Non-life-threatening adverse effects with COVID-19 mRNA-1273 vaccine: A randomized, cross-sectional study on healthcare workers with detailed self-reported symptoms.

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Special Issue on New coronavirus (2019■nCoV or SARS■CoV■2) and the outbreak of the respiratory illness (COVID■19): Part■XIII

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There are concerns regarding the side effects of the new coronavirus disease 2019 (COVID■19) mRNA■1273 vaccine among healthcare workers (HCWs) in the United States. The objective of the study was to investigate the side effects of the mRNA■1273 vaccine with detailed review of organ systems. A randomized, cross■sectional study using an independent online survey questionnaire was conducted to collect responses from HCWs. Of all participants, 87.8% (1116/1271) provided complete responses. Of them, 38.7% (432/1116) received the mRNA■1273 vaccine, among which, 89.35% were females; 425 of these 432 mRNA■1273 vaccine recipients (98.34%) reported at least one or more symptoms. The results were classified based on the frequency of symptoms reported postvaccination. Of these, 254/432 (58.8%) were able to continue their daily routine activities. 108/432 (25%) temporarily had trouble to perform daily activities, 120/432 (27.78%) required transient time off from work, 17/432 (3.94%) required help from an outpatient provider, 1/432 (0.23%) required help from emergency department, and none of them were hospitalized. Despite the wide array of self■reported symptoms, 97.02% of the HCWs did not intend to skip the second dose of vaccine. Among all the symptoms reported, localized pain, generalized weakness, headache, myalgia, chills, fever, nausea, joint pains, sweating, localized swelling at the injection site, dizziness, itching, rash, decreased appetite, muscle spasm, decreased sleep quality, and brain fogging were the most commonly reported symptoms (in descending order of occurrence). Most of the symptoms reported were nonlife threatening. Despite the wide array of self■reported symptoms, there appears to be a higher acceptance for this vaccine.

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Non■life■threatening adverse effects with COVID■19 mRNA■1273 vaccine: A randomized, cross■sectional study on healthcare workers with detailed self■reported symptoms

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Severe acute respiratory syndrome coronaviruses (SARS■CoV and SARS■CoV■2) were thought to have emerged in China, with bats as their original carriers.

The Moderna COVID■19 mRNA■1273 vaccine was authorized by the Food and Drug Administration (FDA) in the United States to prevent COVID■19 infection on December 18, 2020. On December 19, 2020, the Advisory Committee on Immunization Practices issued an interim recommendation for the use of a two■dose regimen of mRNA■1273 vaccine (which was shown to have 94.1% efficacy in prevention of COVID■19 illness, including severe disease) in persons aged 18 years or older.

Overall, the COVID■19 messenger RNA (mRNA)■based vaccination program has generated many concerns, questions, and continuing arguments about the safety issues of both new mRNA vaccines among HCWs and the general population in the United States. However, there are limited data and literature on the side effects that specifically focus on a detailed review of organ systems and the demographic factors, such as age, gender, education level, and ethnicity. The objective of the present study was to analyze the safety and more detailed side effect profile of the mRNA■1273 vaccine using a self■reported online survey questionnaire among HCWs. Therefore, we chose a random population of HCWs and investigated the side effects of these vaccines using responses from the survey questionnaire (consisting of a more detailed review of organ systems in comparison to what the CDC is collecting through the Vaccine Adverse Event Reporting System [VAERS]).

Design and sample selection

After obtaining Institutional Review Board approval for this study, we conducted a cross■sectional study by circulating an independent online survey questionnaire through an internet■based survey platform called “Survey Monkey,” which gathered anonymous responses from HCWs from healthcare communities or groups representing various parts of the country during the early phase of COVID■19 vaccination. No personal identifications were obtained. Survey Monkey weblink was distributed to (1) coordinators of healthcare institutions and (2) communities of HCWs via social media. Informed consent was obtained at the beginning of the survey. Participants who voluntarily agreed and consented to proceed and who chose to receive one of the two mRNA■based COVID■19 vaccines were automatically allowed to move forward to answer subsequent questions about the side effects and other variables. Those who chose “None of them” were diverted to a disqualified page. The study obtained feedback in anonymous mode regarding the side effects and benefit profile during the postvaccination period.

This study included the healthcare providers and workers in healthcare settings (Phase 1a vaccine recipients who may be exposed to suspect or confirmed COVID■19 patients or infective materials) that have received one or two doses of the mRNA■based COVID■19 vaccine.

Those who received one or two doses of the mRNA■based COVID■19 vaccine but belong to one of the following:

Phase 1a “long■term care facility” residents and staff.

Phase 1b population (nonphase 1a persons aged ≥75 years and nonhealthcare frontline essential workers).

Phase 1c population (nonphase 1a persons aged 65–74 years and nonphase 1a persons aged 16–64 years with medical conditions that increase the risk for severe COVID■19).

Other general population.

Those who did not receive mRNA■based COVID■19 vaccine.

The “Survey Monkey” weblink was left open and kept active to collect responses for approximately 4 weeks. The responses were collected between January 24, 2021 and February 24, 2021.

We obtained responses from 1271 HCWs (Figure

Classification of survey responses (attached below). HCWs, healthcare workers; mRNA, messenger RNA

This study primarily focused on the mRNA■1273 vaccine. Of the 1116 respondents who completed the survey, 38.7% (432) received the mRNA■1273 vaccine, and the remaining received the BNT162b2 vaccine (Figure

Demographic data and effect on activity or need for medical attention after administration of mRNA■1273 vaccine

Black or African American

Native American or American Indian

Other (please specify below)

Level of education (answered by only 336 respondents)

Doctorate/professional medical degree

Effect on activity or need for medical attention

Temporarily had trouble to perform regular daily living activities

Required transient time off from work

Required to seek help from outpatient provider

Required to seek help from emergency department provider

Required to hospitalize and subsequent inpatient care

A total of 81.71% of the HCWs (353/432) who received the mRNA■1273 vaccine took both doses, but the remaining 18.29% took only the first dose. Those who received mRNA■1273 vaccine reported the following symptoms based on their complete review of organ systems. A detailed report of the event rate in the descending order of occurrence is displayed in Table

Event rate based on the descending order of occurrence

Symptom/sign/adverse event (after the first and or second dose)

Percentage reported in descending order (

Reported with most frequency

Generalized weakness/fatigue

Arthritis/joint pains

Muscle stiffness/spasm

Decreased sleep quality

Reported with moderate frequency

Heat/cold intolerance

Feelings of joy/relief/gratitude

Residual skin discoloration

Vertigo like symptoms

Ringing sensation in ears

Blood pressure changes

Reported with rare frequency

Increased urine production

Urgent need to urinate

Extremely rare frequency

Manic/hyper manic mood changes

Frequent urination at night

Pain or burning on urination

Swelling in mouth/throat

Decreased urine stream

Incontinence of urine

Swelling of lips or tongue

**Rash reported as both localized side effect and allergic side effect.

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Event rate classified based on review of organ systems

Symptoms after the first dose and or the second dose of vaccine

Number of HCWs reported

Generalized weakness/fatigue

Residual skin discoloration

Neurological symptoms

Vertigo like symptoms

Musculoskeletal symptoms

Arthritis/joint pains

Muscle stiffness/spasm

Gastrointestinal symptoms

Allergic/anaphylaxis symptoms

Swelling in mouth/throat

Swelling of lips or tongue

Cardiac■related symptoms

Blood pressure changes

Head/eyes/ears/nose/mouth/throat

Ringing sensation in ears

Urgent need to urinate

Pain or burning on urination

Frequent urination at night

Incontinence of urine

Decreased urine stream

Heat/cold intolerance

Increased urine production

Psychologic or psychiatric symptoms

Decreased sleep quality

Feelings of joy/relief/gratitude

Manic/hyper manic mood changes

**Rash reported as both localized side effect and allergic side effect.

The generalized symptoms that were primarily reported are generalized weakness or fatigue in 65.74% (284), headache in 59.26% (256), chills in 52.78% (228), fever in 35.65% (154), sweating in 18.52% (80), dizziness in 14.58% (63), and flushing in 9.03% (39) of the recipients (432).

Approximately 94.21% (407/432) of HCWs reported sore arm or pain at the injection site as their primary localized side effect, followed by swelling by 15.05% (65), itching by 14.58% (63), rash** by 13.43% (58), lymphadenopathy (axillary or regional or cervical or ipsilateral supraclavicular) by 4.17%

(18), residual skin discoloration by 3.47% (15), and bleeding by 0.46% (2) of the recipients (432).

Musculoskeletal symptoms

Myalgia (muscle pain) was reported by 54.17% (234), arthritis or joint pain by 24.77% (107), and muscle stiffness/spasm by 11.11% (48) of the recipients (432).

Gastrointestinal symptoms

Nausea was reported by 26.62% (115), decreased appetite by 13.19% (57), diarrhea by 7.87% (34), abdominal pain by 5.56% (24), heartburn by 3.24% (14), vomiting by 3.01% (13), constipation by 1.62% (7), food intolerance by 1.62% (7), and trouble swallowing by 0.23% (1) of the recipients (432).

Psychological or psychiatric symptoms

Decreased sleep quality was reported by 10.65% (46), feelings of joy/relief/gratitude by 4.86% (21), anxiety by 4.86% (21), increased sleep by 4.86% (21), decrease in memory by 1.62% (7), depression by 1.39% (6), manic/hyper manic mood changes by 0.93% (4), psychological stress by 0.69% (3), and behavioral changes by 0.46% (2) of the recipients (432).

Neurological symptoms

Brain fogging or confusion was reported by 9.95% (43), vertigo■like symptoms by 3.47% (15), tingling of the extremity with injection site by 3.24% (14), numbness by 1.39% (6), tremor by 0.93% (4), incoordination by 0.93% (4), extremity weakness by 0.69% (3), fainting by 0.69% (3), and seizures by 0.23% (1) of the recipients (432). Of note, one HCW reported reactivation of herpes or shingle■like lesions after receiving the vaccine.

Head/eyes/ears/nose/mouth/throat symptoms

Nasal stuffiness was reported by 6.48% (28), sore throat by 6.02% (26), eye pain by 3.47% (15), runny nose by 2.78% (12), ringing sensation in the ears reported by 2.31% (10), ear pain by 1.62% (7), blurred vision by 0.93% (4), flashing lights by 0.69% (3), changes in hearing by 0.46% (2), double vision by 0.23% (1), nose bleed by 0.23% (1), bleeding gums by 0.23% (1), and hoarseness by 0.23% (1) of the recipients (432).

Decreased appetite*** was reported by 13.19% (57), heat or cold intolerance by 8.56% (37), increased thirst by 3.24% (14), increased appetite by 1.62% (7), and increased urine production by 1.62% (7) of the recipients (432).

Cardiovascular symptoms

Palpitations/racing heart was reported by 8.1% (35), blood pressure changes by 1.85% (8), chest pain by 1.85% (8), and syncope by 0.93% (4) of the recipients (432).

Shortness of breath was reported by 2.31% (10), and cough by 3.47% (15) of the recipients (432).

Allergic/skin symptoms (except for rash**)

Among the 432 recipients, 1.62% (7) reported hives, 0.93% (4) reported atopic eczema, 0.69% (3) reported hay fever, 0.46% (2) reported swelling in the mouth/throat, 0.46% (2) reported asthma exacerbation, 0.23% (1) swelling of the lips, and 0.23% (1) reported anaphylaxis.

Urgent urination was reported by 1.16% (5), burning with urination by 0.69% (3), frequent urination by 0.69% (3), blood in urine by 0.46% (2), and urinary incontinence by 0.23% (1) of the recipients (432).

We obtained information on chronic medical problems among the study participants (Table

Chronic medical problems reported

Citation

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