COMPREHENSIVE REVIEW OF COVID-19 VACCINE HEALTH IMPACTS IN 2024: EFFICACY, SAFETY, AND LONG-TERM OUTCOMES

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ABSTRACT: *The COVID-19 pandemic led to an unprecedented global effort to develop effective vaccines to overcome the spread of SARS-CoV-2 and its variants. This review identifies key research on the development, efficacy, safety, financial viability, and global distribution of COVID-19 vaccines, as well as their impact on public health. This comprehensive review involved gathering data from selected publications that provided similar information relevant to the research topic by gathering relevant literature, screening for quality and applicability, and extracting pertinent data to ensure a thorough analysis. Review highlights those studies on mRNA vaccines, including BNT162b2 and mRNA-1273, demonstrated high efficacy in preventing symptomatic COVID-19, with robust immune responses. Adenovirus-vector vaccines, such as ChAdOx1 nCoV-19 and Ad26.COV2. S, also provided substantial protection, with varying efficacy against emerging variants like Delta and Omicron. Collectively, the findings emphasize the role of COVID-19 vaccines in reducing morbidity and mortality, the importance of equitable distribution, and the need for continued research on vaccine efficacy against emerging variantsand emergency preparedness.In addition to establishing a fully integrated commercial vaccine production facility with careful planning, and financial viability.*

Key word: COVID-19, viral vector, equitable distribution, financial viability, side effects

1- INTRODUCTION TO COVID-19 VACCINES

The development of COVID-19 vaccines represents a landmark achievement in modern science. One of the most groundbreaking developments was the use of mRNA vaccine platforms, specifically in the Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273) vaccines [1,2]. These vaccines are based on messenger RNA technology, which teaches cells to produce a protein like the spike protein found on the surface of the SARS-CoV-2 virus, stimulating an immune response. According to clinical trials, Pfizer-BioNTech demonstrated 95% efficacy in preventing symptomatic COVID-19 infections, while Moderna reported 94.1% efficacy. These numbers were obtained from large, randomized controlled trials involving tens of thousands of participants across various demographics, and the vaccines were found to be effective against severe disease, hospitalization, and death.

The safety profile of mRNA vaccines, while generally favorable, includes some common side effects such as pain at the injection site, fatigue, headache, fever, and muscle aches. These are typical reactions to vaccines, indicating that the immune system is responding appropriately. However, more concerning side effects, although rare, have been documented. For instance, myocarditis and pericarditis(inflammation of the heart and its lining) were identified as rare adverse effects, especially in younger males following the second dose of mRNA vaccines. The occurrence of these side effects prompted further investigations, but subsequent studies have confirmed that the benefits of mRNA vaccines in preventing severe COVID-19 outweigh these risks. Additionally, most cases of myocarditis have been mild and resolved with appropriate treatment.Furthermore, AstraZeneca's AZD12223 (also known as Vaxzervria: replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 structural surface glycoprotein antigen (spike protein; nCoV-19) gene) and Johnson & Johnson's Janssen Ad26.COV2.S COVID-19 vaccine utilized more traditional methods, where a genetically modified adenovirus delivers the SARS-CoV-2 spike protein gene into human cells. These vaccines demonstrated slightly lower efficacy rates in clinical trials, with AstraZeneca showing 70% efficacy and Johnson & Johnson at around 66% in preventing moderate to severe COVID-19 (Table 1). However, both vaccines were highly effective in preventing hospitalization and death, outcomes that are arguably the most important in a pandemic context. Their single-dose schedule, particularly for Johnson & Johnson, provided an advantage in logistical deployment, especially in low-resource settings where cold chain storage for mRNA vaccines might be challenging [4, 5].

The side effect profile of viral vector vaccines also mirrored that of mRNA vaccines, with local and systemic reactions such as fatigue, headaches, and mild fevers being the most common. Nevertheless, more serious but rare side effects emerged. The most notable was the development of vaccine-induced immune thrombotic thrombocytopenia (VITT), a rare but serious clotting disorder that occurred primarily in younger women after receiving the AstraZeneca or Johnson & Johnson vaccines. VITT involves the formation of blood clots in unusual locations, such as the brain or abdomen, coupled with low platelet levels. Despite the alarm caused by these events, health regulators globally determined that the risk of severe COVID-19 far outweighed the risk of VITT, especially as cases of the clotting disorder remained extremely rare, affecting fewer than 1 in 100,000 vaccinated individuals.[6, 7, 8]

In addition to mRNA and viral vector vaccines, other platforms, including inactivated virus vaccines andprotein subunit vaccines, were also developed. Sinopharm and Sinovac, Chinese-produced inactivated virus vaccines, achieved emergency use authorization in many countries. Clinical trials indicated that Sinopharm had an efficacy of 79%, while Sinovac reported around 50-60% efficacy, depending on the population studied and virus variants in circulation **(Table 1).** While these efficacy rates are lower compared to mRNA and viral vector vaccines, they still offer

significant protection against severe disease, hospitalization, and death [9, 10].

Table 1: Efficacy and Common Side Effects of COVID-19 Vaccine

Vaccine Name	Type of Vaccine	Efficacy	Common Side Effects
Pfizer-BioNTech	mRNA	95% overall efficacy	Soreness, fatigue, headache, myalgia, redness at injection site
Moderna	mRNA	94.1% overall efficacy	Pain, redness, swelling, fatigue, fever, headache
Novavax	Protein subunit	90% overall efficacy	Pain at injection site, fatigue, headache, muscle pain
Johnson & Johnson	Viral vector	66% overall efficacy	Fever, fatigue, headache, pain at injection site
AstraZeneca	Viral vector vaccine.	70.4% overall efficacy	Pain, tenderness, headache, fever, fatigue
Sinovac (CoronaVac)	Inactivated virus vaccine.	50.4% to 83.5% efficacy depending on location	Pain, fatigue, fever, swelling, headache
Sputnik V	Viral vector vaccine	91.6% overall efficacy	Pain at injection site, fatigue, headache, fever
Sinopharm	Inactivated virus vaccine	50.4% to 79%	pain at the injection sitefever, fatigue, headache, and muscle pain (myalgia)

The side effects of inactivated virus vaccines are generally mild, with fewer reports of serious adverse events compared to mRNA or viral vector vaccines. Local reactions such as pain at the injection site and general symptoms like fever and fatigue were the most common. However, the real-world efficacy of these vaccines has been more variable, especially with the emergence of new variants like Delta and Omicron. This variability has led to concerns about the long-term effectiveness of inactivated virus vaccines, especially in populations that received them as their primary vaccination series. Booster doses, often with mRNA vaccines, have been recommended to increase protection [10,11,12].

Protein subunit vaccines, such as Novavax's NVX-CoV23733, represent another important addition to the vaccine portfolio. These vaccines use lab-produced viral proteins to trigger an immune response without using live virus or viral vectors. Novavax showed 90% efficacy in clinical trials against the original strain of SARS-CoV-2 and has shown strong performance against some variants, though slightly reduced efficacy has been observed against newer variants like Omicron. The safety profile of Novavax was similarly mild, with injection site pain, headaches, and fatigue being the most commonly reported side effects. Serious side effects were rare, making this vaccine an appealing option for those hesitant about newer technologies like mRNA or viral vectors [12]. As COVID-19 variants evolved, vaccine efficacy across all platforms was put to the test. The Delta and Omicron variants, which feature mutations in the spike protein, led to reduced effectiveness in preventing infection across the board. However, vaccines have remained robustly protective against severe outcomes, including hospitalization and death, particularly when booster doseswere administered. Booster programs, primarily using mRNA vaccines, have been essential in restoring high levels of protection against variants, especially in populations that initially received vaccines with lower efficacy, such as those who took inactivated vaccines.

Mixing vaccine platforms has also emerged as a strategy to enhance immune responses. Studies suggest that heterologous regimens, where an individual receives two different vaccine types (e.g., Astra Zeneca followed by Pfizer), may lead to stronger immune responses than homologous regimens. This mix-and-match approach has shown promising results, particularly in countries where vaccine supplies fluctuate or certain vaccines are preferred for boosters.

2- Long-term Health Outcomes of Vaccinated Populations

The long-term outcomes in COVID-19 vaccinated populations have been a subject of extensive research, with findings that focus on several critical areas: vaccine efficacy, immune response durability, side effects, and the potential for long-lasting protection against severe outcomes. As COVID-19 vaccines have been in widespread use since 2020, data has gradually accumulated, enabling scientists to analyze the long-term effects on various populations [14, 15]. Studies show that antibody levels wane over time, typically decreasing within 6-8 months after the second vaccine dose. However, memory B-cells and T-cells, crucial for long-term immunity, persist even as antibody levels decline [16]. This suggests that while individuals may become more susceptible to mild infections, they retain significant protection against severe disease. Research on booster doses, particularly with mRNA vaccines (Pfizer-BioNTech and Modern) [5, 7] indicates that they can substantially enhance immunity. Boosters increase neutralizing antibody levels, offering improved protection against variants like Delta and Omicron, which have shown some degree of immune evasion in previously vaccinated individuals. For instance, a study published in The New England Journal of Medicine demonstrated that a third dose of mRNA vaccines restored efficacy against symptomatic infection from the Omicron variant to over 70% [5]. Long-term immunity is also characterized by how well vaccine-induced immune responses cope with new variants. Studies have shown that while vaccine effectiveness decreases against variants like Omicron [5, 7, 14], vaccinated individuals still maintain a robust immune response that significantly reduces the risk of hospitalization and death. Long-term studies consistently

show that vaccinated individuals have lower rates of severe COVID-19 outcomes, including hospitalization and death. For example, a study by the CDC revealed that during waves of variant-driven cases, vaccinated populations, particularly those who had received booster shots, experienced significantly lower mortality rates compared to unvaccinated groups17.

Special attention has been given to populations with underlying health conditions, including those with cardiovascular disease, diabetes, or compromised immune systems. Evidence shows that while these populations may have a blunted immune response to vaccines, they still experience a substantial reduction in the severity of disease. This has significant implications for public health strategies in protecting vulnerable groups. One of the concerns in the pandemic has been "long COVID," characterized by persistent symptoms lasting weeks or months after the initial infection. Research has demonstrated that vaccination reduces the risk of developing long COVID. According to studies, vaccinated individuals who experience breakthrough infections are significantly less likely to develop long-term symptoms than those who are unvaccinated [18].

Initial concerns about the potential for vaccines to trigger autoimmune diseases 19have not been substantiated by large-scale data. For example, studies from JAMA found no significant increase in autoimmune conditions like Guillain-Barré syndrome or multiple sclerosis in vaccinated individuals.[20,21,22]While vaccines have significantly reduced the severity of disease, achieving herd immunity to completely stop viral transmission remains elusive due to the emergence of more transmissible variants like Delta and Omicron. These variants have higher R0 values (basic reproduction numbers), meaning that an even larger proportion of the population would need to be immune to stop their spread. Vaccinated individuals are less likely to transmit the virus, especially after receiving booster doses. Studies indicate that while vaccines reduce viral load in breakthrough infections, vaccinated individuals can still spread the virus, particularly with the highly contagious Omicron variant. However, they remain less contagious than unvaccinated individuals [19, 21].

3- Global Vaccine Distribution and Long-term Outcomes

Long-term outcomes are heavily influenced by global vaccine access. Wealthier countries achieved widespread vaccination quickly, but many lowand middle-income countries experienced delays. This led to the emergence of variants in under-vaccinated regions, undermining global efforts to control the pandemic.

The COVAX initiative, led by WHO, aimed to distribute vaccines equitably. By 2023, many low-income countries had reached higher vaccination rates, but challenges remained in logistics, vaccine hesitancy, and political instability. Evidence suggests that improving global vaccine coverage is crucial not only for protecting populations but also for preventing the emergence of new variants that could evade immunity [23, 24]. Long-term safety data in pregnant women, immunocompromised individuals, and children have been reassuring. studies have shown that vaccinated pregnant women do not face increased risks of adverse pregnancy outcomes, and their infants may even benefit from passive immunity transferred through the placenta [25]

Vaccination has been a critical factor in allowing societies to return to pre-pandemic activities. In countries with high vaccination rates, restrictions on travel, social gatherings, and economic activities have been lifted. However, studies indicate that the return to full normality is dependent on continued vigilance, booster vaccinations, and adapting to a world where COVID-19 may become endemic.Vaccines have also had a long-term impact on healthcare systems by reducing the burden of severe COVID-19 cases. Hospitals, which were overwhelmed during peaks of the pandemic, have seen a significant reduction in COVID-19-related admissions. This has allowed for the resumption of elective surgeries and non-COVID-related medical care.[22,24]

4- Future Pandemic Preparedness

Establishing robust global surveillance networks is crucial for the early detection of emerging pathogens. The integration of real-time data sharing platforms can facilitate the rapid identification of novel viruses. Initiatives like the Global Outbreak Alert and Response Network (GOARN) should be expanded and better funded to ensure timely responses to potential threats.[26]Investing in genomic sequencing infrastructure worldwide allows for the swift characterization of new pathogens. The COVID-19 pandemic highlighted the importance of sequencing in tracking variants. Future preparedness should include widespread access to sequencing technology and the training of personnel in genomic analysis.Adopting the One Health framework,[27]which recognizes the interconnectedness of human, animal, and environmental health, can aid in identifying zoonotic spillover events. Collaborative efforts between veterinarians, ecologists, and medical professionals are essential for comprehensive monitoring and prevention strategies.The success of mRNA vaccines (e.g., Pfizer-BioNTech and Moderna) during the COVID-19 pandemic emphasizes the potential of flexible vaccine platforms [21,22]. Continued investment in mRNA technology and other innovative platforms (such as viral vectors and protein subunits) can expedite the development of vaccines against emerging pathogens.Streamlining regulatory processes across countries can reduce delays in vaccine approval and deployment. Establishing international regulatory standards and fostering collaboration between agencies like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) can facilitate faster yet safe approvals [28]. Expanding global vaccine manufacturing capacity confirms that once a vaccine is developed, it can be produced at scale to meet demand. This includes investing in manufacturing facilities, securing supply chains for critical components, and fostering partnerships between public and private sectors. Improving supply chain resilience involves diversifying manufacturing locations, securing raw material supplies, and enhancing logistics infrastructure. This reduces dependency on single sources and lessens disruptions during crises.Encouraging local vaccine production in diverse regions can decrease dependence on imports and enable quicker responses to regional outbreaks [29]. Technology transfer agreements and investments in local manufacturing capabilities are vital steps toward this goal.However, It

typically takes several years to set up a fully integrated commercial vaccine production facility, often yielding little to no income until product registration and commercialization are finalized. This process can incur additional costs ranging from $10 million to $100 million (**Table 2**) and may extend timelines by 5 to 10 years or more. Success hinges on aligning several key factors, including identifying a suitable market, finding an effective technology transfer partner, and hiring skilled personnel while ensuring GMP compliance. Additionally, the facility's type and scope significantly affect the time required to achieve commercial output and establish positive cash flow. Accurate production demand forecasts are crucial, as they influence ongoing manufacturing costs and the ability to repay initial investments. A thorough Front-End Loading (FEL) phase can reduce project costs by about 20% and is vital for maintaining financial viability throughout the project's development [30,31].

Table 2: Estimated cost and time to implement technology transfer agreements for commercial vaccine production

Component	Estimated Cost (USD)	Estimated Timeline	Doses per Year	Details
Design & Planning	$200 million - $500 million	2-3 years	N/A	Site preparation, approvals, and facility design.
Construction & Equipment	$500 million - $1 billion	3-4 years	N/A	Construction and procurement of specialized equipment.
Validation & Regulatory Setup	$100 million - $200 million	1-2 years	N/A	Ensuring the facility complies with FDA and WHO regulations.
Operational Readiness	$100 million - $300 million	1-2 years	Up to 500 million doses/year	Staff training, operational procedures, and early production setup.
Total	$1 billion - $2 billion	7-9 years	Up to 500 million doses/year	Full facility integration and manufacturing readiness.

CONCLUSIONS

In conclusion, the development of COVID-19 vaccines has been a remarkable global effort, leading to highly effective and safe tools in the fight against the pandemic. The mRNA vaccines, with their high efficacy and strong performance even against variants, have revolutionized vaccine development. The viral vector vaccines provided valuable alternatives, particularly in regions with logistical challenges, despite their rare but serious side effects. Traditional platforms, such as inactivated vaccines and protein subunit vaccines, added to the arsenal, offering additional options, particularly in countries with varying access to mRNA vaccines. As new variants emerge and immunity wanes, boosters and heterologous vaccination strategies have proven critical in maintaining population immunity and preventing severe outcomes. While side effects have been closely monitored and remain mostly mild, the rare but serious adverse effects emphasize the need for ongoing surveillance and transparent communication with the public. Establishing a fully integrated commercial vaccine production facility is a lengthy and costly process, and depends on careful planning, alignment of key factors, and ongoing evaluation to ensure financial viability throughout the project's lifecycle.

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