



# Adverse effects Associated with Third-Booster COVID-19 Vaccine (Heterologous Vaccines by Sinovac- Moderna) among Health Care Workers

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**Abstract**— The mRNA 1273 vaccine by Moderna<sup>®</sup> has recorded to be 94.1% effective against laboratory-confirmed Covid-19 infection. Health care workers in Indonesia are receiving third-booster vaccine by Moderna after the two doses of virus-inactivated vaccine. Further evaluation of Covid-19 mRNA vaccine post-injection effects on health care workers is necessary. This present study assessed the post-immunization adverse events to health care workers in the Port Health Office of Semarang. This was a retrospective, cross-sectional, observational study aimed to the HCWs, both staff and non-staff, of the Port Health Office of Semarang. We identified and analyzed the adverse effects on 132 workers who had been receiving third-mRNA booster vaccine by Moderna. About 37.8% (50 out of 132) respondents experienced adverse events after receiving third-booster vaccine by Moderna. Among them, female workers (62%) had more incidents compared to males (38%). The most common symptoms were localized pain on injected arm (100%), fatigue (44%), fever (42%), myalgia (38%), and chills (30%). Other symptoms like night sleep issue, diarrhea, nausea, and headaches were also reported. The mRNA 1273 vaccine by Moderna<sup>®</sup> injection as booster provides several severe but not life-threatening symptoms, most of the emerging cases are fatigue and fever and possibly correlated with gender.

**Keywords**— SARS-CoV-2, adverse effects, heterologous vaccine.

## I. INTRODUCTION

Globally, the coronavirus disease (Covid-19) has been reported to reach more than 239 million patients and had a mortality of 4.8 million (case fatality rate: 2.03%) as of mid October 2021. At the same period, Indonesia recorded 4,231,046 patients and 142,811 deaths (CFR 3.34%). According to the Covid-19 case report (the 19<sup>th</sup> week of 2021), Central Java province had a worse proportion of cases in health care workers (HCWs) 2.9%.<sup>[1,2]</sup> Indonesian national government responded the vulnerable situation of HCWs the instruction to apply third-booster vaccination

using the mRNA 1273 vaccine by Moderna<sup>®</sup> after primer vaccination with inactive vaccine (booster with heterologous vaccines). The strategy was based on a positive record of Moderna vaccine that reaches 94.1% effectiveness and is listed in the Emergency Use Listing (UEL) by WHO since April 30, 2021.<sup>[3]</sup> Indonesia reported the mild effects of the vaccine emerged by recipients of the third-booster vaccine.<sup>[4]</sup>

Kadali et al. had performed an investigation against the identical vaccine to 432 post-vaccinated people. Various responses from the respondents are the following: 25% had

temporary disturbances in daily activities, 27.78% requested temporary time off from work, 3.94% needed outpatient provider assistance, and 0.23% needed assistance from emergency department, and none requested hospital intensive care. In addition, symptoms recorded during their study – at the most (occurrence descending-order) were 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.<sup>[5]</sup>

Despite Indonesia has confirmed the legal use of third-booster vaccines, specifically for HCWs, yet specific study on the after-injection effects. Our study, therefore, evaluated the short-term side effects after receiving the third-booster mRNA 1273 vaccine by Moderna<sup>®</sup> in a sample of HCWs in the Port Health Office of Semarang.

## II. METHODS

This was a retrospective, cross-sectional, observational study conducted on August 2021 aimed to the HCWs, both staff and non-staff, working in the Port Health Office of Semarang, Central Java Province as population. The targeted samples were workers who had been subjected the third-booster mRNA 1273 vaccine by Moderna<sup>®</sup> and had previously received a complete two-dose inactivated-vaccine. In total, we collected data from 132 respondents as samples. We designed an Indonesian language online questionnaire using Google Forms and delivered it to the targeted participants.

## III. RESULTS

One hundred and thirty two HCWs had participated in our study and met the criteria of third vaccination. Among them, the final samples consists of 65 males (49.2%) and 67 females (50.8%). The proportion of subjects experiencing adverse effects after the third vaccination by gender is shown in table 1 below. Overall, 50/132 participants (37.88%) confirmed to suffer serious effects after injection. The incident of adverse effects was more experienced by female workers than males in both quantity and proportion.

Table 1. Incident of adverse events following the the third-booster mRNA 1273 vaccine by Moderna<sup>®</sup> by gender

Gender	Number of participants	Number of participants with adverse effects	Proportion
Male	65 (49,2%)	19	38%
Female	67 (50.8%)	31	62%
Total	132 (100%)	50	

Respondents had reported to experience adverse effects in various symptoms. Quantity of the adverse events incidence is summarized in table 2. Among 50/132 HCWs (37.88%) that confirmed adverse events, 100% felt arm pain injection area, 42% suffered fever, 44% experienced fatigue, 38% were myalgia, 6% were nausea, 8% suffered from diarrhea, 30% felt chills, 8% sustained a headache, and 10% experienced night sleep issue.

Table 2. The symptoms of adverse effect experienced by health care workers after the third-booster mRNA 1273 vaccine by Moderna<sup>®</sup> injection

Adverse events	number of incidents	Percentage
Arm soreness	50	100%
Fever	21	42%
Fatigue	22	44%
Myalgia	19	38%
Nausea	3	6%
Diarrhea	4	8%
Chills	15	30%
Headache	4	8%
Night sleep issue	5	10%

## IV. DISCUSSION

In this cross-sectional survey among HCWs in the Port Health Office of Semarang receiving third-booster mRNA 1273 vaccine by Moderna<sup>®</sup>, less than two-fifth had follow-up adverse effects. The adverse effects sufferers were 62% female, massively higher than male (38%). Similar result was also reported by Centers for Disease Control and Prevention (CDC), confirmed 77.7% females and 21.9% males experienced AEFI at the first month of Covid-19 safety monitoring.<sup>[6]</sup>

List of adverse events had been felt by the post-third vaccinated HCWs were soreness on subjected arm, fever, fatigue, myalgia, nausea, diarrhea, cramps, headache, and sleeplessness. However, etiology of the identified adverse effects against mRNA 1273 vaccine by Moderna<sup>®</sup> is still recently unknown. CDC defined the post-vaccinated issue of anaphylaxis (signs of breathing difficulty, swelling on face and throat, rash, and low blood pressure) occurs in 2.5 cases per million mRNA-1273 vaccine doses.<sup>[7]</sup>

Kadali et al. discovered diverse symptoms of sore arms or localized pain, generalized weakness or fatigue, headache, myalgia or muscle pain, chills, fever, nausea, joint pain, sweating, dizziness, itching, rash, decreased appetite, muscle stiffness or spasm, decreased sleep quality, and

brain fogging after vaccination with mRNA1273 vaccine by Moderna<sup>®</sup>. However, majority of the symptoms reported during early post-vaccination period were not life-threatening.<sup>[5]</sup> Similarly, this study also revealed the non-life harming symptoms.

Morbidity and Mortality Weekly Report (MMWR) employed Vaccine Adverse Event Reporting System (VAERS) to monitor the first month of Covid-19 vaccine safety. In the report, it wrote a total of 113 deaths, including 78 long-term care facility (LTCF) residents and 35 non-LTCF residents. Among these reports, 19/35 (54.3%) non-LTCF residents' death had followed administration of Moderna vaccine.<sup>[6]</sup> The investigations are ongoing, but the underlying chronic conditions such as heart disease, cancer, stroke, probable pulmonary embolism, and otherwise frail health were thought to be the causes of death. The common adverse reactions to the mRNA vaccines, such as fever, nausea, and diarrhea, may have contributed to fatal outcomes in some of the frail patients.<sup>[6]</sup>

World Health Organization (WHO) released an article comprehensively talking about important details of the vaccine by Moderna. It highlighted the safety events involving the Covid-19 vaccine by Moderna are less frequent and severe in older (65+) adults than in younger adults (18–64 years). Additionally, the possible events are, generally, more frequent after the second dose compared to the first across all age groups.<sup>[8]</sup> The adverse effects on the top list ( $\geq 1/10$ ) are headache, nausea, vomiting, myalgia, arthralgia and stiffness, pain and swelling at the injection site, fatigue, chills, fever, and lymphadenopathy. Rash, redness at the injection site, urticaria, and rash or swelling are classified as common ( $\geq 1/100$  to  $< 1/10$ ). Some being categorized as uncommon (1/1000 to 1/100) are itching at the injection site; while Bell's palsy and facial swelling (acute peripheral facial paralysis) include as extremely rare (1/10000 to 1/1000). Other identified events namely hypersensitivity and anaphylaxis are still unknown<sup>[8]</sup>

## V. CONCLUSION

In this study, we assessed the short-term side effects associated with third-booster mRNA 1273 vaccine by Moderna<sup>®</sup> specifically subjected to HCWs of the port health office of Semarang, Central Java Province. We found that most of the participants reported localized pain on injected arm, fever, fatigue, myalgia, nausea, diarrhoea, chills, headache, and night sleep issue. These listed symptoms are included in 'very common' and 'common' according to WHO. Moreover, about two-fifth subject reported adverse effect follow immunization (AEFI), two of the most-frequent issues are fatigue and

fever. We also observed the higher proportion in female workers compared to males. Fortunately, we had no report of a death. As future direction, a public-access hotline service during the first month of Covid-19 vaccine safety monitoring may help in monitoring reports of adverse effects following immunization (AEFI).

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