

# Post-vaccination systemic adverse effects for three COVID-19 vaccines: a cross-sectional study in Iraq

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## ABSTRACT

The general population can be enlightened and encouraged to get vaccinated by understanding the adverse effects of vaccination. The study aimed at assessing the risk factors and possible systematic side effects of the immunization against coronavirus disease 2019 (COVID-19) by the most used vaccines in Iraq, being the Oxford-AstraZeneca, the Pfizer-BioNTech, and the Sinopharm vaccines. In addition, the study aimed at comparing the side effects between the different vaccine groups. To this end, this cross-sectional retrospective survey-based study was done during August 2022, through a self-administered online-based multiple choice questionnaire that was distributed among the Iraqi population. In total, 215 participants answered the questionnaire from different regions of Iraq, with a response rate of 100%. Of these participants, 13.03% were men and 86.97% were women. A total of 148 (68.8%) of the participants had obvious adverse effects after vaccination, while 67 (31.2%) were asymptomatic. There was a statistically significant correlation ( $p < 0.05$ ) between variables such as sex, age, vaccine dose, history of COVID-19 infection, and comorbidity with the herein recorded side effects. Localized injection pain, fever, fatigue, headache, localized swelling, and myalgia were the top side effects encountered by the present study, with a severity ranging from mild to moderate.

## 1. Introduction

Coronavirus disease 2019 (COVID-19) is brought on by SARS-CoV-2; a virus that causes a severe and acute respiratory illness. The first case of the illness was discovered in Wuhan (China) in December 2019, and it has since spread around the world<sup>1</sup>. Vaccines aid in the prevention of illness from incurable conditions by stimulating the body's adaptive immunity and induce T-cell immunity in addition to neutralizing antibodies. Immunization or vaccination is the administration of certain antigens in order to activate the immune system against an infection<sup>2</sup>. The majority of COVID-19 vaccines that have undergone and passed phase III trials have demonstrated efficiency in avoiding severe illness at about 90%. Ten vaccinations have currently been licensed; of these, the Pfizer-BioNTech, the Sinopharm, and the Oxford-AstraZeneca ones are the most widely used<sup>3</sup>. Most vaccine recipients experience immunological recognition of the vaccine antigens through the stimulation of local immune cells, the recruitment of circulating immune cells, and the induction of local inflammation by vasodilators and cytokines. For the induction of protective reactions without significant systemic consequences, a sufficient vaccination reactogenicity is required. Anti-SARS-CoV-2 antibodies bind to human antigens (like extractable nuclear antigens and myelin basic proteins) because the SARS-CoV-2 spike protein and some human proteins share antigenic similarities. Vasodilators and cytokines enter the bloodstream in the event of hyper-reactogenicity, triggering a state of systemic inflammation. Sometimes side effects are due to immune response after immunization<sup>4</sup>. Therefore, the evaluation of COVID-19 post-vaccination adverse effects evaluation is necessary in order to assess the different administered to the Iraqi population. Our study aimed at detecting the side effects occurring post-immunization, in addition to correlating the severity of these effects with study variables and the different vaccine types.

## 2. Methodology

This study is a cross-sectional retrospective survey-based study. All data were collected on August 8, 2022, among the Iraqi population. An online multiple-questionnaire was prepared, and the link was distributed randomly among different social media (such as Facebook, Telegram, and WhatsApp). The total number of participants was 215; they were all aged >18 years and have been administered different vaccine types.

The study was done after a detailed searching of the available literature in order to predict the most common systemic adverse effects after a COVID-19 vaccination. The questionnaire was distributed in the Arabic language to the participants. SPSS version 25.0 and Microsoft Excel were used for data entry and analysis. Descriptive statistics were used and statistical significance was determined using Fisher's exact test, with  $p$ -values <0.05 being considered as statistically significant. The study was conducted after obtaining approval from the Ethics Committee of the University of Kerbala College of Medicine (number: 1259; date: February 15, 2022), while written informed consent was obtained from the patients for their participation in the study.

## 3. Results

Of the 215 participants that have answered the questionnaire from different regions of Iraq with a response rate of 100%, 28 (13.03%) were men and 187 (86.97%) were women. The age of most of them was of a range of 20–29 years (71.8%). Kerbala recorded the highest participation rate (53.7%), followed by Baghdad (17.1%), Najaf (6.9%), and Babil (6%). The most administered vaccine was the Pfizer-BioNTech vaccine with 169 participants (78.2%) receiving it, of which 84.3% received two doses (Table 1). The Sinopharm vaccine was administered to 13.4% of the study's participants, while only 7.9% of the participants had received the Oxford-AstraZeneca vaccine (Table 1). The majority of the participants

**Table 1.** The frequency of systemic adverse effects associated with receiving three different COVID-19 vaccines.

| Adverse effects reported                    | Pfizer-BioNTech vaccine recipients (N=169) | Sinopharm vaccine recipients (N=29) | Oxford-AstraZeneca vaccine recipients (N=17) | p-value |
|---|--|-------------------------------------|--|---------|
| Fever                                       | 114 (53.0%)                                | 9 (4.2%)                            | 13 (6.0%)                                    | <0.001  |
| Chills                                      | 40 (18.6%)                                 | 3 (1.4%)                            | 8 (3.7%)                                     | 0.129   |
| Myalgia; joint pain                         | 69 (32.1%)                                 | 1 (0.5%)                            | 6 (2.8%)                                     | 0.001   |
| Fatigue                                     | 117 (54.4%)                                | 10 (4.7%)                           | 13 (6.0%)                                    | 0.001   |
| Headache                                    | 67 (31.2%)                                 | 4 (1.9%)                            | 7 (3.3%)                                     | 0.025   |
| Nausea; vomiting                            | 15 (6.9%)                                  | 2 (0.9%)                            | 1 (0.5%)                                     | 0.871   |
| Diarrhoea                                   | 1 (0.5%)                                   | 3 (1.4%)                            | 0  | 0.001   |
| Anorexia                                    | 18 (8.4%)                                  | 1 (0.5%)                            | 2 (0.9%)                                     | 0.463   |
| Dizziness                                   | 29 (13.5%)                                 | 2 (0.9%)                            | 4 (1.9%)                                     | 0.269   |
| Abdominal pain                              | 4 (1.9%)                                   | 1 (0.5%)                            | 0  | 0.753   |
| Chest pain                                  | 5 (2.3%)                                   | 1 (0.5%)                            | 0  | 0.759   |
| Cough; sneezing; other respiratory symptoms | 18 (8.4%)                                  | 0                                   | 0  | 0.069   |
| Sore throat                                 | 5 (2.3%)                                   | 2 (0.9%)                            | 0  | 0.399   |
| Lymph node enlargement                      | 6 (2.8%)                                   | 0                                   | 0  | 0.432   |
| Loss of smell or taste                      | 4 (1.9%)                                   | 2 (0.9%)                            | 1 (0.5%)                                     | 0.365   |
| Increase or decrease of blood pressure      | 2 (0.9%)                                   | 0                                   | 0  | 0.760   |
| Heart palpitations                          | 9 (4.2%)                                   | 1 (0.5%)                            | 2 (0.9%)                                     | 0.471   |
| Loss of consciousness                       | 2 (0.9%)                                   | 0                                   | 0  | 0.760   |
| Rash in another site of the body            | 4 (1.9%)                                   | 0                                   | 0  | 0.574   |

(61.1%) had a history of COVID-19 infection. In the Iraqi recipients of the Pfizer-BioNTech vaccine, the most common systemic adverse effect was fatigue (corresponding to 54.4% of all participants), followed by fever (53.0%), myalgia (32.1%), headache (31.2%), chills (18.6%), dizziness (13.5%), anorexia (8.4%), respiratory symptoms such as cough (8.4%), nausea / vomiting (6.9%), heart palpitations (4.2%), lymph node enlargement (2.8%), chest pain (2.3%), and sore throat (2.3%). Table 1 provides details regarding the recorded adverse effects for the Sinopharm and the Oxford-AstraZeneca vaccines.

#### 4. Discussion

In order to address the severe consequences of the COVID-19 pandemic on the global population, it is essential to implement safe and effective COVID-19

vaccinations and be prepared for potential side effects within our communities. Recent study outcomes reveal that side effects are a common occurrence with vaccination and can vary among the different vaccine types. A total of 148 (68.8%) out of the 215 participants of our study had obvious adverse effects after receiving a vaccine, while 67 (31.2%) were asymptomatic. Our results were in line with those of other studies; for example, a study conducted in Northern Iraq has identified fatigue, headache, myalgia, fever, and chills as the most common side effects<sup>5</sup>. A previous study in Wuhan has revealed that increased temperature, fatigue, headache, and myalgia have been reported post-vaccination at rates of 46%, 44%, 39%, and 17%, respectively<sup>6</sup>. The occurrence of injection site pain as a symptom has been reported in several studies<sup>7</sup>.

The findings of our study indicate that the Iraqi

individuals who have received the Pfizer-BioNTech vaccine were more susceptible to side effects (56.28%) when compared to the other two vaccines (7.44% for the Oxford-AstraZeneca vaccine and 5.12% for the Sinopharm one). In contrast, the frequency of side effects has been reported to be higher in the recipients of the Oxford-AstraZeneca vaccine than in those who have received the Pfizer-BioNTech or the Sinopharm vaccine<sup>8</sup>. Moreover, the Sinopharm vaccines recipients have reported a high rate of adverse reactions than the one recorded in our study<sup>9</sup>. Skin rash was rarely reported by our participants (1.9%) and, when it was, it was only associated with the Pfizer-BioNTech vaccine; this is also supported by another study in which the skin rash was reported by only 0.4% of the study's participants<sup>10</sup>.

## 5. Conclusion

Enhancing public trust in the vaccine and gaining a deeper insight into the potential side effects of the approved COVID-19 vaccines across different demographics are crucial goals. The occurrence of side effects following vaccination is not uncommon and serves as evidence of the immune system's response.

Our data support the safety and efficacy of the COVID-19 vaccines, and indicate that the most frequently reported adverse effects in the Iraqi population are fatigue, fever, headache, and myalgia.

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## Conflicts of interest

None exist.

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