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Special Article

COVID-19 Vaccination in Korea

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ABSTRACT

Since December 2020, various coronavirus disease 2019 (COVID-19) vaccines have been developed and approved. As of February 2023, mRNA vaccines including bivalent vaccines (Pfizer/BioNTech, Moderna), recombinant protein vaccines (Novavax, SK Bioscience), and viral vector vaccines (AstraZeneca, Janssen) have been approved in Korea. COVID-19 vaccination can effectively reduce hospitalization and deaths due to symptomatic COVID-19, especially severe and critical COVID-19. The primary series vaccination against COVID-19 is recommended for all adults aged ≥18 years in Korea. Booster vaccination with the bivalent mRNA vaccine is available for those ≥12 years who have completed the primary series vaccination, regardless of the type of vaccine previously received, and is recommended for all adults. Booster vaccination can be administered since 90 days after the last dose. Localized and systemic adverse events following COVID-19 vaccination are relatively common and more frequently documented in younger age groups. Rare but potentially serious specialized adverse reactions include anaphylaxis, thrombosis with thrombocytopenia syndrome, myocarditis, and Guillain-Barré syndrome. Previous severe allergic reactions, such as anaphylaxis, to any COVID19 vaccine or vaccine component are considered a contraindication for vaccination. The indications and schedule for COVID-19 vaccination are subject to change based on further research results and the COVID-19 pandemic.

Keywords: Vaccination; COVID-19; SARS-CoV-2

SUMMARY

1. Who should get vaccinated and when
   1) Primary series vaccination: Recommended for all adults
   2) Booster vaccination: bivalent mRNA vaccine recommended beginning 90 days after the last dose for adults who have completed the primary series vaccination.

2. Inoculation dose and method
   Intramuscular injection into the deltoid muscle of the shoulder, irrespective of vaccine type and dose

3. Adverse events
   1) Local reactions: Pain, swelling, redness, and itching at the injection site
   2) Systemic reactions: Fatigue, headache, myalgia, chills, fever, arthralgia, lymph node enlargement, hypersensitivity reactions, anaphylaxis, etc.
   3) Vaccine-specific adverse events
      (1) Thrombosis with thrombocytopenia syndrome (TTS): rarely caused by adenovirus vector vaccine (AZD1222, Ad26.COV2.S)
      (2) Myocarditis: Rarely caused by mRNA vaccines

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(BNT162b2, mRNA-1273), also reported with NVX-COV2373
(3) Guillain-Barré syndrome: Known to occur with adenoviral vector vaccine (AZD1222, Ad26.COV2.S), although causality is unclear

4. Precautions and contraindications
1) History of anaphylactic reaction to a COVID-19 vaccine or component (contraindicated for that vaccine)
2) History of COVID-19 vaccine-associated TTS (VITT/TTS) (contraindicated for adenoviral vector vaccines)
3) History of heparin-induced thrombocytopenia, capillary leak syndrome (contraindicated for adenoviral vector vaccines)
4) If a patient has a history of COVID-19 vaccine-induced myocarditis (BNT162b, mRNA-1273) or Guillain-Barré syndrome (AZD1222, Ad26.COV2.S), vaccination or vaccination with a different platform should be considered based on risk-benefit assessment.

*This guidance is current as of February 2023 but subject to change based on further research, the evolving COVID-19 pandemic, and other factors. Specific application should be based on the latest clinical guidelines, approvals, at the time.

1. INTRODUCTION

The Korean Society of Infectious Disease (KSID) has been publishing a textbook on adult immunization since 2007. The most recent version, the 3rd edition of *Vaccination for Adults* (Koonja Publishing, Inc., Seoul) was released in September 2019. Since its last update, the field of adult immunization has undergone significant changes, most notably the emergence of coronavirus disease 2019 (COVID-19). This article aims to provide an overview of COVID-19 vaccination in Korea as part of an update to the textbook by the Committee on Adult Immunization of the KSID.

Given the continuously evolving landscape of COVID-19 vaccination, this article offers an update as of February 2023, providing an overview of the vaccines currently authorized in Korea. This includes an overview of COVID-19, the types of available COVID-19 vaccines, their efficacy and effectiveness, indication, method of administration, adverse events, and contraindications. It is noteworthy that the guidance regarding COVID-19 vaccination is subject to change based on further research, the evolving COVID-19 pandemic, and other factors, and as such, this guidance will be updated accordingly.

2. DISEASE OVERVIEW

On identifying severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as the underlying cause of a pneumonia outbreak in Wuhan, China, in late 2019, the World Health Organization (WHO) named the resulting infection COVID-19 [1]. COVID-19 has spread globally, resulting in a pandemic that remains ongoing as of February 2023, with more than 600 million cumulative confirmed cases and more than 6 million cumulative deaths [2].

1) Causative agent

SARS-CoV-2, a member of the *Coronaviridae* family, is an enveloped positive-sense single-stranded RNA virus that belongs to the *Betacoronavirus* genus, along with Middle East respiratory syndrome coronavirus (MERS-CoV) and SARS-CoV-1 [3].

(1) Virus structure

SARS-CoV-2 is approximately 50 - 200 nm in size and has a lipid membrane envelope embedded with protruding spike (S) proteins. The viral genome within the envelope encodes 4 structural proteins, 16 non-structural proteins, and 9 accessory proteins. S protein, is located on the viral envelope and facilitates virus entry into the cell by binding to receptors on the host cell. The S protein consists of two subunits (S1 and S2), with the receptor binding domain (RBD) of the S1 subunit recognizing the host cell receptor. The S1 RBD binds to the human angiotensin-converting enzyme 2 (hACE2) receptor on bronchial and alveolar epithelial cells and vascular endothelial cells, whereas the S2 subunit mediates viral entry through membrane fusion. Neutralizing antibodies directed against the S protein can interfere with viral entry and prevent infection. Specifically, neutralizing antibodies that target the S1 RBD have been shown to exhibit potent viral inhibition. In addition, S protein is a major target of COVID-19 vaccines, as it contains both $CD4^+$ and $CD8^+$ T-cell epitopes. Currently, all commercially available COVID-19 vaccines in Korea target the S-protein [4]. The other structural proteins, the membrane (M) and envelope (E), also comprise the viral envelope; however, these components exhibit low immunogenicity for humoral reactions owing to their low molecular weight and the small exposed area outside the envelope. The nucleocapsid (N) protein, the only structural protein within the envelope, protects the

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viral genome and is considered a potential target for vaccine development, given that it is highly immunogenic to humoral immune responses and contains a T-cell epitope [3].

(2) SARS-CoV-2 variants

As an RNA virus, SARS-CoV-2 is prone to genetic variation. The WHO tracks outbreaks of clinically significant mutant viruses, designating variants of interest (VOI) if found to have or expected to impact infectivity, disease severity, diagnosis, or treatment. VOIs that cause increased transmissibility and virulence, changes in disease phenotype, or reduced effectiveness in prevention, diagnosis, and treatment are designated as variants of concern (VOC) [5].

As of February 2023, the pandemic is primarily associated with the omicron (B.1.1.529) variant, designated as a VOC in November 2021, along with subvariants named BA.1 through BA.5 and derived sublineages [5]. Previously designated VOCs include alpha (B.1.1.7), beta (B.1.351), gamma (P.1), and delta (B.1.617.2), all contagious and severe when compared with the wild-type virus and poorly neutralized by convalescent sera, post-vaccination sera, or monoclonal antibodies to SARS-CoV-2. In particular, the delta variant, designated as a VOC from May 2021 to June 2022, was highly transmissible and virulent when compared with the alpha variant. The currently circulating omicron variant is known to be more contagious but less virulent than the delta variant [2, 5, 6].

2) Clinical features and risk factors

The clinical presentation of COVID-19 can range from asymptomatic to severe infection requiring mechanical ventilation or extracorporeal life support. Patients with symptomatic infection have a median incubation period of 4 - 5 days, and most develop symptoms within 14 days. These patients may develop fever, cough, rhinorrhea, nasal congestion, sore throat, malaise, headache, myalgia, decreased sense of smell or taste, and in some cases, gastrointestinal symptoms such as decreased appetite, nausea, and diarrhea. Dyspnea during the disease course may indicate worsening disease; dyspnea often develops approximately 5 to 8 days after the first symptoms, and a chest X-ray may show pulmonary infiltrates, and hypoxemia may occur [7, 8].

In a cohort study conducted in China at the onset of the COVID-19 pandemic, 81% of symptomatic patients with COVID-19 were mild without pneumonia; 14% were severe who had dyspnea, tachypnea, hypoxemia, or infiltrates involving more than half of the lung fields; and 5% were critically ill with respiratory failure, septic shock, or multiple organ failure. The authors documented an overall mortality rate of 2.3%, while the mortality rate for critically ill patients was 49% [1].

Severe COVID-19 may occur at any age, although older adults and those with underlying medical conditions exhibit a high risk. Age is the most potent risk factor associated with severe COVID-19, and 81% of COVID-19-related deaths in the United States occurred in individuals aged ≥65 years in 2020. Underlying medical conditions that are known risk factors for severe COVID-19 are shown in **Table 1** [9-11]. In addition, lymphopenia, elevated D-dimer, as well as elevated inflammatory markers on laboratory tests, indicate severe COVID-19 [7, 8].

3) Diagnosis

A diagnosis of COVID-19 can be reached when COVID-19 gene detection or virus isolation is confirmed in an individual with suspected clinical symptoms or an epidemiologic link to COVID-19. Nucleic acid amplification tests detect the COVID-19 gene, with a preference for reverse transcription polymerase chain reaction (RT-PCR) using nasopharyngeal swab specimens owing to the high

Table 1. Risk factors for severe COVID-19[a]

High risk	Asthma, cancer, cerebrovascular disease, chronic kidney disease, chronic lung disease (interstitial lung disease, pulmonary embolism, pulmonary hypertension, bronchiectasis, chronic obstructive pulmonary disease), chronic liver disease (cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, autoimmune hepatitis), cystic fibrosis, type 1 and type 2 diabetes, disability (neurodevelopmental disorders, congenital diseases, spinal cord injury, wheelchair use)[b], heart conditions (heart failure, coronary artery disease, cardiomyopathy), HIV infection, mental illness (mood disorders, schizophrenia spectrum disorders), dementia, obesity (body mass index [BMI] ≥30), physical inactivity, current or recent pregnancy, primary immunodeficiencies, current or past smoking, solid organ transplant or hematopoietic stem cell transplant, tuberculosis, use of corticosteroids or immunosuppressive drugs
Suggestive high-risk	Overweight (25 ≤ BMI <30), sickle cell disease, substance use disorder
Inconclusive	Alpha1-antitrypsin deficiency, bronchopulmonary dysplasia, hepatitis B, hepatitis C, hypertension, thalassemia

[a]Centers for Disease Control and Prevention, USA [9].

[b]For a complete list of disabilities that qualify as risk factors, see the link in Reference 9.

COVID-19, coronavirus disease 2019.

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sensitivity and specificity. In cases where detection of the COVID-19 gene by nucleic acid amplification is difficult or a rapid diagnosis is required, a rapid antigen test, using a point-of-care test, may be used for diagnosis, although it is less sensitive than nucleic acid amplification; hence, results should be carefully interpreted [6, 8].

4) Treatment

Typically, individuals with mild-to-moderate COVID-19 do not necessitate hospitalization and are treated with symptomatic care [8]. Patients with mild-to-moderate COVID-19 who do not require hospitalization and are at high risk for severe disease may be considered for antiviral therapy to reduce hospitalization and death due to COVID-19. Within seven days of symptom onset, 3-day intravenous remdesivir therapy or oral therapy with nirmatrelvir and ritonavir within five days of symptom onset may be initiated. Oral molnupiravir therapy may be initiated within five days of symptom onset [12].

Patients with severe COVID-19 who are hypoxemic or require supplemental oxygen or ventilatory support need to be hospitalized. Reportedly, 5-day intravenous remdesivir therapy can reduce treatment duration in patients with severe COVID-19, while 10-day dexamethasone therapy was shown to reduce mortality. Accordingly, these two treatments are suggested for patients with severe COVID-19. The addition of the Janus kinase inhibitors baricitinib or tofacitinib may be considered for patients with severe COVID-19. The addition of interleukin-6 inhibitor tocilizumab may be considered for patients with severe or critical COVID-19 who continue deteriorating despite standard treatment [7, 12, 13].

In addition, anticoagulation therapy is recommended for patients with COVID-19 who require hospitalization owing to the risk of thrombosis from COVID-19 unless contraindicated. Furthermore, high-titer convalescent serum may be considered within eight days of symptom onset in some high-risk populations for severe COVID-19 progression where other treatments are limited. Monoclonal antibodies with neutralizing activity against SARS-CoV-2 have been employed for pre-and post-exposure prophylaxis and treatment. However, monoclonal antibody use is restricted due to decreased efficacy with viral variation; clinical considerations, including information on prevalent variants, are necessary [7, 8, 12].

5) Management of patients and contacts

SARS-CoV-2 is transmitted from person to person by droplet transmission and can be spread by contact with contaminated hand or fomite. Therefore, hand hygiene and mask-wearing are essential to prevent infection. Although droplets are the primary route of transmission, airborne transmission is also possible. There is a risk of airborne transmission when performing treatments that may produce aerosols in a confined space. Medical masks or respirators rated N95 or higher and eye protection should be used when caring for suspected or confirmed COVID-19 patients. Respirators rated N95 or higher and eye protection should be employed for patient contact that involves treatments that may produce aerosols [14, 15].

Isolation protocols for patients with COVID-19 may vary depending on disease severity, the patient's immune status, and demographics. Symptoms, duration, and testing are used to determine whether to discontinue quarantine, although it is generally recognized that transmission is low seven days after onset. As of February 2023, Korea has employed duration and symptom- and clinical course-based quarantine discharge criteria. Patients should be released from quarantine seven days after COVID-19 specimen collection if they remain fever-free for at least 24 h without antipyretic treatment and their symptoms improve. Usual isolation period for patients with critical COVID-19 is 10 to 20 days from the date of specimen collection. For severely immunocompromised individuals, discontinuation of isolation may be delayed at the discretion of the healthcare provider owing to cases of transmission due to continued viral shedding after the usual isolation period [6, 16].

3. TYPES OF VACCINES

Since December 2020, when the WHO granted Pfizer/BioNTech's Comirnaty® (BNT162b2, Pfizer/BioNTech, New York, NY, USA/Mainz, Germany) Emergency Use Authorization, various COVID-19 vaccines have been approved, and several are under development. COVID-19 vaccines are under development on a variety of platforms [3, 17, 18]. As of February 2023, mRNA vaccines (Pfizer/BioNTech, Moderna), recombinant protein vaccines (Novavax, SK Bioscience), and viral vector vaccines (AstraZeneca, Janssen) have been approved in Korea (**Table 2**) [4]. Pfizer/BioNTech and Moderna have developed BA.1-specific bivalent vaccines that include components of the existing mRNA vaccine (tozinameran and elasomeran) plus components targeting the omicron subvariant BA.1 (riltozinameran and imelasomeran). In September/October 2022, these vaccines were approved for booster vaccination in Korea. In addition, the BA.4/5 bivalent vaccine developed by Pfizer/BioNTech and Moderna, which includes the existing mRNA vaccine components and components targeting the BA.4/5 subtype (famtozinameran and davesomeran), was approved for emergency use in Korea in October and December 2022, respectively [4].

The Pfizer/BioNTech (BNT162b2) and Moderna (mRNA-1273) vaccines consist of lipid nanoparticles surrounding

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Table 2. Commercially available adult COVID-19 vaccines in Korea (as of February 2023)

Product name (codename)	Developers (city, country)	Vaccine platforms	Vaccine approval	Recommendations
Comirnaty® (BNT162b2)	Pfizer/BioNTech (New York, NY, USA/Mainz, Germany)	mRNA	Ages ≥12 years for primary series and booster vaccination	≥12 years of age
Spikevax™ (mRNA-1273)	Modena (Cambridge, MA, USA)	mRNA	Primary series vaccination for those aged ≥12 years, booster vaccination for those aged ≥18 years	≥30 years of age → Primary series vaccination was terminated.
Vaxzevria™ (AZD1222)	AstraZeneca (Cambridge, United Kingdom)	Virus vector (ChadOx1)	Primary series vaccination for those aged ≥18 years	≥50 years of age → Primary series vaccination was terminated.
Janssen COVID-19 Vaccines (Ad26.COV2.S)	Janssen (New Brunswick, NJ, USA)	Virus vector (Ad26)	Primary series vaccination for those aged ≥18 years	≥18 years of age who are contraindicated to mRNA or Novavax vaccines.
Nuvaxovid™ (NVX-COV2373)	Novavax (Gaithersburg, MD, USA)	Recombinant protein	Ages ≥12 years for primary series and booster vaccination	≥12 years of age
SKYCovione™ (GBP510)	SK Bioscience (Seongnam, Korea)	Recombinant protein	Ages ≥18 years for primary series and booster vaccination	≥18 years of age
Spikevax™ Bivalent[a]	Moderna (Cambridge, MA, USA)	mRNA (bivalent)	Booster vaccination for those aged ≥18 years	≥18 years of age
Comirnaty® Bivalent[b]	Pfizer/BioNTech (New York, NY, USA/Mainz, Germany)	mRNA (bivalent)	Booster vaccination for those aged ≥12 years	≥12 years of age

[a]Adapted vaccine targeting BA.1 (elasomeran, imelasomeran; mRNA-1273.214) or BA.4/5 (elasomeran, davesomeran; mRNA-1273.222).
[b]Adapted vaccine targeting BA.1 (tozinameran, riltozinameran) or BA.4/5 (tozinameran, famtozinameran).
COVID-19, coronavirus disease 2019.

the mRNA encoding the S protein of SARS-CoV-2, whereas the Novavax (NVX-COV2373) vaccine consists of recombinant S protein nanoparticles of SARS-CoV-2. The recombinant protein vaccine (GBP510) developed by SK Biosciences in Korea combines the receptor binding domains of the recombinant S protein into a nanoparticle scaffold. AZD1222, developed by AstraZeneca, is a non-replicating chimpanzee adenovirus vector (ChAdOx1), while Ad26.COV2.S, developed by Janssen, is an adenoviral vector vaccine using a non-replicating adenovirus type 26 vector (Ad26), encoding the S protein of SARS-CoV-2. In addition, inactivated virus vaccines (developed by Sinopharm, Sinovac, cand Bharat Biotech) are being administered in some countries, and DNA and live attenuated vaccines are being investigated [3, 4, 17, 18].

4. VACCINE EFFICACY AND EFFECTIVENESS

COVID-19 vaccines reportedly reduce the risk of SARS-CoV-2 infection. It has been suggested that COVID-19 vaccination can effectively reduce emergency department visits, hospitalization, intensive care unit admissions, and deaths due to symptomatic COVID-19, especially severe and critical COVID-19 [17, 19, 20]. Moreover, the protection against SARS-CoV-2 infection is likely to reduce the overall transmission risk [21]. However, the waining of vaccine efficacy and neutralizing antibody titer after vaccination have been reported, and cases of breakthrough infection have been reported two weeks after completing the primary series vaccination [22-25]. The waning of vaccine efficacy and neutralizing antibodies was found to be more pronounced in older adults, males, and immunocompromised individuals [25]. A booster vaccination is recommended for those fully vaccinated with the primary series [17-19]. Moreover, variant viruses can impact vaccine efficacy; vaccine efficacy against the recent omicron variant was significantly reduced [26]. In 2022, a bivalent mRNA vaccine comprising an omicron variant-targeting vaccine component in addition to the existing vaccine component was developed and used as a booster vaccine; it was found to prevent hospitalization and death due to omicron variants [20, 27, 28].

1) BNT162b2 (Pfizer/BioNTech)

In clinical trials, BNT162b2, the mRNA vaccine developed by Pfizer/BioNTech, exhibited 95% effectiveness against symptomatic COVID-19 after two 3-weekly primary series vaccination, with an efficacy of 95% in those aged ≥16 years, 100% in those aged 12 - 15 years, and 90.7% in those aged 5 - 11 years [29-31]. At the 6-month follow-up after two doses, the vaccine showed 91% effectiveness against COVID-19 infection, with the highest efficacy between 7 days and two months after completion of the primary series vaccination, followed by a gradual decline in efficacy, with 84% efficacy at 4 - 6 months [32]. Two doses of BNT162b2 were 89 and 87% effective in reducing

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emergency department visits and hospitalizations due to COVID-19, respectively and >90% effective in reducing asymptomatic and symptomatic infections, hospitalizations, and deaths due to COVID-19 [33, 34]. Although the efficacy of BNT162b2 vaccination in preventing COVID-19 infection declines significantly six months after completion of the primary series vaccination, efficacy against severe and critical disease and death remains relatively high [23]. If a booster vaccination of BNT162b2 is administered six months after completing the primary series vaccination with BNT162b2 (the third dose), vaccine efficacy against COVID-19 infection is restored to 95%, reducing COVID-19 infection by approximately 10-fold and severe COVID-19 by approximately 18-fold [26, 35, 36]. BNT162b2 has lower efficacy against omicron variants, with 65.5% vaccine efficacy against symptomatic infection with omicron variants 2 - 4 weeks after completion of primary series vaccination [26]. Twenty-five weeks after completing the primary series vaccination, vaccine efficacy was rapidly reduced to 8.8%, which recovered to 67.2% against symptomatic infection 2 - 4 weeks after the BNT162b2 booster vaccination [26].

2) mRNA-1273 (Moderna)

In clinical trials, mRNA-1273, the mRNA vaccine developed by Moderna, had 94% effectiveness against symptomatic COVID-19 when administered as a primary series vaccine in adults aged ≥18 years and 86% effectiveness in those aged ≥65 years [37]. Vaccine efficacy exceeded 93% against symptomatic and severe disease approximately five months after vaccination [38]. In observational studies, mRNA-1273 primary series vaccination was >90% effective in reducing emergency department visits and hospitalizations due to COVID-19 and was also effective in reducing deaths due to COVID-19 [34, 39]. The vaccine efficacy of mRNA-1273 decreased gradually. An efficacy of 90% was reported against COVID-19 infection 0 - 2 months after competition of the primary series vaccination, which decreased to <50% at 7 - 8 months [22]. The decline in vaccine efficacy against hospitalization and death from COVID-19 was relatively low, by 15% and 10%, respectively [22]. A booster dose of mRNA-1273 50 μg administered six months after the primary series vaccination with two doses of mRNA-1273 100 μg could restore vaccine efficacy to a similar degree as observed two months after completing the primary series vaccination [26]. The efficacy of two mRNA-1273 doses against omicron variant virus infection was 44%, which decreased rapidly with time post-vaccination [40]. However, the efficacy of two or three mRNA-1273 doses against hospitalization due to omicron variants was 84.5 and 99.2%, respectively [40].

3) AZD1222 (AstraZeneca)

In clinical trials, two doses of AZD1222 given four weeks apart were 74% effective against symptomatic COVID-19, with 83.5% efficacy in those aged ≥65 years [41, 42]. The second dose in the primary series was administered between 4 - 12 weeks apart, and the longer the second dose was delayed, the higher the efficacy [43]. Vaccine efficacy of AZD1222 decreased over time; however, vaccine efficacy against symptomatic infection was >90% after administering the mRNA vaccine (BNT162b2 or mRNA-1273) as a booster after the primary series vaccination [26]. AZD1222 had low efficacy against variant viruses, particularly against omicron variant symptomatic infections at 20 weeks after the second AZD1222 dose. However, booster vaccination with an mRNA vaccine can confer protection against omicron variants [26].

4) Ad26.COV2.S (Janssen)

A single primary series vaccination using Ad26.COV2.S afforded a vaccine efficacy of 66 - 67% against moderate COVID-19 and 77 - 85% against severe and critical COVID-19 [44]. Efficacy against symptomatic infection decreased to approximately 50% two months after vaccination, although efficacy against severe and critical COVID-19 was maintained. A second dose administered two months after the first dose resulted in 75% efficacy against moderate COVID-19 and 100% efficacy against severe and critical COVID-19 [45]. Two Ad26.COV2.S doses were 72 - 74% effective against hospitalization due to the omicron variant [46].

5) NVX-CoV2373 (Novavax)

In the NVX-CoV2373 trial conducted in the United Kingdom during alpha variant prevalence, vaccine efficacy was 90% against symptomatic COVID-19 and 89% in the 65+ age group [47]. In a study in South Africa during the beta variant outbreak, NVX-CoV2373 vaccine efficacy against symptomatic COVID-19 was 49% [48]. Studies in the United States and Mexico during outbreaks with multiple variants showed 90% efficacy against symptomatic COVID-19 and 100% efficacy against moderate and severe COVID-19 [3].

6) GBP510 (SK Bioscience)

GBP510, a recombinant protein vaccine developed by Korean pharmaceutical company [49], demonstrated increased immunogenicity and acceptable safety in a phase 1/2 clinical trial when administered twice, 4 weeks apart, combined with the adjuvant AS03 [50]. Although large-scale clinical data on the efficacy of GBP510 is lacking, it has been approved in Korea based on the results of an interim analysis of a phase 3 study comparing immunogenicity with AZD1222. The geometric mean ratio of neutralizing antibodies in the GBP510 inoculation group (test group) and the AZD1222 inoculation group (control group) was 2.93, satisfying the superiority criterion. The difference in the serological response rate between groups was 10.76%, meeting the

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non-inferiority criterion. In the safety evaluation, the overall safety of both groups was comparable [51].

7) Bivalent mRNA vaccines (Pfizer/BioNTech, Moderna)

Structural changes in the S protein of the omicron variant allow evasion of immune responses to existing COVID-19 vaccines, necessitating a booster vaccination to compensate for the waning of vaccine efficacy after the primary series vaccination [26]. Pfizer/BioNTech and Moderna have developed a bivalent mRNA vaccine that can generate an immune response against the S protein of wild-type SARS-CoV-2 and the S protein of the omicron variant. As of February 2023, a bivalent vaccine against BA.1 or BA.4/5, a subvariant of the omicron variant, is available in Korea [4, 19].

Booster vaccination with the BA.1-specific mRNA-bivalent vaccine, developed by Pfizer/BioNTech and Moderna, increased neutralizing antibody production by 1.5 - 1.75 times when compared with that by monovalent booster vaccination [52, 53]. Both vaccines exhibited comparable safety. As with BA.1 epidemic was rapidly replaced by BA.4/5 in the United States, BA.4/5-targeted bivalent mRNA vaccines were approved. Considering BA.4/5 bivalent booster vaccination, vaccine efficacy against symptomatic COVID-19 was 28 - 31% in those who received the bivalent booster 2 - 3 months after the last vaccination and 43 - 56% in those who received the bivalent booster eight months after their last vaccination [20]. Considering adults aged ≥65 years who received two to four doses of an mRNA monovalent vaccine, the vaccine effectiveness for preventing COVID-19-related hospitalization was 73% in those who received the bivalent mRNA booster [28]. In another cohort study, vaccine efficacy against hospitalization or death due to severe COVID-19 was 24.9% with the monovalent booster vaccination and 61.8% with the BA.4/5 bivalent booster vaccination [27].

5. INDICATIONS

The indications and schedule for COVID-19 vaccination are subject to change based on further research results and the COVID-19 pandemic. It is necessary to confirm the vaccination guidelines, implementation standards, and drug approvals. Currently (February 2023), the primary series vaccination against COVID-19 is recommended for all adults aged ≥18 years in Korea [4, 19]. COVID-19 vaccination is highly recommended for older adults, individuals with underlying medical conditions at increased risk for severe COVID-19, and healthcare workers [54, 55]. A COVID-19 vaccine has been approved and is available for adolescents aged 12 - 17 years, children aged 5 - 11 years, and infants aged 6 months to 4 years. COVID-19 primary series vaccination is highly recommended for children and adolescents who are at increased risk for severe COVID-19 [4, 19]. Booster vaccination with the bivalent mRNA vaccine is available for those ≥12 years who have completed the primary series vaccination, regardless of the type of vaccine previously received, and is recommended for all adults [19]. Booster vaccination can be administered since 90 days after the last dose. Individuals who are contraindicated for mRNA vaccines and those who do not wish to receive mRNA vaccine may be considered for a booster vaccination with a recombinant vaccine (Novavax, SKYCovione™). For confirmed patients with COVID-19, booster vaccination can be delayed by 3 months from the confirmation date, considering natural immunity.

Selecting the type of vaccine is based on approvals and recommendations, contraindications, efficacy, and potential side effects [17-19]. In general, mRNA vaccines (BNT162b2, mRNA-1273) and Novavax vaccine (NVX-CoV2373) are preferred over viral vector vaccines (AZD1222, Ad26.COV2.S). SKYCovione™ (GBP510) is also available in Korea. Some studies have shown that mRNA-1273 has higher vaccine efficacy than BNT162b2, but the clinical implications remain unclear [56]. In addition, it has been reported that the risk of mRNA vaccine-induced myocarditis is higher with mRNA-1273 than that with BNT162b2; hence, BNT162b2 is recommended for young adults considering mRNA vaccination [57]. In Korea, mRNA-1273 primary series vaccination was authorized for those aged ≥18 years and recommended for those aged ≥30 years. However, as of February 2023, mRNA-1273 primary series vaccination has been discontinued in Korea. Moderna's BA.1, BA.4/5 bivalent vaccine, Spikevax™ Bivalent (mRNA-1273.124, mRNA-1273.222), can be used for booster vaccination in those aged ≥18 years, and Pfizer/BioNTech's BA.1, BA.4/5 bivalent vaccine, Comirnaty® Bivalent, can be used in those aged ≥12 years [4, 19].

The vaccination schedule for each vaccine type is shown in **Figure 1**. The primary series of COVID-19 vaccines should be administered using the same vaccine product. Nevertheless, if a patient experiences a serious adverse event that is a contraindication to vaccination after the first dose and is unable to complete the series, the series can be completed with a different vaccine product that is not contraindicated. In adults aged ≥18 years who are moderately or severely immunocompromised, additional primary series vaccine dose with mRNA vaccine may be considered four weeks after the completion of usual primary series vaccination [17-19].

The second dose of the mRNA vaccine primary series can be administered three weeks after BNT162b2 and

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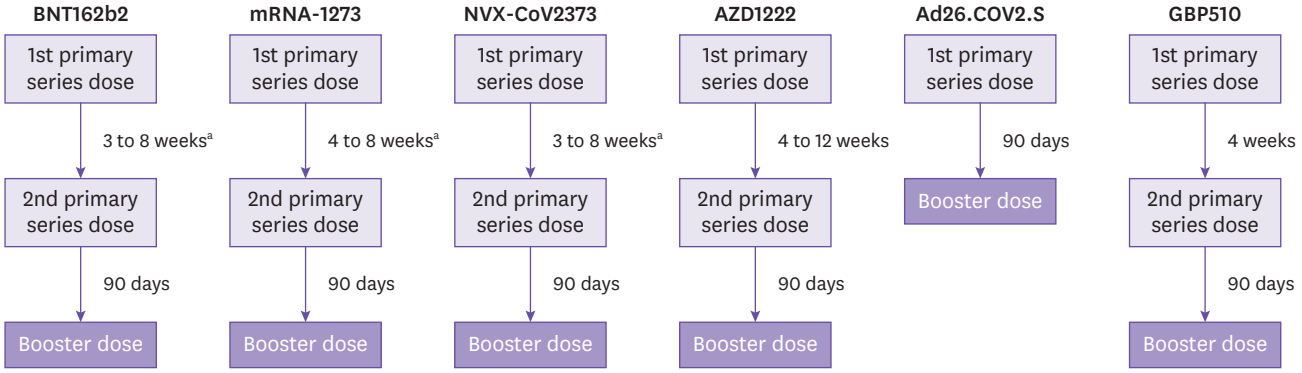

Figure 1. Vaccination schedule for commercially available COVID-19 vaccines in Korea.
It is advised that the primary vaccine series be completed with the same vaccine. However, if the vaccine used for the first primary vaccination is unavailable, the second vaccination is administered using a readily available vaccine. Booster dose should be administered with a bivalent mRNA vaccine regardless of the type of vaccine previously received, starting from 90 days after the last dose of vaccination. In exceptional cases where mRNA vaccination is contraindicated or not desired, recombinant vaccines (NVX-CoV2373, GBP510)) can be administered.
[a]Although the second dose of the primary series can be administered at any time after the minimum interval, there is research suggesting that an 8-week interval between doses of BNT162b2, mRNA-1273, and NVX-CoV2373 reduces the risk of vaccine-associated myocarditis and pericarditis in individuals aged 6 months to 64 years.

four weeks after mRNA-1273. However, reports have suggested that the vaccine immunogenicity increases when the interval between the two doses is extended to ≥8 weeks [58]. Although the second can be administered at any time after the minimum interval in Korea, studies have shown that an 8-week interval between doses of BNT162b2, mRNA-1273, and NVX-CoV2372 can reduce the risk of vaccine-associated myocarditis and pericarditis in individuals aged 6 months to 64 years (especially males aged 12 to 39 years) [57]. Therefore, the Centers for Disease Control and Prevention (CDC) recommends primary series vaccination with mRNA and Novavax vaccines at 8-week intervals. Completing a shorter primary series vaccination is recommended for moderately and severely immunocompromised individuals, individuals aged ≥65 years, and based on individual circumstances where there is an increased risk of severe COVID-19 in the community [17]. AZD1222, a virus vector vaccine, has been approved for a second dose 4 - 12 weeks after the first dose; however, a second dose 8 - 12 weeks after the first dose is recommended owing to reports of improved immunogenicity when the dosing interval exceeds eight weeks [19, 43].

6. METHOD OF ADMINISTRATION

Table 3 summarizes the storage and administration methods for COVID-19 vaccines commercially available in Korea. **Figure 1** illustrates the vaccination administration schedule. The vaccine is injected intramuscularly into the deltoid muscle of the shoulder, and if the deltoid muscle is unavailable, an intramuscular injection into the anterolateral thigh muscle is considered [4, 19].

There are limited safety and efficacy data on the co-administration of COVID-19 vaccines with other vaccines; however, clinical trials have shown that the frequency of adverse events or immunogenicity did not differ on co-administering AZD1222 or BNT162b2, and seasonal influenza vaccines [59]. A small observational study noted no safety concerns when the hepatitis B and COVID-19 vaccines were administered within two weeks of each other [60]. In accordance with the general principles of vaccination, the COVID-19 vaccine can be administered regardless of the vaccination interval with other vaccines for proper vaccination planning. If necessary, co-administration can be considered. However, immunogenicity and safety data on co-administration remain limited, and an individualized approach is needed [19, 61].

7. ADVERSE EVENTS

Localized and systemic adverse events following COVID-19 vaccination are relatively common and more frequently documented in younger age groups [41, 44, 50, 62, 63]. Most mild-to-moderate symptoms that do not interfere with daily activities occur within two days of vaccination and resolve with conservative treatment. Acetaminophen or non-steroidal anti-inflammatory drugs may afford symptomatic relief.

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Table 3. Storage and administration method of adult COVID-19 vaccines

Vaccines Type	Comirnaty[a] (BNT162b2)	Spikevax (mRNA-1273)	Spikevax Bivalent	Vaxzevria (AZD1222)	Janssen COVID-19 Vaccine (Ad26.COV2.S)	Nuvaxovid (NVX-COV2373)	SKYCovione (GBP510)
Storage and distribution	−90 to −60°C (12 to 18 months) 2 - 8°C (1 month to 10 weeks)	−25 to −15°C (9 months) 2 - 8°C (30 days)	−50 to −15°C (9 months) 2 - 8°C (30 days)	2 - 8°C (6 months)	−25 to −15°C (24 months) 2 - 8°C (3 months)	2 - 8°C (5 months)	2 - 8°C (6 months)
Expiration date after opening	2 - 30°C / Stable for 12 h (immediate use)	2 - 25°C / 6 h (immediate use)	2 - 25°C / 6 h (immediate use)	~30°C / 6 h	2 - 8°C / 6 h 9 - 25°C / 3 h	Refrigerate between 2 and 8°C until just before use	Before administration, mixing adjuvant after 15 min at room temperature / 6 h after mixing adjuvant
Capacity	2.25 ml/vial (6 doses)	6.3 ml/vial (10 doses)	3.2 ml/vial (5 doses)	5 ml/vial (10 doses)	2.5 ml/vial (5 doses)	0.5 ml/syringe	After mixing adjuvant, 5 ml/vial (10 doses)
Dosage and method	30 μg/0.3 ml intramuscular injection	100 μg/0.5 ml intramuscular injection[b]	50 μg/0.5 ml intramuscular injection	5×10^{10} viral particles/0.5 ml intramuscular injection	5×10^{10} viral particles/0.5 ml intramuscular injection	5 μg rS & 50 μg Matrix-M™ adjuvant/0.5 ml intramuscular injection	25 μg RBD & AS03 adjuvant/0.5 ml intramuscular injection

[a]This applies to dispersion formulations for injection of Comirnaty® Injection and Comirnaty® Bivalent Injection (gray cap). Before using Comirnaty® Injection of concentrated dispersion formulation for injection (purple cap), it must be diluted.
[b]50 μg of mRNA-1273 should be administered for booster dose.

Considering both mRNA and Novavax vaccines, the frequency of adverse reactions was higher with the second dose than that with the first dose, with local adverse reactions such as injection site pain, redness, edema, and itching occurring in approximately 75% and systemic adverse reactions in approximately 69% of individuals after the second dose of mRNA vaccine [62, 63]. Among systemic adverse events, fatigue, headache, and myalgia were common, observed in 40 - 50% of individuals, and chills, pyrexia, and arthralgia were frequent in 20 - 30% of patients, with a higher frequency of adverse events with mRNA-1273 than with BNT162b2 [62]. After a second dose of NVX-CoV2373 (Novavax), local adverse events occurred in 79% of individuals and systemic adverse events in 70%, with headache, myalgia, and fatigue noted as common systemic adverse events [63]. Considering Ad26.COV2.S (Janssen), a viral vector vaccine, a local adverse event rate of 61% has been documented, along with a systemic adverse event rate of 76%, including fatigue, headache, and myalgia as the most common systemic adverse events [64]. AZD1222 (AstraZeneca) had a higher frequency of adverse events with first-dose administration than the mRNA vaccine, with local adverse events occurring in 61 - 88% and systemic adverse events in 65 – 86% of individuals; fatigue, headache, pyrexia, and myalgia were common systemic events, most of which were mild to moderate [65].

Anaphylaxis is a rare but serious adverse reaction to COVID-19 vaccines. For mRNA vaccines, anaphylaxis has been reported at a rate of 2.5 - 4.7 per million, with most cases occurring within 30 min of vaccination [66]. In addition, there are reports of rare but serious specialized adverse reactions, depending on the type of vaccine, as follows.

1) Thrombosis with thrombocytopenia syndrome (TTS)

The adenoviral vector vaccines, *i.e.*, AZD1222 (AstraZeneca) and Ad26.COV2.S (Janssen), can cause a rare but serious thrombosis known as vaccine-induced immune thrombotic thrombocytopenia (VITT) or TTS. This reaction is accompanied by thrombocytopenia and is characterized by multiple instances of thrombosis in uncommon locations, such as cerebral venous sinuses or intestinal vessels [67]. An anti-platelet factor 4 antibody observed in autoimmune heparin-induced thrombocytopenia (HIT) can be detected in the TTS. An anti-platelet factor 4 antibody is used as one of the diagnostic criterion for TTS. TTS is known to be more common among young females, and its association with mRNA vaccines remains unknown. A Norwegian study reported an incidence of up to 1 per 26,000 AstraZeneca vaccinations, while a UK study reported 1 patient with VITT/TTS per 67,302 and 518,181 first and second doses

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of AstraZeneca vaccines, respectively [67]. Considering the vaccine developed by Janssen, a rate of 1 VITT/TTS per 583,000 doses has been documented in the United States [67]. VITT/TTS is a rare but serious adverse reaction, and AZD1222 or Ad26.COV2.S vaccination is contraindicated in patients diagnosed with VITT/TTS following a previous vaccination or those with a history of HIT, which is expected to have a similar mechanism. However, a history of thrombosis other than VITT/TTS is not a contraindication to vaccination, given that the causal relationship between vaccines and thromboembolic events in general, including pulmonary embolism and deep vein thrombosis, remains unclear. Patients with severe headaches, focal neurologic symptoms, visual disturbances, dyspnea, chest pain, abdominal pain, extremity edema, redness, pallor, purpura, and thrombocytopenia between 4 days to 6 weeks after adenovirus vector vaccination should be considered for VITT/TTS [4, 17, 18, 67].

2) Myocarditis

An increased frequency of myocarditis has been identified in adolescent males and young adults following mRNA vaccination, and cases of myocarditis have also been reported following the Novavax vaccination. In a study conducted in Israel, 2.13 cases of myocarditis per 100,000 were identified after BNT162b2 vaccination, and 10.69 cases per 100,000 were identified in adults aged 16 - 29 years [68]. In addition, a higher frequency of myocarditis has been reported with mRNA-1273 than that with BNT162b2. Myocarditis following mRNA vaccination was frequently observed after the second vaccine dose, with a median age of 21 years, and >80% of cases were reported in males [69]. Chest pain was a common symptom, and most cases occurred within one week of vaccination. Overall, 70% of patients with chest pain had electrocardiogram abnormalities, 77% had cardiac magnetic resonance imaging abnormalities, and 80% had no abnormalities in cardiac contractile function on echocardiography [70]. However, most cases were mild and had a favorable course. Myocarditis should be considered if an adolescent or young adult who received the mRNA vaccine complains of chest pain, shortness of breath, or palpitations.

3) Guillain-Barré syndrome

Cases of Guillain-Barré syndrome have been reported following vaccination with the adenovirus vector vaccine (Ad.COV2.S, AZD1222), but the causal relationship remains unclear. Until further data are accumulated, individuals with a history of Guillain-Barré syndrome should be vaccinated with a vaccine other than an adenoviral vector vaccine. However, if other vaccines are unavailable, adenovirus vector vaccination may be considered based on the patient's individualized risk-benefit profile [17-19].

8. CONTRAINDICATIONS

Previous severe allergic reactions, such as anaphylaxis, to any COVID-19 vaccine or vaccine component are considered a contraindication for vaccination. It should be noted that BNT162b2 and mRNA-1273 contain polyethylene glycol, and mRNA-1273 contains trisaminomethane, NVX-CoV2373, Ad26.COV2.S, AZD1222, and GBP510 contain polysorbate, and GBP510 contains tromethamine. If there is a history of severe allergic reactions to each component, vaccination with that specific vaccine is contraindicated. Patients with a history of COVID-19 vaccine-induced anaphylaxis could receive other types of COVID-19 vaccines. However, caution should be exercised, and observation is advised for at least 30 min post-vaccination [4, 17-19, 66].

AZD1222 and Ad26.COV2.S are contraindicated in patients with a history of VITT/TTS that occurred after receiving the adenoviral vector vaccines (AZD1222 and Ad26.COV2.S), in those with a history of HIT, or those with a history of capillary leak syndrome. A history of thromboembolism unrelated to the COVID-19 vaccine is not a contraindication for COVID-19 vaccination. A history of Guillain-Barré syndrome is not a contraindication to AZD1222 and Ad26.COV2.S. However, if a previous COVID-19 vaccine-induced Guillain-Barré syndrome occurred, the mRNA vaccine or Novavax vaccine should be considered [17-19].

Myocarditis following mRNA COVID-19 vaccination is not a contraindication for mRNA vaccination. However, vaccination should be performed considering the risk-benefit assessment. Other platforms for COVID-19 vaccination may be considered [17-19].

There have been reports of swelling at filler injection sites in patients receiving the mRNA COVID-19 vaccine, but a history of dermal filler procedures is not a contraindication for mRNA COVID-19 vaccination [19].

9. DOMESTICALLY DISTRIBUTED VACCINES

Table 2 presents the COVID-19 vaccines that are domestically distributed in Korea. **Table 3** provides information on their storage and administration methods. The primary series vaccination is authorized for vaccines developed by Pfizer/BioNTech, Moderna, AstraZeneca, Janssen, Novavax, and SK Bioscience. However, the monovalent Spikevax™ and Vaxzevria™ have been discontinued in Korea and are currently unavailable for primary series vaccination. Comirnaty® bivalent and Spikevax™ bivalent are recommend as booster vaccination, while Nuvaxovid™ and SKYCovione™ can serve as alternative options.

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SUPPLEMENTARY MATERIAL

Guideline Korean version

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