



Review on SAR COVID-19 and Vaccine Available on SAR COVID-19

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ABSTRACT

The Coronavirus pandemic has caused negative effects across the globe; mortality and morbidity being the main impact. After WHO, termed the disease a pandemic in March 2020, they gave in health guidelines to follow to control the spread of the disease. The health industry, academia, and different governments are united to develop and test various vaccines at an unprecedented speed to combat the pandemic fully and bring the world back to its feet. Some of the vaccines developed include Pfizer, Moderna, and AstraZeneca. However, just like other viruses, the SAR-CoV-2 virus keeps changing through mutation, as various variants, different from the first one is emerging. Evidence shows that the three new variants; UK, Brazil, and South Africa are more severe in terms of transmissibility, disease severity, evading of the immune response, and reducing the ability to neutralized antibodies, compared to the original coronavirus. With such knowledge of the existence of different strains, the arises concerns on whether the already available vaccines are effective enough in preventing the new COVID-19 strains. Studies are still underdeveloped to learn more on the virologic, epidemiologic, and clinical characteristics of the ever-emerging variants. This research, through a systemic review of literature, seeks to find out whether the variants of SAR-CoV-2 have an impact on the efficacy of various vaccines developed in fighting the disease and the entire body's immune response.

Keywords: COVID-19, Epidemiology, transmission COVAXIN, COVISHIELD, Johnson and Johnson COVID-19 vaccine, Sputnik v, Nanoparticle vaccine (Novavax), Pfizer vaccine, Moderna vaccine

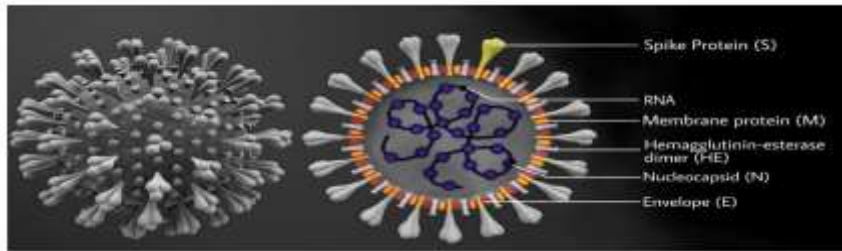
INTRODUCTION:

In late 2019, there was a sudden surge in the number of individuals being admitted to local hospitals of Wuhan, in the Hubei Province of China, with a pneumonia-like illness of unknown etiology [1]. Although results from preliminary epidemiological investigations pointed to-wards a zoonotic origin from a local seafood market in Huanan, the exponential increase in the number of cases suggested the possibility of human-to-human transmission [2,3]. The World Health Organization (WHO) was notified of the outbreak by the Chinese authorities on December 31, 2019. By January 7, 2020, scientists had isolated a novel coronavirus from the lower respiratory tract samples of patients who were admitted to a hospital in Wuhan [4]. This pathogen was later termed as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses (ICTV) [5]. The WHO declared this novel viral disease a Public Health Emergency of International Concern on 30 January 2020, and subsequently termed it as COVID-19 (Coronavirus Disease 2019) [6] on February 11, 2020. The first fatality was reported on Jan 11, 2020. The mass migration of people during the Chinese New Year fuelled the rapid spread of the disease to all parts of the globe, which led to the official declaration of COVID-19 as a pandemic [7] by the WHO on March 11, 2020. COVID-19 has wreaked havoc worldwide, resulting in 15,151,738 confirmed cases and 621,121 deaths across 215 countries and territories [8] as of July 22, 2020. Despite stringent public health measures, the outbreak has continued at a breakneck pace and has laid bare the glaring in-adequacies of the present healthcare systems around the world. Virology

Coronaviruses (derived from the Latin word corona, meaning crown) are positive sense, single-stranded enveloped RNA viruses with a diameter of 60 nm to 140 nm, and are widely dispersed in nature [4]. Four (hCoV-229E, OC43, NL63 and HKU1) out of the seven species of beta-coronaviruses found in humans cause mild illnesses of the upper respiratory tract such as common cold (also caused by rhinoviruses). Two other kinds, Severe Acute Respiratory Syndrome Coronavirus (SARS-Co V) and Middle East Respiratory Syndrome Coronavirus (MERS-Co V), are considerably more dangerous (mortality rates of 9.6% and 35% respectively [9,10]). SARS-Co V first emerged in late 2002 in China and spread rapidly to other parts of the world from Hong Kong via air travel. The virus was believed to have originated from a bat.

Abbreviations: COVID-19, Coronavirus Disease 2019; SARS-CoV-2, Severe Acute Respiratory Syndrome Coronavirus 2; WHO, World Health Organization; ICTV, International Committee on Taxonomy of Viruses; ARDS, acute respiratory distress syndrome; SARS, Severe Acute Respiratory Syndrome; MERS, Middle East Respiratory Syndrome; R0, reproductive ratio; SI, Serial Interval; PPE, Personal Protective Equipment; ACE2, angiotensin I converting enzyme 2; RAS, Renin-Angiotensin System; ATII, alveolar Type II cells; Rd Rp, RNA-dependent RNA polymerase; TMPRSS2, type-2 transmembrane serine protease; IL-6, interleukin 6; TNF α , tumor necrosis factor α ; MCP-1, monocyte chemoattractant protein-1; NK, natural

killer cells; S protein, viral spike protein; a APC, artificial antigen-presenting cells; CP, Convalescent Plasma therapy; CRS, Cytokine-release syndromes; ADR, Adverse Drug Reactions

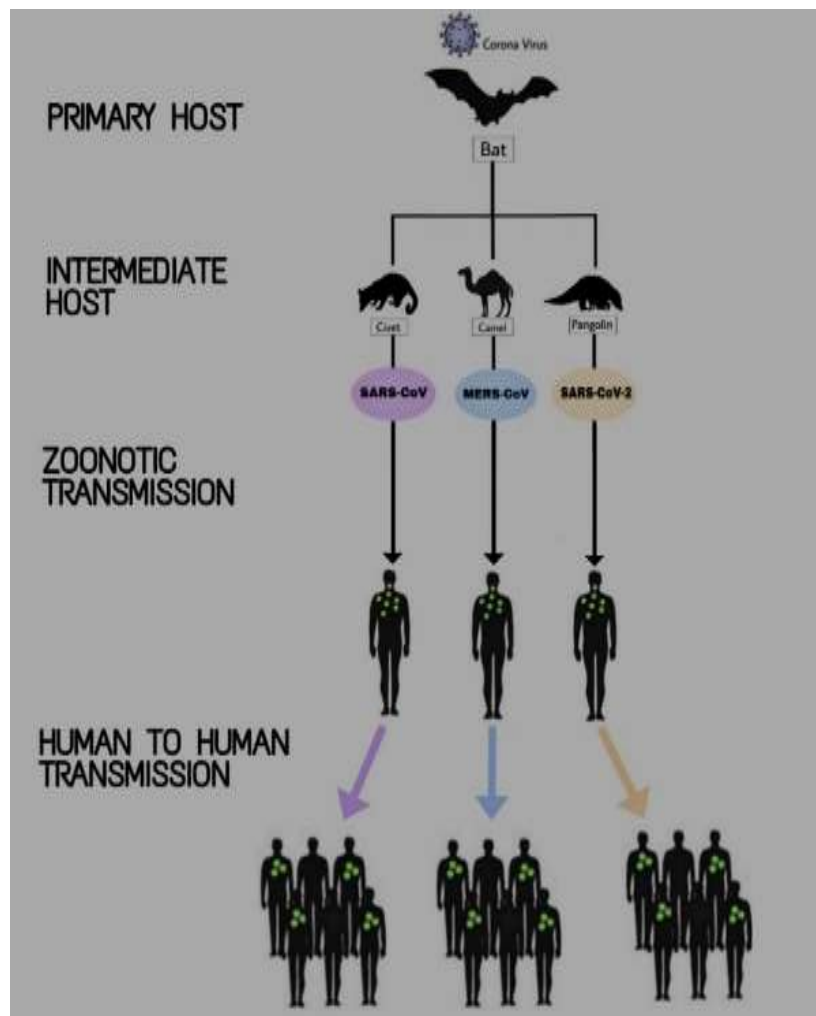


Diagrammatic representation of the structure of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The figure represents the viral structure of SARS-CoV-2. The spike glycoprotein (S protein) confers a crown like appearance to the virus, hence the name 'Coronavirus'. The S protein mediates the binding of the virus to cellular receptors. The role of hemagglutinin-esterase (HE) in Coronaviruses is poorly understood but it is reported to influence virion attachment in other viruses.

susceptible to common disinfectants like sodium hypochlorite, hydrogen peroxide, diethyl ether, 75% ethanol, chloroform etc . Soap is found to be equally effective since it readily dissolves the lipid bilayer of the virus. SARS-CoV-2 can also be inactivated by UV or when heated at 60 °C for 30 min.

Epidemiology

Despite being relatively more benign than its two ancestors, SARS-CoV-2 has crossed the 15 million cases mark worldwide, aided in part by inadequate risk assessment regarding the urgency of the situation. However, the overriding reasons for its exponential growth are the high reproductive ratio (R0) – ranging from 2 to 6.47 , the long incubation period of 2 to 14 days (median 5 days) and a Serial Interval



representation illustrates the ecological origin, different animal hosts, and the subsequent transmission of SARS-Co V, MERS-Co V, and SARS-CoV-2 to the human population, eventually resulting in the three major epidemics/pandemic of the 21st century. SI) of 5–7.5 days [26], which are indicative of an infectious disease that has the potential of rapidly turning into a pandemic. Sanche et al. recently suggested that the disease had a median R0 of 5.7 (95% CI of 3.8–8.9) and SI of 6–9 Ecological origin and transmission of different species of Coronaviruses. This schematic days in China during the initial period of the outbreak .In comparison, the R0 of SARS was 2 and 1.3 for the 2009 H1N1 Influenza .The mortality rate for COVID-19 ranges between 2 and 5%, with ARDS being the leading cause of death.

Transmission -

Inhalation of respiratory droplets generated by symptomatic patients' cough and sneeze is the main mode of transmission of COVID-19. Infected droplets can spread to distances of up to 2 m and deposit on surfaces, which can act as potential fomites for transmission of the virus to seemingly healthy individuals who touch their mucosa (mouth, nose) and conjunctiva (eyes) without proper sanitization. Asymptomatic or pre-symptomatic people can also spread the infection. The virus is also believed to be present in the stool, and transmission via the fecoral route cannot be ruled out [20]. There is currently no evidence of transmission of the virus from a pregnant mother to her foetus via transplacental route.

COVAXIN:

Covaxin is a COVID-19 vaccine developed by Bharat Biotech, an Indian biotechnology company, and the Indian Council of Medical Research. It is a two-dose vaccine with an efficacy rate of 78%, according to interim phase 3 clinical data.

India's drug regulatory authority, the Central Drugs Standard Control Organization, authorized the vaccine for emergency use on January 3, 2021. It can now be used to vaccinate people aged 18 and older. Beyond India, the vaccine is authorized for emergency use in 12 countries: Bahrain, Botswana, Iran, Mexico, Nepal, the Philippines, Vietnam, Paraguay, Zimbabwe, Guyana, Trinidad and Tobago, and Mauritius.

Covaxin, also known as BBV152, is a type of whole-virus vaccine called an inactivated vaccine. An inactivated vaccine incorporates a modified or dead version of the virus, in this case SARS-CoV-2, which cannot replicate and so cannot cause disease.



The virus in an inactivated vaccine triggers an immune response and causes the body to produce antibodies, equipping it to defend itself against potential future infection. Common side effects

According to the Indian government's Ministry of Health and Family Welfare (MoHFW), the vaccine's main side effects include:

1. 1.Fever
2. 2.headaches
3. 3.irritability
4. 4.pain, swelling, or both at the site of injection

These side effects overlap with those of other currently available COVID-19 vaccines. They are expected to last for a few days. The vaccine's phase 1 and 2 clinical trial data Trusted Source state that other reported adverse events include fatigue, body aches, nausea, vomiting, and chills. No serious side effects were reported Of the 380 participants who received the first dose of the vaccine, at a concentration of either 3 or 6 micrograms, 17 participants, or 4.5%, experienced injection-related reactions, and 23 participants, or 6.1%, experienced systemic reactions, such as body aches and fever. A similar number of adverse reactions were reported after the second dose.

MoHFW suggests taking paracetamol, also known as acetaminophen (Tylenol), to alleviate some of these mild side effects. Allergies and other contraindications

Bharat Biotech's vaccine fact sheet notes that a severe allergic reaction is very rare but possible after a dose of Covaxin.

According to the fact sheet, a severe allergic reaction may cause the following symptoms:

1. 1.difficulty breathing
2. 2.swelling of the face and throat
3. 3.a rapid heartbeat rashes throughout the body
4. 4.Dizziness, weakness

The vaccine has a contraindication for people with a history of allergies, although the sheet does not specify whether this is all-encompassing or applies only to people with allergies to the vaccine's ingredients The fact sheet also warns that anyone with a bleeding disorder and anyone who is pregnant or breastfeeding should not receive the vaccine.

The MoHFW website also states that Covaxin does not affect fertility and that such claims have no basis. It notes that there were similar rumors about the measles and polio vaccines, neither of which affect fertility, as studies have demonstrated. Controversy about approvals There have been mixed responses to the speed of Covaxin's emergency use authorization.

Two scientific communities, the All India People's Science Network and the All India Drug Action Network, have criticized the authorization of the vaccine, with the latter citing "intense concerns arising from the absence of the efficacy data. On the other hand, the The New Indian Express has reported that a group of 45 scientists and medical experts signed a statement claiming that the critics' "irresponsible statements of vested interests" are politically driven and harming the credibility of the research. The experts reportedly also noted that "This vaccine is a whole virus inactivated vaccine, which may [provide] better protection, even against mutant strains of the virus, as the immune response will be against multiple antigens and not only against [the] spike protein."

COVISHIELD: -

It is a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Following administration, the genetic material of part of corona virus is expressed which stimulates an immune response



COVISHIELDTM contains the following excipients:

1. L-Histidine
2. L-Histidine hydrochloride monohydrate
3. Magnesium chloride hexahydrate
4. Polysorbate 80
5. Ethanol
6. Sucrose
7. Sodium chloride
8. Disodium edetate dihydrate (EDTA)

There is no difference between the 1st and 2nd dose. Each dose has the same content of viral particles. The Indian government has recommended that the time interval between the 1st and 2nd dose should be between 12-16 weeks.

Patients who have experienced major blood clotting (venous and/or arterial thrombosis) in combination with low platelet count (thrombocytopenia) following any COVID-19 vaccine.

COVISHIELDTM has been administered in people with or without comorbid conditions in clinical trials and the safety profile was comparable in those with or without comorbid condition (e.g.: Hypertension, Cardiovascular Disease, Asthma, Diabetes, etc.). People with clinically stable comorbid conditions can receive the vaccine. Kindly follow up with your treating physician for a risk benefit assessment based on clinical judgement before taking the vaccine.

Following side effects or adverse reactions have been reported with COVISHIELDTM vaccine.

Very common (may affect more than 1 in 10 people) - tenderness, pain, warmth, or itching where the injection is given, generally feeling unwell, feeling tired (fatigue), chills or feeling feverish, headache, feeling sick (nausea), joint pain or muscle ache

Common (may affect more than 1 in 10 people) - swelling or redness where the injection is given, fever, being sick (vomiting) or diarrhoea, pain in legs or arms, flu-like symptoms, such as high temperature sore throat, runny nose, cough and chills

Uncommon (may affect up to 1 in 100 people) – sleepiness or feeling dizzy, abdominal pain, enlarged lymph nodes, excessive sweating, itchy skin, rash or hives

Not known (the frequency cannot be determined from the available data) -severe allergic reaction (anaphylaxis), severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing or breathing)

Rarest: Major blood clotting (venous and/or arterial thrombosis) in combination with low platelet count (thrombocytopenia) have been observed very rarely (with a frequency less than 1 in 100,000 vaccinated individuals)

Johnson and Johnson COVID vaccine



Manufacturer: Janssen Pharmaceuticals Companies of Johnson & Johnson

Type of Vaccine: Viral Vector

How Given: Shot in the muscle of the upper arm

Phase 3 ENSEMBLE Study Design

The Phase 3 ENSEMBLE study is a randomized, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older. The study was designed to evaluate the safety and efficacy of the Company's vaccine candidate in protecting against both moderate and severe COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints. The study enrolled a total of 43,783 participants.

The trial, conducted in eight countries across three continents, includes a diverse and broad population including 34 percent of participants over age 60.

The study enrolled 44 percent of participants in the United States. Seventy-four percent of participants in the U.S. are White/Caucasian; 15 percent are Hispanic and/or Latinx; 13 percent are Black/African American; 6 percent are Asian and 1 percent are Native American.

Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe COVID-19.

Research and development activities for the Company's COVID-19 vaccine, including the ENSEMBLE clinical trial and the delivery of doses for the U.S., has been funded in part with federal funds from the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201700018C, and in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS).

The Company's COVID-19 vaccine leverages the AdVac® vaccine platform, a unique and proprietary technology that was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines.

The Janssen COVID-19 vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized by FDA through an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. There is no FDA-approved vaccine to prevent COVID-19.

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U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for its single-dose COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, to prevent COVID-19 in individuals 18 years of age and older.

a single primary dose to people 18 years and older who are unable to receive or unwilling to receive other FDA-authorized or -approved COVID-19 vaccines.

a single booster dose at least 2 months after the first dose of the Janssen (Johnson and Johnson) COVID-19 vaccine for people 18 years and older who are unable to receive or unwilling to receive other FDA-authorized or -approved COVID-19 vaccines.

a single booster dose to people 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine who are unable to receive or unwilling to receive other FDA-authorized or -approved COVID-19 vaccines

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin, and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, fever.

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Sputnik V:

The Sputnik V vaccine was created at the N.F. Gamaleya Research Center for Epidemiology and Microbiology Ministry of Health of Russia. On August 1, 2020, the Russian Health Minister Mikhail Murashko told reporters the 'clinical trial had been declared completed' and was then registered to 'FSBI "NF Gamaleya NITsEM" of the Ministry of Health of Russia ("Medgama" branch of NF Gamaleya NITsEM "of the Ministry of Health of Russia)' on August 8, 2020.



The Russian Direct Investment Fund announced on August 20, 2020, that the Sputnik V vaccine candidate would be tested on 40,000 volunteers in more than 45 medical centers to confirm clinical efficacy post-approval studies. On October 27, 2020, RDIF announced it had submitted applications to the World Health Organization for an Emergency Use Listing and prequalification of the Sputnik V vaccine candidate. The RDIF and The National Research Center for Epidemiology and Microbiology announced an International Scientific Advisory Board on the Sputnik V vaccine. Leading scientists in virology, microbiology, genetics, and biotechnology from Argentina, Croatia, France, Germany, India, Russia, Sweden, the UK, and the USA, representing top research and medical centers, have joined the Board.

RDIF was established in 2011 and provided support to facilitate partnerships, including Gamaleya National Research Institute of Epidemiology and Microbiology and the Central Research Institute of the Radiation, Chemical, and Biological Defense Troops. The Gamaleya Center used the same human adenoviral platform for their earlier research, including but not limited to vaccines against Ebola in 2017 and MERS in 2019.

The COVID-19 vaccine Sputnik V (Gam-COVID-Vac) is an adenoviral-based, two-part vaccine against the SARS-CoV-2 coronavirus. Initially produced in Russia in 2020, Sputnik V uses a weakened virus to deliver small parts of a pathogen and stimulate an immune response. The Sputnik V (Gam-COVID-Vac) vaccine reduces the time taken for the actual development of immunity to SARS-CoV-2, the beta coronavirus behind the COVID-19 pandemic. Sputnik V is a two-component vaccine used by adenovirus serotypes 5 and 26. A fragment of tissue-type plasminogen activator is not used, and the antigen insert is an unmodified full-length S-protein. Sputnik V vaccine is produced with the HEK293 cell line.

The Sputnik vector vaccine is based on adenovirus DNA, in which the SARS-CoV-2 coronavirus gene is integrated. Adenovirus is used as a "container" to deliver the coronavirus gene to cells and synthesize the SARS-CoV-2 virus's envelope proteins, "introducing" the immune system to a potential enemy. The cells then use the gene to produce the spike protein. A person's immune system will treat this spike protein as foreign and produce natural defenses, antibodies, and T cells, against this protein.

In May 2020, the Russian state institute Gamaleya National Research Centre of Epidemiology and Microbiology announced that it had developed the vaccine, which does not have any side effects. The first vaccination leads to humoral cellular immunity, and once a second vaccination is administered, memory cells are formed.

Side Effects

Nationwide results on safety of Gam-COVID-Vac vaccine (Sputnik V) in the Republic of San Marino using active surveillance on May 20, 2022. After the first dose, systemic reactions were reported by 57.5% of the participants, while injection site reactions were reported by 46.7%. The most common AEFIs were pain at the injection site, fatigue, and headache. Grade 3 or 4 AEFIs were reported by 0.8% and 0.3% of the participants, respectively. After the second dose, systemic reactions were reported by 63.1% of the participants, while injection site reactions by 54.7%. The most common AEFIs were malaise, pain at the injection site, and myalgia. Grade 3 or 4 AEFIs were reported by 2.7% and 1.1% of the participants, respectively. Interpretation: Our results confirm a good tolerability profile for the adult population.

The Lancet published a study on November 2, 2021 that found 'most of the solicited adverse reactions were mild (66.4% from all vaccinees), few were moderate (5.5%). No serious adverse events were detected.' TASS reported on November 19, 2021, the deputy CEO of the Gamaleya Center, Denis Logunov, stated, 'There have been no confirmed cases of deaths triggered by Sputnik V.'

Clinical Trials

The Sputnik V vaccine publishes a list of relevant clinical studies.

Clinical Trial NCT04530396: Phase 3 Clinical Trial of Efficacy, Safety, and Immunogenicity of Gam-COVID-Vac Vaccine Against COVID-19 (RESIST). Randomized, double-blind (blinded for the trial subject and the study physician), placebo-controlled, multi center clinical trial in the parallel assignment of efficacy, immunogenicity, and safety of the Gam-COVID-Vac combined vector vaccine against the SARS-CoV-2-induced coronavirus infection in adults in the SARS-CoV-2 infection prophylactic treatment. Last Update Posted: January 22, 2021.

Clinical Trial NCT04436471 - An open two-stage non-randomized Phase 1/2 study with 38 healthy volunteers.

Sputnik V Dosage

The Sputnik V vaccine is manufactured as a liquid formulation containing 10^{11} vp per 0.5 mL/dose. For intramuscular injection composition for one dose (0.5 ml): Active substance: recombinant serotype 26 adenoviral particles containing the SARS-CoV-2 S protein gene, in the amount of $(1.0 \pm 0.5) \times 10^{11}$ particles per dose

Sputnik V Ingredients

The active components are a modified replication-defective adenovirus of a different serotype (Serotype 26 for the first component and serotype 5 for the second), modified to include the protein S-expressing gene of the SARS-CoV-2 virus. The ingredients include Tris-(hydroxymethyl)-aminomethane, Sodium chloride, Sucrose, Magnesium chloride hexahydrate, Disodium EDTA dihydrate, Polysorbate 80, Ethanol, and Water.

Interfax reported on February 12, 2021, that the Sputnik V coronavirus vaccine does not contain any components prohibited by Islam, Vladimir Gushchin, head of the laboratory of mechanisms of population change of pathogenic microorganisms at the Gamaleya Center, said.

Novavax vaccine:

The Novavax vaccine will be manufactured in two different facilities. In Europe, the vaccine will be manufactured under the trade name Nuvaxovid and has been approved by the European Medicines Agency, and in India, the vaccine will be manufactured by Serum Institute of India under the trade name Covovax and has been approved by the Drugs Controller General of India.



The WHO Strategic Advisory Group of Experts on Immunization (SAGE) has issued interim policy recommendations for the use of the Novavax (NVX-CoV2373) vaccine. This article provides a summary of those interim

Ingredients

L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate (EDTA), Water for injection

Dose

You need 2 doses of the Novavax vaccine, given at least 3 weeks apart. The interval can be extended to 8 weeks in certain circumstances, including to potentially improve effectiveness and reduce the risk of rare side effects such as myocarditis and pericarditis.

You may not be fully protected against COVID-19 until 7 to 14 days after your second dose.

Novavax (Novavax) is approved for use in people aged 18 years and over

Common side effects after Novavax include:

1. 1.injection site pain or tenderness
2. 2.tiredness
3. 3.headache
4. 4.muscle or joint pain
5. 5.generally feeling unwell.

Mechanism:

Novavax vaccine technology in action: fighting COVID-19 In our vaccine, we organize spike proteins into a nanoparticle to help your immune system recognize the target spike. Learning to recognize the spike proteins in this way helps your immune system protect you from getting sick from COVID-19.

Efficacy: The incidence of Covid-19 was lower among vaccine recipients, and only five cases of severe Covid-19 occurred, all in the placebo group. Vaccin efficacy was 89.7% overall and 86.3% against the B.1.1.7 (alpha) vari ant and 96.4% against non-B.1.1.7 variants in post hoc analysis.

Pfizer-BioNTech COVID-19 Vaccine:



Manufacturer: Pfizer, and BioNTech

Type of Vaccine: mRNA

How Given: Shot in the muscle of the upper arm

Number of Shots: 2 doses in the primary series, given 3–8 weeks apart.

Name: BNT162b2

Brand name: COMIRNATY

People ages 6 months – 4 years who are moderately or severely immunocompromised should get a third dose at least 8 weeks after their second dose. For those five years and older who are moderately or severely immunocompromised the third dose should be at least 4 weeks after the second dose.

Booster Shots: At this time, only those 5 years of age and older should get a booster.

Does NOT Contain: Eggs, preservatives, latex, metals

COVID-19 vaccination helps protect people from getting severely ill with COVID-19. Side effects and adverse events could follow any vaccination, including COVID-19 vaccination.

Side effects: Not everyone experiences side effects. However, some people do. Side effects are normal signs that your body is building protection. Side effects may have a short-term affect on your ability to do daily activities and should go away in a few days. If you would like to report a side effect, use V-safe.

Adverse events: Adverse events are rare but could cause a long-term health problem. If an adverse event occurs, it will generally happen within six weeks of receiving a vaccine dose. If you would like to report an adverse event, use Vaccine Adverse Event Reporting System (VAERS).

During clinical trials, the U.S. Food and Drug Administration (FDA) collected data on each of the authorized COVID-19 vaccines for a minimum of two months (eight weeks) after the final dose. Currently, CDC, FDA, and other federal agencies continue to monitor the safety of COVID-19 vaccines.

Ingredients of Pfizer vaccine:

Dibasic sodium phosphate dihydrate. Monobasic potassium phosphate. Potassium chloride (common food salt) Sodium chloride (basic table salt)

Moderna vaccine:

Manufacturer: Moderna TX, Inc.

Type of Vaccine: mRNA

How Given: Shot in the muscle of the upper arm

Name: mRNA-1273

Brand name: Spikevax



Moderna (Spikevax) COVID-19 vaccine received U.S. Food and Drug Administration (FDA) approval on January 31, 2022, for individuals ages 18 years and older. Once vaccines are approved by the FDA, companies can market the vaccines under brand names. Spikevax is the brand name for the Moderna COVID-19 vaccine. The FDA-authorized Moderna COVID-19 vaccine for individuals ages 18 years and older will now be marketed as Spikevax. No change has been made to the vaccine's formula with the name change. The Moderna vaccine name remains for individuals ages 6 months to 17 years since the vaccine is authorized (but not yet approved) for this age group.

Safety Data Summary

COVID-19 vaccines have undergone—and will continue to undergo—the most intensive safety monitoring in U.S. history. Evidence from the hundreds of millions of COVID-19 vaccines already administered in the United States, and the billions of vaccines administered globally, demonstrates that they are safe and effective.

Side effects that happen within 7 days of getting vaccinated are common but are mostly mild. Some people have reactions that affect their ability to do daily activities.

Side effects throughout the body (such as fever, chills, tiredness, and headache) are more common after the second dose of the vaccine.

Severe allergic reactions to vaccines are rare but can happen.

There is a rare risk of myocarditis and pericarditis associated with mRNA COVID-19 vaccination, mostly among males ages 12 through 39 years. The rare risk may be further reduced with a longer interval between the first and second dose. Learn more about the timing for your second dose.

The Moderna COVID-19 vaccine contains the following ingredients:

Messenger ribonucleic acid (mRNA): Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.

Ingredient:

*Lipids (fats):

*PEG2000-DMG:

*1,2-dimyristoyl-rac-glycerol, methoxy polyethylene glycol

*1,2-distearoyl-sn-glycero-3-phosphocholine

*BotaniChol® (non-animal origin cholesterol)

*SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate

Work together to help the mRNA enter cells.

Salt, sugar, acid stabilizers, and acid:

Sodium acetate

Sucrose (basic table sugar)

Tromethamine

Tromethamine hydrochloride

Acetic acid (the main ingredient in white household vinegar)

Purpose

Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

S. No	Product	Indian Manufacturer	Collaborator
1	Covishield (Chimpanzee Adenovirus)	Serum Institute of India, Pune	Astra Zeneca
2	Covaxin (Inactivated Virus)	Bharat Biotech International Ltd, Hyderabad	Indian Council of Medical Research, India
3	ZyCoV-D (DNA vaccine)	Cadila Healthcare Ltd, Ahmedabad (Zydus Cadila)	Dept of Biotechnology, India
4	Sputnik V (Human Adenovirus vaccine)	Trialed and manufactured in India by Dr. Reddy Lab.	Gamaleya National Center, Russia
5	NVX-CoV2373 (Protein Subunit)	Serum Institute of India, Pune	Novavax
6	Recombinant Protein Antigen based vaccine	Biological E Ltd, Hyderabad	MIT, USA
7	HGCO 19 (mRNA based vaccine)	Genova, Pune	HDT, USA
8	Inactivated rabies vector platform	Bharat Biotech International Ltd, Hyderabad	Thomas Jefferson University, USA
9	Vesiculo Vax Platform	Aurobindo Pharma Ltd, Hyderabad	Aurovaccine, USA

Conclusions

COVID-19 vaccinations combined with COVID-19 appropriate behaviour are the most effective tools for individual protection and pandemic containment. Despite rapid development of the vaccines, their access and efficacy remain limited. Second-generation vaccines with improved efficacy and safety are urgently needed. Vaccinating the targeted number of beneficiaries shall be a daunting task for any government and SARS-CoV-2 variants are likely to play an important obstructive role²⁸, in the context of vaccine hesitancy. Extensive risk communications and continued efforts to win public confidence in the vaccine must persist. Surveillance is also critical.

References

1. Johns Hopkins University & Medicine. COVID-19 dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). Coronavirus Resource Center, Johns Hopkins University & Medicine, 2021, <https://coronavirus.jhu.edu/map.html>
2. McCormick LC, Benhamou M and Pogkas D. The Covid-19 pandemic has added \$19.5 trillion to global debt. Bloomberg, 27 January 2021, <https://www.bloomberg.com/graphics/2021-coronavirus-globaldebt/#:~:text=The%20Covid%2D19%20Pandemic%20Has%20Added%20%2419.5%20Trillion%20to%20Global%20Debt>
3. Dan JM, Mateus J, Kato Y, et al. Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. *Science* 2021; 371(6529): eabf4063.
4. WHO. COVID-19 vaccine tracker and landscape, 2021, <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>
5. N. Zhu, et al., A novel coronavirus from patients with pneumonia in China, 2019, *N. Engl. J. Med.* 382 (2020) 727–733.
6. WHO Director-General's opening remarks at the media briefing on COVID-19-11 March 2020 <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020>. (2020). Accessed 28 April 2020.
7. Rothan HA, Byrareddy SN. The epidemiology and pathogenesis of coronavirus disease (COVID-19) outbreak. *J Autoimmun.* 2020;109:102433.
8. Khamsi R. If a coronavirus vaccine arrives, can the world make enough. *Nature.* 2020;580(7805):578-80.
9. Ricks D. Race for a coronavirus vaccine: thanks in part to institutional support, CanSino biologics, Moderna therapeutics, and other developers are exploring diverse approaches against SARS-CoV-2. *Genet*
10. Pfizer COVID-19 Vaccine EUA Letter of Authorization. Sect. Section 564(b)(1)(C) (2020).
11. Walsh EE, Frenck RW, Falsey AR, et al. Safety and immunogenicity of two RNA-based Covid-19 vaccine candidates. *N Engl J Med* 2020; 383(25): 2439–2450.
12. WHO. Statement for healthcare professionals: how COVID-19 vaccines are regulated for safety and effectiveness, 2021, <https://www.who.int/news/item/11-06-2021-statement-for-healthcare-professionals-how-covid-19-vaccines-are-regulated-for-safety-and-effectiveness>
13. Novavax COVID-19 vaccine demonstrates 89.3% efficacy in UK phase 3 trial. Novavax, Inc, 2021, <https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3>
14. Moderna. Clinical trial results, 2021, <https://www.modernatx.com/covid19vaccine-eua/providers/clinical-trial-data>
15. Vaccines and Related Biological Products Advisory Committee Meeting December 17, 2020. Sect. Section 564 of the Federal Food, Drug, and Cosmetic Act (2020), <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement>
16. The peer-review journal *The Lancet* published: ROCCA cohort study: Nationwide results on safety of Gam-COVID-Vac vaccine (Sputnik V) in the Republic of San Marino using active surveillance on May 20, 2022.
17. WHO. WHO coronavirus (COVID-19) dashboard. Covid19. who.int, 2021. Available: <https://covid19.who.int/> [Accessed 1 May 2021].