*Jordan Journal of Pharmaceutical Sciences, Volume 15, No. 2, 2022*

# A Comprehensive Review on Efficacy and Adverse Events Associated With Different Covid-19 Vaccines

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## ABSTRACT

To combat COVID-19, various health agencies around the world gave emergency approval for vaccines. Therefore, the long-term protective effect and the potential adverse effects of the vaccines on immunocompromised patients, pregnant women and geriatrics might not be well-established. The aim of this review was to assess the safety and efficacy of a number of the most commonly approved vaccines all over the world. A review was made to identify clinical trials that studied the vaccines' efficacy and case reports of potential suspected vaccine-related adverse events. The electronic databases searched to identify relevant studies were Science Direct, PubMed/Medline, Scopus and MedRxiv. Seven randomized controlled trials which assessed the efficacy of COVID-19 vaccines and case reports which reported the vaccines' adverse events were included in the review. The efficacy of the vaccines was found to be 94.6% for Pfizer vaccine, 94.1% for Moderna vaccine, 66.1% for Johnson and Johnson's, 76.4% for Covishield, 91.6% for Sputnik, and 77.8% for Covaxin. No severe adverse events were reported in the studies. All the reported adverse events were mild, self-sustaining and did not require any medical intervention. All the COVID-19 vaccines demonstrated promising immunogenicity profile, different degrees of protective effectiveness and a tolerable safety profile. However, further research to evaluate the efficacy and safety in vulnerable populations including immunocompromised patients, pregnant women and geriatric populations are needed. The long term post marketing surveillance becomes a very important part of identifying the efficacy and side effects among different populations.

**Keywords:** COVID-19 Vaccine, Vaccine Efficacy, Vaccine Adverse effects.

## INTRODUCTION

The novel human viral pathogen severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was identified as the source of the coronavirus disease 2019 (COVID-19) pandemic in Wuhan, China, in late 2019 [1]. As a major worldwide public health event, the COVID-19 outbreak has become the world's principal health concern, having a significant political, economic, and cultural influence. COVID-19 causes fever and a dry cough, as well as damage to various organs, particularly the lungs. The use of a mask and keeping social distance has been established as one of the most effective ways to prevent the virus from spreading, and isolation and symptomatic supportive therapy continue to be the most common treatments for COVID-19 patients.

To contain the COVID-19 pandemic, a protective vaccine will be required in order to achieve sufficient herd immunity against SARS-CoV-2 infection. According to the World Health Organization (WHO), more than 200 COVID-19 vaccines are being developed [2]. The effectiveness of vaccinations in preventing disability and mortality from other infectious illnesses validates the belief that COVID-19 may

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Received on 15/9/2021 and Accepted for Publication on 26/12/2021.

 

be controlled by preventive immunisation. Vaccines against infectious illnesses are expected to save at least 23 million lives between 2011 and 2020.

When emergency approval for COVID-19 vaccines is granted due to high necessity, it is important to demonstrate the vaccines' safety [2]. Identifying, measuring, and balancing known and speculated safety concerns against possible benefits is a crucial part of the vaccine development process. This is notably essential for protecting individuals who are at a higher risk of severe illness from COVID-19, such as healthcare providers, older or elderly adults, and people with other chronic illnesses.

In this review, we will discuss the efficacy and adverse events of a few of the most commonly approved vaccines around the world, i.e, Pfizer, Moderna, Johnson and Johnson, AstraZeneca/Oxford Vaccine, Sputnik, Covishield and Sinopharm vaccines.

**Materials and Methods**

*Search Strategy:*

This review was carried out according to the "Preferred Reporting Project for Systematic Evaluation and Meta-Analysis" criteria" (PRISMA) shown in Figure 1.To identify the clinical trials evaluating COVID-19 vaccines and case reports regarding adverse events of COVID-19 Vaccine, Databases searched for data until June 2021 were Science Direct, PubMed/Medline, Scopus and MedRxiv were systematically screened for medical literature.

The searching strategy(s) employed were “AZD1222, SARS-CoV-2, Covid-19, BNT162b1, mRNA-1273, rAd26, rAd5, AD5-nCOV, Ad26.COV2, BBIBP-CorV, BBV152 and CoronaVac”.

*Literature Inclusion Criteria:*

1. Randomised Controlled Trials in phase I/II/III of COVID-19 vaccines were included.
2. Case reports reporting the suspected adverse events due to COVID-19 vaccines were included.

*Literature Exclusion Criteria:*

1. Non-RCT studies, research without a control group, preclinical studies, animal phase studies, meta-analyses, letters to the editor, studies with no extractable data, and news items were all excluded from this study.
2. One of the two studies that overlapped was eliminated;
3. Articles published in Languages other than English were eliminated.

*Data Extraction:*

Data was extracted from the papers by three independent reviewers. First authors, published year, vaccine name, company, study type, vaccine type, trial phase, injection interval (days), trial country, all adverse events, and efficacy-related data were all gathered from each publication. Two authors extracted data separately, while a third author randomly evaluated the collected data.

The vaccine's safety and efficacy were among the key findings of this review. Local adverse reactions and systemic adverse reactions were used to evaluate safety. Geometric mean titres (GMT) of SARS-CoV-2, seroconversion rate, and the reaction of IgG or other specific antibodies to the receptor binding site of the SARS-CoV-2 spike protein were all used as immunogenicity markers

Literature Search Flowchart:

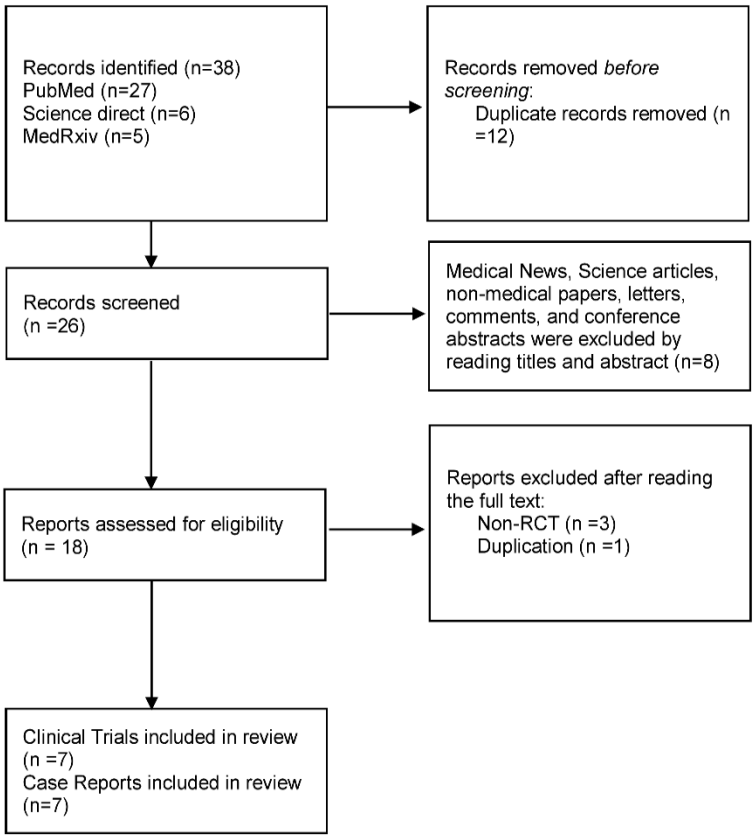


**Figure 1**

**Results**

PFIZER/BIONTECH (BNT162b2)

Efficacy:

The findings of the phase II/III trial, released on December 31, 2020, showed that a two-dose regimen of the Pfizer vaccine provides 94.6% protection against symptomatic COVID-19 for at least 7 days after the second dose. There was only one incidence of severe COVID-19 in the vaccination group, compared to nine in the placebo group (Table-1). According to data from an observational research involving 7,000 Israeli healthcare workers, vaccination effectiveness against symptomatic COVID-19 infection was 85 percent after 15–28 days from the first dose. [20]

**Table1:**
**Efficacy of Various Vaccines from Clinical Trials:**

| Author Name(s) | Vaccine | Vaccine Type | Mechanism Of Immune Stimulation | Sample Size | Study Site(s) | Adverse Effects | Overall Efficacy | Emergency Use Authorization |
|---|---|---|---|---|---|---|---|---|
| F.P. Polack, et al. December 2020 [3] | BNT162b2 mRNA Covid-19 Vaccine (Pfzier) | Nucleoside-modified RNA vaccine | mRNA induces cells to produce spike proteins which trigger antibody production. | Total Size-43,448 Dose-1 Vaccine-18,860 Placebo-18,846 Dose-2 Vaccine-18,556 Placebo-18,530 | Argentina Brazil United States | Fatigue and headache (59% and 52%, respectively ) | 94.6% | Approved in several countries. Emergency use in USA, EU, UK, Bahrain, Canada, Saudi Arabia, Mexico, etc. |
| L.R. Baden, et al. December 2020 [4] | mRNA-1273 (Moderna) | Lipid nanoparticle (LNP)-encapsulated mRNA vaccine. | mRNA induces cells to produce spike proteins which trigger antibody production. | Total Size-30,351 Vaccine-15,181 Placebo-15,170 | United States | Injection site pain (91.6%), fatigue (68.5%), headache (63.0%), muscle pain (59.6%), joint pain (44.8%) | 94.1% | Approved in Switzerland. Emergency use in USA, UK and EU |
| Denis Y Logunov, et al.[5] | Gam-COVID-Vac (Sputnik V) | Heterologous recombinant adenovirus (rAd)-based vaccine | Induce antigen-specific cellular immunity (specific T-cell immunity) | Total Size-19,866 Vaccine-14964 Placebo-4902 | Russia | Pain at the site of injection (58%), headache (42%), hyperthermia (50%), asthenia (28%) and muscle and joint pain 18 of 76 (24%). | 91.1% | Early use in Russia |
| J. Sadoff, et al. January 2021[6] | Ad26.COV2.S Vaccine (Johnson and Johnson) | Recombinant, replication-incompetent human adenovirus type 26 (Ad26) vector | Induce antibody-based immune responses | Total Size-43,783 Vaccine-21,895 Placebo-21,888 | Argentina Brazil Chile Colombia Mexico Peru South Africa United States. | | 66.1% | Emergency use in USA and Bahrain |

| Author Name(s) | Vaccine | Vaccine Type | Mechanism Of Immune Stimulation | Sample Size | Study Site(s) | Adverse Effects | Overall Efficacy | Emergency Use Authorization |
|---|---|---|---|---|---|---|---|---|
| Merryn Voysey, et al December 2020 [7] | ChAdOx1 nCoV-19 vaccine (Covishield) | Viral vector (Non-replicating) | Induce anti-spike IgG responses and spike-specific T-cell responses. | UK-1 Total Size-2741 Vaccine-1376 Placebo-1374 UK-2 Total Size-4807 Vaccine-2377 Placebo-2430 Brazil Total Size-4088 Vaccine-2036 Placebo-2025 | UK Brazil | Fatigue and headache | 76.4% | UK, Argentina, El Salvador, Dominican Republic, India, Bangladesh, Mexico, Nepal, Pakistan, Brazil, Saudi Arabia, Iraq, Hungary, Thailand |
| Shengli Xia, et al January 2021 [8] | BBIBP-CorV Vaccine (Sinopharm) | Inactivated vaccine | Antibody-based immune responses | China Total Size-448 Vaccine-336 Placebo-112 | China | Pain and fever | Day 14 seroconversion rates: 97.6% | China, Bahrain, United Arab Emirates, Egypt, Jordan, Iraq, Pakistan, Serbia. |
| Ella, et al. March 2021[9] | BBV152(Covaxin) | Inactivated Vaccine | Humoral and Immune mediated responses. | Total Size-370 | India | Pain and Fatigue | 77.8% | India |

**Table 2:**
**Covid Vaccine Adverse Events in Case Reports:**

| Author, Publication Year | Vaccine | Main Diagnosis | Age and Co-Morbidities | Presenting Symptoms | Outcome | Proposed Pathophysiology |
|---|---|---|---|---|---|---|
| Omar Fueyo-Rodriguez. 2021[10] | BNT162b2 mRNA Covid-19 Vaccine(Pfizer) | Immune thrombocytopenia | 41 Year/F Multiple Allergies (Quinolones, Cephalosporins) | Fever, tachycardia and nausea. | Patient Improved | Molecular mimicry |
| Erika Z. Lopatynsky-Reyes. 2021[11] | BNT162b2 mRNA Covid-19 Vaccine (Pfizer) | BCG Scar Local Skin Inflammation | 31 year old/F Nil | Headaches, chills, and myalgias in the upper and lower limbs. | Patient Improved on his own. | delayed inflammatory reactions (DIR) to HA fillers |
| Erika Z. Lopatynsky-Reyes. 2021[11] | mRNA-1273 (Moderna) | BCG Scar Local Skin Inflammation | 28 year old/F Nil | headache, nausea, myalgias, arthralgias, and malaise lasting for two days | Patient Improved on his own. | delayed inflammatory reactions (DIR) to HA fillers |
| Shreena Umit Patel. 2021[12] | ChAdOx1 nCoV-19 vaccine (Covishield) | Guillain-Barre syndrome | 37 year old/M Nil | 2 weeks following the vaccination, the patient developed persistent back pain, new onset of distal paraesthesia within the hands and feet alongside a symmetrical, progressive ascending muscle weakness | Patient was treated with IVIG. His neurological symptoms have been slow to recover and he is currently under observation in a quaternary neurology centre. | Molecular mimicry response (antibodies against neuronal myelin sheaths and resulting in GBS). |
| Josef Finsterer. 2021[13] | Covaxin | Guillain-Barre syndrome | 32 Year old/ M Nil | Developed paraesthesia on both foot soles two days prior to admission followed by paraesthesias of both palms and dysphagia one day later. Additionally, he reported bilateral frontal and nuchal headache on day-1 | - | - |
| Jackie M Helms. 2021[14] | mRNA-1273 (Moderna) | Immune Thrombocytopenic Purpura | 72 Year Old/M Hypertension, gout, hyperlipidaemia and nonischaemic cardiomyopathy | Acute epistaxis and diffuse cutaneous purpura a few hours after receiving the first dose of the Moderna SARS-CoV2 vaccine. | The patient was treated with prednisolone, romiplostim and plasma exchange. | - |
| Larissa Lebedev. 2021[15] | BNT162b2 mRNA Covid-19 Vaccine(Pfizer) | Minimal Change Disease | 50 year Old/ M Nil | On the third day after the injection, he developed abdominal pain and diarrhoea. One day later, he noticed swelling of the lower extremities, which gradually worsened over the next 6 days. | The patient was treated with steroids and anti-hypertensives. | T cell–mediated podocyte injury. |

| Author, Publication Year | Vaccine | Main Diagnosis | Age and Co-Morbidities | Presenting Symptoms | Outcome | Proposed Pathophysiology |
|---|---|---|---|---|---|---|
| Elisabeth Albert. 2021[16] | mRNA-1273 (Moderna) | Myocarditis | 24 Year Old/ M Nil | The patient experienced subjective fever, chills, and body aches in the first 24 hours after the shot. His symptoms progressed to a substernal chest pain, which was exacerbated with deep inspiration and supine position. | - | - |

**Table 3:**
**COVID Vaccine Side effects Profile according to CDC in people aged 18-55 years:**

| Vaccine | Total Size | Dose-1 | | Dose-2 | |
|---|---|---|---|---|---|
| | | Any Systemic Adverse Reactions | Systemic Adverse Reactions | Any Systemic Adverse Reactions | Systemic Adverse Reactions |
| Pfizer Vaccine[17] | Dose-1 = 2291<br>Dose-2 = 2098 | 82.8% | Headache-41.9%<br>Fatigue-47.4%<br>Chills-14%<br>Myalgia-21.3%<br>Arthralgia-11%<br>Diarrhea-11.1% | 82.8% | Headache-51.7%<br>Fatigue-59.4%<br>Chills-35.1%<br>Myalgia-37.3%<br>Arthralgia-21.9%<br>Diarrhea-10.4% |
| Moderna Vaccine[18] | Dose-1 = 11405<br>Dose-2 = 10358 | 57% | Headache-35.4%<br>Fatigue-38.5%<br>Myalgia-23.7%<br>Arthralgia-16.6%<br>Nausea / Vomiting-9.3%<br>Chills-9.2% | 81.9% | Headache-62.8%<br>Fatigue-67.6%<br>Myalgia-61.3%<br>Arthralgia-45.2%<br>Nausea / Vomiting-21.3%<br>Chills-48.3% |
| Janssen COVID-19 vaccine[19] | Total-2036 | 61.5% | Fatigue-43.8%<br>Headache-44.4%<br>Myalgia-39.1%<br>Nausea-15.5%<br>Fever-12.8% | - | - |

**Table4:**
**COVID Vaccine Side effects Profile according to CDC in persons aged >55 years:**

| Vaccine | Total Size | Dose-1 | | Dose-2 | |
|---|---|---|---|---|---|
| | | Any Systemic Adverse Reactions | Systemic Adverse Reactions | Any Systemic Adverse Reactions | Systemic Adverse Reactions |
| Pfizer Vaccine[17] | Dose-1=1802<br>Dose-2=1660 | 70.6% | Fatigue-34.1%<br>Headache-25.2%<br>Chills-6.3%<br>Diarrhoea-8.2%<br>Myalgia-13.9%<br>Arthralgia-8.6% | 70.6% | Fatigue-50.5%<br>Headache-39%<br>Chills-22.7%<br>Diarrhoea-8.3%<br>Myalgia-28.7%<br>Arthralgia-18.9% |
| Moderna Vaccine[18] | Dose-1=3761<br>Dose-2=3589 | 48.3% | Headache-33.3%<br>Fatigue-38.5%<br>Myalgia-19.8%<br>Arthralgia-16.4%<br>Nausea / Vomiting-5.2%<br>Chills-5.4% | 71.9% | Headache-46.4%<br>Fatigue-58.4%<br>Myalgia-46.9%<br>Arthralgia-34.9%<br>Nausea/Vomiting-11.8%<br>Chills-30.6% |
| Janssen COVID-19 vaccine[19] | Total-1320 | 45.3% | Fatigue-29.7%<br>Headache-30.4%<br>Myalgia-24%<br>Nausea-12.3%<br>Fever-3.1% | - | - |

Additionally, observational data from a U.S. study compiled by the U.S. Centres for Disease Control and Prevention (CDC), reported that mRNA vaccines (Pfizer and Moderna) efficacy was 80% at least after one day from the first dose and 90% at least after one day from the second dose for asymptomatic and symptomatic infections. [21]

Alpha (B.1.1.7) and Beta (B.1.351) - Observational data from Qatar stated that vaccine efficacy was 89.5% in preventing symptomatic COVID-19 for a minimum of 14 days. Vaccine efficacy against severe, critical, or fatal illnesses caused by Alpha or Beta variants was 97.4%. [22]

Delta (B.1.617.2) - An observational study conducted by Public Health England, found that the Pfizer/BioNTech vaccine has an efficacy of 87.9% against symptomatic disease from the B.1.617.2 variant 2 weeks after the second dose. Vaccine efficacy against the B.1.617.2 variation was 33.2% after one dose. [23]

Geriatric Population: An earlier observational study reported that the population over 85 years old were found to have 94.1% protection against Symptomatic COVID-19, 96.9% protection against hospitalization, and 97% protection against death after seven days from receiving the second vaccine dose. [24]

**Adverse effects:**

The Phase II/III research found that people who took Pfizer vaccine demonstrated transitory adverse effects more frequently than placebos.

Fever, cough, tiredness, headache, shortness of breath, chills, muscular discomfort, sore throat, diarrhoea, or vomiting were the most often reported occurrences after months follow-up.(Table-4)

**Updates**:

On August 23, 2021, the FDA has approved the use of Pfizer-BioNTech COVID-19 Vaccine, marketed as COMIRNATY, for the prevention of COVID-19 in children above 16 years of age. [36] As of October 29, 2021, the vaccine has been approved for emergency use in children 5 through 11 years of age. [37] The FDA had issued an EUA for the vaccine on November 22, 2021, for the use of a 3rd primary series dose for immunocompromised individuals above the age of 12 years. [38]

**MODERNA (mRNA-1273)**

**Efficacy:**

The findings of a phase III trial released on February 4, 2021 show that a complete regimen of Moderna provided 94.1% protection against symptomatic COVID-19 for a minimum of 14 days after complete vaccination. (Table1)

Observational data from a US study published by the Centers for Disease Control and Prevention reported that mRNA vaccine (Pfizer/Moderna) efficacy against COVID-19 infection was 80% at least 14 days after the first dose and 90% at least 14 days after the second dose. [21]

Moderna also released topline findings from a phase II/III study in teenagers, which revealed that vaccination effectiveness was 100% in populations aged 12 to 17 years old, 14 days after receiving the second dose. [25]

Alpha (B.1.1.7): There was no change in the antibody titres produced against this variant, according to a small laboratory research. Clinical investigations are still needed to establish the impact. [26]

Beta (B.1.351): Antibody titres are decreased by 6.5-fold according to a small laboratory research. Clinical investigations are still needed to establish the impact. [26]

Gamma (P1): Antibody titres are decreased by 2.6-fold according to a small laboratory research. Clinical investigations are still needed to establish the impact. [27]

Delta (B.1.617.2): No evidence yet.

Geriatric Population: In clinical studies, vaccination effectiveness against symptomatic illness 14 days after the second dose was 86.4 % in individuals over 65 years old. [4]

**Adverse Effects:**

Fever, local discomfort, swelling, soreness, erythema at the injection site, axillary lymphadenopathy, tiredness, headache, myalgia, arthralgia, chills, and nausea/ vomiting were the most prevalent side events in clinical studies after the Moderna COVID-19 vaccination.(Table-3)

**JANSSEN VACCINE**

**Efficacy:**

According to findings from a phase III study released on April 21, 2021, vaccine effectiveness against moderate to severe/critical illness was 66.1 % overall 28 days following immunisation. In terms of avoiding severe/critical illness, it was 85.4 % successful. At least 28 days following immunisation, vaccine effectiveness against COVID-19 needing critical care was 100.0 %. [6] (Table1)

Alpha (B.1.1.7): A real-world study published on 30 April 2021 and conducted in the United States when Alpha was the predominant variant circulating found that vaccine effectiveness against SARS-CoV-2 infection was 76.7 % two weeks after vaccination among 1,779 vaccinated individuals matched with 17,744 unvaccinated controls. [28]

Beta (B.1.351): According to Phase III trial results, vaccination effectiveness against moderate to severe/critical disease was 64.0 %, and 81.7 % against severe disease. [6]

Gamma (P1): Phase III trial findings show vaccination effectiveness was 68.1 % against moderate to severe/critical disease and 87.6 % against severe disease due to the gamma variant.[6]

Delta (B.1.617.2): No evidence yet.

Geriatric Population: Phase III trial findings showed that the vaccine had an efficacy of 67.9% 28 days after immunisation in individuals aged 60 years, however vaccine efficacy estimates were greater in persons aged 60 years without comorbidities than in participants aged 60 years with comorbidities. To further understand these possible disparities, more follow-up data is required. [6]

**Adverse Effects:**

Mild to severe fever episodes occurred after immunisation and disappeared within 1 to 2 days. Injection site discomfort, tiredness, headache, and myalgia were the most common local adverse events. (Table3)

The Janssen vaccination was temporarily halted in the United States from April 13, 2021, to April 23, 2021, due to reports of six thrombocytopenia cases. [39] The CDC had found 28 occurrences of blood clots with insufficient platelets among more than 8.7 million individuals who had been vaccinated as of May 12, 2021.[29] (Table-2)

**COVISHIELD VACCINE-**

**Efficacy:**

On March 25, 2021, results from a Phase III study in the United States, Peru, and Chile were published, indicating that when two doses are administered four weeks apart, vaccination effectiveness was 76.4 % in preventing symptomatic illness and 100% against severe COVID-19 infection.[12](Table1)

Alpha (B.1.1.7): Statistics from the United Kingdom (UK) immunisation campaign, published on March 1, 2021, and April 23, 2021, indicated that the vaccine was very effective against the UK variation. Furthermore, despite the fact that there was 9-fold decrease in antibody titres against UK variation, vaccine effectiveness was equal for Alpha and non-Alpha lineages, according to research published in The Lancet on March 30, 2021 (70.4% and 80.5%, respectively). [30]

Beta (B.1.351): According to a modest laboratory research utilising vaccination sera, the number of antibodies that neutralise this variation had decreased by 12.4-fold. According to a research published in The New England Journal of Medicine on March 16, 2021, a two-dose regimen had only a 10.4 % effectiveness in preventing mild to severe COVID-19 infection in young adults. [31]

Gamma (P1): Antibody titres against this variation were decreased by 2.9-fold in a small laboratory study using vaccination sera. [27]

Delta (B.1.617.2): PHE's observational study, which included 1,054 people confirmed to have the Delta variant and was published on May 22, 2021, found that the Oxford/AstraZeneca vaccine had an efficacy of 59.8% against symptomatic disease from the Delta variant two weeks after the second dose, compared to 66.1% against

the Alpha variant. Vaccine effectiveness against the Delta variant was 32.9 % after one dose, compared to 51.4 % against the Alpha version.

PHE issued a revised analysis on 14 June 2021 as a pre-print, which included 14,019 symptomatic patients infected with the Delta strain. According to the study, the delta variant's vaccination effectiveness against hospital admission was 71 % after one dose and 92 % after two doses.

A Scottish research published in The Lancet on June 14, 2021 contained 19,543 instances (7,723 with the Delta variation), with 377 of them requiring hospitalisation (134 with the Delta variant). The vaccination provided 60% (protection against the Delta variant) and 73 %( protection against the Alpha variant) protection.[32]

Geriatric Population: Vaccine effectiveness in people aged 70 years was 56% from 28 - 34 days after getting the vaccine, and improved to 58 % from day 35 onwards, according to data from the UK immunisation programme. The data also reported that one dose of vaccination was around 80% effective at avoiding hospitalization in geriatric population. [24]

The vaccination effectiveness in people aged over 65 years after two doses, four weeks apart, was found to be 85 % in the US trial. [33]

Another observational data from PHE, published in trial on May 10, 2021, showed that one dose of the Covishield vaccine reduced the risk of mortality in people 70 years and older by 55% compared to those who are not vaccinated. First of all, this corresponds to about 80% protection from death in the event of an accident. [24]

Another preprint, released on the same day by PHE, claimed that one dosage of the Covishield vaccine decreased the chance of hospitalization by 73% in people over the age of 80. One dosage decreased the chance of hospitalisation by 84% in those aged 70 to 79.

**Adverse Effects:**

As of 7 April 2021, the Medicines and Health Products Regulatory Agency (MHRA) reported 79 cases of Thrombocytopenia in the UK, with low platelet counts after 22 million doses of the Covishield vaccine. It is associated with this very rare side effect, but more work is needed.[34]

According to the Joint Committee on Vaccination and Immunization (JCVI) if an alternate vaccination is available, all remaining unvaccinated individuals in phases 1 and 2 of the programme who are 18 to 29 years old and do not have an underlying health condition that puts them at increased risk of severe COVID-19 should be provided it.(Table 2)

**SPUTNIK VACCINE**

**Efficacy:**

Results from Phase III trial in the Russia, published on 18 February 2021, reported that the vaccine had an overall efficacy of 91.6% against symptomatic disease 21 days after vaccination and 100% efficacy against moderate or severe COVID-19.[5](Table 1)

Gamma (P1): An Observational study from Brazil/Argentina reported that 99.65% of subjects induced IgG antibodies to COVID-19 on 42nd day after receiving the 2nd dose; 85.5% of subjects induced IgG antibodies to COVID-19 on 14th day after receiving the 1st dose. [35]

Delta (B.1.617.2): The Gamaleya Center study reported that Sputnik vaccine had the most efficacy against the delta variant than any other vaccine. [35]

Geriatric Population: The phase III trial reported that the vaccine had an efficacy of 91.8% of preventing symptomatic COVID-19 in people aged more than 60 year old.[5](Table-4)

**Adverse Effects:**

The most common adverse effects seen in clinical trials were pain at the injection site, hyperthermia, headache, asthenia and muscle and joint pain and were ranged from mild to moderate and with no severe adverse event.

**Update:**

The Russian Ministry of Health had validated Sputnik V's efficacy against the Delta variant on July 12, 2021. The vaccine reduced the risk of illness by 6 times and was 83.1%

effective. It was also 94.4% effective in preventing hospitalizations, with a risk decrease of 18 times. According to a non-peer-reviewed study published on August 25, 2021, the Sputnik V vaccination provided 81 percent protection against hospitalisation during the SARS-CoV-2 virus Delta variant surge in Argentina in July-August 2021. [40]

**SINOPHARM VACCINE**

**Efficacy:**

When compared to alternative vaccination regimens, the phase 2 study found that 4 µg on day 0 and 21 was linked with the greatest neutralising antibody (GMT). Due to self-limiting grade 3 fever, one grade 3 or higher adverse event was reported. [8](Table 1)

There was no data available on the efficacy against different covid variants.

Geriatric Population: No adequate data available.

**Adverse effects:**

Adverse responses were reported by 15% of study participants within 7 days of injection. Injection site discomfort was the most prevalent adverse response, followed by fever. All the adverse responses were moderate (grade 1 or 2), transitory, and self-limiting, and no therapy was required.[8]

**COVAXIN VACCINE**

**Efficacy:**

The interim reports from phase-3 study showed the vaccine had overall efficacy of 77.8% against symptomatic covid infections.[9]

There was no data available on the efficacy against different covid variants.

Geriatric Population: No adequate data available

**Adverse effects:**

No serious adverse events were reported in the study. Protective efficacy was not reported.

**Update:**

COVAXIN had been given an emergency use listing (EUL) by the World Health Organization (WHO) for the prevention of COVID-19 on November 03, 2021. [41]

**Discussion**

Based on the aspects discussed in this review, we conclude that not all vaccines are equally safe and efficacious. Nevertheless, the risk of severe adverse events or even death was very low. However, questions of efficacy against new variant strains have been raised. The UK variation B.1.1.7 (Alpha variant) has been demonstrated to change the spike protein, which might impair immunological recognition of antibodies generated from current vaccinations. The COVID vaccines Vaxzevria (Oxford – AstraZeneca) and NVX-CoV2373 (Novovax) have been found to be protective against the Alpha variant of the virus, while the latter and Janssen vaccine were protective against the Beta variant (B.1.351). [42] The vaccines Comirnaty and Vaxzevria were found to be 92% and 69% effective respectively against the highly infectious Delta variant (B.1.617.2) of SARS-CoV2, but their protection fades away with time according to a study conducted in the United Kingdom. [43] To evaluate the effectiveness of current vaccinations against mutant versions, more clinical studies are needed and there is an increasing need for inventing vaccines. [44,45]

The vaccinations exhibited limited immunogenicity in older persons over 60(Table-4), but a low risk of adverse reactions. One probable explanation is that elderly population have a lower level of immunity. Many more research on the vaccine's tolerability in the older population are needed. Furthermore, no findings of clinical trials involving juveniles have been reported to far. The majority of studies advocate a two-dose vaccine, although the interval has to be investigated further. In comparison to the other vaccinations evaluated in this study, mRNA vaccines had a greater effectiveness (about 94%).

There is a need for different types of vaccinations for diverse groups, such as babies and children, pregnant women, and immunocompromised people, because most vaccines in development are aimed at the healthy

population, i.e., adults aged 18 to 55.

However, there have been some limitations:

1. There is no proof of the vaccine's long-term efficacy or safety. Most vaccine studies only followed up to 28 days following immunisation due to the necessity of vaccine development. It will need more time to see if neutralising antibodies can be maintained for a long time and if there are any delayed adverse effects following immunisation.

2. Because of variations in the design of numerous clinical studies, it was difficult to compare the benefits and drawbacks of various vaccinations.

3. The published case reports on vaccination adverse effects were short-term, i.e. 1 or 2 weeks after the injection date. As a result, we can't rule out the possibility that these side effects are unrelated to the vaccination. The link between specific adverse effects, like as thrombotic events that occur after taking Pfizer, Moderna, and other vaccinations, has to be investigated further.

In conclusion, the short-term side effects of the vaccine are mild and short-lived. Side effects were more common in younger people (18-55 years) than in older adults. The post-vaccination symptoms often last for one or two days from the injection.

Our findings can assist the public understand the risk of adverse effects based on their age and the type of vaccination they received.

Furthermore, our research backs up the findings of randomised controlled studies that show indications of infection decrease after 12 days and significant protection after 3 weeks.

**Conclusion**

To summarise the report, adverse effects of the vaccine are minimal and transient with a duration of one or two days. The most affected population were found to be Younger people between 18-55 years age. This Study can help the general public to understand the risk of adverse effects based on their age and type of vaccination. All of the reviewed COVID-19 vaccines have demonstrated promising immunogenicity profile with different degrees of protective effect and a good safety profile. Future studies are needed to evaluate the safety and efficacy of the vaccines among vulnerable population such as immunocompromised patients, geriatrics, paediatrics, pregnant woman and patients with multiple co-morbidities. With the increasing occurrence of new variants of various COVID-19 strains, it is critical to conduct routine efficacy studies. Furthermore, because the clinical trial study population is not very diverse and the vaccines are approved on an emergency basis, long-term postmarketing surveillance becomes an extremely important part of determining efficacy and side effects in different populations.

**Conflict of interest:** The authors have declared no conflict of interests.

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# مراجعة شاملة حول الفعالية والأحداث السلبية المرتبطة بلقاحات COVID-19

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## ملخص

لمكافحة COVID-19، أعطت العديد من الوكالات الصحية في جميع أنحاء العالم موافقة طارئة على اللقاحات. ولذلك، فإن الأثر الوقائي الطويل الأجل والآثار الضارة المحتملة للقاحات على المرضى الذين يعانون من نقص المناعة والنساء الحوامل وطب الشيخوخة قد لا يكونان راسخين. وكان الهدف من هذه المراجعة هو تقييم سلامة وفعالية عدد من اللقاحات الأكثر شيوعا المعتمدة في جميع أنحاء العالم. وأجريت مراجعة لتحديد التجارب السريرية التي درست فعالية اللقاحات وتقارير الحالات عن الأحداث الضائرة المحتملة المشتبه في ارتباطها باللقاحات. وكانت قواعد البيانات الإلكترونية التي تم البحث فيها لتحديد الدراسات ذات الصلة هي Science Direct وPubMed/Medline و Scopus و MedRxiv. وشملت المراجعة سبع تجارب معشاة ذات شواهد قيمت فعالية لقاحات كوفيد-19 وتقارير الحالات التي أبلغت عن الأحداث الضائرة للقاحات. وتبين أن فعالية اللقاحات بلغت 94.6٪ للقاح فايزر، و94.1٪ للقاح موديرنا، و66.1٪ للقاح جونسون آند جونسون، و76.4٪ لكوفيشيلد، و91.6٪ لسبوتنيك، و77.8٪ لكوفاكسين. لم يتم الإبلاغ عن أي أحداث سلبية شديدة في الدراسات. وكانت جميع الأحداث الضائرة المبلغ عنها خفيفة ومكتفية ذاتيا ولا تتطلب أي تدخل طبي. أظهرت جميع لقاحات كوفيد-19 ملامح مناعة واعدة، ودرجات مختلفة من الفعالية الوقائية، وملامح سلامة مقبولة. ومع ذلك، هناك حاجة إلى مزيد من البحوث لتقييم الفعالية والسلامة في الفئات السكانية الضعيفة بما في ذلك المرضى الذين يعانون من نقص المناعة والنساء الحوامل والسكان المسنين. تصبح مراقبة ما بعد التسويق على المدى الطويل جزءا مهما جدا من تحديد الفعالية والآثار الجانبية بين مختلف السكان.

**الكلمات الدالة:** لقاح كوفيد-19، فعالية اللقاح، الآثار الضارة للقاح.

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تاريخ استلام البحث 2021/5/19 وتاريخ قبوله للنشر 2021/12/26.