УДК 61:615.1(06) ББК 5:72 А 43 ISBN 978-985-21-1009-9

## *M.E.S. Madduma Ralalage, C.U. Madduma Ralalage* АССОЦИИРОВАННЫЕ ФАКТОРЫ ОСТРОГО ПОБОЧНОГО ПОСЛЕДСТВИЯ ПОСЛЕ ВВЕДЕНИЯ ВАКЦИНЫ COVID 19

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## M.E.S. Madduma Ralalage, C.U. Madduma Ralalage ASSOCIATED FACTORS OF ACUTE ADVERSE EFFECTS AFTER THE COVID 19 VACCINE ADMINISTRATION *Tutor: Ph.D., associate professor L.P. Mamchits*

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**Резюме**. В этой реальной когорте серьезные побочные эффекты вакцины против COVID-19 были редки, а общие факторы, связанные с побочными эффектами, были аналогичны текущим опубликованным отчетам.

Ключевые слова: вакцинация против COVID-19, побочные эффекты, SARS-CoV-2.

**Resume.** In this real-world cohort, serious COVID-19 vaccine adverse effects were rare, and overall adverse effects associated factors were similar to current published reports.

Keywords: COVID-19 vaccination, adverse effects, SARS-CoV-2.

**Relevance.** In response to the SARS-CoV-2 outbreak, and the resulting COVID-19 pandemic, a global competition to develop an anti-COVID-19 vaccine has ensued. The targeted time frame for initial vaccine deployment is late 2020. [3] The new outbreak of SARS-CoV-2 from December 2019 precipitated a world-wide crisis. Globally, lockdowns of different severity levels were imposed (4). While the number of daily deaths attributable to COVID-19 appears to have decreased substantially by June 2020, the increasing numbers of 'cases' (positive test results for viral exposure) have raised some concerns regarding the ability of governments and decision-making authorities to reduce viral transmission and subsequent consequences [5-7]To quickly respond to the COVID-19 pandemic, a broad range of COVID-19 vaccine candidates have been investigated using various technologies and platforms including, nucleic acid (DNA, RNA) vaccines, viral vectored vaccines, inactivated vaccines, protein subunit and live attenuated vaccines [8, 9].

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was declared a pandemic by WHO on March 11, 2020 (World Health Organization, 2020), resulting in devastating medical, economic, and social consequences worldwide. Safe and effective vaccines are therefore very crucial and urgently needed in order to contain the pandemic. Because COVID-19 spreads swiftly, newer vaccine platforms, including mRNA and adenovirus vector-based, were quickly developed and distributed worldwide [2].

Anaphylaxis after COVID-19 vaccination is rare and has occurred in approximately 5 people per one million vaccinated in the United States. Anaphylaxis, a severe type of allergic reaction, can occur after any kind of vaccination [1].

Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare. DC has also identified nine deaths

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that have been caused by or were directly attributed to TTS following J&J/Janssen COVID-19 vaccination. Women ages 30-49 years, especially, should be aware of the increased risk of this rare adverse event. Myocarditis and pericarditis after COVID-19 vaccination are rare. As of March 17, 2022, VAERS has received 2,309 preliminary reports of myocarditis or pericarditis among people ages 30 years and younger who received COVID-19 vaccines. Reports of death after COVID-19 vaccination are rare. More than 558 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through March 21, 2022. During this time, VAERS received 13,434 preliminary reports of death (0.0024%) among people who received a COVID-19 vaccine [1, 2. 3].

**Purpose:** the objectives of this study is to describe adverse effects and identify factors associated with adverse effects after COVID-19 vaccination in participants in an online cohort study. In addition, the study sought to identify factors associated with more severe adverse effects. These results may help to gain a greater understanding of the real-world experience of adverse effects after COVID-19 vaccination.

**Tasks:** our study aimed to explore the rates and types of acute adverse effects after the first, second and third doses of nCoV-19 vaccine in Colombo, Gomel, and Grodno. It also analyzed the factors associated with acute adverse effects (AAEs) after vaccination.

**Material and methods.** Study is an online cohort study that began enrolling participants on March 22<sup>rd</sup> till March 28th of March 2022 year. Study was basically targeted the population in three cities Colombo, Gomel, and Grodno. Participants are recruited to the study through a digital platform by inviting via social Medias. 140 participants were joined to the survey, who are 18 years or older, and provided consent to participate in the study. After providing electronic consent, participants completed survey.

The results and their discussion. After reporting vaccination, participants were asked to report vaccine adverse effects, with response options including fever, chills, fatigue, sore/scratchy throat, muscle pain, joint pain, headache, other pain, and redness/swelling at the injection site, rash other than at the injection site, allergic reaction/anaphylaxis, other, and none of the above. These response options were chosen because these adverse effects had been reported in vaccine clinical trials. Participants could provide free-text responses to the option of other. Following branching logic, participants reporting adverse effects were also asked the duration of adverse effects and self-rated adverse effect severity (very mild, mild, moderate, severe, and very severe).

At baseline, participants reported characteristics, including age, sex, gender, and highest educational attainment, medical conditions (hypertension, diabetes, cardiovascular diseases, chronic respiratory illnesses, obesity, joint inflammation, osteoporosis, autoimmune diseases, thyroid diseases, cancer, and other diseases). Participants reported receiving at least 1 dose of vaccine were 7 (4.9%), 2 doses 91 (64.1%) and 3 doses were 44 (31%). 75 (53.57%) participants were non healthcare workers and 65 (46.4%) participants were health care workers. Most respondent's received at least 2 doses of vaccination were (95.1%). 74% of participants belongs to 20 -29 age group.

Onset of the side effects within 4 hours were 26% and within 5-8hour (35%). (Diagram 1).

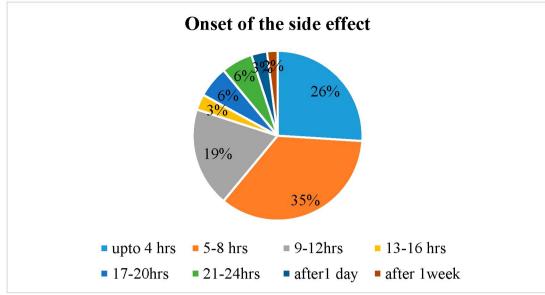


Diagram 1 – Onset of the development of the side effects

Within 3 days most of the participant's got rid of the adverse effects (88%)(Chart 1)

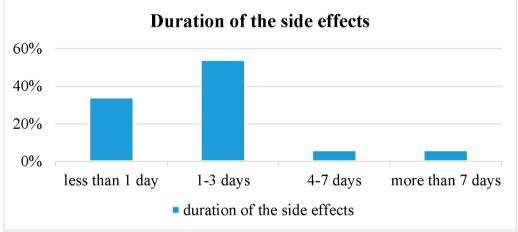


Chart 1. – Duration of the side effects

Most of the participant's received brand name is Sinopharm (70) and sputnik v (31) AstraZeneca/ Oxford (24) Pfizer-Biotech was (13) and Covaxin (3) Moderna (1).

Participants were asked to report vaccine adverse effects, with response options including fever, chills, fatigue, sore/scratchy throat, muscle pain, joint pain, headache, other pain, and redness/swelling at the injection site, rash other than at the injection site, allergic reaction/anaphylaxis, other, and none of the above. These response options were chosen because these adverse effects had been reported in vaccine clinical trials. Participants could provide free-text responses and text responses to the option of other. Self evaluated side effects categorization. Mild AAEs were local site reactions, feverishness, headache, nausea/vomiting, and fatigue. Moderate AAEs were palpitation, high-grade fever, chills, chest tightness and with or without mild AAEs. Severe AAEs categorized according to headache, facial weakness, limb weakness, skin lesions, bleeding gums, nosebleed, and bruises in the body, joint pain, and thrombocytopenia, thrombosis with hospitalized participants and with or without mild and moderate AAEs.

Symptoms recorded in 14 participants who are with previously known allergies to food and drink. Among the 10 participants reported mild symptoms. 2 participants reported moderate symptoms and 2 participants reported severe issues. Depending upon the vaccine brand with sputnik v no symptoms reported in 9, mild symptoms recorded in 17 and moderate symptoms recorded in 4. Brand name Sinopharm No symptoms recorded in 45, mild symptoms recorded in 20, moderate symptoms recorded in 4 and one severe case was reported under this model of vaccine brand. AstraZeneca/Oxford vaccination was 2 severe reported cases 3 moderate cases represented, 14 mild cases, 5 vaccinated participants were without symptoms. Regarding Pfizer-Biotech 7 participants no symptoms 5 participants with mild symptoms and q participant had severe symptoms. Among covaxin participants 2 with no symptoms and 1 with mild symptoms were recorded.

Also participants were reported the duration of adverse effects and self-rated adverse effect severity (no symptoms, mild, moderate, severe).

The most common vaccine adverse effects were fatigue (49.2%), muscle pain (40%), headache (37.5%), chills 18.9%, and redness/swelling at the injection site (50.8%), joint pain (27.5%), and fever (42.5%) decreased sleep quality (18.3%)

Sweating for no reason (9%) Nausea (7.4%), abdominal pain (5.8%) diarrhea (7.4%)

Outcome of severe or very severe adverse effects (compared with no adverse effects, very mild, mild, or moderate), the strongest factor associated with severe or very severe adverse effects was vaccine 3rd dose

By this survey try evaluated the possible relationships between the people who has previous allergic persons to foods and medications, were 14 in number from all 140 participants

**Findings:** in this real-world digital cohort of 140 people who reported receiving COVID-19 vaccination, serious adverse effects, such as anaphylaxis or allergy, were rare. Adverse effects were more common after the full vaccination dose, and in participants with younger age, female sex, prior COVID-19, according to the data reported by this cohort as adverse effects. This study has limitations some groups, such as men, older adults, and people belonging to minorities' racial and ethnic groups, rural residents and pregnant women.

Given the online nature of the study, not all participants responded to all surveys.

Outcome of moderate and severe adverse effects, associated with previously known allergies to food or medicine after the full vaccination dose, in participants with younger age, female sex, prior COVID-19 infection, and anemia.

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