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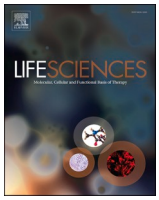

Efficacy and limitations of SARS-CoV-2 vaccines - A systematic review

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ABSTRACT

The emergence of the SARS-CoV-2 virus worldwide led to the call for the development of effective and safe vaccines to contain the spread and effects of COVID-19. Using information from 40 publications, including clinical trials and observational studies from 2019 to 2024, this review assesses the effectiveness, safety, and limitations of four major vaccines: Sinopharm (BBIBP-CorV), Moderna (mRNA-1273), Pfizer-BioNTech (BNT162b2), and CoronaVac. Pfizer-BioNTech and Moderna's mRNA vaccines proved to be more effective than others; Moderna's vaccines showed an efficacy of 94.1 % against symptomatic infection, while Pfizer-BioNTech's vaccines showed an efficacy of up to 95 %, against severe diseases and hospitalization. These vaccinations, which included protection against Omicron and Delta variants, offered notable protection against serious illness, hospitalization, and mortality. Severe adverse events were rare while most adverse events were mild to moderate, such as headaches, fatigue, and localized reactions.

In contrast, inactivated virus vaccines such as Sinopharm and CoronaVac with efficacies ranging from 50 to 79 % against symptomatic infection showed lower levels of effectiveness. In Phase 3 trial, Sinopharm showed 72.8 % efficacy, whereas CoronaVac demonstrated roughly 67 % efficacy in population against hospitalization and severe disease. Booster doses were required for adequate immunological response, especially against novel strains, as these vaccinations proved to be less effective in older populations. They showed considerable safety profiles, with mild side effects, but their low immunogenicity is concerning. This review emphasizes the importance of continuously evaluating vaccines in response to the evolving virus, essential for improving international immunization programs.

1. Introduction

1.1. Background

Novel coronavirus pneumonia was first reported in Wuhan, China, in December 2019. It was initially linked to being transmitted from animals to humans within the local wet markets. Later, it was confirmed to spread through airborne transmission and respiratory droplets. The disease then spread to urban areas in China's Hubei province, quickly spreading to >200 countries around the world by early 2020 [1]. As of January 2025, there were 777,074,803 total cases of COVID-19 worldwide, with 7,079,142 deaths [2]. Wildlife animals and patients already affected by the disease are said to be the primary source of transmitting the virus, and the transmission occurs through direct contact and respiratory droplets [3]. The virus is highly transmissible as one person can on average transmit the disease to about 2.2 other individuals. The means incubation period is 5.8 days [4]. The disease can also be transmitted from individuals showing no symptoms of infection [5]. The emergence of disease as a pandemic suggested that the virus's control was impossible without the prospect of vaccination [4]. Chinese government and community rapidly worked on the identification of the causative agent of SARS-CoV-2 since the beginning of the outbreak. The government also shared the viral genome sequence to facilitate researchers in finding appropriate measures to deal with the pandemic situation [3]. Vaccine development has become the need of the hour to address the health destruction caused by the virus across the world. However, vaccine development is a lengthy process that takes years to complete and several million dollars, especially due to the use of new technologies that have not been previously tested for their efficacy, safety, and mass production parameters [6]. Based on previous

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experiences and drawbacks of the COVID-19 vaccines, all vaccines must be subjected to proper testing and evaluation of side effects. Harmful risks associated with an antibody-dependent enhancement that might contribute to eosinophilic infiltration or augmented infectivity and protective effects are essential to be examined before launch [6]. The current study provides an overview of the limitations and efficacy of different vaccines developed and used during 2019–2024.

1.2. Structure of SARS-CoV-2

Coronaviridae is a monophyletic cluster in the order Nidovirales, whose members have a positive sense, single-stranded RNA genome measuring 30 KBS on average [7].

The subfamily of Ortho-coronavirinae is comprised of four genera's including alpha-corona virus, beta-coronavirus, gamma-coronavirus and delta-coronavirus. SARS-COV-2 is associated with and belongs to the beta-coronavirus genus [8]. As coronavirus is made up of single-stranded and non-segmented RNA genome having positive polarity, the virion comprises three kinds of structural proteins named nucleo-capsid, trans-membrane envelop, and spike protein. However, some coronavirus does not require the complete presence of all structural proteins to become an infectious virion. Additional proteins might be encoded by overlapping compensatory purposes [9].

Spike (S) protein comprises two subunits called S1 and S2. Both proteins carry different functions, i.e. S1 proteins have RBD (receptor-binding proteins) that play an essential role in recognizing and binding with the cell receptors, whereas S2 is a structure's 'stem' and contains elements needed for membrane fusion. For neutralizing vaccines and antibodies, spike protein is the most common target. The entry of COVID-19 into human host cells is linked to its binding to ACE2 (Angiotensin-converting enzyme 2) receptors. It has been reported that human respiratory epithelial cells get infected by coronavirus when it interacts with ACE2 receptors [7].

1.3. Problem statement

SARS-Cov-2 emerged as a deadly or harmful virus and caused deaths all over the world. Over time, five different variants of the virus (alpha, beta, gamma, delta, and omicron) have evolved and been seen to cause different symptoms among people. The information about the efficacy of different commercially available licensed vaccines, along with their limitation is a need of the hour.

1.4. Research question

What are the limitations and efficacy of different SARS-CoV-2 vaccines developed between 2019 and 2024?

1.5. Aims and objectives

- To provide an overview of the SARS-CoV-2 vaccines developed between 2019 and 2024.
- To determine the limitations of different vaccines.
- To determine the efficacy of different SARS-CoV-2 vaccines.
- To compare the limitations and efficacy of different SARS-CoV-2 vaccines.

1.6. Overview of the project

The current project provides a detailed analysis of vaccines developed from 2019 to 2024 and currently in use to provide immunity against different strains of the SARS-CoV-2 virus. The project also covers brief details about the history, origin, mode of transmission, pathogenesis, and need for vaccines. A detailed analysis of different types of vaccines and their efficacy is also discussed. However, the limitations in developing different vaccines are also an essential parameter to discuss. Therefore, an overview of the different side effects and complications of the vaccines mentioned above are analyzed in this report.

2. Research methodology

2.1. Research approach

The research includes a systematic review of secondary sources available online especially on PubMed database, a platform useful for relevant articles selection in the medical field. The elements of systemic review include the research question, information about search sources, their relevancy, used search engines, dates, data extraction method, and entire search strategies. The systematic review also covers the inclusion and exclusion criteria of the research and screening methods [10]. The current study is a systematic review of multiple sources relevant to the effectiveness and limitations of commercially available SARS-CoV-2 vaccines, shortlisting four different vaccines, as stated in the next section.

2.2. Search strategy and data extraction

Out of numerous commercially available vaccines for SARS-CoV-2, some vaccines are selected to comparatively evaluate their efficacy and limitations. The shortlisted vaccines for this systematic review are Pfizer, Moderna, CoronaVac, and Sinopharm. The reason behind the selection of these vaccines is their widespread usage all over the world. The vaccines are licensed and are underused in many countries worldwide as compared to other approved vaccines. More research and clinical trials are being conducted on these vaccines. Therefore, there is an ultimate need to investigate their side effects and efficacy. Numerous keywords were tried to retrieve the data from PubMed. Boolean operators were used along with different filters provided by PubMed: (*Pfizer or BNT162b2 and Covid-19, Moderna efficiency and SARS-CoV-2, CoronaVac or Sinovac and Covid-19, Sinopharm and Covid-19 vaccines*). The initial database searched articles ranging from 2019 to 2024. Using (*Pfizer or BNT162b2 and Covid-19*) as a keyword, 12,578 results were obtained from PubMed. In the case of 'Covid-19 AND Moderna', 3266 initial results were obtained 'Sinopharm AND Covid-19' yielded 511 results. 268 results were obtained using CoronaVac'. It seemed that keywords were general and wide which resulted in unnecessary information. To get the best results and useful information the final search was conducted using these keywords: Covid-19 AND Vaccines AND Treatment. This time it resulted in 1137 hits using the filter like Search period: 2019–2024, Text Availability: Full text, Article Type: Clinical study, Clinical trials, Language: English, Journal: Medline. This makes it quite easy to shortlist and download the articles based on titles. 55 articles were shortlisted which were further screened by using inclusion-exclusion criteria via brief reading. 40 articles were selected for this study based on an investigation of the efficacy and efficiency of COVID-19 vaccines and their limitations. To build the basis of this study, some study protocols, general research, retrospective studies, and statistical analysis were used but all of these studies were selected through systematic search and screening.

2.3. PRISMA flow diagram

The PRISMA diagram (Fig. 1) is an essential part of the systemic review that shows the flow of information throughout different phases of research. It includes the checklist of items included and excluded in the study and visualizes screening and exclusion records [11]. The PRISMA flow diagram below provides information about the number of articles that were searched, examined, screened, excluded, and included for this review.

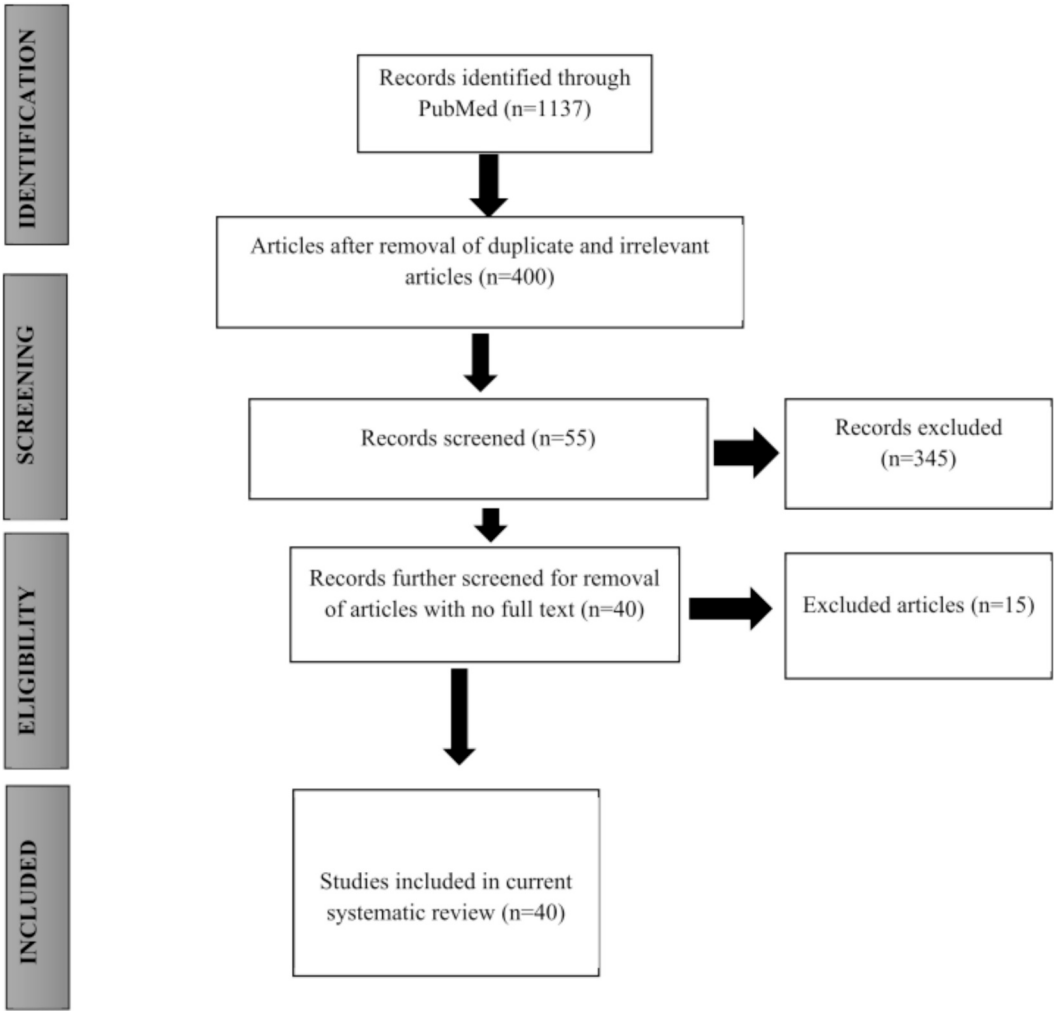

Fig. 1. PRISMA diagram.

2.4. Inclusion and exclusion criteria

In Table 1 the inclusion and exclusion criteria for articles selection is depicted.

3. Results and discussion

3.1. Overview of vaccines developed against SARS-CoV-2

To compare the effectiveness of different vaccines, a study was conducted, in which 360 (4.4 %) out of 8165 healthcare workers (HCWs), accounting for 4.4 % of the sample, were tested positive for SARS-CoV-2 by RT-PCR. Vaccine efficiency was assessed against symptomatic infection using the Cox model to be 86.2 %, 38.2 %, as well as 49.2 % for "Vaxzevria (ChAdOx1 nCoV-19), Moderna (mRNA-1273), and Pfizer-BioNTech (mRNA-BNT162b2)" 14 days after first dosage. After two doses, Moderna (mRNA-1273) and Pfizer-BioNTech (mRNA-BNT162b2) showed 100 % and 94.6 % efficacy against symptomatic infection, respectively [12]. CoronaVac has been well-tolerated and effectively triggered an immune response in individuals aged 50–64, supporting its usage in this age group. In upcoming phase 3 studies to evaluate COVID-19 vaccine safety, the 3 g dosage of CoronaVac with 2 different vaccination programs is used due to its safety and manufacturing capacity [13]. In preliminary phase 3 clinical studies, the immobilized Sinopharm BBIBP-CorV vaccine showed lower efficacy (ranging from 72.8 to 78 %, depending on the virus strain employed). Early findings suggest that two dosages of the vaccine had similar real-world efficacy, ranging from 80 % to 97 % regarding the outcome examined [14]. This level of efficacy is comparable to that observed with mRNA-based vaccines in real-world settings, but BBIBP-CorV offers a distinct advantage for low-resource countries. While mRNA vaccines require freezing temperatures for transportation and storage, BBIBP-CorV only needs routine refrigeration (4 °C), making it more accessible in regions with limited cold-chain infrastructure [14].

Table 1
Inclusion and exclusion criteria.

Criteria	Inclusion	Exclusion
Date	The articles were published from 2019 to 2024 based on keywords.	Articles published before 2019.
Language	Articles in English are used only.	All articles in languages other than English.
Type of study	Clinical trials, Clinical study Control trails Retrospective studies	Irrelevant studies focusing on other topics than efficacy, limitations of vaccines
Availability	Free full online text articles are included in this study.	Articles with no full text and only abstracts.

3.2. Efficacy and limitations of mRNA-based vaccines: Pfizer vs. Moderna

3.2.1. Efficacy and limitations of Pfizer

Adults aged 16 and older who participated in global Phase 1/2/3 trials with 30 mg BNT162b2 exhibited no adverse events, immunogenicity, or effectiveness issues. JAMA Internal Medicine published findings [15]. Participants were randomly assigned to receive either BNT162b2 or a placebo, while a third group received no intervention. A total of 43,448 patients were randomized to receive injections, with 21,720 patients received BNT162b2, and 21,728 a placebo. Among those who received BNT162b2, eight cases of Covid-19 were reported at least seven days after the second dose, compared to 162 cases in the placebo group. 95 % of the time, BNT162b2 demonstrated a 95 % efficacy against symptomatic infection (95 % credible interval, 90.3 to 97.6) [15]. The vaccine's effectiveness was consistent across various subgroups, including different age, gender, color, ethnicity, BMI at baseline, or other factors, with efficacy typically ranging from 90 % to 100 % against symptomatic infection. Although nine participants in the placebo group developed Covid-19, only one person who received BNT162b2 developed severe Covid-19 after the first dose. Short-term adverse effects of BNT162b2 included mild-to-moderate pain at the injection site and fatigue. No increase in severe adverse events was observed in the vaccination or placebo groups [15]. Additionally, the injection site was irritating. Importantly, no deaths were reported due to the vaccine, placebo, or Covid-19 during the study period, and no violations of the trial's stopping rules occurred. The effectiveness of the vaccine will be evaluated two years after the second dose is provided [15].

During the study conducted in 2021, 2260 adolescents aged 12–15 were randomly assigned to receive either two doses of 30 mg BNT162b2 or a placebo, administered every 21 days (2021). 1131 of them received BNT162b2, while the remaining 1129 received a placebo. This study discovered that BNT162b2 had an outstanding safety profile with minimal serious adverse events [16]. The most common adverse responses were pain, tiredness, and headache. There were no severe vaccine-related adverse events and just a few severe reactions. After the second dose, no cases of Covid-19 were reported among those who received the vaccine. However, 16 cases of SARS-CoV-2 infection were discovered in placebo recipients with no prior illness symptoms. The vaccine was shown to be 100 % effective, with a 95 % confidence interval ranging from 75,3 to 100 [16].

A study was conducted to assess the potential adverse effects of the BNT162b2 vaccine across all organ systems. HCWs were invited to participate in an impartial online poll to evaluate the likelihood of harm from the vaccine [17]. The poll comprises 1415 respondents, with 87.98 % of healthcare professionals participating. Among those who received the BNT162b2 mRNA vaccine, 65 % reported adverse effects. Of the 803 participants who were able to resume their daily activities, 79.7 % reported no significant impact [17]. In contrast, 12.83 % experienced temporary difficulties, 12.33 % missed work, 2.49 % required outpatient care, 0.62 % sought emergency department treatment, and 0.25 % were hospitalized. Most participants (97 %) expected or had already received a second dose, and 92.9 %.

640 patients out of 803 who were able to resume their daily activities were successful (79.7 %). Instead, 12.83 % experienced temporary difficulties, 12.33 % missed work, 2.49 % required outpatient support from a healthcare practitioner, 0.62 % required emergency department treatment, and 0.25 % required hospitalization. Most participants (97 %) anticipated or had already received a second dose, while 92.9 % of respondents had completed their vaccination regimen. The most commonly reported side effects, in decreasing order of frequency, included soreness and fatigue, myalgia, headache, chills, fever, joint pain, nausea, muscle spasms, sweating, and dizziness, as well as sensations of relief, brain fog, anorexia, localized swelling, and poorer sleep quality [17].

In a trial conducted by Favresse et al. 231 healthcare workers received two doses of the Covid-19 vaccine over a two weeks period [18]. Only 73 cases of SARS-CoV-2 were identified among the 158 persons who were examined; the remaining 73 patients were both seropositive and had never been exposed to the illness-causing virus. Blood samples were collected from the first group at the beginning of the study and at intervals of 2, 4, 7, 10, 14, and 28 days. For the second group blood samples were collected at the time of pre-test and post-test at 14 and 28 days. All the subjects had detectable IgG antibodies to the SARS-CoV-2 nucleocapsid, and to the receptor-binding region of S1 of the spike protein at different time points post infection. After receiving the second dose, 95 % of patients showed an increase in antibody titres. 5 % of people who had not been sensitized to the spike, rose by 24. 9-fold. However, after 7 days, the second dose (6347 U/mL) did not enhance the antibody titers (8856–11,911 U/mL) in the exposed persons (8856–11,911 U/mL). The subjects who had previously infection, had higher levels of antibodies compared to those without prior exposure, suggesting that a single dose of BNT162b2 may be sufficient for individuals who had previous exposure to the virus [18].

The Pfizer-BioNTech vaccine has proved to be safe and very effective in trials conducted both in laboratories and in the population. Clinical trials have shown that the vaccine is highly effective in preventing SARS-CoV-2 infection; with an efficacy rate of 92 % in preventing hospitalization among adolescents [19]. Such evidence is consistent with real-world data suggesting that the vaccine protects children and adolescents not only from infection but also from severe outcomes like hospitalization and ICU admission [20]. However, the vaccine's effectiveness can be influenced by factors such as the prevalence of different virus variants, notably the Omicron variant [20]. Although the vaccine is generally well-tolerated, some side effects have been reported. Common local reactions include injection site pain, fatigue, headache, and fever while systemic reactions are less frequent and may include chest pain, and shortness of breath [21]. These side effects are normally nonserious and of short duration [22]. However, serious adverse effects such as uveitis and inflammatory glaucoma with amlodipine have been reported [23]. Also, the severity and frequency of side effects may differ according to the demographic data: females and younger patients [24,25]. Overall, the vaccine developed by Pfizer and BioNTech is safe and effective in preventing the Covid-19 and its severe consequences, but the effectiveness might be differential against the different variants, and although the adverse effects are relatively mild, it is crucial to report any rare side effects [19,20,22,23].

3.2.2. Efficacy and limitations of Moderna

In phase 3, 30,420 participants of 99 sites across the United States were involved in a randomized, observer-blind, placebo-controlled study. The majority of participants completed the trial and received both doses, with over 96 % experiencing positive outcomes, with the vaccine demonstrating 94.1 % relative risk reduction against symptomatic infection. Covid-19 positive cases were recorded both in placebo as well as in mRNA-1273 group; in the placebo group thirty people contracted severe Covid-19 with one fatality. The mRNA-1273 group experienced a higher incidence of moderate, transient reactogenicity compared to the placebo group. Overall, the study was considered successful, because only a small percentage of participants reported severe side effects [26].

A phase 1 clinical trial dose was conducted to assess the safety and immunogenicity of mRNA-1273, a mRNA vaccine encoding the SARS-CoV-2 S-2P. The study initially involved 40 participants but was later expanded to 60, with participants grouped by age (56–70 years or 71+ years). The participants received either two doses of 25 μg or two doses of 100 μg of the vaccine, administered 28 days apart, with the order of dose administration reversed for each participant [27]. The trial found that the vaccine was effective and well-tolerated, with no significant adverse effects. The most commonly reported side effects included mild to moderate myalgia, injection site discomfort, fatigue, and headache. These reactions were generally rare and mild, with myalgia and

injection site pain being less frequent. Notably, the severity of side effects appeared to be dose-related [27]. The first vaccine administration facilitated the proliferation of binding-antibody reactions, which became more visible following the second vaccination. By day 56, participants aged 56–70 had a GMT of 323,945, participants between the ages of 71 and older had a GMT of 1,128,391 25- the dose group; on day 57, participants between the ages of 56 and 70 had GMTs of 1,183,066 and 3,638,522, while those aged 71 and older had GMTs of 1,128,391 in 100-g dose group. After the second vaccination, all participants displayed serum-neutralizing activity. When compared to the median levels from a control group of participants who had recovered from a previous SARS-CoV-2 infection, the vaccine-induced immune response showed a statistically significant increase. A recent study has revealed that Type 1 helper T cells are responsible for the potent CD4 cytokine response induced by vaccination [27].

The Moderna COVID-19 vaccine, mRNA-1273, has demonstrated high efficacy in clinical trials, with a relative risk reduction of 94.1 % [28]. This figure, however, is complemented by an absolute risk reduction of 1.1 %, which is substantially lower and highlights the importance of understanding both measures to fully interpret vaccine efficacy [28].

3.2.3. Pfizer vs. Moderna

All mRNA vaccines target the same SARS-CoV-2 antigen and incorporate mRNA encoding the full-length, transmembrane anchored S protein. The genetic sequence is slightly altered to stabilize the prefusion conformation of the glycoprotein using two proline (2P) substitutions (K986P and V987P mutations). Several optimizations to the structural elements of the mRNA, such as the CAP structure, poly(A) tail and untranslated regions (UTRs), improve the mRNA stability and translation capacity [29]. The lipid nanoparticle (LNP) formulation plays a crucial role in enhancing the stability and delivery efficiency of the mRNA-based vaccine. LNPs act as carriers, protecting the fragile mRNA from degradation and facilitating its uptake into host cells. The LNPs in mRNA COVID-19 vaccines consist of four key components: a neutral phospholipid, cholesterol, a polyethylene glycol (PEG)-lipid, and an ionizable cationic lipid. Additionally, the PEG-lipid helps regulate the particle size and serves as a steric barrier to prevent aggregation during storage [30]. Both Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273) utilize distinct LNP compositions, which contribute to differences in storage requirements and immunogenicity. To provide a structured comparison of the LNP components used in these vaccines, Table 2 summarizes the detailed composition of LNP in Pfizer-BioNTech and Moderna vaccines.

The real assessment of the interactions between mRNA and lipid components is difficult and could have implications for the stability of the different formulations. Real-world effectiveness has been supported by the Advisory Committee on Immunization Practices (ACIP), which, after considering additional follow-up time in clinical trials and real-world studies, concluded that the benefits of the vaccine in preventing symptomatic and asymptomatic SARS-CoV-2 infection, hospitalization, and death outweigh the associated risks [33]. Despite the high efficacy, there are limitations to consider. The emergence of SARS-CoV-2 variants may affect the vaccine's effectiveness, although specific data on variant resistance was not provided in the context. Additionally, while the vaccine is generally safe, side effects have been reported. Common adverse events (AEs) include localized injection site pain, fatigue, headache, myalgia, and chills [34]. Rare but more severe AEs such as myocarditis and pericarditis have been observed, particularly in young males [34]. Other reported side effects include hypersensitivity reactions, "COVID arm," and in very rare cases, encephalopathy [35,36]. In summary, the Moderna COVID-19 vaccine has shown high efficacy in clinical trials and real-world application, contributing to the prevention of COVID-19-related outcomes [28,33]. However, the full spectrum of its effectiveness against emerging variants remains to be fully understood. Side effects are mostly mild and transient, but awareness of rare severe AEs is necessary for informed healthcare decisions. Further large-scale epidemiological studies are recommended to monitor rare safety outcomes and to maintain an up-to-date understanding of the vaccine's efficacy and safety profile [34]. A comparison between Pfizer-BioNTech and Moderna vaccines is summarized in Table 3.

Table 2
Detailed lipid nanoparticle composition of mRNA vaccines.

Component	Pfizer-BioNTech	Moderna
Ionizable lipid	ALC-0315	SM-102
PEGylated lipid	Lipid functionalized with PEG-2000	Lipid functionalized with PEG-2000
Helper lipid	DSPC	DSPC
Other	Cholesterol	Cholesterol
PEG content	0.05 mg per dose	0.10 mg per dose
Reference	Polack et al., 2020 [15]; Walsh et al., 2020 [31]	Baden et al., 2021 [26]; Jackson et al., 2020 [32]

3.3. Efficacy and limitations of inactivated virus vaccines: Sinopharm vs. CoronaVac

The inactivated virus vaccines like Sinopharm (BBIBP-CorV) and CoronaVac from require β-propiolactone (BPL) to inactivate SARS-CoV-2. The virus-neutralizing capability of BPL remains strong but the protein modification caused by BPL fixes the spike protein in a post-fusion state that limits immune system access to vital neutralizing sites [37,38]. The modified spike protein in this vaccine reduces its ability to create robust neutralizing antibody responses in contrast to mRNA vaccines that show the spike protein in its natural pre-fusion state [39].

Moreover, the inactivated vaccines containing aluminum hydroxide as adjuvant that selectively stimulate a Th2 immune response. While potentially failing to activate protective Th1 cytotoxic T-cell responses [40]. The molecular constraints which affect the weak response of inactivated vaccines encourage use of booster doses along with heterologous vaccination techniques to enhance immunity against new variants [13].

3.3.1. Efficacy and limitations of Sinopharm

To determine the effectiveness of the BBIBP-CorV immunization, researchers conducted retrospective observational studies using real-world hospitalizations and fatalities. The investigators used a random sample of 214,940 COVID-19 cases that were reported to the Abu Dhabi Emirate's Health Department between September 1, 2020, and May 31, 2021 (the study period). There were around 170,000 participants who took part in the research because they had immunization records that could connect to their COVID-19 status and because they had tested

Table 3
Comparison of key features for the Pfizer-BioNTech and Moderna COVID-19 vaccines.

	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)
Strain used	Wuhan-Hu-1 (original strain)	Wuhan-Hu-1 (original strain)
mRNA length	~4000 nucleotides	~4100 nucleotides
5′ UTR	Optimized for stability and translation efficiency	Optimized for stability and translation efficiency
3′ UTR	Shortened to enhance mRNA stability	Shortened to enhance mRNA stability
Efficacy (1 dose)	~52 % (after 12 days)	~80 % (after 14 days)
Efficacy (2 doses)	~95 %	~94.1 %
Booster requirement	Recommended after 6 months for certain populations	Recommended after 6 months for certain populations
Storage	−70 °C (ultra-cold storage)	−20 °C (standard freezer)
References	Polack et al. 2020 [15], Walsh et al. 2020 [31]	Baden et al. 2021 [26], Jackson et al. 2020 [32]

positive for COVID-19. The three groups: fully vaccinated (two doses), partially vaccinated (single dose), and non-vaccinated, included 62,931, 21,768, and 91,941 people [14]. The outcomes divided into three categories: hospital admissions, critical care admissions and deaths, that resulted in 80 %, 92 %, and 97 % respectively for fully vaccinated individuals when compared to the non-vaccinated group. The partially immunized group recorded a statistically significant reduction in death, even though revealed no protection against critical and non-critical care hospital admissions [14].

Phase 1/2 trial of a vaccine was conducted in Henan Province, China, by the Shangqiu City Liangyuan District Center for Disease Control and Prevention. It was a randomized, double-blind, controlled trial [41]. Between August 14 and September 24 of the following year, it selected 288 persons at random from a pool of 445 eligible to receive vaccination during that period. In Phase 2, the vaccine was provided to 720 people randomly from among those it found to be suitable in the first phase. The concern was highlighted by more than half of the 252 participants in all immunization groups and one participant in the control group when it came to children aged 6–12 years (out of 84). There were 32 children with fevers across all immunization groups and six (aged 3–5 years old) with madness in the control group. Frequent fever bouts were the most common recurrence in the 6–12-year-old cohort, affecting 26 children from all vaccination groups and 8 from the control group [41].

The Sinopharm vaccine (BBIB—CorV) has been evaluated in various observational studies, which provide insights into its real-world efficacy and limitations. In Egypt, an observational study reported a vaccine effectiveness of 67 % against symptomatic PCR-confirmed cases among healthcare workers, with a significant reduction in COVID-19-related work absenteeism and a low incidence rate of severe hospitalization in the vaccinated group [42]. Similarly, in Morocco, the vaccine demonstrated high effectiveness against serious or critical hospitalization, particularly in working-age adults, with an adjusted vaccine effectiveness of 88.5 %. However, efficacy in older adults (≥60 years) was lower, at around 53.3 %, suggesting reduced immune response in this population [43]. In a study from Pakistan, Sinopharm showed 94.3 % efficacy in preventing symptomatic infection, 60.5 % efficacy against hospitalization, and 98.6 % efficacy against COVID-19 mortality [44]. Contradictorily, a study in Belarus comparing Sinopharm with Sputnik V found that Sinopharm elicited lower IgG levels, suggesting potentially lower immunogenicity [45]. Additionally, there have been reports of adverse events, such as a case of ANCA-associated vasculitis following vaccination, highlighting the need for awareness of potential autoimmune responses [46]. However, the vaccine appears to be safe for people with multiple sclerosis, with no significant increase in relapse rates post-vaccination [47]. In summary, the Sinopharm vaccine has shown to be effective in reducing the risk of symptomatic COVID-19, hospitalizations, and mortality in real-world settings, with particularly strong results in working-age adults. However, its efficacy appears to be lower in older adults and may induce lower immunogenic responses compared to other vaccines and need for vigilance regarding rare but serious adverse events [42–47].

3.3.2. *Efficacy and limitations of CoronaVac*

CoronaVac, the inactivated SARS-CoV-2 vaccine, has shown varying levels of efficacy and effectiveness in both clinical trials and real-world studies. A study found that a third dose booster of the four studied vaccinations, approximately six months after the second dose of CoronaVac, significantly improved antibody responses. Even though the researchers found modest levels of neutralizing antibodies six months after two doses of the inactivated CoronaVac vaccine, booster doses of the Covid-19 vaccine provided by the same or a different physician were equally efficient in enhancing humoral immune responses. Inactivated vaccines have the potential to offer stronger protection than live vaccines in terms of protection and efficacy because they retain viral proteins such as nucleoprotein, which may give protection superior to anti-spike protein reactions and hinder the development and spread of vaccine-evading variations. Despite a 21-fold increase in anti-N IgG concentrations following a homologous boost, these antibodies can provide therapeutic protection. Even in the absence of a viral vector or mRNA boost, anti-N responses can be observed; however, the neutralizing efficiency of these reactions is lower than when a viral vector or mRNA boost is present. Upon completion of this study, it concluded that all four vaccines administered in a third dosage level were safe and effective. The immunological response induced by a heterologous vaccine was weaker than anticipated [48]. In Renqiu, Chinese researchers conducted a clinical trial of the CoronaVac device on 60-year-olds in good health. The research evaluation utilized randomized, double-blind, and placebo-controlled protocols [49]. The individuals received two intramuscular injections of either the vaccine or placebo on separate occasions (days 0 and 28). Each intervention group included 24 participants (mean age: 65.8 years) and 24 participants in the placebo group. Registration for Phase 2 occurred between June 12 and June 15, 2020. Even though soreness at the injection site was the most often reported adverse event, in all it was mild to moderate in degree (39 of 421 individuals). On August 28, 2020, seven individuals reported adverse reactions to vaccines, all of which were ruled out due to the immunization. In phase 1, seroconversion occurred following the second dosage in the 3 g and 6 g groups, but in phase 2, seroconversion occurred following the double dose. In Phase 2, the 1.5 g group experienced seroconversion >90 % of the time (83.1–95.7), the 3 g group 96 % of the time (83.1–95.7), and the 6 g group always (83.1–95.7). There were no detectable antibody responses in the placebo groups [49].

A phase 3 randomized, placebo-controlled, double-blind research concluded that CoronaVac was effective. The SARS-CoV-2 virus was employed during the research vaccination, and the results showed that SARS-CoV-2 PCR and antibody results were negative. The research immunization utilized a 0.05 mL aqueous suspension containing three grams of inactivated SARS-CoV-2 virus absorbed on aluminum hydroxide. It undertook testing for the SARS-CoV-2 virus at 24 sites around Turkey on volunteers aged 18 to 59. Between September 14, 2020, and January 5, 2021, a total of 11,303 applicants submitted applications, which were assessed throughout the duration. It chose 10,288 individuals randomly from the applicant pool. A violation of procedure led to the withdrawal of four vaccination volunteers from the study. 10,214 individuals have then been selected for the intent-to-treat (ITT) analysis of the data. The immunization group reported 1599 adverse events, while the placebo group reported 603. Neither group reported any fatalities nor graded 4 adverse events during the trial. Immunizations were administered to 546 participants (8.2 %), while they administered placebos to 248 individuals (7 %). The most often reported systemic adverse impact was fatigue ($p = 0.0228$). Swelling and pain at the injection site were the most frequently reported local adverse effects among those who received the vaccination [50].

Clinical trials indicated an overall efficacy of 67.7 % for symptomatic COVID-19 prevention, with higher effectiveness against severe outcomes such as hospitalizations and deaths [51]. Real-world evidence, however, revealed lower effectiveness rates; for instance, a study among healthcare workers in Turkey reported an adjusted effectiveness of 39 % against COVID-19 infection during the alpha variant dominance [52]. Long-term effectiveness studies suggest that a third booster dose, particularly with an mRNA vaccine, significantly enhances protection, with the highest effectiveness observed shortly after vaccination and a gradual decline over time [53]. Contradictions in the data are evident when comparing different studies. For example, one study reported a high efficacy rate of 96.8 % severe disease and hospitalization for CoronaVac, although this figure is notably higher than those found in other studies and may be influenced by factors such as age, BMI, gender or individual immune response [54]. The impact of variants on vaccine effectiveness is a critical consideration; the Delta variant partially escaped the immunity provided by two doses of CoronaVac, prompting the use of heterologous prime-boost regimens, which showed higher immunogenicity and a tolerable safety profile [55]. Further, in

adolescents, heterologous boosters were established to be safe in terms of reactogenicity and immunogenicity; they also generated strong T-cell responses [56]. As for side effects, most of the AE to CoronaVac were mild, and there were few serious adverse reactions [51]. The safety profile was mainly mild in all age groups and in heterologous boosting strategies [55,56]. Consequently, it can be stated that CoronaVac has a moderate efficacy in preventing symptomatic COVID-19 with better results in severe outcomes. The appearance of variants has made booster doses as a way of enhancing the effectiveness of vaccines with heterologous boosting strategies proving to be effective. The side effects of the vaccine are not severe most of the time with some of the adverse effects being mild. These findings highlight the need for assessing vaccine effectiveness in the presence of emerging viral strains and possible changes in the vaccination schedule [51–56].

The molecular and formulation differences between Sinopharm and CoronaVac vaccines are outlined in Table 4.

3.4. Vaccination in children below 12 years old

The safety and effectiveness of COVID-19 vaccines for children under 12 years old has been tested through recent research studies. mRNA vaccines such as Pfizer-BioNTech and Moderna received pediatric-specific dose modifications to maintain both safety and effectiveness levels. Pfizer-BioNTech delivers a 10 μg dose to children between 5 and 11 years old achieving 90.7 % symptomatic COVID-19 protection rate [16]. Moderna delivers 50 μg to children between 6 and 11 years old demonstrating robust immune responses together with positive safety results [59].

Some countries have provided authorization for Sinopharm and CoronaVac to protect children starting from age 3. Sinopharm demonstrates both safety and immunogenicity in children between 3 and 17 years old though studies are ongoing to determine its effectiveness [37]. CoronaVac demonstrates average protection rates among children while maintaining similar safety characteristics observed in adult populations [38].

The doses for mRNA vaccines in children have been reduced to minimize the occurrence of rare side effects like myocarditis especially in adolescents and young adults [60].

3.5. Correlates of protection for SARS-CoV-2 vaccines

The immune markers which indicate vaccine-induced protection consist of neutralizing antibodies together with binding antibodies and T-cell responses. The strongest immune marker predicting vaccine-induced immunity is neutralizing antibodies that prevent viral entry because higher levels of these antibodies result in lower infection rates and reduced severe disease outcomes [61,62]. mRNA vaccines such as Pfizer-BioNTech and Moderna generate robust neutralizing antibody responses that correspond to their high efficacy rates exceeding 90 % [15,26]. The moderate efficacy of Sinopharm and CoronaVac vaccines together with the requirement for booster doses can be attributed to their lower ability to generate immune responses [37,38,63].

Anti-spike IgG antibodies demonstrate predictive value for severe disease protection yet they do not always match functional neutralization effectiveness [64]. The primary function of T-cells including CD4+ and CD8+ T-cells enables long-term protection through their ability to destroy infected cells even when antibodies decline [65]. The immune response generated by mRNA vaccines is strong for T-cells but inactivated vaccines might need booster doses to achieve equivalent T-cell protection [66].

Table 4
Molecular and formulation differences between Sinopharm (BBIBP-CorV) and CoronaVac COVID-19 vaccines.

	Sinopharm (BBIBP-CorV)	CoronaVac
Strain used	Wuhan-Hu-1 (original strain)	Wuhan-Hu-1 (original strain)
Inactivation method	β-Propiolactone	β-Propiolactone
Adjuvant	Aluminum hydroxide	Aluminum hydroxide
Formulation	Inactivated virus particles + adjuvant	Inactivated virus particles + adjuvant
Efficacy (1 dose)	~50–60 % (varies by study)	~50–60 % (varies by study)
Efficacy (2 doses)	~79 % (varies by study)	~51–84 % (varies by study)
Booster requirement	Recommended after 6 months	Recommended after 6 months
Reference	Al Kaabi et al. 2022 [37], Xia et al. 2022 [57]	Ranzani et al. 2021 [38], Zhang et al. 2021 [58]

3.6. Comparison between Pfizer, Moderna, Sinopharm and CoronaVac

The Pfizer-BioNTech and Moderna vaccines, both developed using messenger RNA (mRNA), have a high efficacy symptomatic infection, severe disease, and hospitalization with the Pfizer-BioNTech having a vaccine effectiveness (VE) of 91.2 % while Moderna was at 98.1 % against SARS-CoV-2 infection in fully vaccinated persons. The VE of these vaccines against severe disease, hospitalization, and death is also very high for these vaccines [67]. On the other hand, the inactivated virus vaccine CoronaVac has a lower vaccine efficacy of 65.7 % against symptomatic infection and 80 % against hospitalization, and 97 % against mortality [67] and efficacy of 54 % to 99.9 % in other research studies [68]. Although the VE of Sinopharm is not stated in the papers above, Pfizer-BioNTech triggers a higher immunological response than Sinopharm [69,70]. A comparison of key features across all four vaccines, including platform, strain used, efficacy, booster requirements, storage temperature, and target population, is summarized in Table 5.

Notably, the efficacy of vaccines can be affected by geography and people. For instance, ChAdOx1 vaccine (AstraZeneca) had the highest VE in Malaysia compared to other studies [68] while Pfizer was higher among Jordanian patients with comorbidity [71]. Further, the immune response, including the antibody titer and IgA levels, was significantly higher among the participants who received Pfizer-BioNTech than those who received Sinopharm or CoronaVac [69,70,72]. Therefore, mRNA vaccines (Pfizer-BioNTech and Moderna) have a higher efficacy and VE than inactivated virus vaccines (CoronaVac and Sinopharm) based on the systematic review of the literature. However, the effectiveness of vaccines is seen to differ with the demographic characteristics and regional analysis. The drawbacks associated with the vaccines, especially for the inactivated virus vaccines include lower immune response and the possibility of requiring booster shots especially in the light of the new SARS-CoV-2 variants [69,73].

Research indicates that inactivated vaccines generate immune responses that fade faster than those produced by mRNA vaccines so booster doses become necessary for protection enhancement [37,38]. Sinopharm and CoronaVac show reduced effectiveness against Delta and Omicron variants which drives health authorities to advise booster shots six months after initial vaccination [13,57]. Heterologous booster strategies work well when people get an mRNA vaccine (Pfizer-BioNTech or Moderna) after their initial vaccination with an inactivated vaccine. The immune response triggered by heterologous boosting strategies surpasses the immune response triggered by homologous boosting strategies (using the same vaccine type for boosting). Research conducted in Brazil demonstrated that patients who received Pfizer-BioNTech as their heterologous booster following CoronaVac primary doses achieved better protection against variants while showing elevated neutralizing antibody levels. Similarly, Moderna boosters strengthen immunity among people who received their first doses of Sinopharm [13,74].

The research emphasizes the necessity of adaptive vaccination strategies that must be implemented because of variant evolution and diminishing immune response. The utilizatiton of heterologous boosters improves vaccination results and expands possibilities for vaccination control especially when inactivated vaccines dominate local usage. In

Table 5
Comparison of key features across all vaccines.

	Pfizer-BioNTech	Moderna	Sinopharm	CoronaVac
Platform	mRNA	mRNA	Inactivated virus	Inactivated virus
Strain used	Wuhan-Hu-1	Wuhan-Hu-1	Wuhan-Hu-1	Wuhan-Hu-1
Efficacy (1 dose)	~52 %	~80 %	~50–60 %	~50–60 %
Efficacy (2 doses)	~95 %	~94.1 %	~79 %	~51–84 %
Booster requirement	Yes (6 months)	Yes (6 months)	Yes (6 months)	Yes (6 months)
Storage temperature	−70 °C to −80 °C	−20 °C to −25 °C	2 °C to 8 °C	2 °C to 8 °C
Target population	Adults and children ≥12	Adults and children ≥12	Adults and children ≥3	Adults and children ≥3
Reference	Polack et al. 2020 [15], Walsh et al. 2020 [31]	Baden et al. 2021 [26], Jackson et al. 2020 [32]	Al Kaabi et al. 2022 [37], Xia et al. 2022 [57]	Tanriover et al. 2021 [38], Zhang et al. 202 [50]

general, all vaccines help to decrease the incidence of severe COVID-19 outcomes; however, mRNA vaccines seem to provide the best protection [67].

3.7. Concluding statement

The review also describes the peculiarities of the mRNA vaccines (Pfizer-BioNTech and Moderna) in terms of their ability to prevent COVID-19 for an extended period and minimize the threat of severe clinical manifestations. These vaccines have been proven to be highly effective in clinical trials and in real life use and they only cause few and mild side effects which are short-lived. On the other, the inactivated virus vaccines including Sinopharm and CoronaVac are relatively effective with low efficacy in elderly population and may need booster doses to maintain adequate immunity against the variants like Delta and Omicron.

These variants have thus demanded new vaccination strategies including the application of heterologous boosters to enhance immune response. Therefore, all the vaccines have played a role in reducing the effects of COVID-19, but their efficacy varies and this makes it necessary to have different strategies of vaccination depending on the population density and the strains in circulation.

4. Conclusion and limitations

4.1. Conclusion

This comprehensive review outlines the effectiveness and drawbacks of four main SARS-CoV-2 vaccines and offers essential data about their work in the fight against COVID-19 worldwide. The results support the effectiveness of the mRNA vaccines (Pfizer-BioNTech and Moderna) in preventing symptomatic and severe COVID-19 illness, strengthening their role as frontrunners for mass vaccination programs. Still, the lower effectiveness of inactivated vaccines (Sinopharm and CoronaVac) indicates that these types of vaccines may be less effective in some cases, especially for elderly people, meaning booster doses are needed to sustain immunity. Since SARS-CoV-2 is constantly mutating, the immunization approaches should be flexible and involve booster shots and, possibly, the use of different types of vaccines. Continued studies and monitoring are necessary to make sure that the vaccination programs are proportional to the viral mutation to protect the population.

4.2. Research limitations

However, there are major limitations to this systematic analysis. First, this is a secondary investigation based on published interventions, prohibiting this research from being replicated in the laboratory for first-hand reporting. Secondly, the review only covers the articles published during the last four years because the outbreak of SARS-CoV-2 began in 2019. The development of vaccines to control the emergency began at that time, keeping the research time limited. Thirdly, the articles and publications used in this research are only those that were available in the English language.

CRediT authorship contribution statement

Muhammad Azeem: Writing – original draft, Methodology, Conceptualization. **Patrizia Cancemi:** Writing – review & editing, Supervision. **Farwa Mukhtar:** Visualization, Methodology, Formal analysis. **Sefora Marino:** Writing – original draft, Formal analysis. **Emanuela Peri:** Formal analysis. **Giulia Di Prima:** Writing – review & editing, Data curation. **Viviana De Caro:** Writing – review & editing, Supervision.

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Declaration of competing interest

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