
# Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People

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## Key Points

- COVID-19 vaccines currently authorized in the United States are effective against COVID-19, including severe disease.
- Preliminary evidence suggests that the currently authorized COVID-19 vaccines may provide some protection against a variety of strains, including B.1.1.7 (originally identified in the United Kingdom). However, reduced antibody neutralization and efficacy have been observed for the B.1.351 strain (originally identified in South Africa).
- A growing body of evidence suggests that fully vaccinated people are less likely to have asymptomatic infection and potentially less likely to transmit SARS-CoV-2 to others. However, further investigation is ongoing.
- Modeling studies suggest that preventive measures such as mask use and social distancing will continue to be important during vaccine implementation. However, there are ways to take a balanced approach by allowing vaccinated people to resume some lower-risk activities.
- Taking steps towards relaxing certain measures for vaccinated persons may help improve COVID-19 vaccine acceptance and uptake.
- The risks of SARS-CoV-2 infection in fully vaccinated people cannot be completely eliminated as long as there is continued community transmission of the virus. Vaccinated people could potentially still get COVID-19 and spread it to others. However, the benefits of relaxing some measures such as quarantine requirements and reducing social isolation may outweigh the residual risk of fully vaccinated people becoming ill with COVID-19 or transmitting the virus to others.
- Guidance for fully vaccinated people is available and will continue to be updated as more information becomes available.

# Background

Comprehensive prevention measures are critical strategies to reduce the burden of SARS-CoV-2 in the United States. These prevention measures include wearing a mask, maintaining at least six feet of physical distance from others, avoiding crowds, avoiding poorly ventilated spaces, hand hygiene, cleaning and disinfection, following CDC travel guidance, and following workplace or school guidance related to personal protective equipment use or SARS-CoV-2 testing [1].

COVID-19 vaccination is an additional critical prevention measure to help end the COVID-19 pandemic. There are currently three COVID-19 vaccines authorized by the Food and Drug Administration for emergency use: two mRNA vaccines (Pfizer-BioNTech, Moderna) and one viral vector vaccine (Janssen [Johnson & Johnson]). People are considered fully vaccinated if they are ≥2 weeks following receipt of the second dose in a 2-dose series (mRNA vaccines), or ≥2 weeks following receipt of a single-dose vaccine (Janssen).

While some prevention measures will continue to be necessary regardless of vaccination status, fully vaccinated persons may be able to engage in some activities with low or reduced risk of acquiring or transmitting COVID-19. The benefits of avoiding disruptions such as unnecessary quarantine and social isolation may outweigh the residual risk of becoming ill with COVID-19 or transmitting the virus to others. The ability of vaccinated people to gradually resume some aspects of normal life will optimize well-being and may help improve vaccine acceptance [2].

Public health recommendations for people fully vaccinated with COVID-19 vaccines must consider the evidence, including vaccine efficacy against symptomatic and asymptomatic COVID-19, as well as vaccine impact on SARS-CoV-2 transmission. However, other individual and societal factors are important when evaluating the benefits and potential harms of prevention measures among vaccinated individuals. The Advisory Committee on Immunization Practices and CDC routinely consider factors such as population values, acceptability among stakeholders, and feasibility of implementation when making vaccine recommendations [3]. These considerations are also useful when making public health recommendations for fully vaccinated people.

In this scientific brief, we summarize evidence available through March 3, 2021 for the currently authorized COVID-19 vaccines (administered according to the recommended schedules) and additional considerations used to inform public health recommendations for fully vaccinated people, including:

- Vaccine efficacy and effectiveness against SARS-CoV-2 infection
- Vaccine performance against emerging SARS-CoV-2 variant strains
- Impact of prevention measures in the context of vaccination
- Population attitudes and behaviors towards vaccination and prevention measures

# COVID-19 vaccine efficacy and effectiveness

Vaccine efficacy refers to how well a vaccine performs in a carefully controlled clinical trial, whereas effectiveness describes its performance in the real world. Evidence demonstrates that the authorized COVID-19 vaccines are both efficacious and effective against symptomatic, laboratory-confirmed COVID-19, including severe forms of the disease. In addition, a growing body of evidence suggests that COVID-19 vaccines may also reduce asymptomatic infection, and potentially transmission. Substantial reductions in SARS-CoV-2 infections (both symptomatic and asymptomatic) will have the positive benefit of helping to reduce overall levels of disease, and therefore, transmission in the United States. However, further investigations are ongoing to assess the impact of COVID-19 vaccination on transmission.

### Animal challenge studies

Rhesus macaque challenge studies provided the first evidence of the potential protective effects of Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines against SARS-CoV-2 infection, including asymptomatic infection. Vaccinated macaques developed neutralizing antibodies that exceeded those in human convalescent sera and showed no or minimal signs of clinical disease after SARS-CoV-2 challenge [4-6]. In addition, COVID-19 vaccination prevented or limited viral replication in the upper and lower respiratory tracts, which may have implications for transmission of the virus among humans [4-6].

### Vaccine efficacy from human clinical trials

Clinical trials have demonstrated the authorized COVID-19 vaccines to be efficacious against laboratory-confirmed, symptomatic COVID-19, including severe forms of the disease, with evidence for protection against asymptomatic SARS-CoV-2 infection as well [7-13] (**Box 1**).

**Box 1. Summary of vaccine efficacy estimates for authorized COVID-19 vaccines**

All authorized COVID-19 vaccines demonstrated efficacy (range 65% to 95%) against symptomatic laboratory-confirmed COVID-19.

- For each authorized COVID-19 vaccine, the overall efficacy was similar to the efficacy across different populations, including elderly and younger adults, in persons with and without underlying health conditions, and in persons representing different races and ethnicities.

All authorized COVID-19 vaccines demonstrated high efficacy (≥89%) against COVID-19 severe enough to require hospitalization.

All authorized COVID-19 vaccines demonstrated high efficacy against COVID-19 associated death.

- In the vaccine trials, no participants who received a COVID-19 vaccine died from COVID-19; the Moderna and Janssen trials each had COVID-19 deaths in the placebo arm.

Preliminary data suggest COVID-19 vaccination may also protect against asymptomatic infection.

- In the Moderna trial, among persons who had received a first dose, the number of asymptomatic persons who tested positive for SARS-CoV-2 at their second-dose appointment was approximately two-thirds lower among vaccines than among placebo recipients (0.1% and 0.3%, respectively)
- Efficacy of Janssen COVID-19 vaccine against asymptomatic seroconversion was 74% in a subset of trial participants.

No trials have compared efficacy between any of the authorized vaccines in the same study at the same time.

- All Phase 3 trials differed by calendar time and geography.
- Vaccines were tested in settings with different background COVID-19 incidence and circulating variants.

### Real-world vaccine effectiveness

Preliminary analyses from the United States, United Kingdom, and Israel demonstrate that a two-dose mRNA COVID-19 vaccination series is highly effective against SARS-CoV-2 infection (including both symptomatic and asymptomatic infections). In the United States, the effectiveness of mRNA COVID-19 vaccination (either Pfizer-BioNTech or Moderna) was 89% against SARS-CoV-2 infection; vaccinated persons who were diagnosed with COVID-19 had a 60% lower hospitalization rate than unvaccinated persons [14]. Among U.K. healthcare personnel, Pfizer-BioNTech COVID-19 vaccination was 86% effective against SARS-CoV-2

infection [15]. In U.K. adults aged ≥ 80 years, including those with multiple underlying medical conditions, vaccine efficacy against symptomatic disease was estimated at 85% [16]. In Israel, two doses of Pfizer-BioNTech COVID-19 vaccine was 90–94% effective against a spectrum of illness: asymptomatic SARS-CoV-2 infection, symptomatic COVID-19, as well as specifically severe COVID-19 [17]. Preliminary data from Israel suggest that persons vaccinated with Pfizer-BioNTech COVID-19 vaccine who develop COVID-19 have a four-fold lower viral load than unvaccinated persons [18]. This observation may indicate reduced transmissibility, as viral load has been identified as a key driver of transmission [19].

# Vaccine performance against emerging SARS-CoV-2 variant strains

SARS-CoV-2 variants of concern (B.1.1.7 [first described in the United Kingdom]; B.1.351 [first described in South Africa]; P.1 [first described in Brazil]) have emerged with mutations that alter the receptor binding domain of the spike protein (notably the N501Y mutation occurring in all three variants, as well as E484K and E417T/N mutations in B.1.351 and P.1) [20-23]. These mutations appear to confer greater resistance to neutralization by sera from persons vaccinated with COVID-19 vaccines, raising concerns that these vaccines may have reduced effectiveness against COVID-19 illness, particularly against the B.1.351 variant. Therefore, vaccine performance against emerging SARS-CoV-2 variants is an important consideration when evaluating the need for continued prevention measures in vaccinated persons, and will require continued monitoring.

### Immunogenicity

Sera from mRNA COVID-19 vaccine (both Pfizer-BioNTech and Moderna) recipients have generally demonstrated modest reductions in antibody neutralization activity against a variety of mutations; one study demonstrated poor neutralization activity for B.1.351 [24-48]. Across studies, the greatest reductions were observed for B.1.351, followed by P.1 and P.2 (another variant first described in Brazil); reductions for B.1.1.7 were minimal. The E484K mutation alone or in combination with other mutations in the receptor binding domain has been shown to account for the majority of reduction in vaccine-induced neutralizing antibody activity for the B.1351, P.1, and P.2 variants [26, 29, 31, 42, 43]. For the Janssen viral vector COVID-19 vaccine, spike protein-specific antibody levels and seroresponse rates were similar between U.S. clinical trial participants and participants from Brazil and South Africa, where the viral variants were circulating [8]. In the absence of a biological correlate of protection, it is difficult to predict how reduced immunogenicity may affect COVID-19 vaccine effectiveness. However, across studies, antibody neutralizing activity of sera from vaccinated persons was still generally higher than that observed for convalescent sera from persons who have recovered from COVID-19 [26, 27, 30-32, 36-39, 41-43, 48].

### Efficacy and effectiveness

As described above, preliminary results from the United Kingdom demonstrate that vaccination with two doses of Pfizer-BioNTech COVID-19 vaccine was highly effective (85–86%) against SARS-CoV-2 infection and symptomatic COVID-19 during a period when B.1.1.7 was the predominant circulating strain [15, 16]. Similarly, high Pfizer-BioNTech vaccine effectiveness (92%) against infection was observed in Israel in the context of multiple circulating strains, with the proportion of cases due to the B.1.1.7 variant

increasing to 80% towards the end of the evaluation period [17]. Preliminary data suggest that the Janssen COVID-19 vaccine may have reduced overall efficacy against the B.1.351 variant [8]. In the United States, efficacy was 74% and in Brazil (where ~69% of infections were due to P.2) efficacy was 66%, but in South Africa (~where 95% of infections were due to B.1.351) efficacy was 52% [8], [11]. However, Janssen vaccine efficacy against severe or critical disease was high and similar across sites (73–82%) [8].

# Impact of prevention measures in the context of vaccination

Individual and community-level prevention measures have been shown to help reduce the spread of SARS-CoV-2. These measures form the cornerstone for strategies to reduce viral transmission in the United States [1], [49-53]. However, there are individual and societal costs related to physical distancing, quarantine, school and business closures, and other prevention measures [54-61].

Modeling studies suggest that adherence to prevention measures, such as wearing masks and physical distancing, will continue to be important in the context of vaccine implementation [62-68]. In one study, complete relaxation of prevention measures prior to adequate vaccination coverage resulted in essentially no reductions in SARS-CoV-2 infections [62]. However, preliminary data suggest that rapidly increasing vaccination rates may allow for the phasing out of some prevention measures as coverage increases [68] [CDC unpublished]. Furthermore, there may be certain activities that can be performed after vaccination, such as nursing home visitation, as long as other measures are maintained [CDC unpublished].

In summary, prevention measures will continue to be important for all people, regardless of vaccination status, especially during this period of vaccine deployment. However, as vaccination coverage increases, a balanced, stepwise approach to phasing out certain prevention measures in fully vaccinated people, ideally those that are the most disruptive to individuals and society, can be taken.

# Population attitudes and behaviors towards vaccination and prevention measures

In surveys conducted since vaccination started in December 2020, approximately two-thirds of U.S. adults stated that they were at least somewhat likely to receive a COVID-19 vaccine (or had received one already) [69-71]. This suggests that continued efforts are needed to strengthen vaccine confidence and uptake, including addressing common concerns around COVID-19 vaccines (such as vaccine side effects, the speed of vaccine development, and mistrust of government), improving health equity by removing barriers to vaccine access, and using evidence-based approaches to improving uptake such as providing incentives for vaccination [70], [72]. Leading reasons cited by U.S. adults for intending to be vaccinated include being able to return to more normal life, feeling safe around other people, and resuming activities like going to work or school [2], [73]. Although it remains unknown which of these incentives would achieve the greatest increases in vaccination, information about activities that fully vaccinated people can safely undertake must be communicated in a clear and unambiguous fashion. Maintaining a requirement

to continue all prevention measures after vaccination may disincentivize vaccine uptake. In a recent survey, one in five people reported being less likely to get vaccinated if they heard that they will need to continue to wear a mask and practice social distancing even after getting vaccinated [2].

According to a survey conducted right as the first COVID-19 vaccine was authorized in the United States, most people expected it would take at least 6 months after vaccine rollout before they were able to resume activities such as going out to dinner, going to a gym class, or staying in a hotel [74]. However, a survey conducted less than 2 months into the vaccination program suggest that over half of the general U.S. adult population have already started resuming some of these activities despite the risk of COVID-19 because they "just want their life back" [75]. Reasons for taking fewer COVID-19 precautions than they did a month ago included COVID-19 fatigue, belief that population-based immunity has been achieved through vaccination or disease, belief about reduced disease risk for themselves as others get vaccinated, belief that they no longer pose a threat to high-risk people because high-risk groups are receiving protection through vaccination, and receipt of the vaccines themselves [75].

In summary, relaxing certain prevention measures for fully vaccinated persons may be a powerful motivator for vaccination, and thus should be an important goal of the U.S. vaccination program.

# Conclusions

COVID-19 vaccines currently authorized in the United States have been shown to be efficacious and effective against SARS-CoV-2 infections, including asymptomatic infection, symptomatic disease, severe disease, and death. These findings, along with the potential for reduced viral load in vaccinated persons who develop COVID-19, suggest that any associated transmission risk is likely to be substantially reduced in vaccinated people. While vaccine efficacy against emerging SARS-CoV-2 variants remains under investigation, preliminary evidence suggests that the COVID-19 vaccines presently authorized in the United States will likely be effective against emerging variants, though reduced antibody neutralization and efficacy has been observed for the B.1.351 variant.

Evidence suggests the U.S. COVID-19 vaccination program has the potential to substantially reduce the burden of disease in the United States by preventing illness in fully vaccinated people and interrupting chains of transmission. The risks of SARS-CoV-2 infection in fully vaccinated people cannot be completely eliminated in the setting of continued widespread community transmission of the virus. Vaccinated people could potentially still become infected and spread the virus to others. However, the benefits of avoiding disruptions such as unnecessary quarantine and social isolation may outweigh these potential residual risks. A balanced approach to phasing out certain prevention measures may be a powerful motivator for vaccination, and thus should be an important goal of the U.S. vaccination program.

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**Note: Preprints have not been peer-reviewed. They should not be regarded as conclusive, guide clinical practice/health-related behavior, or be reported**

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