the directly exposed group. Supplement intake of vitamin D, vitamin C, zinc, and magnesium, known to be protective against COVID-19 (Butters and Whitehouse 2021, Shakoor, Feehan et al. 2021, Mohammadi, Behjati et al. 2022, Argano, Mallaci Bocchio et al. 2023), were all significantly higher in the indirect exposure group versus the direct exposure group, with intakes of 17.3% vs. 13.6% for zinc to 26.1% vs. 22.8% for Vitamin D. Both exposure groups considered themselves to be healthy, with a difference of 96.7% of the indirect exposure group versus 94.4% of the direct exposure group ($p < .001$). The reported stress level category frequencies followed a somewhat normal distribution, with the indirect exposure group being generally less stressed. These stress levels align with national data for normal levels of stress in daily living (Anderson, Nordal et al. 2010). The indirect exposure group was slightly less likely to work or work in a job with public interaction, which is aligned with their status of not being as likely to be exposed to the COVID-19 virus.

The MCS survey included two key questions to assess a participant's usual proximity to vaccinated individuals and related physical effects. The frequency of a participant's proximity to vaccinated individuals is shown in Figure 2. The red bars of the histogram represent proximity within 6 feet The cumulative percentage of participants that reported some level of contact within 6 feet was 86.4% for the total sample.

Table 2 below contains frequencies and percentages for collapsed categories, both overall and by exposure groups. Closer usual proximity to vaccinated individuals was generally reported for the indirect versus the direct exposure group. The percentage of participants in the indirect exposure group who had some level of contact within 6 feet was 85.5%.

**Table 1**
**Demographic and Lifestyle Characteristics by Indirect COVID-19 Vaccine Exposure versus Direct COVID-19 Vaccine or Other Exposure: Frequency (%) or Mean ± Standard Error or Median [Q1, Q3]**

| Respondents<br>Number of Cases | All Cases<br>*n* = 6049 | Indirect COVID-19 Vaccine Exposure<br>*n* = 3390 (56%) | Direct COVID-19 Vaccine or Other Exposure<br>*n* = 2659 (44%) | Contrasting *p*-value* |
|---|---|---|---|---|
| **Age** | 37.8 ± 0.1 | 37.9 ± 0.1 | 37.8 ± 0.2 | 0.903† |
| **Race/Ethnicity** | | | | 0.115‡ |
| Non-Hispanic White | 4537 (86.7) | 2636 (87.7) | 1901 (85.4) | |
| Hispanic | 300 (5.8) | 158 (5.2) | 142 (6.4) | |
| Multiracial | 264 (5.0) | 145 (4.8) | 119 (5.4) | |
| Other | 131 (2.5) | 68 (2.3) | 63 (2.8) | |
| **Country** | | | | 0.398‡ |
| United States | 3884 (81.2) | 2306 (80.8) | 1578 (81.6) | |
| Canada | 390 (8.1) | 245 (8.6) | 145 (7.5) | |
| Other country | 512 (10.7) | 302 (10.6) | 210 (10.9) | |
| **Employment** | | | | **0.008**‡ |
| Not working | 1075 (23.9) | 680 (25.5) | 395 (21.6) | |
| Work from home | 1326 (29.5) | 780 (29.2) | 546 (29.8) | |
| Part-time job — interact with public | 572 (12.7) | 344 (12.9) | 228 (12.4) | |
| Full-time job in public place | 752 (16.7) | 419 (15.7) | 333 (18.2) | |
| Part-time job — no public interact | 237 (5.3) | 147 (5.5) | 90 (4.9) | |
| Full-time job in office — no public interact | 539 (12.0) | 294 (11.2) | 241 (13.2) | |
| **Tobacco use in the past 6 months** | 742 (12.3) | 350 (10.3) | 392 (14.7) | **<.001**‡ |
| **Alcohol use in the past 6 months** | 2764 (45.7) | 1484 (43.8) | 1280 (48.1) | **<.001**‡ |
| **Supplement intake** | | | | |
| Vitamin D | 1490 (24.6) | 885 (26.1) | 605 (22.8) | **0.003**‡ |
| Vitamin C | 1468 (24.3) | 865 (25.5) | 603 (22.7) | **0.011**‡ |
| Magnesium | 985 (16.3) | 601 (17.7) | 384 (14.4) | **<.001**‡ |
| Zinc | 948 (15.7) | 586 (17.3) | 362 (13.6) | **<.001**‡ |
| **Consider yourself healthy (yes)** | 4963 (95.7) | 2872 (96.7) | 2091 (94.4) | **<.001**‡ |
| **General Stress Level** | | | | **<.001**‡ |
| Low to none | 381 (7.3) | 260 (8.6) | 121 (5.4) | |
| Mild | 1746 (33.1) | 1047 (34.6) | 699 (31.2) | |
| Moderate | 2177 (41.3) | 1231 (40.7) | 946 (42.2) | |
| Heavy at times | 874 (16.6) | 449 (14.8) | 425 (19.0) | |
| Unbearable at times | 92 (1.7) | 40 (1.3) | 52 (2.3) | |
| **Number of hours sleep/night** | 7.2 ± 0.02 | 7.2 ± 0.01 | 7.1 ± 0.02 | 0.114† |

* Significant contrasts at $p < .05$ are given in bold print.

†Contrast by Student's *t*-test.

‡Contrast by Chi square.

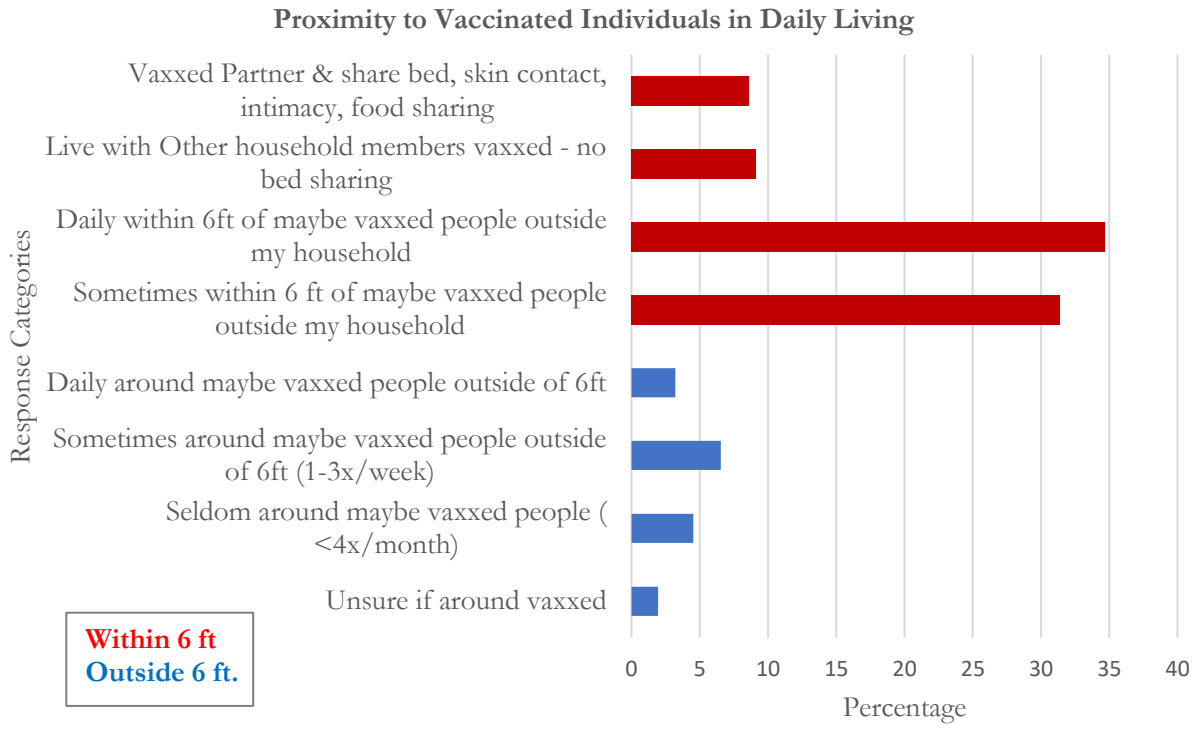


Figure 2. A bar chart of the frequency percentages of the response categories to the survey question, "How often are you in close proximity with individuals who have been vaccinated? (choose closest option)" The red bars signify the cumulative responses of proximity within 6 feet, whereas the blue bars signify the cumulative responses of proximity outside 6 feet.

For the women who recall, Figure 3 represents the number of days between being close to a vaccinated individual and the onset of abnormal or irregular symptoms. Thirty-nine percent of the participants could not recall how many days until symptoms onset. The MCS study team found that 68.4% (orange columns) showed symptoms within 1 week, and nearly half (48.6%) showed symptoms within 3 days or the same day.

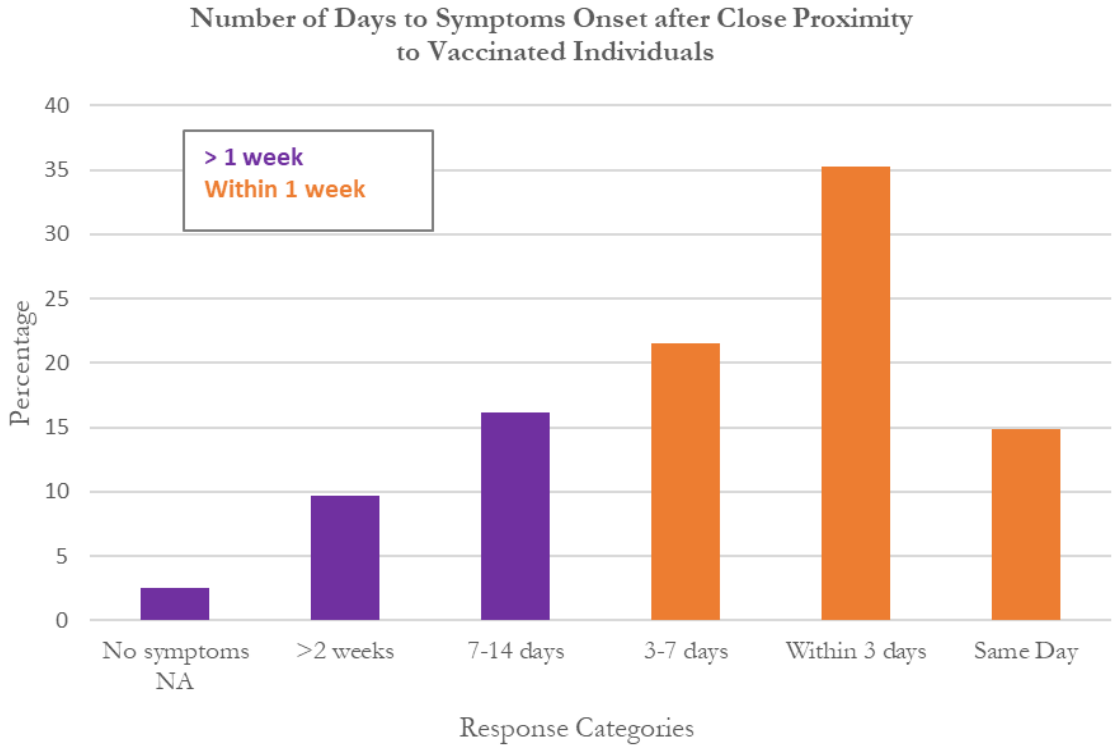


Figure 3. A bar chart of the frequency percentages of the response categories to the survey question: "Do you know how many days between being within close proximity to someone who has been vaccinated and when you began showing symptoms?" The purple bars signify the cumulative responses of symptoms onset >1 week, whereas the orange bars signify the cumulative responses of symptoms onset within 1 week of being in close proximity to a vaccinated person.

Table 2 below contains frequencies and percentages, both overall and by exposure group. A higher percentage of participants had symptoms on the same day in the direct exposure group, but fewer in this group had symptoms within 3 days or more, possibly suggesting a more immediate reaction for those exposed directly to the COVID-19 vaccine injection and/or to infection by SARS-CoV-2 and, thereafter, a higher degree of sensitivity for the indirectly exposed group after two or more days. The percentage of participants in the indirect exposure group who had symptoms within one week was 71.7%, and within 3 days or the same day was 50.1%.

**Table 2**
**Proximity to Vaccinated Individuals Overall and by Exposure Status Frequency (%)**

| Respondents | All Cases | Indirect Exposure Only | Direct Exposure | Contrasting *p*-value* |
|---|---|---|---|---|
| **Number of Cases** | ***n* = 6049** | ***n* = 3390 (56%)** | ***n* = 2659 (44%)** | |
| **Proximity with Individuals who have been Vaccinated (closest option)** | | | | **<.001‡** |
| Seldom/Sometimes/Daily outside 6 feet | 773 (13.7) | 463 (14.5) | 310 (12.5) | |
| Sometimes within 6 feet | 1656 (29.3) | 1020 (32.0) | 636 (25.7) | |
| Daily within 6 feet outside household | 2496 (44.1) | 1424 (44.7) | 1072 (43.3) | |
| Partner/Live with vaccinated person | 736 (13.0) | 279 (8.8) | 457 (18.5) | |
| **Number of days between being in close proximity to someone who was vaccinated and when began showing symptoms†** | | | | **<.001‡** |
| Same day | 526 (15.2) | 299 (14.9) | 227 (15.6) | |
| Within 3 days | 1158 (33.4) | 709 (35.2) | 449 (30.9) | |
| 3 – 7 days | 687 (19.8) | 434 (21.6) | 253 (17.4) | |
| 7 – 14 days | 487 (14.1) | 324 (16.1) | 163 (11.2) | |
| More than 2 weeks | 322 (9.3) | 195 (9.7) | 127 (8.8) | |
| No symptoms/NA | 283 (8.2) | 51 (2.5) | 232 (16.0) | |

† Sample for number of days reported is for women that had symptoms and knew the number of days when symptoms began.
* Significant contrasts at $p < .05$ are given in bold print.
‡Contrast by Chi square Test.

Table 3 details data on the key proximity measures and clinical characteristics of women in the indirect exposure subgroup ($n = 3390$) overall and by age groups. Women 55+ years reported seldom/sometimes/daily being around vaccinated individuals outside 6 feet twice as often as women under 46 years (24% vs. 12%), whereas more than half (51.5%) of 18-34 year-olds reported being daily within 6 feet of vaccinated individuals outside the household. Daily rates decreased over each older age category. Older women reported living with or partner with a vaccinated person (13.5%) compared to 18-34 years (5.6%) and 35-45 years (9.1%). Overall, there were no statistically significant differences between age groups as to the onset of abnormal or irregular symptoms after being around a vaccinated person in the indirect exposure group. Percentages "within 3 days" were generally much higher across all age groups than other temporal categories. The youngest age group of 18-34 year-olds had the highest rate of being "daily within 6 feet outside of the household" (51.5%), whereas the 55+ years group had the lowest rate (28.8%). In terms of the timing of the onset of symptoms, there was no significant difference between the age groups.

Seven abnormal or irregular symptoms experienced for the first time are reported, with heavier menstrual bleeding than usual and early period (>7 days early) being the most frequently cited (23% and 20%, respectively). Younger women experienced considerably more symptoms overall than older women. In women ages 18-34, almost three times as many (64.2%) reported at least one of the most prevalent first-time symptoms as compared to women 55+ (22%). The median number of first-time symptoms was 2 (interquartile range was 4) and decreased with age in number and variability.

**Table 3**
**Clinical Characteristics of Women with No Direct Vaccine or SARS-CoV-2 Exposure, Overall and by Age Groups**
**Frequency (%), Mean ± Standard Error of Measurement or Median [Q1, Q3]**

| **Respondents** | **All Cases** | **18 – 34 years** | **35 – 45 years** | **46 – 54 years** | **55+ years** | ***Contrasting p-value*** |
|---|---|---|---|---|---|---|
| **Number of Cases** | *n* = 3390 | *n* = 1149 (41.4%) | *n* = 1043 (37.5%) | *n* = 469 (16.9%) | *n* = 118 (4.3%) | |
| **Proximity with individuals who have been vaccinated (closest option)** | | | | | | **<.001‡** |
| Seldom/Sometimes/Daily outside 6 feet | 463 (14.5) | 136 (12.4) | 124 (12.6) | 80 (18.4) | 27 (24.3) | |
| Sometimes within 6 feet | 1020 (32.0) | 336 (30.6) | 343 (35.0) | 144 (33.0) | 37 (33.3) | |
| Daily within 6 feet outside household | 1424 (44.7) | 566 (51.5) | 425 (43.3) | 159 (36.5) | 32 (28.8) | |
| Partner/Live with vaccinated person | 279 (8.8) | 62 (5.6) | 89 (9.1) | 53 (12.2) | 15 (13.5) | |
| **Number of days between being in close proximity to someone who was vaccinated and showing symptoms**** | | | | | | 0.546‡ |
| Same day | 299 (15.3) | 98 (14.4) | 93 (15.4) | 43 (14.1) | 11 (13.8) | |
| Within 3 days | 709 (36.2) | 230 (33.8) | 231 (38.2) | 103 (33.8) | 32 (40.0) | |
| 3 – 7 days | 434 (22.1) | 160 (23.5) | 125 (20.7) | 68 (22.3) | 18 (22.5) | |
| 7 – 14 days | 324 (16.5) | 103 (15.2) | 101 (16.7) | 54 (17.7) | 7 (8.8) | |
| More than 2 weeks | 195 (9.9) | 73 (10.7) | 45 (7.4) | 31 (10.2) | 9 (11.3) | |
| No symptoms/NA | 51 (2.5) | 16 (2.4) | 10 (1.7) | 6 (2.0) | 3 (3.8) | |
| **Abnormal or irregular symptoms experienced for the 1st time#** | | | | | | |
| Heavier menstrual bleeding than usual | 774 (22.8) | 309 (26.9) | 260 (24.9) | 92 (19.6) | 4 (3.4) | **<.001‡** |
| Early menses (>7 days early) | 688 (20.3) | 265 (23.1) | 234 (22.4) | 77 (16.4) | 2 (1.7) | **<.001‡** |
| Extended menstrual bleeding (>7 days) | 659 (19.4) | 259 (22.5) | 206 (19.8) | 93 (19.8) | 6 (5.1) | **<.001‡** |
| Severe cramping and abdominal discomfort | 584 (17.2) | 272 (23.7) | 165 (15.8) | 53 (11.3) | 9 (7.6) | **<.001‡** |
| Heavy menstrual clotting (larger than a dime) | 501 (14.8) | 198 (17.2) | 174 (16.7) | 57 (12.2) | 4 (3.4) | **<.001‡** |
| Spotting between Periods | 492 (14.5) | 212 (18.5) | 141 (13.5) | 54 (11.5) | 8 (6.8) | **<.001‡** |
| Decidual cast shedding | 160 (4.7) | 65 (5.7) | 56 (5.4) | 15 (3.2) | 1 (0.9) | **0.030‡** |
| **At least 1 of 6 most prevalent abnormal or irregular 1st time symptoms** | 1889 (55.7) | 738 (64.2) | 617 (59.2) | 236 (50.3) | 26 (22.0) | **<.001‡** |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Average number of abnormal symptoms experienced for the 1st time** | 2 [0, 4] | 2 [1, 5] | 2 [1, 4] | 1 [0, 3] | 0 [0, 2] | **<.001‡** |
| **Abnormal health reactions or menstrual irregularities that started after January 2021** | 3063 (92.3) | 1067 (93.1) | 969 (93.4) | 436 (94.0) | 95 (86.4) | **0.039‡** |
| **Age first menstrual period** | 12.8 ± 0.03 | 12.6 ± 0.1 | 12.8 ± 0.1 | 12.9 ± 0.1 | 12.9 ± 0.2 | **<.001†** |
| **Past miscarriage** | 212 (6.3) | 110 (9.6) | 65 (6.2) | 16 (3.4) | 1 (0.9) | **<.001‡** |
| **Typical menstrual regularity** | | | | | | **<.001‡** |
| Do not menstruate now | 339 (10.1) | 33 (2.9) | 31 (3.0) | 103 (22.3) | 102 (91.1) | |
| Rarely menstruate | 79 (2.4) | 18 (1.6) | 20 (1.9) | 26 (5.6) | 1 (0.9) | |
| Irregular or occasional | 190 (5.7) | 69 (6.0) | 44 (4.2) | 38 (8.2) | 6 (5.4) | |
| Regularly occurring | 2737 (81.2) | 1025 (89.5) | 945 (90.9) | 295 (63.9) | 3 (2.7) | |
| **Typical menstrual length** | | | | | | **<.001‡** |
| Rarely or do not menstruate now | 338 (10.1) | 29 (2.5) | 41 (3.9) | 106 (22.9) | 97 (88.2) | |
| 1 - 3 days | 274 (8.2) | 76 (6.6) | 103 (9.9) | 51 (11.0) | 0 (0) | |
| 3 - 5 days | 1588 (47.7) | 624 (54.4) | 516 (49.6) | 168 (36.4) | 3 (2.7) | |
| 5 - 7 days | 1031 (31.0) | 382 (33.3) | 353 (33.9) | 124 (26.8) | 6 (5.5) | |
| 7+ days | 95 (2.9) | 36 (3.1) | 27 (2.6) | 13 (2.8) | 4 (3.6) | |
| **Typical menstrual flow** | | | | | | **<.001‡** |
| Unpredictable | 71 (2.1) | 25 (2.2) | 17 (1.6) | 12 (2.6) | 3 (2.8) | |
| Rarely or do not menstruate now | 335 (10.1) | 31 (2.7) | 41 (3.9) | 105 (22.6) | 94 (86.2) | |
| Light | 406 (12.2) | 139 (12.1) | 129 (12.4) | 68 (14.7) | 3 (2.8) | |
| Moderate | 2045 (61.4) | 803 (70.0) | 685 (65.8) | 217 (46.8) | 4 (3.7) | |
| Heavy | 473 (14.2) | 150 (13.1) | 169 (16.2) | 62 (13.4) | 5 (4.6) | |
| **Peri- or post-menopausal** | 355 (10.5) | 6 (0.5) | 29 (2.8) | 153 (32.6) | 96 (81.4) | **<.001‡** |
| **Currently breastfeeding** | 353 (16.6) | 197 (32.8) | 112 (13.5) | 6 (1.6) | 0 (0) | **<.001‡** |
| **Trying to conceive** | 319 (10.4) | 187 (16.5) | 97 (9.4) | 7 (1.5) | 0 (0) | **<.001‡** |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Past Pregnancies and Births** | | | | | | |
| Ever pregnant | 2368 (76.3) | 701 (61.2) | 892 (86.1) | 415 (89.1) | 96 (85.0) | **<.001**‡ |
| Previous live births | 2139 (68.9) | 598 (52.2) | 829 (79.8) | 381 (81.8) | 88 (77.2) | **<.001**‡ |
| Average number of pregnancies | 2 [0, 3] | 1 [0, 3] | 2 [1, 4] | 3 [2, 4] | 2 [1, 4] | **<.001**^ |
| Average number of live singleton births | 1 [0, 2] | 1 [0, 2] | 2 [1, 3] | 2 [1, 3] | 2 [0, 3] | **<.001**^ |
| **Any Prescription Medications** | 232 (6.8) | 70 (6.1) | 71 (6.8) | 45 (9.6) | 18 (15.3) | **<.001**‡ |
| **Contraception and Hormone Therapies** | | | | | | |
| Hormonal contraception | 169 (5.0) | 99 (8.6) | 43 (4.1) | 9 (1.9) | 0 (0) | **<.001**‡ |
| Intrauterine Device (IUD) | 162 (4.8) | 63 (5.5) | 60 (5.8) | 16 (3.4) | 3 (2.5) | 0.132‡ |
| Other hormonal therapies | 279 (8.2) | 49 (4.3) | 94 (9.0) | 65 (13.9) | 39 (33.1) | **<.001**‡ |
| **Past Ever Diagnoses** | | | | | | |
| Bleeding or clotting disorder | 65 (1.9) | 18 (1.6) | 16 (1.5) | 16 (3.4) | 9 (7.6) | **<.001**‡ |
| Heavy menstrual bleeding/Menorrhagia | 294 (8.7) | 69 (6.0) | 94 (9.0) | 68 (14.5) | 31 (26.3) | **<.001**‡ |
| Abnormal uterine bleeding | 45 (1.3) | 10 (0.9) | 14 (1.3) | 11 (2.4) | 4 (3.4) | **0.033**‡ |
| Endometriosis | 167 (4.9) | 48 (4.2) | 52 (5.0) | 33 (7.0) | 12 (10.2) | **0.009**‡ |
| Adenomyosis | 25 (0.7) | 2 (0.2) | 9 (0.9) | 8 (1.7) | 2 (1.7) | **0.006**‡ |
| Fibroids | 203 (6.0) | 28 (2.4) | 65 (6.2) | 63 (13.4) | 27 (22.9) | **<.001**‡ |
| Polycystic ovarian syndrome | 198 (5.8) | 81 (7.1) | 77 (7.4) | 14 (3.0) | 7 (5.9) | **0.009**‡ |
| Autoimmune disorder | 498 (14.7) | 150 (13.1) | 168 (16.1) | 100 (21.3) | 29 (24.6) | **<.001**‡ |
| Allergies or asthma | 807 (23.8) | 271 (23.6) | 280 (26.9) | 145 (30.9) | 45 (38.1) | **<.001**‡ |
| **Currently being treated for cancer** | 57 (1.7) | 9 (0.8) | 14 (1.3) | 19 (4.1) | 11 (9.3) | **<.001**‡ |

* Significant contrasts at $p < .05$ are given in **bold print**.

† Contrast by ANOVA.

‡ Contrast by Chi square or Fisher's Exact Test.

# Kuder-Richardson Coefficient (KR-20) for complete list of first-time symptoms is 0.74

** Sample for number of days reported is for women that had symptoms and knew the number of days when symptoms began.

One of our most striking findings was that 92.3% of the indirect exposure sample said that their abnormal or irregular first-time symptoms started after January 2021, including the 46-54 year-olds at 94%. The CDC and other reporting agencies reported high infection rates for COVID-19 in 2020, yet these women began experiencing abnormal menses, serious enough to seek out a voluntary online survey to document what was happening with their bodies in 2021. While the vaccines were initially available in the US in early December 2020, the wide dissemination of COVID-19 vaccinations in the United States began in February 2021, with approximately 75.1 million doses administered by the end of February (Our World In Data 2023).

Past miscarriages overall were experienced by 6.3% of the indirect exposure group, with a wide range of prevalence. Notably, 9.6% of 18-34-year olds reported having had a miscarriage sometime in their life, with prevalence decreasing with age — 6.2% in 35-45 years, 3.4% in 46-54 years, and 0.9% in 55+ years. Before experiencing minor and severe menstrual abnormalities, the cohort of women with no spike protein exposure reported typical menstrual regularity, length, and flow that were reflective of normal ranges for menses. As expected, these measures differed by age. Similarly, the percentages of women who were peri/post-menopausal, breastfeeding, and trying to conceive were within normal ranges (11%, 17%, and 10%, respectively), therefore not indicating why these women with no direct exposure to COVID-19 vaccine injection would be experiencing menstrual irregularities. Also, only 7% overall reported being on any prescription medications. Seventy-six percent of the indirect exposure cohort had previously been pregnant, with two-thirds of the sample having had a previous live birth. The prevalence of these two measures was markedly lower (<24%) for 18-34 year old women versus all other age groups. Hormonal contraception or intrauterine device (IUD) use was low (<8.6% for any age group). Other hormonal therapies were 8.2% overall and varied greatly by age group but were not excessive in this population. To determine if this group of women with no direct exposure to COVID-19 vaccine injection had ever been diagnosed with conditions or disorders that might explain why they were experiencing menstrual irregularities, the MCS survey collected data on seven related gynecological diagnoses, including bleeding or clotting disorders, menorrhagia, abnormal uterine bleeding, endometriosis, adenomyosis, fibroids, and polycystic ovarian syndrome. The study found that overall, previous diagnoses of any of these ranged from 0.7% to 8.7%, which aligns with the statistic that 92.3% of these women began having these irregularities after January 2021. Less than 2% overall reported that they are currently being treated for cancer (Table 3).

In addition to descriptive statistics, generalized linear mixed modeling was used to examine the relative risk (RR) of abnormal symptoms within the two key measures of proximity. Three category comparisons were evaluated (Table 4), and there was no significant relative risk when examining the first association, between "partner/live with the vaccinated person" versus "seldom/sometimes/daily outside 6 feet," except for the symptom "heavy menstrual clotting," which was protective. The strongest association lies within the comparison of "Daily within 6 feet outside the household" vs. "Seldom/Sometimes/Daily outside 6ft". The RR is higher for "Daily contact within 6 feet" for heavier menstrual bleeding than usual, early menses (>7 days early) and extended menstrual bleeding (>7 days), [1.34, 95% CI= (1.08,1.65), $p$=0.007]; [1.28, 95% CI= (1.03,1.59), $p$=0.03]; and [1.26, 95% CI= (1.01,1.57), $p$=0.04] respectively. In the same proximity dyad, the RR was 1.16 for having at least one of the six most prevalent abnormal or irregular symptoms. The proximity measure of "Sometimes within 6ft". compared to "Seldom/Sometimes/Daily outside 6 feet" resulted in a RR of 1.26 (95% CI= (1.01,1.57), $p$=0.04) for heavier menstrual bleeding than usual, as well as the RR of 1.13 (95% CI= (1.02,1.25), $p$=0.02) for having reported at least one of the most prevalent symptoms.

**Table 4**
**Relative Risk for Abnormal Menstrual Symptoms by Proximity to Vaccinated Individuals in Women with No Direct Vaccine or SARS-CoV-2 Exposure *(n* = 3390)**

| **Abnormal Symptom Experienced for the First Time** | **Partner/Live with vaccinated person(s)** **vs** **Seldom/Sometimes/ Daily outside 6 feet** *RR* [95% CI] | **Daily within 6 feet outside household** **vs** **Seldom/Sometimes/ Daily outside 6 feet** *RR* [95% CI] | **Sometimes within 6 feet** **vs** **Seldom/Sometimes/ Daily outside 6 feet** *RR* [95% CI] | **Contrasting *p*-value*** |
|---|---|---|---|---|
| Heavier menstrual bleeding than usual | 1.16 [0.86, 1.55] | **1.34 [1.08, 1.65]** | **1.26 [1.01, 1.57]** | **0.048** |
| Early menses (>7 days early) | 0.72 [0.50, 1.03] | **1.28 [1.03, 1.59]** | 1.09 [0.86, 1.37] | **<.001** |
| Extended menstrual bleeding (>7 days) | 0.98 [0.70, 1.35] | **1.26 [1.01, 1.57]** | 1.07 [0.85, 1.36] | 0.055 |
| Severe cramping and abdominal discomfort | 0.99 [0.70, 1.40] | 1.23 [0.97, 1.56] | 1.05 [0.82, 1.36] | 0.127 |
| Heavy menstrual clotting (larger than a dime) | **0.64 [0.42, 0.97]** | 1.13 [0.88, 1.44] | 0.92 [0.71, 1.20] | **0.011** |
| Spotting between periods | 0.76 [0.50, 1.16] | 1.22 [0.93, 1.58] | 1.12 [0.85, 1.48] | 0.062 |
| Decidual cast shedding | 1.17 [0.57, 2.42] | 1.40 [0.83, 2.34] | 1.34 [0.78, 2.29] | 0.621 |
| **At least 1 of 6 most prevalent abnormal or irregular symptoms** | 0.90 [0.77, 1.06] | **1.16 [1.05, 1.28]** | **1.13 [1.02, 1.25]** | **<.001** |

RR = Relative Risk; CI = Confidence Interval; Significant contrasts at $p < .05$ are given in bold print.
* *p*-value from generalized linear mixed models.

Table 5 examines the relative risk for the number of days to the onset of abnormal symptoms after being in close proximity to a vaccinated individual. The statistical model compares symptoms onset within 3 days of being around a vaccinated person to symptoms onset 3 or more days after being around a vaccinated person or no symptoms. All RR point estimates were higher for symptoms onset ≤ 3 days and four were statistically significant. These included early menses (>7 days early), extended menstrual bleeding (>7 days), decidual cast shedding (Parotto, Thorp et al. 2022), and reported having had at least one of the most prevalent abnormal or irregular symptoms. The RRs were [1.2, 95% CI=(1.01,1.42), $p$=0.04]; [1.25, 95% CI=(1.05,1.49), $p$=0.01]; [1.6, 95% CI=(1.08,2.38), $p$=0.01]; and [1.09, 95% CI=(1.01,1.17), $p$=0.03] respectively. Three of the four statistically significant symptoms were also significant for the "Daily within 6 feet outside the household" comparison in Table 4.

**Table 5**
**Relative Risk for Abnormal Menstrual Symptoms Onset by Proximity to Vaccinated Individuals in Women with No Direct COVID-19 Vaccine Exposure ($n$ = 2012)**

| **Abnormal Symptom Experienced for the First Time** | **Symptoms Onset within 3 days of being around vaccinated person** ( $n$ = 48.6%) **versus** **Symptoms Onset 3 or more days after being around vaccinated person or No Symptoms** ( $n$ = 51.4%) *RR* [95% CI] | **Contrasting $p$-value*** |
|---|---|---|
| Heavier menstrual bleeding than usual | 1.13 [0.96, 1.32] | 0.140 |
| Early menses (>7 days early) | **1.20 [1.01, 1.42]** | **0.037** |
| Extended menstrual bleeding (>7 days) | **1.25 [1.05, 1.49]** | **0.011** |
| Severe cramping and abdominal discomfort | 1.13 [0.94, 1.36] | 0.185 |
| Heavy menstrual clotting (larger than a dime) | 1.05 [0.86, 1.28] | 0.654 |
| Spotting between periods | 1.19 [0.97, 1.46] | 0.104 |
| Decidual cast shedding | **1.60 [1.08, 2.38]** | **0.020** |
| **At least 1 of 6 most prevalent abnormal or irregular symptoms** | **1.09 [1.01, 1.17]** | **0.028** |

RR = Relative Risk; CI = Confidence Interval; Significant contrasts at $p < .05$ are given in bold print.
* $p$-value from generalized linear mixed models.

In summary, these combined findings lead us to suggest that the unvaccinated study participants with no known direct exposure to COVID-19 vaccine reported menstrual abnormalities, similar to those abnormalities experienced by the directly exposed, i.e., vaccinated subgroup.

## Discussion

To our knowledge, this is the first peer-reviewed study that shows an increased risk for menstrual irregularities in individuals who had not received COVID-19 vaccinations and, to their knowledge, were not exposed to the COVID-19 vaccine ingredients but were in close proximity to individuals who had received one or more injections of the COVID-19 vaccines.

### *Proximity to Vaccinated Persons and Timing of Exposure*

We had two survey questions that involved both usual proximity to a vaccinated person and timing of symptoms onset after being in close proximity to a vaccinated person, which allowed us to focus on the key area of interest of shedding or transmission of vaccine products to the unvaccinated. Out of our total sample, 86.4% reported some level of contact within 6 feet of vaccinated individuals, and of those women who could recall when their symptoms began, 68.4% showed symptoms within one week, and 48.6% were within 3 days or the same day of being near a vaccinated person. As stated in the documentation of the FDA Design and Analyses of Shedding Studies, shedding may occur immediately following product administration and again days to weeks later (FDA, 2015). Therefore, the FDA has recommended that in a study of human shedding, the "sampling should start immediately after product administration, with frequent sampling during the initial weeks following treatment to capture the shedding pattern accurately (e.g., sampling on day 1, 3, 7, 10 and then weekly)" (FDA, 2015).

With respect to the COVID-19 mRNA vaccines and the related timing of biodistribution, vaccine mRNA fragments have been found in the blood up to 28 days post-vaccination (Fertig, Chitoiu et al. 2022, Castruita, Schneider et al. 2023), and spike protein has been reported in recipients' blood up to 100 days (Patterson, Francisco et al. 2022) and 187 days (Brogna, Cristoni et al. 2023) post-injection. These reports provide evidence that both components (mRNA fragments) and products (spike protein) of the mRNA vaccines are circulating through the bloodstream of those who have received the vaccines for at least 1-6 months or longer (Brogna, Cristoni et al. 2023).

Interestingly, when we analyzed the present results for the direct vaccine exposure group, participants who had previously been exposed ($n$ = 2659) had a higher rate of symptoms on the same day of the new exposure and a lower rate of symptoms at all other time frames (within 3 days, 3-7 days, 7-14 days, 2 weeks) when compared to those who had no direct COVID-19 vaccine exposure and no evidence of having been infected by SARS-CoV-2. The pattern suggests a dose-response effect as seen with higher rates of menstrual irregularities after the second COVID-19 injection (Lagana, Veronesi et al. 2022, Trogstad, Laake et al. 2023) or after severe COVID-19 disease and one injection (Muhaidat, Alshrouf et al. 2022, Alvergne, Kountourides et al. 2023), however in these studies there was no test for significance in terms of the timing of symptoms.

The study team hypothesized that the closer one is to a vaccinated person on a daily basis, the higher the relative risk of abnormal symptoms. This was not our finding. The analyses of the proximity dyad of "Partner/Live with vaccinated person" vs. "Seldom/Sometimes/Daily outside 6 feet" revealed an unexpected significant protective effect for heavy menstrual clotting of the closest day-to-day exposure with a vaccinated partner/cohabitating companion. However, the significant and highest relative risk across several symptoms, including heavier bleeding (34%), early period onset (28%), and extended bleeding (26%), was for those who were exposed to the vaccinated daily and within 6 feet, but outside of the household. One possible explanation for this result is that daily exposure to a larger public group of vaccinated individuals could increase the concentration and duration of exposure to vaccine components being transmitted in the environment.

The first study to detect a signal indicating that COVID-19 vaccines were associated with adverse events in an unvaccinated sample was an all-cause mortality study of 22 European countries in 2021 prior to emergency authorization of vaccines for children (Pantazatos and Seligmann 2021). At the 15-17th week of the adult vaccine rollout, there was a significant positive association between regional vaccination rates, measured as weekly increases, and regional all-cause mortality in the 0-14 year-old age group (Pantazatos and Seligmann 2021).

### *Plausibility of Excretion and Transmission of mRNA Vaccine Components or Products*

As previously discussed, both the vaccine mRNA and the spike protein have been detected in the circulatory system and are not strictly localized at the injection area. The lipid nanoparticles (LNP), which are the packaging for the mRNA, have also been shown to have wide biodistribution in rodent studies (CHMP EMA, 2021, TGA Australian DOH, 2021). LNPs are primarily excreted from the experimental animals through feces and urine but also via saliva, sweat, breastmilk (Li, Al-Jamal et al. 2010), or exhalation (Leong and Ge 2022). When mRNA is released from the LNP, it can remain naked or be encapsulated in a natural extracellular vesicle or exosome (Bansal, Perincheri et al. 2021, Machhi, Shahjin et al. 2021). Spike protein, produced from the mRNA, will also circulate freely or be encapsulated in an exosome. Both can be excreted in human breast milk (Hanna, Heffes-Doon et al. 2022, Yeo, Chia et al. 2022) and human sweat glands (Liu, Li et al. 2020). In general, exosomes can be released through respiratory excretions and exhalation (Lucchetti, Santini et al. 2021, Machhi, Shahjin et al. 2021, Banoun 2022). The proposed transmission routes to others include inhalation (aerosol) (Chow, Qiu et al. 2020, Zhang, Leal et al. 2020, Yeo and Ng 2021, Banoun 2022, Leong and Ge 2022, Kedl, Hsieh et al. 2023), breast milk (Liao, Du et al. 2017), transdermal (through keratinocytes), and transplacental (Banoun 2022). There is accumulating evidence that there can be vaccine component or antibody transmission following COVID-19 vaccination, including via exhaled breath aerosol (Kedl, Hsieh et al. 2023). Biodistribution of these components has also been a topic of an in-depth review (Banoun 2022).

### *Menstrual Irregularities Align with COVID-19 Vaccine Studies*

Two large National Institutes of Health-funded retrospective cohort studies have assessed the correlation between COVID-19 vaccines and menstrual irregularities (Edelman, Boniface et al. 2022, Wang, Mortazavi et al. 2022, Darney, Boniface et al. 2023). These were the first COVID-19 vaccination studies to use a within-subject design for pre- (control) and post-vaccination, while the other studies to which we referred used a cross-sectional retrospective design. In a study of 2835 vaccinated women and 349 unvaccinated, but with COVID-19 infection, Wang et al. affirmed that the COVID-19 vaccination (mRNA and the adenovirus-vectored vaccine) in the US and Canada is associated with an increase in menstrual cycle length and a change in regularity in the first six months after vaccination. Furthermore, Wang et al. reported that "SARS-CoV-2 infection alone (unvaccinated) was not associated with changes in cycle length or regularity" (Wang, Mortazavi et al. 2022).

Edelman and colleagues did not consider COVID-19 infections in their global population (14,936 vaccinated) but did include a comparative unvaccinated group (4686) with data recorded in the same calendar period as the vaccinated group. A proportion of individuals "had a clinically significant change in cycle length of 8 days or more and was significantly higher in the vaccinated group during both the first and second vaccine dose cycles"; 6.2% compared with 5% in the unvaccinated (Edelman, Boniface et al. 2022). There were also significant changes in menses length (shorter) in the unvaccinated group, as reported in a critique of this study (Trogstad, Juvet et al. 2022).

In a follow-up study with the same dataset, researchers reported a 4% adjusted difference in the number of participants who experienced an increase in total bleeding quantity (34.5% in the unvaccinated and 38.4% in the vaccinated). Across all participants, there was a 17-20% change in the number of heavy bleeding days (including fewer or more heavy days) after the first dose, second dose, and in post-exposure menses. For total bleeding quantity, there was a 34-47% change in both groups, both less and more quantity, during this global mass vaccination campaign period. These additional findings by Edelman and colleagues, when taken together with our results of 25-27% of this 18 to 45-year-old age group experiencing heavier bleeding and 20-23% experiencing extended menstrual bleeding (>7 days), support the possible effect of vaccine-related transmission causing menstrual-related symptoms in the unvaccinated population (Darney, Boniface et al. 2023).

Additionally, the *unvaccinated* group in the Edelman study had a significant change in their own menstrual patterns, with 34.5% experiencing an increase in bleeding quantity and 5% experiencing a clinically significant change in cycle length of 8 days or more. The timeline of these post-vaccination data approximately aligns with the present study and the timing of the peak of the vaccination campaign when the shedding of vaccine components and products would be prominent (Edelman, Boniface et al. 2022, Darney, Boniface et al. 2023).

In a large independent study that investigated the effect of COVID-19 injections on women's menstrual cycles, K. Lee et al. (Lee, Junkins et al. 2022) observed stark correlations between COVID-19 vaccination status and an increase in menstrual irregularities originating in the early months of 2021. They examined data from 39,129 fully vaccinated female respondents between the ages of 18 and 80 years and found that 42.1% of respondents experienced heavier menstrual flow after vaccination. Overall, this study noted that heavier bleeding — in currently menstruating, and previously menstruating respondents — was the most frequent post-vaccination adverse effect.

Globally, reports of women experiencing menstrual irregularities continue to increase rapidly. As of November 23, 2022, the United Kingdom (UK) alone identified 51,695 Yellow Card reports of experienced menstrual disorders after the administration of COVID-19 vaccines (UK MHRA, 2023). These adverse experiences included periods that are heavier than usual, delayed periods, and unexpected vaginal bleeding. In an Israeli questionnaire-based cross-sectional study, Lessans et al. found that 23.3% of women in their sample, ages 18-50 years old and fully vaccinated with two doses of the Pfizer BioNTech vaccine, experienced irregular bleeding post-inoculation, and nearly 40% of those individuals reported a menstrual change after receiving the vaccine (Lessans, Rottenstreich et al. 2022).

Likewise, in a pilot study based in Italy, Laganá et al. found that 50%-60% of pre-menopausal women in their sample experienced menstrual irregularities, which primarily consisted of extended cycle length and increased bleeding after receiving the first and second doses of the COVID-19 vaccine (Lagana, Veronesi et al. 2022). Published in 2022, a retrospective cross-sectional online survey administered in Spain, "The Effect of Vaccination against SARS-CoV-2 on the Menstrual Cycle (EVA Project)", produced similar findings (Baena-García, Aparicio et al. 2022). This sample included 14,153 vaccinated women, and of those, 78% experienced menstrual cycle changes, including more menstrual bleeding (43%), more menstrual pain (41%), delayed menstruation (38%), fewer days of menstrual bleeding (34.5%), and shorter cycle length (32%). Most recently, Blix et al. used self-reported data from an August and September 2021 Norwegian study and found that 3.3%, 14.1%, and 13.1% of groups averaging in size of 7300, of postmenopausal, perimenopausal, and premenopausal women respectively, experienced unexpected vaginal bleeding during a period of 8-9 months after COVID-19 vaccination. The Spikevax (Moderna) vaccine was associated with a 32% increased risk as compared to the Comirnaty (Pfizer) vaccine (Blix, Laake et al. 2023).

These reports are in line with most of our findings, with the notable exception that our study population is unvaccinated and had no known direct exposure to COVID-19 vaccine ingredients and no detected SARS-CoV2 viral infection. We found the highest relative risk to be associated with heavier bleeding, shorter cycle intervals, and prolonged bleeding.

### *Theoretical Causes of Menstrual Irregularities*

The specific cause(s) of the abnormal vaginal bleeding is(are) unknown. Our findings suggest that something may be being shed from the vaccinated to the non-vaccinated, causing heavy vaginal bleeding. While not proven, the most likely shedding substance, we believe, would be the COVID-19 vaccine spike protein, which has been shown to bind and modulate estrogen receptors (Solis, Beccari et al. 2022) and is known to be cytotoxic (Trougakos, Terpos et al. 2022).

Other possibilities of transmitted vaccine contents include lipid nanoparticles (Wang, Song et al. 2018) and exosomes containing pseudouridylated mRNA, which have been found secreted in breastmilk (Hanna, Heffes-Doon et al. 2022). Other proteins coded for by the mRNA are less likely candidates. Additional possible etiologies include the pheromone hypothesis (Jahanfar, Awang et al. 2007) and endocrine disruption (Wang, Song et al. 2018, Lauretta, Sansone et al. 2019) at the hypothalamic-pituitary-ovarian axis (HPO) level (Mikhael, Punjala-Patel et al. 2019). However, it seems unlikely that these are contributing factors because of the magnitude of these bleeding events. One would expect lighter and less frequent bleeding with a disrupted HPO axis. Other possible contributory factors to the heavy vaginal bleeding include the extreme inflammatory effects of the vaccine itself, micro-clotting in the vasculature of the endometrium, and autoimmune reactions which are known complications from the vaccine (Berild, Larsen et al. 2022).

Due to the unknown underlying etiology of these bleeding disturbances, an appropriate therapy cannot be extrapolated from the pre-pandemic treatments. An interim approach, until a clearer understanding of the mechanisms is elucidated, might be to consider using strategies for managing spike pathology based on current knowledge and experience (Halma, Plothe et al. 2023).

With the ongoing current exposure to vaccinated individuals in society at large, these data capture a unique moment in time when there was a considerable unvaccinated and unexposed (to spike protein via COVID-19 vaccine injection, or SARS-CoV-2 infection) population. There is minimal peer-reviewed literature on the effects of shedding/transmission of vaccine components or products from a COVID-19 vaccinated person to the unvaccinated, and this report suggests a need for increased funding and research in this area.

### *Strengths of our Methodology*

An inherent strength of our methodology is for respondents to serve as their own controls. We found that 92.3% of them, as noted in our **Abstract**, did not have irregular menses before the rollout of the COVID-19 vaccines. This, we believe is indicative that the changes occurring just prior to and during the rollout probably played a causative role in the onset of irregular menstruation. We do not infer this from our statistics alone, though they are consistent with this inference. Another strength offsetting the common complaint that "self-reported" data are less reliable than more objective measures taken from a third person perspective is that self-reports are the gold standard for information about menstrual cycles. All that being said, we are nonetheless cautious and refrain from definitive generalizations about what factors specifically have caused the problems uncovered with respect to irregular menstrual cycles.

## Conclusion

Over the past three years, there has been a growing volume of scientific literature reporting adverse effects of exposure to COVID-19 mRNA gene therapies. Unvaccinated women have been sharing personal stories of adverse health effects after exposure to vaccinated individuals, such as heavier menstrual bleeding than usual, early menses, and extended menstrual bleeding. This observational study found that women with no direct COVID-19 vaccine or SARS-CoV-2 exposure seemed to be having menstrual abnormalities similar to those reported by the vaccinated population. Our findings suggest possible indirect transmission of ingredients or products of the COVID-19 vaccines, presumably through shedding, from people who received one or more of the COVID-19 injections. Aside from the COVID-19 mRNA vaccines, several new mRNA-based vaccines are now in clinical trials. Our findings support the need for shedding studies for current and future gene therapy products, as detailed in the 2015 FDA guidance.

## Author Contributions

Project Conceptualization and Survey Design – TP, CN, WG, MM, LM
Data Curation – WG, JN
Methodology and Study Design – SP, JN, TP, CN, WG, MM, LM, HR, BH, DM, JT
Formal Analysis – JN
Data Interpretation and Validation - SP, JN, TP, CN, WG, MM, LM, HR, BH, DM, JT, RS, PM
Writing – Original draft – JN, SP, CN, DM, JT, BH, HR
Writing – Review and editing – SP, JN, TP, CN, WG, MM, LM, HR, BH, DM, JT, RS, PM

## Author Declarations

James A. Thorp MD is currently Chief of Maternal and Prenatal Health at The Wellness Company (TWC). The author declares that there is no conflict of interest that could have influenced the research or its interpretation. All work on the manuscript was performed prior to his affiliation with TWC. All other co-authors declare no conflicts of interest.

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