



Public Health  
England

Protecting and improving the nation's health

# **COVID-19 vaccination programme**

## **Information for healthcare practitioners**

Republished 31 December 2020

Version 3

# 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.

Public Health England  
Wellington House

133-155 Waterloo Road  
London SE1 8UG  
Tel: 020 7654 8000

[www.gov.uk/phe](http://www.gov.uk/phe)

Twitter: [@PHE\\_uk](https://twitter.com/PHE_uk)

Facebook: [www.facebook.com/PublicHealthEngland](https://www.facebook.com/PublicHealthEngland)



© Crown copyright 2020

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v3.0. To view this licence, visit [OGL](https://www.ogil.io). Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

Republished 31 December 2020

PHE publications

gateway number: GW-1791

PHE supports the UN

Sustainable Development Goals



## Document information

This document was originally published provisionally, ahead of authorisation of any COVID-19 vaccine in the UK, to provide information to those who will be involved in the COVID-19 national vaccination programme 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, this document has been updated to provide specific information about the storage and preparation of this vaccine.

Information about 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

Version number	Details	Date
1.0	Document created	27 November 2020
2.0	Vaccine specific information about the COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech) added	4 December 2020
2.1	<p>Additional section added on timing of administration of COVID-19 vaccine to individuals who are immunosuppressed</p> <p>New guidance added on not giving COVID-19 mRNA Vaccine BNT162b2 to those with a history of anaphylaxis to a vaccine, medicine or food</p> <p>Some amendments to the COVID-19 mRNA Vaccine BNT162b2 storage and reconstitution section following republication of updated <a href="#">Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine</a> document</p>	11 December 2020
3.0	<p>Vaccine specific information about the COVID-19 Vaccine AstraZeneca added</p> <p>Advice about 6<sup>th</sup> dose from COVID-19 mRNA Vaccine BNT162b2 vial added</p> <p>Pregnancy and breastfeeding sections updated</p> <p>Revision of specific precautions to the COVID-19 mRNA Vaccine BNT162b2</p>	31 December 2020

# Contents

About Public Health England .....	2
Document information.....	3
Document revision information.....	4
Contents.....	5
Background.....	8
COVID-19 disease .....	9
Clinical symptoms .....	9
Transmission .....	10
Groups affected by COVID-19.....	10
COVID-19 vaccination programme .....	11
Aim of the programme .....	11
Vaccine history and development.....	11
Duration of protection .....	11
COVID-19 vaccination eligibility .....	12
Vaccine priority groups – provisional list.....	12
Pregnant women .....	12
Breastfeeding .....	13
Immunosuppression and HIV .....	13
COVID-19 vaccines .....	13
COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech) .....	14
COVID-19 Vaccine AstraZeneca.....	14
Interchangeability of different COVID-19 vaccines .....	14
COVID-19 vaccines schedule.....	15
Administration of COVID-19 vaccine.....	15
Infection prevention and control .....	15
Injection technique .....	15
Administering COVID-19 vaccine to individuals with a bleeding disorder.....	16

Administering COVID-19 vaccine to individuals taking anticoagulants .....	16
Timing of administration of COVID-19 vaccine to individuals who are immunosuppressed ..	16
Period of observation following immunisation with COVID-19 vaccine.....	17
COVID-19 vaccine and clinical trial participants .....	17
Adverse reactions following vaccination .....	17
Possible adverse reactions following vaccination .....	17
Reporting adverse reactions.....	18
Differentiating between a reaction to the vaccine and symptoms of COVID-19 disease .....	19
COVID-19 vaccine contraindications and precautions .....	20
COVID-19 vaccine contraindications .....	20
Precautions to COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech) .....	20
COVID-19 vaccine precautions .....	21
Current or previous history of COVID-19 disease .....	21
Vaccination of people experiencing prolonged COVID-19 symptoms ('Long COVID') .....	21
Time interval between treatments for COVID-19 disease (for example dexamethasone, convalescent plasma, monoclonal antibody or antiviral medicines) and vaccine administration .....	22
Co-administration of COVID-19 vaccine with other inactivated or live vaccines .....	22
Legal aspects of vaccine administration .....	24
Using a Patient Group Direction (PGD) to give COVID-19 vaccine authorised under regulation 174.....	24
Protocols for the supply and/or administration of COVID-19 vaccine .....	24
Accountability .....	25
Inadvertent vaccine administration errors .....	26
Inadvertent administration of the diluent only (for COVID-19 vaccines that require dilution) .	26
Inadvertent administration of the whole multi-dose vial of vaccine instead of the recommended dose.....	26
Reporting vaccine errors .....	28
Useful links.....	29
Appendix One .....	30
Storage and preparation of the COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech) .....	30

Precautions to COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech) .....	31
Ordering .....	33
Storage.....	33
Delivery in a thawed state .....	34
Appendix Two .....	37
Storage and preparation of the COVID-19 Vaccine AstraZeneca .....	37

## 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**.

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.

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.

Asymptomatic infection has been reported but 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.

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 are thought 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 people<sup>1</sup>. 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.

---

<sup>1</sup> 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.

## Vaccine history and 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 will be presented and prepared differently, immunisers must ensure they are familiar with the specific details of the vaccine that they will be 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 – provisional list

The objectives of the COVID immunisation programme is to protect those who are at highest risk from serious illness or death. The Joint Committee on Vaccination and Immunisation (JCVI) therefore 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 a 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.**

## 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

JCVI does not advise routine pregnancy testing before receipt of a COVID-19 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, she should 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 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 (<https://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 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.

## Immunosuppression and HIV

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 PGD or [Protocol](#) and [Green Book COVID-19 chapter](#). These individuals may not make a full antibody response and should therefore continue to follow advice to avoid exposure unless they are advised otherwise by their doctor.

# COVID-19 vaccines

In the UK, two COVID-19 vaccines have been given authorisation for temporary supply by the MHRA for use in the UK national COVID-19 vaccination programme. One vaccine, the COVID-19 mRNA Vaccine BNT162b2 (manufactured by Pfizer-BioNTech) was given authorisation for temporary supply by the MHRA on 2 December 2020. The other vaccine, COVID-19 Vaccine AstraZeneca, was given authorisation for temporary supply by the MHRA on 30 December 2020. Information about 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 SARS-CoV-2 antigen. The adenovirus has been modified so that it cannot replicate (grow and multiply by making copies of itself) in human cells and therefore cause any disease.

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, it enters the host's cells which then 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.

## 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 and to complete 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 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. Evidence from Phase 3 trials indicate high levels of protection against serious disease and death from around 2 weeks after the first dose<sup>2</sup>. Longer term protection will then be provided by the second dose.

# 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 disease 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.

## Injection technique

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

---

<sup>2</sup> 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](http://www.gov.uk/government/news/jcvi-issues-advice-on-the-astrazeneca-covid-19-vaccine)

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 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.

As two doses are required to make a full response, a decision to defer any possible benefit from vaccination or to suspend therapy should not be taken without due consideration of the risks from COVID 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 and that as fainting can occur following vaccination, all those vaccinated with either COVID-19 vaccine should either be driven by someone else or should not drive for 15 minutes after vaccination.

### 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 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.

## 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 (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 used<sup>3</sup>.

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 frequently<sup>3</sup>. Prophylactic use of paracetamol was found not to affect the immune response to this vaccine<sup>4</sup>.

## 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/](https://coronavirus-yellowcard.mhra.gov.uk/) or call 0800 731 6789). Both patients and healthcare providers can and should 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.

---

<sup>3</sup> 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](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)

<sup>4</sup> 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

## 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 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 confirmed anaphylactic reaction to a previous dose of COVID-19 vaccine
- a confirmed anaphylactic reaction to any components 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).

## 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).

- 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.

## 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. 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.

## 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.

## 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](http://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them)).

PHE will develop and publish 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.

## 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) 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 events<sup>2</sup>.

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.

### 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.

There is no time limit as to when the vaccine dose can be repeated but giving the full dose as soon as possible reduces the time a person is left susceptible to infection and would reduce the risk of the individual experiencing any reactions to the incomplete dose and then to the full dose of vaccine.

The second dose should still be given at the recommended interval.

### 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 efficacy.

## 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](https://www.gov.uk/guidance/vaccination-in-pregnancy-vip) or telephone: 020 8200 4400).

## Useful links

Green Book COVID-19 chapter [www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book](http://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book)

Public Health England Coronavirus resources  
[www.gov.uk/government/collections/immunisation](http://www.gov.uk/government/collections/immunisation)

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

WHO COVID-19 Worldwide Dashboard  
[https://covid19.who.int/?gclid=EAlaIqobChMIInr6P36Dc7AIVBWHmCh3IswIXEAAAYASAAEgIPT\\_D\\_BwE](https://covid19.who.int/?gclid=EAlaIqobChMIInr6P36Dc7AIVBWHmCh3IswIXEAAAYASAAEgIPT_D_BwE)

LSHTM COVID-19 vaccine tracker [https://vaclshtm.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vaclshtm.shinyapps.io/ncov_vaccine_landscape/)

Royal College of Nursing. Immunisation services and large-scale vaccination delivery during COVID-19. [www.rcn.org.uk/clinical-topics/public-health/immunisation/immunisation-services-and-large-scale-vaccination-delivery-during-covid-19#planningandriskassessmentprocess](http://www.rcn.org.uk/clinical-topics/public-health/immunisation/immunisation-services-and-large-scale-vaccination-delivery-during-covid-19#planningandriskassessmentprocess)

Royal College of Nursing - COVID-19 vaccination page [www.rcn.org.uk/clinical-topics/public-health/immunisation/covid-19-vaccination](http://www.rcn.org.uk/clinical-topics/public-health/immunisation/covid-19-vaccination)

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](http://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) and <https://coronavirus-yellowcard.mhra.gov.uk/productinformation>

Product information for the COVID-19 mRNA Vaccine BNT162b2 is available at [www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca](http://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca) and <https://coronavirus-yellowcard.mhra.gov.uk/productinformation>

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](http://www.gov.uk/government/publications/vaccine-update-issue-315-december-2020-covid-19-special-edition)

## 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 and also in household goods and cosmetics. Known allergy to PEG is extremely rare but would contraindicate receipt of this vaccine. Patients with undiagnosed PEG allergy may have a history of unexplained anaphylaxis or of anaphylaxis to multiple classes of drugs. The AstraZeneca COVID-19 vaccine does not contain PEG and is a suitable alternative.

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 <https://coronavirus-yellowcard.mhra.gov.uk/productinformation>.

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).
- 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.

### 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 5 or 6 doses of 0.3 ml (30 mcg).

After withdrawing 5 full 0.3ml doses from the vial, there may be potential for a sixth full dose with some vials due to variances in fill volume and the syringe/needle hold up volume combinations used. This should be subject to health care professional judgement on a case by case basis. Care should be taken to ensure a full 0.3 ml dose will be administered to the patient from the same vial. Where a full 0.3 ml dose cannot be extracted the contents should be discarded.

If further advice is required, in hospitals and vaccination centres please discuss with the Chief Pharmacist, and in local vaccination services, the Lead Responsible CCG Chief Pharmacist and Lead GP.

### 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

COVID-19 mRNA Vaccine BNT162b2 should be ordered via PHE's **ImmForm** platform. The vaccine is only available to order by the pre-agreed providers for pre-authorised 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  $-75^{\circ}\text{C}$  and  $\pm 15^{\circ}\text{C}$
- the vaccine should be kept upright, in its original packaging and away from prolonged light exposure
- the vaccine packs must not be opened until the vaccine is going to be thawed
- once thawed, the vaccine cannot be re-frozen
- shelf-life is 6 months at  $-80^{\circ}\text{C}$  to  $-60^{\circ}\text{C}$

## 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. **Do not shake**
- check the expiry date and the appearance of the vaccine. Prior to dilution, the vaccine should be an off-white solution with no particulates visible. Return the vial to the manufacturer if particulates or discolouration are present
- 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.**

### 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 (30 mcgs). Two doses of COVID-19 mRNA Vaccine BNT162b2 are required with a minimum 21-day interval between doses (see also: [COVID-19 vaccines schedule](#) p13) .

## 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 this COVID-19 vaccine
- any components of this vaccine

### Precautions to the COVID-19 Vaccine AstraZeneca

Precautions to this vaccine include current illness and pregnancy. See pages 10 and 19 above.

### 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.

## 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 8 doses per vial)
- 100 dose packs (Ten 5 ml vials with 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.**

## Ordering

AstraZeneca COVID-19 vaccine should be ordered via PHE's ImmForm platform. The vaccine is only available to order by the pre-agreed providers for pre-authorised sites.

Combined 1 ml fixed-needle (23g or 25g, 25mm length) dose-sparing syringes for administration will be available to order separately on ImmForm

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](http://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 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 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 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
- there will be a small amount of vaccine left in the vial after withdrawing the expected number of doses

### 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](#) p13).