# COMMON ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH MODERNA COVID-19 VACCINE AMONG VIETNAMESE ADULTS AT HANOI MEDICAL UNIVERSITY IN 2021

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*The rapid creation of vaccinations has increased the risk of vaccine safety. In less than two years, a significant number of COVID-19 vaccines were developed and approved in various countries to control the COVID-19 pandemic. This study was conducted to identify the common adverse events following immunization with mRNA-1273 (Moderna COVID-19) vaccine among adults in 2021. A cross-sectional study using randomized sampling was conducted in Hanoi, Vietnam, with 766 participants. The results show that the prevalence of AEFIs after the 1st dose was significantly lower than after the 2nd dose (41.25% vs. 85.64%, p < 0.05). Local effects, fever, fatigue, and increased pain sensation were the most common side effects encountered in both 1st and 2nd dose. The AEFIs are mostly mild and automatically wore off after one to three days. Therefore, the Moderna COVID-19 vaccine is safe for injection.*

**Keywords: Adverse events, immunization, Moderna COVID-19 vaccine, mRNA-1273, adult.**

## I. INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic is an ongoing global pandemic. Globally, as of 5:12 pm CEST, August 16, 2022, there have been 588.757.628 confirmed cases of COVID-19, including 6.433.794 deaths, reported to WHO.[1] While a specific treatment for this disease was still lacking,[2] and social distancing has negative impacts on many aspects of people's lives,[3] the COVID-19 vaccines are developed and are strongly recommended for effective prevention and control of the pandemic. Therefore, in less than two years, a significant number of COVID-19 vaccines were developed and approved in many countries.[4]

As of February 27, 2022, 62.8% of the world population has received at least one dose of a COVID-19 vaccine, but only 12.6% of people in low-income countries have received at least one dose. In Vietnam, around 81.7% of the population has received at least one dose.[5] As of February 28, 2022, there were ten vaccines granted emergency use listing (EUL) by WHO, one of them was mRNA-1273 (Moderna).[6]

Despite the benefits the vaccine offers to global health, concerns about vaccine safety have increased significantly over the years. Adverse event following immunization (AEFI) is any untoward medical occurrence that follows immunization anddoes not necessarily have a causal relationship with the usage of

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the vaccine.[7] In this study, we mainly use the classification of local and systemic reactions:

- Local effects: reactions at the injection site (swelling, redness, itchy, pain)

- Systemic effects: affecting the whole body, or at least multiple organ systems.

Based on evidence from clinical trials of people aged 18 years and older, mRNA-1273 was 94.1% effective at preventing laboratory-confirmed COVID-19 infection in people who received two doses and had no evidence of being previously infected.[8] Most reported AEFI of Moderna COVID-19 vaccine were not severe, the local reactions to vaccination were mild, and systemic side effects, such as fatigue, myalgia, arthralgia, and headache, were noted in about 50% of participants after the second dose.[7] Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) had seldom occurred.[9]

There are several global studies that analyze the adverse event following immunization of COVID-19 vaccines.[10-13] However, there are not many conducted in Vietnam, especially regarding the Moderna COVID-19 vaccine. It is crucial to report AEFI in Vietnam to inform the population with the goal of reducing apprehension about COVID-19 vaccination. Therefore, we conduct this study in order to identify the common adverse events following immunization with mRNA-1273 (Moderna) among adults in Vietnam. The findings from the study will inform the population about the safety of the vaccine and also reduce vaccine hesitancy, which was named one of the top ten threats to global health in 2019 by the World Health Organization.[14]

## II. METHODS AND MATERIALS

### 1. Study subjects

Vietnamese adults who received Moderna COVID-19 vaccine at the Vaccination Department, Hanoi Medical University.

***Inclusion criteria:***

- Aged 18 or above at the time of vaccination.

- Injected both primary doses of Moderna COVID-19 vaccine at Vaccination Department, Hanoi Medical University.

- Voluntary informed consent (verbal).

***Exclusion criteria:***

- Cannot contact by cell phone.

- Cannot answer the question by cell phone.

### 2. Methods

***Study design:***

A cross-sectional descriptive study was applied.

***Sample size:***

The sample size was calculated using the formula for estimating a population proportion:

$$n = Z^2_{(1-\alpha/2)} \cdot \frac{p\,(1 - p)}{(\varepsilon \cdot p)^2}$$

Where:

n: Sample size

p: The percentage of people having moderate fever as the most common AEFI of COVID-19 vaccine from previous research was 69.4%.[15]

ε: Relative precision = 0.05

1-α: Confidence level = 95%

The sample size calculated by the formula gives a result of 678 participants. In reality, 766 study participants were recruited.

***Sampling:***

In this study, the method of a random sampling of all cases of vaccination with two primary doses of Moderna COVID-19 vaccine at Hanoi Medical University was selected.

The initial list of all Vietnamese adults who received two primary doses of the Moderna

COVID-19 vaccine in September 2021 at Hanoi Medical University was extracted from the administrative vaccination system. A total of 3068 participants was made. The list is composed of ID immunization, full name, and telephone contact. Then the list was sorted by immunization ID. Finally, the participants were randomly selected by Stata software (using the command: sample 800, count).

We selected a random sample of 800 participants, where 766 adults agreed to participate in our study, with a response rate of 95.8%.

***Study time:***

Data was collected by the author and research team from September 2021 to September 2022.

***Study variables:***

- General information: age, gender, occupation.

- Medical history: allergy history, allergic disease, chronic disease.

- AEFI: local effects, systemic effects, appearance time, prolong time period, treatment methods.

***Data collection method***

AEFI information was collected through a face-to-face interviews with participants when they registered for the first dose of vaccination, followed by an online interviews for the 2nd dose using a structured questionnaire.

The participants filled in the form with their personal information and adverse events after immunization of the first dose when registered for 2nd dose at the vaccination unit. Then AEFI was verified by a medical doctor before administrating the 2nd dose. For AEFI after the 2nd dose, data were collected by cellphone, from the participants' contact list provided by the vaccinated program for Moderna COVID-19 vaccines at the Vaccination Department, Hanoi Medical University. The time for data collection was 28 days, right after the study participants received the 2nd dose of the vaccine and using the same structure questionnaire as the 1st dose. Each case took about 15-25 minutes to report specific AEFI, if any. The demographic information of the subject was collected from the online system using an immunization ID.

***Statistical analysis***

data was processed and entered into the computer using Epidata 3.1 software. Analysis were performed using STATA 16 software. Descriptive statistics were used to examine characteristics of AEFI data, including frequency, percentage, mean, and standard deviation. It is considered as having AEFI if there is the presence of one of the symptoms such as fever, tired sensation, manifestations at the injection site, increased pain, skin expressions, oral expressions, throat manifestations, respiratory, digestive disorders, or any other unusual symptoms after 1st dose or in 28 days after 2nd injection.

**3. Ethics approval**

The research was ethically approved by the Scientific Proposal Review Committee of the School of Preventive Medicine and Public Health, Hanoi Medical University, in 2021. The researcher presented and explained the content and purpose of the study to the participants. Subjects participated in the study voluntarily, without obligation, and had the right to opt-out of the study without any reason. Subject information is kept confidential and is only used for beneficial research purposes.

## III. RESULTS

**Table 1. General information of research subjects**

| General information | Frequency | Percentage |
|---|---|---|
| **Gender** | | |
| Male | 359 | 46.9 |
| Female | 407 | 53.1 |
| **Age group** | | |
| 18 - 30 years old | 201 | 26.2 |
| 31 - 45 years old | 290 | 37.9 |
| 46 - 60 years old | 135 | 17.6 |
| > 60 years old | 140 | 18.3 |
| **Occupation** | | |
| Medical staff | 24 | 3.1 |
| Public servants | 191 | 25.0 |
| Business/services | 256 | 33.4 |
| Medical Student | 7 | 1.0 |
| Retired | 32 | 4.2 |
| Other | 238 | 31.0 |
| Missing | 18 | 2.3 |
| **Allergy history** | | |
| None | 746 | 97.4 |
| Medicine | 1 | 0.1 |
| Vaccine | 0 | 0 |
| Food | 9 | 1.2 |
| Weather | 4 | 0.5 |
| Cosmetic | 3 | 0.4 |
| Unknown cause | 4 | 0.5 |
| **Total** | **766** | **100** |

Among 766 participants, female participants were more popular (53.1%). The majority of participants were from 31 to 45 years old (290 people, accounting for 37.9%). The most common occupation was the business/services field (33.4%). There were 18 participants

missing occupation information, accounting for 2.3%. The least common occupation was medical student, which took up only 1%. Table 1 also presents the details of the participant's medical history. In particular, only 20 participants reported having allergies before vaccination. In which the most common allergy was food, accounting for 1.2% of total participants.

**Table 2. Comparison between the rate of AEFIs in 1st and 2nd dose**

| Dose | | Yes (n/%) | No (n/%) | p-value |
|---|---|---|---|---|
| **The appearance of AEFIs** | | | | |
| 1st dose | | 316 (41.25) | 450 (58.75) | < 0.001 |
| 2nd dose | | 656 (85.64) | 110 (14.36) | |
| **Adverse Events** | | | | |
| Local effects | 1st dose | 220 (28.72) | 546 (71.28) | **< 0.001** |
| | 2nd dose | 369 (48.17) | 397 (51.83) | |
| Systemic effects | 1st dose | 184 (24.02) | 582 (75.98) | **< 0.001** |
| | 2nd dose | 600 (78.33) | 166 (21.67) | |

The number of people having AEFIs after the 2nd dose was more than twice as many as those having AEFIs after the 1st dose. This difference between the appearance of AEFIs after the 1st dose and the 2nd dose was statistically significant ($p < 0.05$).

Both local and systemic effects were more frequent after the 2nd dose. Participants experienced local effects after the 1st dose was much lower than after the 2nd dose. The same as local effects, the number of people who had systemic effects after the 2nd dose was three times higher than that of the 1st dose. These differences were statistically different ($p < 0.001$).

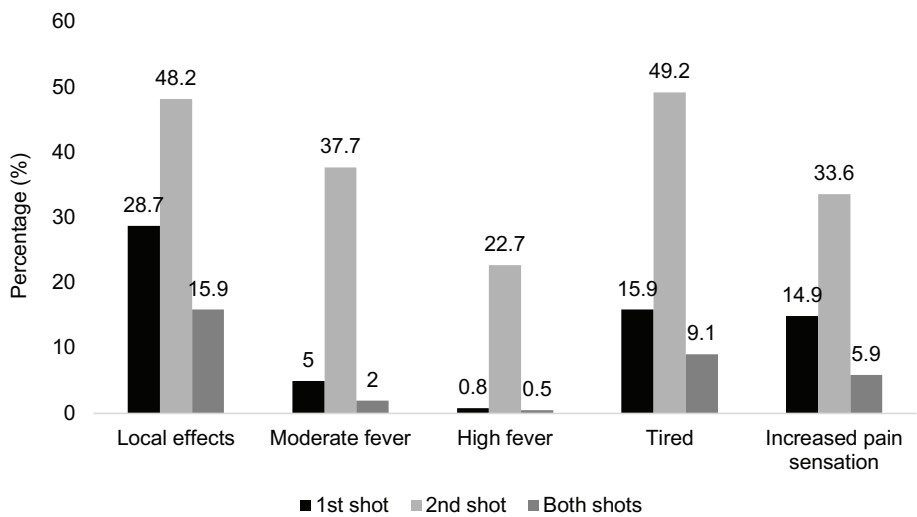


**Figure 1. The proportion of the most common AEFIs in participant**

Local effects, fever, fatigue, and increased pain sensation were the most common in both 1st dose and 2nd dose. In detail, the most common AEFI after the 1st dose was local effects (28.7%), while that of the 2nd dose was fatigue (49.2%). 48% of participants who experienced local effects after the 2nd dose, was quite similar to fatigue. There were only 44 people who reported having fever after the 1st shot, with the percentage of moderate fever (< 38.5°C) being more than six times higher than high fever (≥ 38.5°C). 60.7% of participants reported having a fever (moderate fever with 37.7% and high fever with 22.7%) after the 2nd dose, was more than ten times higher than the 1st dose. The number of people having moderate fever was also higher than the number of people having high fever.

**Table 3. Appearance time of different AEFI in participants after two doses**

| AEFI | | Participants with the symptom that appeared within | | | | | | | | Mean (SD) (h) | Min-max (h) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | < 6 hours | | 6 - <12 hours | | 12 - <24 hours | | ≥ 24 hours | | | |
| | | n | % | n | % | n | % | n | % | | |
| **After 1st dose** | | | | | | | | | | | |
| ***Having local effects*** | | 80 | 36.4 | 92 | 41.8 | 31 | 14.1 | 17 | 7.7 | 9.6 | 0 -168 |
| ***Systemic effects*** | Fever | 14 | 31.8 | 14 | 31.8 | 12 | 27.3 | 4 | 9.1 | 9.5 | 1 - 30 |
| | Fatigue | 36 | 29.5 | 57 | 46.7 | 17 | 13.9 | 12 | 9.8 | 9.3 | 1 - 72 |
| | Increased pain sensation | 35 | 30.7 | 51 | 44.7 | 15 | 13.2 | 13 | 11.4 | 10.5 | 1 - 168 |
| **After 2nd dose** | | | | | | | | | | | |
| ***Having local effects*** | | 146 | 39.6 | 132 | 35.8 | 69 | 18.7 | 22 | 6.0 | 8.5 | 0 - 168 |
| ***Systemic effects*** | Fever | 55 | 11.9 | 187 | 40.4 | 178 | 38.4 | 43 | 9.2 | 10.9 | 1 - 40 |
| | Fatigue | 55 | 14.6 | 176 | 46.7 | 112 | 29.7 | 34 | 9.0 | 10.5 | 0 - 144 |
| | Increased pain sensation | 50 | 19.5 | 117 | 45.5 | 68 | 26.5 | 22 | 8.6 | 10.1 | 0 - 72 |

Table 3 illustrates the appearance of the symptom after the two shots. AEFIs' first appearance in participants ranged from immediately to 168 hours. In which, most adverse events appeared from 6 to less than 12 hours after the vaccination, both the 1st dose and the 2nd dose. The three most common symptoms, including local effects, fever, and fatigue, have similar mean appearance times.

**Table 4. Duration of different AEFI in participants after two doses**

| n | | Participants with the symptom that lasted | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AEFI | | < 12h | | ≥ 12 - 24h | | 1 - 3 days | | 3 - 7 days | | 7 - 14 days | | > 14 days | | Mean (SD) (h) | Min-max (h) |
| | | n | % | n | % | n | % | n | % | n | % | n | % | | |
| **After 1st dose** | | | | | | | | | | | | | | | |
| ***Having local effects*** | | 36 | 16.3 | 22 | 10.0 | 141 | 64.1 | 18 | 8.2 | 3 | 1.4 | 0 | 0 | 32.6 | 2 - 168 |
| ***Systemic effects*** | Fever | 19 | 43.2 | 5 | 11.4 | 20 | 45.4 | 0 | 0 | 0 | 0 | 0 | 0 | 15.5 | 1 - 48 |
| | Fatigue | 32 | 26.2 | 21 | 17.2 | 63 | 51.6 | 4 | 3.3 | 2 | 1.6 | 0 | 0 | 27.6 | 1 - 168 |
| | Increased pain sensation | 21 | 18.4 | 21 | 18.4 | 67 | 58.8 | 5 | 4.4 | 0 | 0 | 0 | 0 | 25.8 | 1 - 72 |
| **After 2nd dose** | | | | | | | | | | | | | | | |
| ***Having local effects*** | | 17 | 4.6 | 24 | 6.5 | 222 | 60.2 | 87 | 23.6 | 13 | 3.5 | 6 | 1.6 | 55.4 | 1 - 720 |
| ***Systemic effects*** | Fever | 119 | 25.7 | 87 | 18.8 | 246 | 53.1 | 11 | 2.4 | 0 | 0 | 0 | 0 | 22.7 | 1 - 96 |
| | Fatigue | 231 | 61.3 | 112 | 29.7 | 33 | 8.7 | 1 | 0.3 | 0 | 0 | 0 | 0 | 43.9 | 2 - 720 |
| | Increased pain sensation | 12 | 4.7 | 24 | 9.3 | 172 | 66.9 | 44 | 17.1 | 4 | 1.6 | 1 | 0.4 | 46.6 | 1 - 600 |

Table 4 demonstrates the amount of time that each AEFI prolonged after two doses of the mRNA-1273. The local effects usually lasted 1-3 days (64.1% and 60.2%, respectively). Most AEFIs lasted for under 14 days. Overall, the lasting period of each AEFI after the 2nd shot was longer than that of the 1st shot.

## IV. DISCUSSION

So far, vaccination is the best solution to protect people against the disease. In Vietnam, the largest vaccination campaign had been deployed. To the best of our knowledge, this study is among the first to describe the common adverse events among participants aged 18 and above vaccinated with the Moderna COVID-19 vaccine at Hanoi Medical University in 2021. Seven hundred sixty-six participants who took part in this research had diverse occupations and health histories.

Research results show that among 766 participants, the number of females was slightly higher than males by 53.1% (407 females); 359 participants were males representing 46.9%. 37.9% of the participants were from 31 to 45 years old (290). The most common occupation was business/services workers, with 256 people (33.4%). As for health-related jobs, 7 participants were medical students (1%), and 24 participants were healthcare workers (3.1%). Thirty-two people (4.2%) participants were retiree. This occupational distribution is reasonable because, at the time of the implementation of the mRNA-1273 injection at HMU, the Ministry of Health issued Decision No. 3802 (August 11st, 2021) recommending all healthy adults over 18 years of age who are eligible for vaccination will receive the COVID-19 vaccine.[16] Among the participants with a history of allergies, the most common allergic factor was food, with nine reported cases, and there were no cases of allergy to the vaccine. The participant's medical history was understandable because knowledge about the vaccination's safety was limited at the time participants received the immunization. Consequently, before being vaccinated, participants must undergo comprehensive screening, and most individuals with serious underlying conditions would be excluded.[16]

Among 766 participants, the number of people having AEFIs after the 2nd dose (85.64%) was more than twice as many as those having AEFIs after the 1st dose (41.25%) ($p<0.001$). This result was similar to the study of Oleguer Parés-Badell in Spain when comparing BNT162b2 with mRNA-1273 COVID-19 vaccines.[17] In contrast, Minji Jeon's research on the ChAdOx1 nCoV-19 vaccine showed a higher AEFI frequency after the 1st dose when compared to the 2nd dose.[11] Both local and systemic effects were more frequent after the 2nd dose than the 1st dose. This result was consistent with the results of the Moderna COVID-19 vaccine clinical trials.[10] Participants experiencing local effects after the 1st dose (28.72%) were much lower than after the 2nd dose (48.17%) ($p<0.001$). However, this finding was different from the previous study of Hiroki Kitagawa in Japan, in which there was no significant difference in the frequency of pain at the injection site between the 1st and 2nd doses of both BNT162b2 and mRNA-1273.[12] The finding also differed from the study among hospital workers of Marta Valera-Rubio.[13] Regarding systemic effects, there was a significant difference between the 1st and 2nd dose reported cases. This result was similar to several the research.[12,13] The explanation for this result is the response of the immune system to the COVID-19 mRNA vaccine (Pfizer-BioNTech Comirnaty vaccine). After the first dose, the the body's cells to produce the spike protein which the body recognizes as an antigen, or something foreign, and starts reacting to it with inflammation at the injection site. This is also why the most common AEFI is localized pain in the injection site.[18] After causing inflammation at the injection site, the cells send signals for the body to create antibodies against the spike

protein. This process can cause inflammation in other parts of the body, resulting in headaches, fatigue, and fever.[19] When receiving the second shot, as the body already has some antibodies and some cells that remember the spike protein from the first dose, the body launches a very quick and stronger response. This is the reason why the adverse effects are more prevalent after the second dose.[20]

The results also demonstrated that the period of AEFIs onset was within the first 24 hours after the participants received the vaccine, and the first dose' AEFIs onset time period was earlier than the second dose. This result was consistent with the results of the mRNA-1273 vaccine clinical trials and several studies.[10,12,21]

Most common adverse events: local effects, fatigue, and increased pain sensitivity lasted within three days after onset, and the lasting period of each AEFI after the 2nd shot was longer than that of the 1st shot. This result was similar to the previous study of Pares-Badell and Chapin-Bardeles.[17,21] This finding indicated that participants were more likely to experience mild to moderate reactions because anaphylaxis usually occurs within the first hour after immunization. Furthermore, most symptoms lasted only for one to three days, indicating that participants did not have to suffer from serious reactions after injection. Hence, the Moderna COVID-19 vaccine is safe to be injected.

The study had some limitations. Firstly, the adverse events described in this study were subjective and depended on the patients' recall. There was no medical control, thus everything was dependent on the patients' evaluation at the time, which we cannot link with an objective scale, therefore there might be uncertainty of the number of adverse effects. Furthermore, the data was collected 28 days after the participants received each dose; recall bias might be a concern that leads to inaccuracies. We also did not obtain specific data about the symptoms and the severity of the local or systemic adverse reactions.

## V. CONCLUSION

Our findings indicated that the prevalence of AEFIs after the 1st dose was significantly lower than after the 2nd dose (41.25% vs. 85.64%). Local effects, fever, fatigue, and increased pain sensation were the most common in both 1st dose and 2nd dose. The Moderna COVID-19 vaccine is considered as safe for vaccination because the AEFIs are mostly mild and automatically wore off after one to three days.

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