



Public Health
England

Protecting and improving the nation's health

COVID-19 vaccination programme

Information for healthcare practitioners

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About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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Document information

This document was originally published provisionally, ahead of authorisation of any COVID-19 vaccine in the UK, to provide information to those involved in the COVID-19 national vaccination programme which was expected to start in December 2020.

Following authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines & Healthcare products Regulatory Agency being given to the COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech) on 2 December 2020, and then the COVID-19 Vaccine AstraZeneca on 30 December 2020, this document has been updated to provide specific information about the storage and preparation of these vaccines. The COVID-19 Vaccine Moderna was authorised for temporary supply on 8 January 2021 but as this vaccine is not currently available in the UK, details about this vaccine have not yet been included in this document. Information about this vaccine and any other COVID-19 vaccines which are given regulatory approval will be added when this occurs.

The information in this document was correct at time of publication. As COVID is an evolving disease, much is still being learned about both the disease and the vaccines which have been developed to prevent it. For this reason, **some information may change**. Updates will be made to this document as new information becomes available. Please use the online version to ensure you are accessing the latest version.

Document revision information

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2.0	Vaccine specific information about the COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech) added	4 December 2020
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Background

On 31 December 2019, the World Health Organization (WHO) was informed of a cluster of cases of pneumonia of unknown cause detected in Wuhan City, China.

On 12 January 2020, it was **announced** that a novel coronavirus was identified as the cause of the illnesses being detected. This virus is referred to as SARS-CoV-2, and the associated disease as COVID-19.

On 30 January 2020, the WHO Emergency Committee agreed that the outbreak met the criteria for a Public Health Emergency of International Concern and on 11 March 2020, the **WHO declared COVID-19 as a pandemic**.

On 8 December 2020, a COVID-19 vaccination programme began in the UK.

The **Coronavirus (COVID-19) in the UK dashboard** shows the UK summary of the daily number of cases and deaths from COVID-19. The dashboard also shows the number of virus tests processed daily and healthcare figures including the daily number of patients admitted to hospital, patients in hospital and patients in ventilator beds. It also shows the number of people vaccinated (both daily and cumulative) and the numbers of people who have received their first dose and those who have received their second dose.

Further information on COVID-19 disease, epidemiology, the vaccination programme and vaccine efficacy can be found in the **Green Book COVID-19** chapter.

Further information on vaccine eligibility is described in the **JCVI advice, Green Book COVID-19 chapter** and the PHE COVID-19 **PGD** and **Protocol**.

Patient information leaflets and resources can be ordered from the **Health Publications** website.

COVID-19 disease

Clinical symptoms

COVID-19 is an emerging disease and complications can be severe and fatal, particularly for those in risk groups.

Whilst many people may have asymptomatic infection, those who do develop symptoms report a range of symptoms which include fever, a new and continuous cough, shortness of breath, fatigue, loss of appetite, anosmia (loss of smell) and ageusia (loss of taste). Other symptoms include: myalgia, sore throat, headache, nasal congestion, diarrhoea, nausea and vomiting.

Around 40% of people who develop symptoms report mild symptoms and typically present without hypoxia or pneumonia. A further 40% present with moderate symptoms which may include non-severe pneumonia and 15% present with severe pneumonia and significant disease.

Critical disease can lead to life threatening complications and is reported in around 5% of cases. Patients with critical disease may experience acute respiratory distress syndrome (ARDS), sepsis, septic shock, cardiac disease, thromboembolic events such as pulmonary embolism and multi-organ failure.

Evidence is growing that the longer-term consequences of more severe complications associated with the inflammatory response may be considerable in those who experience critical and life-threatening illness. Rare neurological and psychiatric complications, which can also occur in patients without respiratory symptoms, include stroke, meningo-encephalitis, delirium, encephalopathy, anxiety, depression and sleep disturbances. The [long-term effects of coronavirus \('long COVID'\)](#) are described on the NHS UK website.

Fewer than 5% of SARS-CoV-2 infection cases are amongst children and in general, they appear to experience milder symptoms than adults. Further evidence is needed about the association between underlying conditions and risk of COVID-19 disease in children. A rare presentation of [multisystem inflammatory syndrome temporarily associated with COVID-19 in children and adolescents](#) has been noted.

Transmission

SARS-CoV-2 virus is primarily transmitted between people through respiratory droplets expelled from the nose and mouth through coughing, sneezing or speaking or when people touch their eyes, nose or mouth following contact with contaminated objects and surfaces.

Groups affected by COVID-19

Increasing age and male gender have been shown to be significant risk factors for severe disease and infection fatality ratios are highest in the oldest age groups. Co-morbidities such as diabetes and severe asthma are associated with an increased risk of death and obesity and other underlying health conditions can increase the risk for some people¹. Further information on high risk groups (those who are clinically extremely vulnerable) and moderate risk groups (those who are clinically vulnerable) can be found on the NHS.UK webpage: [Who's at higher risk from coronavirus \(COVID-19\)](#). Deprivation and being from a black, ethnic and minority group also results in an increased risk of death from COVID-19. Additionally, health and social care workers are at increased risk of acquiring infection in their work setting and they may potentially transmit the virus to their families and to those in their care.

¹ Williamson EJ, Walker AJ et al. Factors associated with COVID-19-related death using OpenSAFELY. Nature 2020 July 8. 584:430–436 <https://doi.org/10.1038/s41586-020-2521-4>

COVID-19 vaccination programme

Aim of the programme

The aim of the COVID-19 vaccination programme is to protect those who are at most risk from serious illness or death from COVID-19 or at risk of transmitting infection to multiple vulnerable persons or other staff in a healthcare environment.

Vaccine development

Over 280 different COVID-19 vaccines are in various stages of development. Some have been made using currently used vaccine technology, whilst others have been made using completely new approaches. While it normally takes several years to develop a vaccine, scientists across the world have worked collaboratively and rapidly to achieve the same amount of work in a few months in order to make a safe and effective vaccine available as soon as possible. Although clinical trials have been carried out more rapidly than they have for other vaccines, this has been achieved by conducting some of the steps in parallel rather than sequentially and vaccine safety has not been compromised. The vaccine trials have been subject to all of the usual strict trial and regulatory requirements.

For more information about COVID-19 vaccines in development, see the [LSHTM COVID-19 vaccine tracker](#).

This document will discuss the first two COVID-19 vaccines to be authorised for supply in the UK. The guidance will be updated as more information about these vaccines become available and will include other vaccines as they become available for use. **As each vaccine is presented, stored and prepared differently, immunisers must ensure they are familiar with the specific details of the vaccine that they are working with.**

Duration of protection

As COVID-19 vaccines have only been given in clinical trials in recent months, there is currently no data available to describe how long protection from vaccination will last. Post-authorisation surveillance and continued follow-up of trial participants may indicate the need for booster doses but they are not currently recommended.

COVID-19 vaccination eligibility

Vaccine priority groups

The Joint Committee on Vaccination and Immunisation (JCVI) considered the available epidemiological, microbiological and clinical information on the impact of COVID-19 in the UK and provided the Government with advice to support the development of the COVID-19 vaccine strategy. See **Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination 30 December 2020**.

Full details on vaccine eligibility, with detail on the at-risk conditions and the eligibility of health and social care and laboratory staff groups, are included in the Green Book COVID-19 chapter.

COVID-19 vaccines

In the UK, three COVID-19 vaccines have been given authorisation for temporary supply by the MHRA for use in the UK national COVID-19 vaccination programme to date. The COVID-19 mRNA Vaccine BNT162b2 (manufactured by Pfizer BioNTech) was given authorisation for temporary supply by the MHRA on 2 December 2020. The COVID-19 Vaccine AstraZeneca, was given authorisation for temporary supply by the MHRA on 30 December 2020 and the COVID-19 Vaccine Moderna was given authorisation for temporary supply by the MHRA on 8 January 2021. As the COVID-19 Vaccine Moderna is not currently available in the UK, information about this vaccine will be added into a later publication of this document. Any other COVID-19 vaccines which are given regulatory approval will be added when this occurs.

The COVID-19 mRNA Vaccine BNT162b2 uses an mRNA platform and the COVID-19 Vaccine AstraZeneca is an adenovirus vector vaccine.

Both vaccines are presented in multi-dose vials and require completion of a two-dose course. Using multi-dose vials can improve the efficiency of vaccine manufacture and distribution, enabling vaccine availability for those eligible at the earliest opportunity.

COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech)

The COVID-19 mRNA Vaccine BNT162b2 is an mRNA (messenger ribonucleic acid) vaccine. It contains the genetic sequence (mRNA) for the spike protein which is found

on the surface of the SARS-CoV-2 virus, wrapped in a lipid envelope (referred to as a nanoparticle) to enable it to be transported into the cells in the body.

When injected, the mRNA is taken up by the host's cells which translate the genetic information and produce the spike proteins. These are then displayed on the surface of the cell. This stimulates the immune system to produce antibodies and activate T-cells which prepare the immune system to respond to any future exposure to the SARS-CoV-2 virus by binding to and disabling any virus encountered.

As there is no whole or live virus involved, the vaccine cannot cause disease. The mRNA naturally degrades after a few days.

COVID-19 Vaccine AstraZeneca

COVID-19 Vaccine AstraZeneca is a viral vector vaccine which uses a weakened adenovirus as a carrier to deliver the genetic sequence for the SARS-CoV-2 spike protein. The adenovirus has been modified so that it cannot replicate in human cells and therefore cannot cause any disease. Once it has delivered the SARS-CoV-2 spike protein genetic code, the adenovirus is destroyed by the body.

The genes that encode for the spike protein on the SARS-CoV-2 virus have been inserted into the adenovirus's genetic code to make the vaccine. When the vaccine is injected, the modified adenovirus binds to the surface of human cells and delivers the genetic code (mRNA) for the spike protein. The cells then process the mRNA and manufacture the spike protein. This then stimulates the immune system which reacts by producing antibodies and memory cells to the SARS-CoV-2 virus without causing disease. If the SARS-CoV-2 virus is later encountered, the immune system should be able to respond rapidly.

Interchangeability of different COVID-19 vaccines

There is no evidence as to the interchangeability of the different COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received for their first dose **and to complete the two dose course with the same vaccine.**

For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or where the first product received is unknown, it is reasonable, in these circumstances, to offer a single dose of the locally available product. This option is preferred if that individual is likely to be at immediate high risk or is considered unlikely to attend again. In these circumstances, as both the Pfizer BioNTech and AstraZeneca vaccines are based on the spike protein of the virus, it is

likely that the second dose will help to boost the response to the first dose. Further doses of vaccine are not required unless additional information becomes available.

COVID-19 vaccines schedule

Although the two recommended doses of Pfizer BioNTech vaccine can be given a minimum of 21 days apart and the AstraZeneca vaccine doses can be given a minimum of 28 days apart, operationally, it is recommended that the second dose of both vaccines should be routinely scheduled between four and 12 weeks after the first dose. This will allow more people to benefit from the protection provided from the first dose during the roll out phase and will have a greater impact in reducing mortality, severe disease and hospitalisation. Evidence from Phase 3 trials indicate high levels of protection against serious disease and death from around 2 weeks after the first dose². Longer term protection will then be provided by the second dose. More detailed information about scheduling of COVID-19 vaccines is provided in the [JCVI](#) statement and the letter from the [UK Chief Medical Officers](#).

Administration of COVID-19 vaccine

Infection prevention and control

All those attending for vaccination and those delivering vaccination should wear appropriate personal protective equipment (PPE) as described in the infection prevention and control (IPC) advice current at the time of administering the vaccine.

Hand hygiene is critical to prevent the spread of infection and hands should be cleaned with alcohol-based gel or soap and water before vaccine preparation, between patients, etc. Those preparing and administering the vaccine should maintain good hand hygiene throughout and should take care not to touch the vial bung with their fingers.

² GOV.UK Press release. JCVI issues advice on the AstraZeneca COVID-19 vaccine. 30 December 2020. www.gov.uk/government/news/jcvi-issues-advice-on-the-astrazeneca-covid-19-vaccine

Injection technique

COVID-19 vaccines should be administered by intramuscular (IM) injection, preferably into the deltoid muscle of the upper arm.

Individuals who have minimal muscle mass in the deltoid area of the upper arm, or a particular reason to avoid immunisation in the deltoid muscle, can be given their vaccine in the vastus lateralis muscle in the thigh if necessary.

The area for injection should be clearly visible and accessible. Garments with long or tight sleeves may need to be removed. The injection site does not need to be cleaned unless visibly dirty. If cleaning is required, water should be used and the area dried with a gauze swab. It is not necessary to disinfect the skin.

Insert the needle into the injection site far enough to ensure it will deliver the vaccine into the muscle and depress the plunger. There is no need to pull back on the plunger (aspirate) before the plunger is depressed to release the vaccine into the muscle because there are no large blood vessels at the recommended injection sites.

Ensure the full dose is administered as a partial dose will not evoke a full immune response. Remove the needle and if there is any visible blood at the injection site, the patient can apply pressure to the site with a piece of gauze/cotton wool.

Administering COVID-19 vaccine to individuals with a bleeding disorder

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes (ACIP, 2019). The individual/carer should be informed about the risk of haematoma from the injection.

Administering COVID-19 vaccine to individuals taking anticoagulants

Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.

Timing of administration of COVID-19 vaccine to individuals who are immunosuppressed

Individuals who have immunosuppression and HIV infection (regardless of CD4 count) should be given COVID vaccine in accordance with the recommendations and contraindications stated in the [COVID-19 vaccine PGDs and Protocols](#) and [Green Book COVID-19 chapter](#).

Individuals with immunosuppression may not make a full immune response to vaccination. As there is no evidence on response in immunosuppressed individuals there is also no evidence upon which to base advice on the optimal timing of delivery. Specialists may advise their patients based on their knowledge and understanding of their immune status and likely immune response to vaccination but should also consider the risk from COVID and the patient's likelihood of exposure.

The small number of patients who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID- 19 and from their underlying condition.

Although the immune correlates of protection are currently unknown, post-vaccination testing may be considered. Until further information becomes available, vaccinated patients with immunosuppression should continue to follow advice to reduce the chance of exposure.

Period of observation following immunisation with COVID-19 vaccine

Following COVID-19 vaccine administration, individuals should be observed for any immediate reactions whilst they are receiving any verbal post vaccination information (such as possible reactions and what, if anything, to do about these). They, or their carers, should also be informed where they can obtain further advice if they require it following vaccination. It is recommended that individuals are observed for a minimum of 15 minutes following administration of the Pfizer BioNTech vaccine. There is no requirement for 15 minutes observation following the AstraZeneca vaccine. However, as fainting can occur following vaccination, all those vaccinated with either of the COVID-19 vaccines should either be driven by someone else or should not drive for 15 minutes after vaccination.

Advice to vaccine recipients following immunisation with COVID-19 vaccine

Following COVID-19 vaccine administration, vaccinees should be advised that it may take a few weeks for protection from the vaccine to develop.

Everyone given the vaccine should continue to follow advice current at the time regarding practicing social distancing, wearing a face mask and washing their hands thoroughly and frequently. Those who have been told to shield should continue to do so until advised otherwise.

Vaccinees should also be advised to follow the current advice on testing and self-isolation if they develop any coronavirus symptoms or undergo regular testing as a health or social care worker. Vaccination will not affect testing. The lateral flow device (LFD) test detects a different protein of the virus than the one encoded in the vaccine, and the PCR test detects different genes of the virus than the one included in the vaccine.

It is not yet known whether vaccination will stop people from catching and passing on the virus and as no vaccine is completely effective, some people may still become infected with COVID-19 despite having been vaccinated (although this should be less severe). The vaccine cannot cause COVID-19 infection.

COVID-19 vaccine and clinical trial participants

Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the trial investigators. Eligible individuals who are enrolled in vaccine trials should then be provided with written advice on whether and when they can be safely vaccinated in the routine programme.

Surveillance of COVID-19 cases in vaccinated individuals.

The PHE Immunisation Department is conducting enhanced surveillance of cases of infection in vaccinated individuals in England, in order to confirm infection, identify risk factors and outcomes, and monitor phenotypic and genetic characteristics of SARS-CoV-2 isolates and to compare these cases to those in unvaccinated individuals. Individuals will mainly be identified by active follow up of a sample of cases identified by linkage between community testing and vaccination data.

Clinicians who are seeing patients face to face are also encouraged to report any confirmed cases in partially or fully vaccinated individuals if they tested positive within the preceding 7 days. This provides the best opportunity to get early and complete sampling from these cases. Further information, criteria for reporting and the reporting

form are available at www.gov.uk/government/publications/covid-19-enhanced-surveillance-of-cases-in-vaccinated-individuals

Adverse reactions following vaccination

Possible adverse reactions following vaccination

Local reactions at the injection site were found to be fairly common after vaccination with the COVID-19 mRNA Vaccine BNT162b2 during clinical trials. Over 80% of trial participants reported pain at the injection site. This occurred within 7 days after the injection and resolved after a few days. In clinical trials, the most frequently reported systemic reactions in participants were tiredness (reported by more than 60% of participants), headache (> 50%), muscle aches (> 30%), chills (> 30%), joint pain (> 20%) and a raised temperature (pyrexia) (> 10%). These symptoms were usually mild or moderate in intensity and resolved within a few days after vaccination. If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (eg paracetamol-containing products) may be used³.

More than 60% of COVID-19 Vaccine AstraZeneca trial participants reported tenderness at the injection site with redness, swelling, itching, warmth and pain at the injection site also being reported. The most frequently reported systemic reactions were headache and tiredness (by more than 50% of participants); muscle aches and feeling generally unwell (>40%); raised temperature (pyrexia) and chills (>30%) and joint pain and nausea (>20%). The majority of adverse events reported during the clinical trials of the COVID-19 Vaccine AstraZeneca were mild to moderate and short-lasting, usually resolving within a few days of vaccination. When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently³.

³ COVID-19 mRNA Vaccine BNT162b2 .REG 174 Information for UK Healthcare professionals. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940565/Information_for_Healthcare_Professionals_on_Pfizer_BioNTech_COVID-19_vaccine.pdf

Prophylactic use of paracetamol was found not to affect the immune response to this vaccine⁴.

Reporting adverse reactions

Suspected adverse reactions following administration of COVID-19 vaccine should be reported to the MHRA using the specially established Coronavirus Yellow Card reporting scheme (coronavirus-yellowcard.mhra.gov.uk/ or call 0800 731 6789). Both patients and healthcare providers can report any possible adverse reactions observed with these vaccines using the Yellow Card scheme. As a new vaccine product, MHRA have a specific interest in the reporting of adverse drug reactions for the new COVID-19 vaccines.

Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.

Differentiating between a reaction to the vaccine and symptoms of COVID-19 disease

Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless there are epidemiological or other clinical reasons to suspect SARS-CoV-2 infection.

Feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally these symptoms were found to resolve within one to two days without treatment but analgesics and/or anti-pyretics can be given if necessary to relieve any of these symptoms.

The most commonly reported COVID-19 symptoms are: a high temperature, a new, continuous cough, or a loss or change to sense of smell or taste. If someone

⁴ Folegatti, P et al. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2 single-blind, randomised controlled trial. *Lancet* 2020 August 15, 396(10249): 467-478

experiences any of these symptoms they should get tested. The COVID-19 vaccine will not interfere with testing for COVID-19 infection.

As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS 111.

COVID-19 vaccine contraindications and precautions

COVID-19 vaccine contraindications

COVID-19 vaccine should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- a previous dose of the same COVID-19 vaccine
- any components (excipient) of the vaccine

The **COVID-19 chapter of the Green Book** provides full details about the contraindications and precautions to COVID-19 vaccine. Where there is any doubt as to whether the vaccine can be given, appropriate advice should be sought from the relevant specialist, or from the local immunisation team or health protection team. There are **some additional specific precautions for the COVID-19 mRNA Vaccine BNT162b2 Pfizer BioNTech vaccine** (see below).

Polyethylene glycol (PEG)

The Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 contains polyethylene glycol (PEG). PEGs are a group of known allergens commonly found in medicines, many household products and cosmetics. Known allergy to PEG is very rare but would contraindicate receipt of this vaccine. The AstraZeneca vaccine does not contain PEG and may be used as an alternative. Whether PEG is the cause of reactions in patients with systemic allergic symptoms after the first dose of Pfizer BioNTech vaccine is unclear; people who have developed systemic allergic symptoms after the Pfizer BioNTech vaccine may be considered for a second dose using the AstraZeneca vaccine and should be observed for 30 minutes following vaccination.

Many biologics/monoclonal preparations contain PEG or related compounds. Individuals who have a history of systemic allergic reactions to biologics should not receive the Pfizer BioNTech vaccine except on the expert advice of an allergy specialist. Patients with undiagnosed PEG allergy may have a history of unexplained anaphylaxis or anaphylaxis to multiple classes of drugs (see precautions).

Precautions to COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech)

A very small number of individuals have experienced anaphylaxis when vaccinated with the Pfizer BioNTech vaccine. Following close surveillance of the initial roll-out, the

MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to any component (excipient) of the vaccine.

All recipients of this vaccine should be kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites.

The British Society for Allergy and Clinical Immunology (BSACI) has advised that:

- individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated)
- individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital). If the first dose was with Pfizer BioNTech vaccine, then AstraZeneca vaccine can be considered as an alternative (if not otherwise contraindicated) - this could be delivered in a primary care setting but with a 30 minute prolonged observation period
- individuals with non-allergic reactions (vasovagal (fainting) episodes, non-urticarial skin reaction or non-specific symptoms) can receive the second dose of vaccine in any vaccination setting

COVID-19 vaccine precautions

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms of the illness as being possible reactions to the vaccine.

Vaccination of individuals with a current or previous history of COVID-19 disease

People currently unwell and experiencing COVID-19 symptoms should not receive COVID-19 vaccine until they have recovered. This is to avoid wrongly attributing any new symptom or the progression of symptoms to the vaccine (and to prevent infecting anyone else in the vaccination centre). As deterioration in some people with COVID-19 can occur up to two weeks after infection, ideally vaccination should be deferred until they have recovered and around four weeks after onset of symptoms or four weeks from the first positive test in those who are asymptomatic.

There is no evidence from clinical trials of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody so people who have had COVID-19 disease (whether confirmed or suspected) can still receive COVID-19 vaccine. This is because it is not known how long antibodies made in response to natural infection persist and whether immunisation could offer more protection. If antibodies have already been made to the disease following natural infection, receiving COVID-19 vaccine would be expected to boost any pre-existing antibodies.

Children or adults who have tested positive for COVID-19 infection in the previous 28 days and who require other vaccines (such as DTaP/IPV/Hib/HepB etc) can receive these vaccines once they have recovered and have completed the required isolation period for COVID-19. If they fulfil these two conditions, they do not have to wait 28 days but the parent/carer who brings them for vaccination would need to ensure they are following current COVID-19 guidance and not attend if they are symptomatic or self-isolating.

Vaccination of people experiencing prolonged COVID-19 symptoms ('Long COVID')

Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

Time interval between treatments for COVID-19 disease (for example dexamethasone, convalescent plasma, monoclonal antibody or antiviral medicines) and vaccine administration

Dexamethasone is a steroid treatment given to patients experiencing severe COVID-19 symptoms to suppress the immune response and reduce inflammation.

Convalescent plasma is a preparation of pooled antibodies taken from people who have recently recovered from COVID-19. The antibodies bind to the surface of the SARS-CoV-2 virus and stop it from attaching to the body's cells and replicating further.

Monoclonal antibody treatment works in the same way as convalescent plasma but is a specific preparation containing two specific man-made antibodies.

As the COVID-19 mRNA Vaccine BNT162b2 Pfizer BioNTech and COVID-19 Vaccine AstraZeneca are non-live vaccines, it is not anticipated that these treatments would contraindicate the vaccine. Although theoretically, high levels of antibodies in the convalescent plasma could interfere with the immune response to the vaccine,

passively acquired antibodies from the plasma treatment are not thought to persist for long so by the time a person who has received this is well enough to receive a COVID-19 vaccination, these antibodies are likely to have gone.

Antivirals prevent the further replication of viruses. As neither of the above mentioned COVID-19 vaccines contain live replicating virus, response to the vaccine will not be affected by prior or recent receipt of anti-viral medication.

Co-administration of COVID-19 vaccine with other inactivated or live vaccines

Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated (weaker) immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult.

Because of the absence of data on co-administration with COVID-19 vaccines, COVID-19 vaccine should not be routinely offered at the same time as other vaccines. Based on current information about the first authorised COVID-19 vaccines, scheduling of COVID-19 vaccine and other vaccines should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events.

As both the Pfizer BioNTech and AstraZeneca COVID-19 vaccines are considered inactivated, where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring two vaccines. In most cases, vaccination should proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.

Pregnant women

Although the available data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend the routine use of COVID-19 vaccine during pregnancy.

However, the JCVI has advised that, for women who are offered COVID-19 vaccine, vaccination in pregnancy should be considered where the risk of exposure to SARS-CoV-2 infection is high and cannot be avoided, or where the woman has underlying

conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnancy.

Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination.

If a woman finds out she is pregnant after she has started a course of COVID-19 vaccine, routine advice is to complete her pregnancy before finishing the recommended schedule. Women should be offered vaccine as soon as possible after pregnancy.

Termination of pregnancy following inadvertent immunisation should not be recommended. Surveillance of inadvertent administration of COVID-19 vaccine in pregnancy is being conducted for the UK by the PHE Immunisation Department. If a pregnant woman is inadvertently given COVID-19 vaccine, this should be reported to PHE (www.gov.uk/guidance/vaccination-in-pregnancy-vip).

Breastfeeding

There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the COVID-19 mRNA Vaccine BNT162b2 or COVID-19 Vaccine AstraZeneca.

The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.

Legal aspects of vaccine administration

All vaccines are classified as prescription only medicines (POMS). This means that they are subject to legal restrictions and in order to give them, there needs to be an appropriate legal framework in place before they can be supplied and/or administered to eligible people. Additionally, any person who supplies and administers a vaccine must have a legal authority to do so. This legal authority may be in the form of a written patient specific prescription, a Patient Specific Direction (PSD), a Patient Group Direction (PGD) or another process such as a Written Instruction or a Protocol.

Using a Patient Group Direction (PGD) to give COVID-19 vaccine authorised under regulation 174

In response to certain public health threats, such as the current pandemic, the UK Medicines and Healthcare products Regulatory Agency (MHRA) can temporarily authorise the supply of an unlicensed medicine or vaccine for use, under regulation 174 of The Human Medicines Regulations 2012, when it is satisfied that there is robust evidence to show the safety, quality and effectiveness of the medicine/vaccine.

In October 2020, new legislation amending The Human Medicines Regulations 2012 was passed. Prior to this, PGDs could only be used for licensed medicines. The change to legislation allows medicines which have been temporarily authorised for supply in the UK under regulation 174 to be administered in accordance with a PGD. So registered healthcare professionals who are allowed to work to a PGD may supply and administer COVID-19 vaccines, temporarily authorised under Regulation 174, using a PGD. The workforce that can administer under PGDs has not changed (see www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them). Registered doctors are appropriate prescribers so have their own prescribing rights and do not need to work under a PGD.

PHE are developing and publishing PGDs for COVID-19 vaccines. See [www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-\(pgds\)](http://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds)) for the COVID-19 mRNA Vaccine BNT162b2 PGD and Protocol. A PGD and Protocol for the COVID-19 Vaccine AstraZeneca will be added to this webpage once available.

Protocols for the supply and/or administration of COVID-19 vaccine

In order to ensure that the UK has a sufficiently sized workforce to deliver a COVID-19 vaccine programme, the changes to the Human Medicines Regulations (The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020), also brought

about a new regulation (247A). While a disease is pandemic, regulation 247A permits the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus in accordance with a protocol that is approved by ministers. The **national protocol** allows specified classes of people, which need not be limited to registered healthcare professionals, to administer COVID-19 vaccine.

In accordance with regulation 247A, the protocol specifies: the characteristics of and training required for health care workers permitted to administer vaccine under the protocol, the requirement for individuals to be designated and authorised to administer medicines under the protocol by an appropriate manager (in the employing organisation), record keeping requirements (including the requirement to record the name of the person who administers the vaccine) and requirements for the supervision, where appropriate, of the people administering the vaccine.

The protocol also includes information similar to that commonly found in PGDs, for example, who is eligible for vaccination under the protocol and who is not, actions to be taken if the patient is excluded or declines the medicine, a description of the vaccine(s), route of administration, dose, frequency, reporting of adverse reactions, recording, storage and disposal.

The protocol may be followed wholly from patient assessment through to post-vaccination by a single person. Alternatively, multiple health care workers may undertake stages in the patient vaccination pathway in accordance with the protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that health care workers are trained and competent to safely deliver the activity they are employed to provide under the protocol.

Accountability

When working to some or all of the protocol, registered healthcare workers are responsible and accountable for their practice. They are accountable to their regulatory body and to their employer.

When administering vaccines under the protocol, non-registered healthcare workers are accountable to their employer. Their employer is responsible for ensuring they are suitably trained, have completed the necessary competency assessment and are provided with an appropriate level of supervision when carrying out their duties under the protocol.

Consent

Before giving a COVID-19 vaccine, vaccinators must ensure that they have obtained Informed consent from the individual or a person legally able to act on the person's behalf, and that this has been recorded appropriately. Where a person lacks the capacity to consent at the time of vaccination, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. Obtaining consent is discussed in [Chapter 2 of "Immunisation against infection disease" \(the Green Book\)](#). Best interest decisions are discussed below.

Administering COVID-19 vaccine to individuals without the mental capacity to consent

If offering a COVID-19 vaccine to someone who may lack the mental capacity to consent, in the first instance, all practicable steps should be taken to support the person to make the decision for themselves.

Where it has been established that the person lacks capacity to consent, a best interests decision should be taken in line with the best interest checklist in [Section 4 of the Mental Capacity Act](#). This means that the decision-maker must consider all the relevant circumstances, including the person's wishes, beliefs and values, the views of their family and what the person would have wanted if they had the capacity to make the decision themselves. The decision maker should make a record of their best interests decision. Best interests decisions should be made on an individual basis.

Where appropriate, the person's advocates or those with power of attorney should be consulted, and if there is a deputy or attorney with relevant authority then consent must be sought from them to be able to make a decision on the person's behalf to receive the vaccination.

If there are any issues or uncertainties when making a best interests decision, ask for advice from an experienced colleague.

For further information on caring for, or treating, a person who lacks the relevant mental capacity during the COVID-19 pandemic see [The Mental Capacity Act \(2005\) \(MCA\) and deprivation of liberty safeguards \(DoLS\) during the coronavirus \(COVID-19\) pandemic: additional guidance](#).

Inadvertent vaccine administration errors

Inadvertent administration of the diluent only (for COVID-19 vaccines that require dilution)

The diluent for the COVID-19 mRNA Vaccine BNT162b2 is sodium chloride, which is purified water with a very small amount of salt in it. This diluent is commonly used to dilute other medicines and no adverse reactions would be expected if it was inadvertently administered alone. However, the diluent alone will not evoke an immune response so the person should be given a dose of properly reconstituted COVID-19 mRNA Vaccine BNT162b2 as soon as the error is realised.

Inadvertent administration of the whole multi-dose vial of vaccine instead of the recommended dose

In a **Phase I/II study of COVID-19 mRNA vaccines in adults**, different strength doses of COVID-19 mRNA Vaccine BNT162b2 were given. This means that some people in the trials have already received higher doses of a similar vaccine (BNT162b1) than the currently recommended dose. The trial showed that although a stronger dose (100 micrograms instead of the recommended 30 microgram dose) was not harmful, the recipients experienced more local reactions with very painful arms being reported. Participants who received 58 micrograms of COVID-19 mRNA Vaccine in clinical trials did not report an increase in reactogenicity or adverse events².

If a person is given more than the recommended dose, they should be monitored and treated for any symptoms as required. They should be reassured that this is not harmful but that they may be more likely to experience pain in their injected arm.

The second dose of vaccine should still be given as per the recommended schedule.

Inadvertent administration of over-diluted vaccine

As the amount of active content in a dose of over-diluted vaccine will be less, the vaccine dose should be repeated as soon as the error is realised using a correctly reconstituted vaccine (or 48 hours later if not repeated on the same day).

Inadvertent administration of incomplete dose of vaccine

If less than the full dose of COVID-19 vaccine is inadvertently given, for example, if some vaccine leaks out as it is being administered, a full dose should be drawn up and given as soon as possible after the error is realised. If a full dose is not given on the same day as the partial dose, for example if the error is realised after the individual has left the vaccination centre, or if it is suspected but not known for certain whether an individual received a partial dose, a full repeat dose should be offered 48 hours after the possible partial dose was given. The 48 hour wait period is to allow for any reactions experienced following the incomplete dose to resolve before the repeat dose is given. It is recommended that the repeat dose should be given within 7 days of the incomplete dose to minimise the time the individual may be left susceptible to infection. If more than 7 days have elapsed, seek expert advice.

If this was the first dose, the 'second' dose of the two dose schedule (which will actually be the third dose in this case) should still be given at the recommended interval from the additional dose.

Administration of a dose of vaccine whose potency may have been adversely affected by an inadvertent storage or preparation error

If a dose of COVID-19 vaccine is given following an incident in which the potency may have been affected, for example, a storage or preparation error, and expert advice has recommended that the dose of vaccine should be repeated, this should either be given on the same day as the potentially affected dose was given or, from 48 hours after the potentially affected dose was given. The 48 hour wait period is to allow for any reactions experienced following the potentially affected dose to resolve before the replacement dose is given. It is recommended that the replacement dose should be given within 7 days of the potentially affected dose to minimise the time the individual may be left susceptible to infection. If more than 7 days have elapsed, seek expert advice.

If this was the first dose, the 'second' dose of the two dose schedule (which will actually be the third dose in this case) should still be given at the recommended interval from the additional dose.

Second dose given at less than the minimum recommended interval

If the second dose of the COVID-19 mRNA Vaccine BNT162b2 is given less than 19 days after the first dose, the dose should be discounted and another dose (a third dose) should be given at least 21 days after the dose given too early. The 19 day interval is the minimum interval that was used in the clinical trials.

If the second dose of the AstraZeneca COVID-19 vaccine is given at less than the recommended 28 day interval, but at least 21 days after the first dose, it does not need to be repeated. If the second dose is given less than 21 days after the first, it should be discounted and another dose (a third dose) should be given at least 28 days after the dose given too early.

Longer than recommended interval left between doses

If an interval longer than the recommended interval is left between doses, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted.

Different COVID-19 vaccine given for second dose than was given for first dose

There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete the course with the same vaccine. However, as both of the currently authorised vaccines discussed in this document are based on the spike protein, it is likely that even if the vaccine given for the second dose is different to the first, it will help to boost the response to the first dose. For this reason, until additional information becomes available, further doses are not required.

COVID-19 vaccine administered to a person not in an eligible cohort

If COVID-19 vaccine is inadvertently administered to a person not in an eligible cohort and the person is aged 50 or over, they should be offered a second dose as per the recommended schedule. If the person is under 50 years of age, they should be advised to wait for their second dose until their age group is invited to attend for vaccination. They can be reassured that the longer interval between doses should not affect vaccine effectiveness.

Reporting vaccine errors

Errors or incidents in vaccine storage, preparation or administration should be reported to the vaccination session team leader or the local Screening and Immunisation team. As some errors will require immediate action, they should be reported as soon as possible after they are realised.

They should also be reported to the MHRA, CQC or HSE as appropriate and recorded on STEIS, the NRLA or any locally-established or specially-established COVID-19 vaccine reporting systems.

COVID-19 vaccine inadvertently administered to a pregnant woman should be reported to the PHE Immunisation Department (www.gov.uk/guidance/vaccination-in-pregnancy-vip or telephone: 020 8200 4400).

Useful links

British Society of Immunology. A guide to vaccinations for COVID-19.

www.immunology.org/public-information/guide-vaccinations-for-covid-19

GOV.UK Coronavirus (COVID-19) in the UK <https://coronavirus.data.gov.uk/>

Green Book COVID-19 chapter www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

LSHTM COVID-19 vaccine tracker https://vaclshtm.shinyapps.io/ncov_vaccine_landscape/

Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 Handling and preparation video and poster www.cvdvaccine.co.uk/

Product information for the COVID-19 mRNA Vaccine BNT162b2 is available at

www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

Product information for the COVID-19 Vaccine AstraZeneca is available at

www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

Public Health England. Coronavirus resources

www.gov.uk/government/collections/immunisation

Royal College of Nursing. COVID-19 vaccination page www.rcn.org.uk/clinical-topics/public-health/immunisation/covid-19-vaccination

Specialist Pharmacy Services. COVID-19 Vaccines. www.sps.nhs.uk/home/covid-19-vaccines/

Vaccine update: issue 315, December 2020, COVID-19 special edition

www.gov.uk/government/publications/vaccine-update-issue-315-december-2020-covid-19-special-edition

WHO COVID-19 Worldwide Dashboard

https://covid19.who.int/?gclid=EAlaIQobChMIInr6P36Dc7AIVBWHmCh3IswIXEAAAYASAAEgIPT_D_BwE

Appendix One: Storage and preparation of the COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech)

Vaccine contraindications

COVID-19 mRNA Vaccine BNT162b2 should not be given to people who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- a previous dose of the same COVID-19 vaccine
- any component (excipient) of the COVID-19 vaccine (see Vaccine composition section below)

Vaccine composition

In addition to the highly purified BNT162b2 messenger RNA, the COVID-19 mRNA Vaccine BNT162b2 also contains:

- ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium hydrogen phosphate dihydrate
- sucrose
- water for injections

Polyethylene glycol (PEG) is from a group of known allergens commonly found in medicines, many household goods and cosmetics. Known allergy to PEG is very rare

but would contraindicate receipt of this vaccine. The AstraZeneca COVID-19 vaccine does not contain PEG and may be used as an alternative.

Whether PEG is the cause of reactions in patients with systemic allergic symptoms after the first dose of the Pfizer BioNTech COVID-19 vaccine is unclear. Patients who have experienced systemic allergic symptoms after the Pfizer BioNTech vaccine may be considered for a second dose using the AstraZeneca vaccine and should be observed for 30 minutes following vaccination.

Many biologics/monoclonal preparations contain PEG or related compounds. Expert advice from an Allergy Specialist should be sought for individuals with a history of systemic allergic reactions to biologics. Patients with undiagnosed PEG allergy may have a history of unexplained anaphylaxis or anaphylaxis to multiple classes of drugs.

COVID-19 mRNA Vaccine BNT162b2 does not contain any preservative and no animal products are contained in the vaccine product. Comprehensive information about the excipients contained in this vaccine is available on the [Specialist Pharmacy Service website](#).

Full product information about the COVID-19 mRNA Vaccine BNT162b2 is available at www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine.

Vaccinators may also wish to refer to the position statement written by the [British Islamic Medical Association](#) which recommends the vaccine for the Muslim community.

Precautions to COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech)

A very small number of individuals have experienced anaphylaxis when vaccinated with the COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech) vaccine. Following close surveillance of the initial roll-out, the MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to component (excipient) of the vaccine.

All recipients of this vaccine should be kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites.

The British Society for Allergy and Clinical Immunology (BSACI) has advised that:

- individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated)
- individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital). If the first dose was with Pfizer BioNTech vaccine, then AstraZeneca vaccine can be considered as an alternative (if not otherwise contraindicated) - this could be delivered in a primary care setting but with a 30 minute prolonged observation period
- individuals with non-allergic reactions (vasovagal (fainting) episodes, non-urticarial skin reaction or non-specific symptoms) to their first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting

Vaccine presentation

The COVID-19 mRNA Vaccine BNT162b2 packs contain 195 vials of vaccine.

The vaccine is contained in a multidose clear glass vial. The vial has a rubber (bromobutyl) stopper, aluminium seal and a flip-off plastic cap. Bromobutyl is a synthetic rubber – the vial stopper does not contain latex.

Each vial contains 0.45 ml of vaccine and should be diluted with 1.8 ml of Sodium Chloride 0.9% Solution for Injection (also referred to as normal saline). Once diluted, each reconstituted vaccine will supply 6 doses of 0.3 ml.

If the dose-sparing needles and syringes being supplied with the vaccine are used, it should be possible to obtain 6 full 0.3ml doses from the vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Care should be taken to ensure a full 0.3 ml dose will be administered to the patient from the same vial. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Diluent for reconstitution

A separate ampoule containing a minimum of 2 ml of Sodium Chloride 0.9% Solution for Injection is required for vaccine reconstitution. Each ampoule of diluent is single use and any remaining diluent must be discarded after 1.8 ml has been withdrawn, regardless of the ampoule volume.

There are no special storage requirements for the diluent and this can be stored with other ambient products (needles and syringes) in a dry environment away from direct sunlight.

Ordering

Pre-authorized NHS Trusts should order the Pfizer BioNTech COVID-19 vaccine via PHE's [ImmForm platform](#). PCN designated sites need to use the Foundry system to order vaccines. Ordering is only available for pre-authorized sites.

Each pack of vaccine ordered should automatically generate an order for the required number of packs of diluent, dilution syringes and needles and combined syringes and needles for vaccine administration for that vaccine pack. Vaccination record cards and information leaflets for vaccine recipients will also be provided with each vaccine pack.

Longer length (38mm) needles are recommended for morbidly obese individuals to ensure the vaccine is injected into muscle. These can be ordered from ImmForm when ordering vaccine if required in addition to the 25mm needles and syringes that will be supplied.

Storage

The Pfizer BioNTech COVID-19 vaccine will be **delivered frozen to healthcare facilities with ultra low temperature (ULT) freezers**. The following is provided for information only as those handling vaccines at ultra low temperatures should have received specific additional training for this and should be working to detailed standard operating procedures.

- vaccine packs will be shipped inside isothermic boxes (validated boxes which will maintain a constant temperature for a specified period of time) inside a cardboard box
- the isothermic box will also contain dry ice which should be disposed of carefully following local protocols
- upon delivery, the vaccine packs should be removed from the isothermic boxes and transferred to a suitable ULT freezer to ensure ongoing storage between -80°C and -60°C
- the vaccine should be kept upright, in its original packaging and away from prolonged light exposure
- when required, frozen vials should be transferred to 2°C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw at this temperature

- alternatively, frozen vials may also be thawed at temperatures up to 25 °C for a maximum of 2 hours of following removal from the freezer in preparation for dilution for use.
- once thawed, the vaccine cannot be re-frozen
- shelf-life is 6 months at -80°C to -60°C

Delivery in a thawed state

The COVID-19 mRNA Vaccine BNT162b2 may then be delivered to where it is going to be administered thawed but refrigerated between +2 and +8°C:

- refrigerated vaccine must be transferred immediately to a vaccine fridge on arrival and stored in a carefully monitored temperature range of +2 and +8°C
- when removed from the freezer, the undiluted vaccine has a maximum shelf life of up to 5 days (120 hours) at +2 and +8°C and an additional 2 hours at temperatures up to 25°C in preparation for dilution
- the vaccine pack will have a yellow label on the front stating the time it was removed from the freezer into storage at +2 to +8°C and the date and time by which it must be discarded 5 days (120 hours) later if it has not been used
- vaccine should be stored in the original package to protect it from light. Exposure to room light should be minimised and exposure to direct sunlight and ultraviolet light should be avoided

Storage and use of the vaccine

The COVID-19 mRNA Vaccine BNT162b2 has very specific storage, reconstitution and 'use within' requirements.

All those involved in the delivery of the COVID-19 vaccination programme must be aware of the recommended storage requirements.

The vaccine must not be given if you are not confident that it has been stored or reconstituted as recommended by the manufacturer or as advised by a vaccine expert.

If the vaccine is stored incorrectly:

- label and isolate affected vaccines in the fridge and do not use until further notice
- seek advice from the manufacturer or a source of expert advice

Equipment required to reconstitute the vaccine

The following equipment is required for reconstitution:

- one COVID-19 mRNA Vaccine BNT162b2 multidose vial
- one plastic ampoule of Sodium Chloride 0.9% Solution for Injection - this will be supplied in multiple presentations (different manufacturers and different sized ampoules). It does not need to be kept in the fridge
- an alcohol swab, a green hubbed needle and a 2 ml syringe to reconstitute - needles and syringes will be supplied together in boxes of 100 units

Reconstituting the vaccine

- clean hands with alcohol-based gel or soap and water
- assemble one ampoule of Sodium Chloride 0.9% Solution for Injection, a single use alcohol swab, a needle with a green hub and a 2ml syringe
- from cold storage, remove one vial of vaccine
- if removing the multidose vaccine vial directly from a ULT freezer, allow the vaccine to thaw at temperatures up to 25°C and reconstitute within 2 hours
- if removing the multidose vaccine vial from cold storage between +2 and +8°C, check that it has not been stored there for longer than 5 days (120 hours)
- when the thawed vaccine is at room temperature, gently invert the vial 10 times prior to dilution. One inversion means turning the vial upside down and back again. **Do not shake** – this could affect the potency of the vaccine.
- check the expiry date and the appearance of the vaccine. Prior to dilution, the thawed vaccine may contain white to off-white opaque amorphous particles. Return the vial to the manufacturer if the appearance of the vaccine does not match this description
- connect the needle with a green hub to the 2 ml syringe
- clean the vial stopper with the single use antiseptic swab and allow to air dry fully
- draw up 1.8 ml of Sodium Chloride 0.9% Solution for Injection, then discard the diluent ampoule and any remaining diluent in it. Do not use any other type of diluent

- add diluent to the vaccine vial. You may feel some pressure in the vial as you add the diluent. Equalise the vial pressure by withdrawing 1.8 ml of air into the empty diluent syringe before removing the needle from the vial
- gently invert the diluted solution 10 times. **Do not shake**
- the diluted vaccine should be an off-white solution with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present
- dispose of green hub needle and syringe into yellow sharps bin
- the diluted vial should be clearly labelled with the dilution time and date

After dilution the vaccine should be used as soon as is practically possible.

Reconstituted vaccine can be stored between 2°C and 25°C but **must be used within 6 hours following dilution.**

A video showing how to reconstitute and prepare the vaccine is available at www.cvdvaccine.co.uk/

Vaccine dose preparation

- if the vaccine has previously been reconstituted, check that the time of reconstitution was within the last 6 hours
- clean top of vial with a single use antiseptic swab and allow to air dry fully
- unwrap one of the 1 ml combined 23g/25mm blue hub needle and syringes provided (recommended needle length depends on body mass of patient. Longer length (38mm) needles are recommended for morbidly obese individuals to ensure the vaccine is injected into muscle. These can be ordered from ImmForm when ordering vaccine if required in addition to the 25mm length needles and syringes that will be supplied)
- withdraw a dose of 0.3 ml of diluted product for each vaccination. Take particular care to ensure the correct dose is drawn up as a partial dose may not provide protection
- any air bubbles should be removed before removing the needle from the vial in order to avoid losing any of the vaccine dose
- the same needle and syringe should be used to draw up and administer the dose of vaccine to prevent under dosing of the vaccine to the person

- the needle should only be changed between the vial and the patient if it is contaminated or damaged

Dose and schedule

A single dose is 0.3 ml. Two doses of COVID-19 mRNA Vaccine BNT162b2 are required with a minimum 21-day interval between doses (see also: [COVID-19 vaccines schedule](#) above).

Appendix Two: Storage and preparation of the COVID-19 Vaccine AstraZeneca

Contraindications

COVID-19 Vaccine AstraZeneca should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- a previous dose of the same COVID-19 vaccine
- any component (excipient) of the COVID-19 vaccine (see Vaccine composition section below)

Precautions to the COVID-19 Vaccine AstraZeneca

Precautions to this vaccine include current illness and pregnancy. See relevant sections in this document about these precautions.

Vaccine composition

The COVID-19 Vaccine AstraZeneca contains recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein.

It also contains:

- L-Histidine
- L-Histidine hydrochloride monohydrate
- Magnesium chloride hexahydrate
- Polysorbate 80
- Ethanol
- Sucrose
- Sodium chloride
- Disodium edetate dihydrate
- water for injections

The vaccine does not contain preservative and it does not contain any components of animal origin.

Comprehensive information about the excipients contained in this vaccine is available on the [Specialist Pharmacy Service website](#).

Presentation

COVID-19 Vaccine AstraZeneca vaccine is presented in a multidose vial containing a solution which should be colourless to slightly brown, clear to slightly opaque and free of particles. **It does not require reconstitution.** The vial has a halobutyl rubber stopper and is sealed with an aluminium overseal. There is no latex in the vial stopper (bung).

COVID-19 Vaccine AstraZeneca will be delivered in packs that contain 10 vials.

Two different presentations of the AstraZeneca vaccine are expected to be provided:

- 80 dose packs (Ten 4 ml vials with at least 8 doses per vial)
- 100 dose packs (Ten 5 ml vials with at least 10 doses per vial)

Only one product presentation will be available to order at one time. The majority of the vaccine provided will be the 8 doses per vial presentation but the 10 doses per vial presentation may be provided initially. **Vaccinators must check how many doses the vial they are using contains so that vaccine is not wasted.**

Each vial contains at least the number of doses stated. After withdrawing 8 or 10 full 0.5ml doses from the vial (depending on vial size), it may be possible to withdraw an additional full dose if the dose-sparing needles and syringes being provided with the vaccine are being used. Care should be taken to ensure a full 0.5 ml dose will be administered to the patient from the same vial. Where a full 0.5 ml dose cannot be extracted, the remaining contents should be discarded.

Ordering

NHS Trusts should order the COVID-19 Vaccine AstraZeneca via PHE's ImmForm platform. PCN designated sites need to use the Foundry system to order vaccines. Ordering is only available for pre-authorized sites.

Combined 1 ml fixed-needle (23g or 25g, 25mm length) dose-sparing syringes for administration will be available to order separately on ImmForm, as will syringes and longer-length (38mm) needles for administration to those who are morbidly obese.

Each carton of vaccine vials will include one Healthcare Professional Information sheet and one pad of the corresponding number of Patient Information Leaflets. Patient vaccination record cards will also be supplied with vaccine ordered.

Vaccinators are advised to read the latest administration instructions in the product information electronically (www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca).

Storage

Upon delivery, COVID-19 Vaccine AstraZeneca should be transferred to a fridge immediately and stored between +2°C and +8°C. Vials should be kept upright in their box (mulberry colour panel is the bottom) and away from direct sunlight to prevent prolonged light exposure.

Once the vial bung is punctured, the vaccine must be used as soon as possible and within 6 hours of first puncture (during which time it can be stored between at +2°C to +25°C).

As the vaccine does not contain preservative, any unused vaccine must be discarded if not used within this 6 hour time period.

Vaccine dose preparation

COVID-19 Vaccine AstraZeneca does not require reconstitution.

- before drawing up a dose of vaccine from the multidose vial, clean hands with alcohol-based gel or soap and water
- each multi-dose vial should be clearly labelled with the date and time of expiry (which should be 6 hours from when it was first punctured)
- do not use the vaccine if the time of first puncture was more than 6 hours previously
- check the appearance of the vaccine. It should be colourless to slightly brown, clear to slightly opaque and free of any particles. Discard the vaccine if particulates or discolouration are present
- do not shake the vaccine vial
- the vial bung should be wiped with an alcohol swab and allowed to air-dry fully

- a 1 ml dose-sparing syringe with a 23g or 25g, 25mm fixed-needle should be used to draw up and administer the AstraZeneca vaccine
- separate 38mm length needles and syringes should be used for morbidly obese patients to ensure the vaccine can be injected into the muscle
- withdraw a dose of 0.5 ml for each vaccination. Take particular care to ensure the correct dose is drawn up as a partial dose may not provide protection
- any air bubbles should be removed before removing the needle from the vial in order to avoid losing any of the vaccine dose

Dose and schedule

A single dose is 0.5ml.

Two doses of AstraZeneca vaccine are required with a minimum 28-day interval between doses (see also: [COVID-19 vaccines schedule](#) above).