

# Interim recommendations for use of the Novavax NVX-CoV2373 vaccine against COVID-19

Interim guidance  
20 December 2021



## Background

This interim guidance has been developed on the basis of the advice issued by the Strategic Advisory Group of Experts (SAGE) on Immunization at its meeting on 16 December 2021 (1).

Declarations of interests were collected from all external contributors and assessed for any conflicts of interest. Summaries of the reported interests can be found on the [SAGE meeting website](#) and [SAGE Working Group website](#).

These interim recommendations refer to the COVID-19 vaccine developed by Novavax and Serum Institute of India using the Novavax platform of recombinant protein nanoparticles formulated with the adjuvant Matrix M (NVX-CoV2373) and authorized under the emergency use listing (EUL) procedure by WHO. They are based on the Novavax core non-clinical and clinical data for regulatory evaluation. NVX-CoV2373 will be marketed as Nuvaxovid (Novavax) and COVOVAX (Serum Institute of India). These vaccines are considered fully equivalent, although they are produced at different manufacturing sites and assigned different product names.

The recommendations contained in this publication are based on the advice of independent experts, who have considered the best available evidence, a risk–benefit analysis and other factors, as appropriate. This publication may include recommendations on the use of medicinal products for an indication, in a dosage form, dose regimen, population or other use parameters that are not included in the approved labelling. Relevant stakeholders should familiarize themselves with applicable national legal and ethical requirements. WHO does not accept any liability for the procurement, distribution or administration of any product for any use.

The guidance is based on the evidence summarized in the [background document](#) on the NVX-CoV2373 Nuvaxovid vaccine against COVID-19 developed by Novavax, and the [annexes](#), which include GRADE and Evidence to Recommendations tables. Both documents are available on the SAGE COVID-19 webpage: <https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials>.

## Methods

SAGE applies the principles of evidence-based medicine and has set in place a thorough methodological process for issuing and updating recommendations (2). A detailed description of the methodological processes as they apply to COVID-19 vaccines may be found in the SAGE evidence framework for COVID-19 vaccines (3). This framework contains guidance on considering data emerging from clinical trials and post-introduction effectiveness and safety monitoring.

## General goal and strategy for the use of the vaccine against COVID-19

The COVID-19 pandemic has caused significant morbidity and mortality throughout the world, as well as major social, educational and economic disruptions. There is an urgent global need to develop effective and safe vaccines and to make them available at scale and equitably across all countries. The main immediate goal of vaccination against COVID-19, especially in low- and middle-income countries with limited vaccine supply, is to protect against severe COVID-19 and death.

The Novavax vaccine (NVX-CoV2373) consists of a recombinant SARS-CoV-2 spike protein nanoparticle administered as a formulation with the adjuvant Matrix-M. Protein-based vaccines have been used against diseases such as pertussis, human papillomavirus, and hepatitis B. Matrix-M is a novel saponin-based adjuvant that has been used in studies of NVX-CoV2373 (~30 000 recipients across phase 1 to phase 3 trials) and in prelicensure studies targeting other pathogens (~4200 recipients overall),

but has not previously been used in any licensed vaccine. Matrix-M promotes the activation of innate immune cells and antigen processing (4) and is added to NVX-CoV2373 to enhance its immunogenicity.

The efficacy of NVX-CoV2373 has been assessed in three phase 2 and phase 3 trials involving participants aged 18 years or older. In a phase 3 study conducted in the United Kingdom during a period in which the SARS-CoV-2 Alpha variant was predominant, vaccine efficacy (VE) against mild, moderate, or severe COVID-19 was 90% (95% CI: 80–95) from 7 days after the second vaccine dose, with a median follow-up of 56 days after the second dose. VE against mild, moderate, or severe disease in persons less than 65 years of age was 90% (95% CI: 80–95) and in those 65 years and older 89% (95% CI: 20–100). VE against moderate or severe COVID-19 across all age groups was 87% (95% CI: 74–94). In a phase 2a/b study conducted in South Africa during a period in which the Beta variant was predominant, VE against mild, moderate, or severe COVID-19 was 49% (95% CI: 28–63), with a median follow-up of 105 days after the second dose. In a phase 3 study conducted in Mexico and the USA during a period in which multiple variants were in circulation, VE against mild, moderate, or severe COVID-19 was 90% (95% CI: 83–95), with a median follow-up of 64 days after the second dose. VE against moderate or severe COVID-19 across all age groups was 100% (95% CI: 87–100).

Studies of NVX-CoV2373 have demonstrated an acceptable safety and reactogenicity profile in adults  $\geq 18$  years of age. The safety data encompass approximately 30 000 individuals who received NVX-CoV2373 with Matrix-M adjuvant in phase 1, 2 or 3 clinical studies. More detailed data on the efficacy and safety of this vaccine can be found in the background document on the NVX-CoV2373 vaccine. The data reviewed by WHO support the conclusion that the known benefits of NVX-CoV2373 outweigh the risks that are known or considered possible. Therefore, WHO recommends the use of NVX-CoV2373 in persons aged  $\geq 18$  years.

As sufficient vaccine supply will not be immediately available to immunize all who could benefit from it, countries are recommended to use the WHO Prioritization Roadmap (5) and the WHO Values Framework (6) as guidance for prioritized vaccine use, based on population subgroup. As long as vaccine supplies are very limited, in settings with community transmission (stage I in the WHO Prioritization Roadmap), the Roadmap recommends that priority be given initially to health workers and older people with and without comorbidities. As more vaccine becomes available, additional target groups should be vaccinated (5), taking into account national epidemiological data and vaccine-specific characteristics, as outlined in vaccine product information leaflets approved by regulatory authorities, and other relevant considerations.

### **Intended use**

Persons aged 18 years and above.

### **Administration**

The recommended primary vaccine series is two doses (5  $\mu$ g of recombinant spike protein with 50  $\mu$ g of Matrix-M adjuvant per 0.5 ml dose) given intramuscularly into the deltoid muscle at an interval of 3–4 weeks. The vaccine should not be administered with an interval of less than 3 weeks.

### **Additional doses to the primary series**

Additional doses of vaccine may be needed as part of an extended primary series for target populations where the immune response following the standard primary series is likely to be insufficient (see “Moderately and severely immunocompromised persons, including persons living with HIV with CD4 cell count of  $<200$  cells/ $\mu$ l”, below).

### **Booster doses**

WHO is currently assessing the need for and timing of booster doses. Data on the duration of continued protection are currently still missing. Administration of an additional booster dose following the primary series have elicited a strong immune response (see presentation to SAGE (1)).

### **Interchangeability with other COVID-19 vaccines in heterologous schedules**

Homologous schedules are considered standard practice because of the substantial safety, immunogenicity, and efficacy data available for each WHO EUL COVID-19 vaccine. WHO supports a flexible approach to homologous versus heterologous

vaccination schedules, and considers two heterologous doses of any EUL COVID-19 vaccine to be a complete primary series (7).<sup>1</sup> However, the available evidence on NVX-CoV2373 in the context of heterologous usage is currently limited to two studies assessing the use of NVX-CoV2373 as a second or booster dose (8, 9). Heterologous vaccination should be implemented with careful consideration of current vaccine supply, vaccine supply projections, and other access considerations, alongside the potential benefits and risks of the specific products being used.

### **Co-administration with inactivated influenza vaccines**

Co-administration of the NVX-CoV2373 COVID-19 vaccine and seasonal inactivated influenza vaccines demonstrated the safety and immunogenicity of the seasonal influenza vaccine and the safety and efficacy of the NVX-CoV2373 vaccine (10). WHO recommends that co-administration of an inactivated seasonal influenza vaccine and any dose of the NVX-CoV2373 vaccine is acceptable, given that the known risk of serious illness in adults infected with influenza virus or SARS-CoV-2 is substantial and to maximize the uptake of both influenza and COVID-19 vaccines. Different arms should be used for injection when both vaccines are delivered during the same visit. Continued pharmacovigilance monitoring is recommended.

### **Co-administration with vaccines other than inactivated influenza vaccines**

No data are available on co-administration with other live-attenuated or inactivated vaccines. There should be a minimum interval of 14 days between administration of NVX-CoV2373 and all other vaccines except inactivated influenza vaccine. This recommendation will be updated as data on co-administration with other vaccines, including live vaccines, become available.

### **Contraindications**

A history of anaphylaxis to any component of this vaccine is a contraindication to its use. People who have an anaphylactic reaction following the first dose of NVX-CoV2373 should not receive a second dose of the same vaccine.

### **Precautions**

No serious allergic reactions or anaphylaxis caused by NVX-CoV2373 have been recorded in clinical trials. As for all vaccine administration, NVX-CoV2373 should be given under health care supervision, with an observation period of 15 minutes after vaccination and the appropriate medical treatment available in case of allergic reactions.

A history of anaphylaxis to any other vaccine or injectable therapy (i.e. intramuscular, intravenous, or subcutaneous vaccines or therapies) is not a contraindication to vaccination. For such persons, a risk assessment should be conducted by a health professional. Such individuals should be observed for 30 minutes after vaccination in a health care setting where anaphylaxis can be immediately treated (11).

Anyone with an acute febrile illness (body temperature over 38.5 °C) should postpone vaccination until they are afebrile. However, the presence of a minor infection, such as a cold or low-grade fever, should not delay vaccination.

## **Vaccination of specific populations**

### **Populations for which clinical trial and/or post-introduction data exist**

#### **Older people**

Vaccination is recommended for older persons without an upper age limit. The risk of severe COVID-19 and death increases steeply with age. Of participants in the phase 2 and phase 3 efficacy studies, 16% were aged  $\geq 65$  years. In the United Kingdom, the vaccine was shown to be efficacious against mild, moderate, or severe COVID-19 in this population but with a wide confidence interval (VE 89%; 95% CI: 20–100). Although older adults were included in other study populations, the sample size was insufficient to enable an estimate of VE. The trial data across studies indicate that the vaccine has an acceptable safety profile for this age group and induces a robust antibody response. Post-introduction vaccine effectiveness studies are not yet available.

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<sup>1</sup> In moderately and severely immunocompromised individuals, WHO recommends an extended primary series including an additional dose (see “Moderately and severely immunocompromised persons, including persons living with HIV with CD4 cell count of <200 cells/ $\mu$ l” below).

### **Persons with comorbidities**

Certain comorbidities, such as diabetes, hypertension, obesity, and neurodevelopmental and neurodegenerative conditions, have been identified as increasing the risk of severe COVID-19 and death. The phase 3 trials have demonstrated that NVX-CoV2373 has similar efficacy in persons with various underlying medical conditions that place them at increased risk for severe COVID-19. The comorbidities studied included cardiovascular, respiratory, renal, neurological, hepatic, and immunocompromising conditions, as well as obesity and diabetes. Vaccination is recommended for persons with comorbidities that have been identified as increasing the risk of severe COVID-19.

### **Populations for which limited or no data exist from the clinical trials**

#### **Children and adolescents less than 18 years of age**

Most children and adolescents are at lower risk of severe COVID-19 compared to adults (12). Safety and immunogenicity data are currently being generated for those aged <18 years. Until such data are available, NVX-CoV2373 should not be routinely used in this age group.

#### **Pregnant women**

Pregnant women with COVID-19 are at higher risk of developing severe disease, with increased risk of admission to an intensive care unit and invasive ventilation, compared with non-pregnant women of reproductive age. COVID-19 in pregnancy is also associated with an increased risk of preterm birth and of the neonate requiring intensive care. It may also be associated with an increased risk of maternal mortality (13, 14). Pregnant women who are aged  $\geq 35$  years, or have high body mass index, or an existing comorbidity, such as diabetes or hypertension, are at particular risk of serious outcomes from COVID-19.

Developmental and reproductive toxicology (DART) studies have not shown harmful effects of NVX-CoV2373 in pregnant animals and their offspring. Available data on vaccination of pregnant women with NVX-CoV2373 vaccine are insufficient to assess vaccine safety or efficacy in pregnancy. No vaccine-specific studies in pregnant women are currently planned by the manufacturer. Post-marketing surveillance data are being collected via pregnancy registries. The Matrix-M adjuvant has not been used in any other licensed vaccine. Available safety data specific to this adjuvant come from the clinical trials of NVX-CoV2373 and other vaccines, which did not include a sufficient number of pregnant women to allow conclusions to be drawn regarding adjuvant safety. Post-marketing safety data relating to the use of NVX-CoV2373 in pregnant women are not yet available, and neither are data on neonatal outcomes. On the basis of previous experience with use of other protein-based vaccines during pregnancy, the effectiveness of NVX-CoV2373 vaccine in pregnant women is expected to be comparable to that observed in non-pregnant women of similar age.

WHO has identified pregnant women as a priority group for COVID-19 vaccination, given the increased risk of severe outcomes. WHO recommends the use of NVX-CoV2373 vaccine in pregnant women if the benefits of vaccination to the pregnant woman outweigh the potential risks, for example, if there is elevated community transmission and no other WHO EUL COVID-19 vaccine with a more established safety record in pregnancy is locally available. To help pregnant women make this assessment, they should be provided with information about the risks of COVID-19 in pregnancy, the likely benefits of vaccination in the local epidemiological context, and the current limitations of the safety data in pregnant women. WHO does not recommend pregnancy testing prior to vaccination. WHO does not recommend delaying pregnancy or terminating pregnancy because of vaccination.

#### **Breastfeeding women**

WHO recommends the same use of NVX-CoV2373 vaccine in breastfeeding and non-breastfeeding women. This is based on the following considerations: breastfeeding offers substantial health benefits to breastfeeding women and their breastfed children; vaccine effectiveness in breastfeeding women is expected to be similar to that in other adults. Data are not available on the potential benefits or risks of the NVX-CoV2373 vaccine to breastfed children. However, as NVX-CoV2373 vaccine is not a live virus vaccine, it is biologically and clinically unlikely to pose a risk to the breastfeeding child. WHO does not recommend discontinuing breastfeeding because of vaccination.

**Moderately and severely immunocompromised persons, including persons living with HIV with CD4 cell count of <200 cells/μl**

Moderately and severely immunocompromised persons (ICPs) are at higher risk of severe COVID-19, regardless of age, although increasing age remains an important co-factor (15). No data are available regarding the response to a standard (two-dose) or extended (three-dose) primary series of NVX-CoV2373 among moderately or severely immunocompromised persons.<sup>2</sup> On the basis of the available evidence for other vaccine platforms and extrapolating from knowledge of vaccine immunology, it is expected that this vaccine will induce a lower immune response rate in ICPs than in non-immunocompromised persons. Therefore, for ICPs who have received a standard two-dose primary series of NVX-CoV2373, WHO recommends an additional (third) dose. For the purposes of this interim recommendation, moderately and severely immunocompromised persons include those with active cancer or immunodeficiency, transplant recipients, and persons receiving active treatment with immunosuppressives. It also includes people living with HIV with a current CD4 cell count of <200 cells/μl, evidence of an opportunistic infection, not on HIV treatment, and/or with a detectable viral load (i.e. advanced HIV disease).<sup>3</sup> More details are given elsewhere (15).

For other WHO EUL COVID-19 vaccines, the benefit of an additional dose in an extended primary series among ICPs has largely been assessed using the same vaccine product as for the first two doses. A homologous additional dose as part of an extended primary series is therefore considered standard practice. However, WHO supports a flexible approach to homologous versus heterologous vaccination schedules (7). Accordingly, alternative heterologous platforms can also be considered for those requiring an additional dose in the primary vaccination series, taking into account current vaccine supply, vaccine supply projections, and other access considerations.

Available evidence (15) suggests that the additional (third) dose should be given between 1 and 3 months after dose 2 of the standard primary series in order to increase protection as quickly as possible in ICPs. If more than 3 months have elapsed since dose 2 of the primary series, the additional (third) dose should be given at the earliest opportunity. The most appropriate timing for the additional dose may vary depending on the epidemiological setting and the extent and timing of immunosuppressive therapy, and should be discussed with the treating physician.

Information and, where possible, counselling about the limitations in the data on administration of an additional dose to ICPs should be provided to inform individual benefit–risk assessment. Given that protection may remain inadequate in some ICPs, even after administration of an additional dose, WHO further recommends that close contacts (particularly caregivers) of such individuals should be vaccinated with a WHO EUL COVID-19 vaccine if eligible. Additional public health and social measures at household level to protect ICPs are also warranted, depending on local epidemic circumstances.

**Persons living with HIV who are stable on antiretroviral therapy**

Persons living with human immunodeficiency virus (PLWH) may be at higher risk of severe COVID-19. Preliminary findings highlight the safety and immunogenicity of NVX-CoV2373 in PLWH. It is possible that the immune response to the vaccine may be reduced, which may lower its clinical effectiveness. In the interim, given that the vaccine is nonreplicating, persons living with HIV that is well controlled (e.g. current CD4 count >200 cells/μl and viral suppression), and who are part of a group recommended for vaccination, may be vaccinated with the standard primary series of two doses. Information and, where possible, counselling about vaccine safety and efficacy profiles should be provided to inform individuals about the potential benefit and risks. It is not necessary to test for HIV infection prior to vaccine administration.

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<sup>2</sup> People living with medically stable HIV were included in several of the clinical trials of NVC-CoV2373 but did not fall within the definition of moderately or severely immunocompromised persons for which WHO recommends an additional dose in an extended primary series (15). WHO. Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons. 2021 ([https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE\\_recommendation-immunocompromised-persons](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-immunocompromised-persons), accessed 26 October 2021).

<sup>3</sup> Active cancer: persons receiving active immunosuppressive treatment for solid tumour or haematological malignancy (including leukaemia, lymphoma, and myeloma), or within 12 months of ending such treatment. Transplant recipients: persons who have received a solid organ transplant and are taking immunosuppressive therapy, or who have received a stem cell transplant (within 2 years of transplantation, or taking immunosuppressive therapy). Immunodeficiency: persons with severe primary immunodeficiency or receiving chronic dialysis or with HIV/AIDS with a current CD4 count of <200 cells/μl or lacking viral suppression. Immunosuppressives: persons receiving active treatment causing significant immunosuppression (including high-dose corticosteroids), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents, tumour-necrosis factor (TNF) blockers, and other drugs that are significantly immunosuppressive; or treatment in the previous 6 months of immunosuppressive chemotherapy or radiotherapy.

### **Persons who have previously had SARS-CoV-2 infection**

Vaccination should be offered regardless of a person's history of symptomatic or asymptomatic SARS-CoV-2 infection. Viral or serological testing for prior infection is not recommended for the purpose of decision-making about vaccination. Data from the phase 3 study in the United Kingdom indicate that the vaccine is safe in people with evidence of prior SARS-CoV-2 infection. Symptomatic reinfection with the same variant is uncommon within 6 months of an initial natural infection. Since vaccine supply is limited, persons who have had PCR-confirmed SARS-CoV-2 infection in the preceding 6 months may therefore choose to delay vaccination until near the end of this period.

However, emerging data indicate that symptomatic reinfection may occur with new circulating variants of concern (VOCs), which are associated with markedly reduced protection conferred by previous natural infection and reduced VE. In these settings, earlier immunization is advisable, for example, within 90 days after natural infection. As more data become available on duration of immunity after natural infection and against different virus variants, the length of this time period may be revised.

### **Persons with current acute COVID-19**

Persons with acute PCR-confirmed COVID-19, including those with onset between doses, should not be vaccinated until they have recovered from acute illness, and the criteria for discontinuation of isolation have been met. The optimal minimum interval between a natural infection and vaccination is not yet known.

### **Persons who previously received passive antibody therapy for COVID-19**

Currently there are no data on the safety or efficacy of vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. As a precautionary measure, WHO recommends that vaccination should be deferred for at least 90 days to avoid interference of the antibody treatment with vaccine-induced immune responses.

## **Special settings**

Persons in refugee and detention camps, prisons, slums, and other settings with high population densities, where physical distancing cannot be implemented, should be prioritized for vaccination, as outlined in the WHO Prioritization Roadmap (5), taking into account national epidemiological data, vaccine supply and other relevant considerations.

As noted in the Roadmap, national programmes should give special consideration to groups that are disproportionately affected by COVID-19, or that face health inequities as a result of social or structural inequities. Such groups should be identified, barriers to vaccination should be addressed, and programmes should be developed to allow equitable access to vaccines.

## **Other considerations**

### **SARS-CoV-2 variants of concern (VOC)**

SARS-CoV-2 continues to evolve (16). Some VOCs may be associated with greater transmissibility, disease severity, risk of reinfection, or a change in antigenic composition resulting in lower vaccine effectiveness.

Data from the phase 2a/b and phase 3 clinical trials included individuals infected with the Alpha and Beta variants. In the United Kingdom, VE against the Alpha variant was 86% (95% CI: 71–94); a similar VE against this variant was observed in Mexico and the USA (VE 94%, 95% CI: 82–98). In South Africa, VE against mild, moderate, or severe COVID-19 during a period in which the Beta variant was predominant was 49% (95% CI: 28–63). Samples collected 14 days after the second dose of NVX-CoV2373 during a phase 2 study in Australia and the USA showed antibody responses were reduced relative to the Wuhan D614G strain by 4-fold, 4.8-fold, and 3-fold for Alpha, Beta, and Delta variants, respectively. Currently, no data exist for the Omicron variant. These findings must be interpreted with caution since the relationship between reduction in antibody responses and vaccine performance against clinical disease has not yet been established.

In view of these findings, WHO currently recommends the use of NVX-CoV2373 vaccine according to the WHO Prioritization Roadmap (5), even if VOCs are present in the country. Countries should conduct a benefit–risk assessment in relation to the local epidemiological situation, including the extent of circulating VOCs. Countries using the vaccine in the presence of variants of interest and VOCs are encouraged to monitor vaccine effectiveness, in particular to capture data on the frequency and severity of any breakthrough infections due to variants.

There is an urgent need for a coordinated approach to surveillance and evaluation of variants and their potential impact on vaccine effectiveness. WHO will continue to monitor this situation; as new data become available, recommendations will be updated accordingly.

### **SARS-CoV-2 diagnostic tests**

Prior receipt of the vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests for diagnosis of acute/current SARS-CoV-2 infection. However, it is important to note that the antibody tests currently available for SARS-CoV-2 assess levels of IgM and/or IgG to the spike or the nucleocapsid protein. The vaccine contains a recombinant SARS-CoV-2 spike protein; thus, a positive result in a test for spike protein IgM or IgG could indicate either prior infection or prior vaccination. To evaluate for evidence of prior infection in an individual who has received NVX-CoV2373, a test that specifically evaluates IgM or IgG to the nucleocapsid protein should be used. A positive nucleocapsid protein-based assay indicates prior infection. Antibody testing at an individual level is not currently recommended to assess immunity to COVID-19 following vaccination with NVX-CoV2373.

### **Role of vaccines among other preventive measures**

Because the evidence to date on the impact of vaccination on transmission is insufficient, public health and social measures should continue, including use of well-fitted masks, physical distancing, handwashing, adequate ventilation, and other measures as appropriate in particular settings, depending on the COVID-19 epidemiology and potential risks of emerging variants. Government advice on public health and social measures should continue to be followed by both vaccinated and unvaccinated individuals. This advice will be updated as information on the impact of vaccination on virus transmission and indirect protection in the community is assessed.

Country strategies related to COVID-19 control should be designed to minimize disruption to children's participation in education and other aspects of social life.

### **Community engagement, effective communication, and legitimacy**

Community engagement and effective communication (including risk communication) are essential to the success of COVID-19 vaccination programmes. The decisions and processes for vaccination prioritization should be transparent, and based on shared values, the best available scientific evidence, and appropriate representation and input by affected parties. Communication about the mechanism of action of vector-based vaccines needs to be strengthened, along with efficacy and safety data derived from clinical trials and post-marketing studies, background mortality, maternal and neonatal outcomes, and rates of adverse events of special interest (AESIs) in groups prioritized for vaccination. Strategies should include: (i) culturally acceptable and linguistically accessible communications regarding COVID-19 vaccination, made freely available; (ii) active community engagement and the involvement of community opinion leaders and trusted voices to improve awareness and understanding of such communications; and (iii) inclusion of diverse and affected stakeholder opinions in decision-making. Such efforts are especially important in subpopulations who may be unfamiliar with or distrustful of health care systems and immunization.

### **Vaccination logistics**

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