



UK Health
Security
Agency

COVID-19 vaccination programme

Information for healthcare practitioners

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Document history

Version number	Change details	Date
1.0	Document created	27 November 2020
2.0	Vaccine specific information about the coronavirus (COVID-19) mRNA Vaccine BNT162b2 (Pfizer BioNTech) added	4 December 2020
2.1	<ol style="list-style-type: none"> 1. Additional section added on timing of administration of COVID-19 vaccine to individuals who are immunosuppressed 2. New anaphylaxis guidance added for the COVID-19 mRNA Vaccine BNT162b2 <p>Amendments to the COVID-19 mRNA Vaccine BNT162b2 storage and reconstitution section following republication of updated Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine document</p>	11 December 2020
3.0	<ol style="list-style-type: none"> 1. Vaccine specific information about the COVID-19 Vaccine AstraZeneca added 2. Advice about obtaining sixth dose from COVID-19 mRNA Vaccine BNT162b2 vial added 3. Pregnancy and breastfeeding sections updated 4. Revision of specific precautions to the COVID-19 mRNA Vaccine BNT162b2 	31 December 2020
3.1	<ol style="list-style-type: none"> 1. Advice about additional dose from COVID-19 Vaccine AstraZeneca vial added 2. Section about best interest decision added 3. Section on advice following immunisation added 	11 January 2021
3.2	<ol style="list-style-type: none"> 1. Timing of offer of vaccine to those who are about to receive immunosuppressive therapy and allergy advice sections updated to reflect updated advice in Green Book COVID-19 chapter 2. Section on surveillance of COVID-19 cases in vaccinated individuals added 3. Revised advice for action to take following inadvertent administration of incomplete dose of vaccine and new advice following administration of vaccine whose potency may have been adversely affected by an inadvertent storage or preparation error added 4. Change from 5 doses in a vial of Pfizer BioNTech (Comirnaty) vaccine to 6 doses as per updated Regulation 174 Information for UK healthcare 	3 February 2021

	professionals on Pfizer/BioNTech COVID-19 vaccine	
3.3	Advice added regarding inadvertent administration of a different COVID-19 vaccine at a short interval after the first dose	11 February 2021
3.4	<ol style="list-style-type: none"> 1. Updated advice in contraindications and precautions section to include updated advice on allergy and vaccinating those with a history of reaction to the first dose of a COVID-19 vaccine in line with updates to the Green Book COVID-19 chapter 2. Pregnancy section updated 3. Vaccine specific information about the COVID-19 Vaccine Moderna added 	26 February 2021
3.5	<ol style="list-style-type: none"> 1. Pregnancy section updated 2. New contraindications for COVID-19 vaccine AstraZeneca added 3. Advice about which vaccines to give those vaccinated abroad added 	28 April 2021
3.6	Added information about the exceptional circumstances in which a different second vaccine to the first can be given	11 May 2021
3.7	Updated vaccine schedule section and added section about administering second dose beyond recommended interval	20 May 2021
3.8	Pfizer BioNTech vaccine storage conditions updated from 5 days to 31 days to reflect change in the Information for Healthcare Professionals on Pfizer BioNTech (Comirnaty) Vaccine document.	9 June 2021
3.9	<ol style="list-style-type: none"> 1. Updated the following sections in line with revisions made to the Green Book COVID-19 Chapter: <ul style="list-style-type: none"> - duration of protection and booster doses - interchangeability of different COVID-19 vaccines - COVID-19 vaccines schedule - advice to vaccine recipients following immunisation - COVID-19 vaccine contraindications and precautions - co-administration of COVID-19 vaccine with other inactivated or live vaccines 2. Appendix 1 Vaccine interchangeability guidance updated 	6 July 2021
3.10	<ol style="list-style-type: none"> 1. Updated to include: <ul style="list-style-type: none"> - revisions to the Green Book COVID-19 Chapter - GBS and Capillary Leak syndrome - vaccination of 12 to 17 year olds - consent for children and young people 2. Appendix 2 revised to detail transition from use of the Pfizer BioNTech (Comirnaty) vaccine under Reg 174 to use under Conditional Marketing Authorisation 	6 August 2021

3.11	<ol style="list-style-type: none"> 1. Document changed from PHE into UKHSA branding 2. Updated to include revisions to the Green Book COVID-19 Chapter 3. Information and guidance about booster doses, third primary dose and boosters for severely immunocompromised, and vaccination of 12 to 17 year olds added 4. Advice for 15 minute observation period following vaccination with Pfizer or Moderna vaccines changed 5. Advice following administration of partial dose revised 6. Revisions to the Interchangeability table in Appendix A 	21 December 2021
4.0	<ol style="list-style-type: none"> 1. Vaccine specific information about the Pfizer BioNTech Comirnaty 10 micrograms/dose vaccine added in Appendix 5 2. Updated to include revisions to the Green Book COVID-19 Chapter 3. Advice about under 18 year olds who received vaccination overseas added 4. Advice added about booster doses for all young people aged 16 to 17 years, young people aged 12 to 15 who are in a clinical risk group or who are a household contact of someone who is immunosuppressed and young people aged 12 to 17 years who are severely immunocompromised and who have had a third primary dose 5. JCVI recommendations for offer of a lower dose (10 micrograms) of the Pfizer BioNTech COVID-19 vaccine to children aged 5 to 11 years in a clinical risk group or who are a household contact of someone who is immunosuppressed added 	2 February 2022
4.1	Amended wording in table in Appendix 1 to clarify recommendation of additional dose	11 February 2022
4.2	<ol style="list-style-type: none"> 1. Updated to include revisions to the Green Book COVID-19 chapter 2. Added information about spring booster and vaccination programme for all 5 to 11 years olds 3. Added advice for individuals given a booster dose overseas 	9 March 2022

Document information

This document was originally published provisionally, ahead of authorisation of any coronavirus (COVID-19) vaccine in the UK, to provide information to those involved in the COVID-19 national vaccination programme before it began in December 2020.

Following authorisation by the UK Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) being given to the COVID-19 Vaccine Pfizer BioNTech 30 micrograms/dose on 2 December 2020, the COVID-19 Vaccine AstraZeneca on 30 December 2020, the COVID-19 Vaccine Moderna on 8 January 2021 and the COVID-19 Vaccine Pfizer BioNTech Comirnaty 10 micrograms/dose on 22 December 2021, this document has been updated to provide specific information about the storage and preparation of these vaccines. 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-19 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.

Background to the COVID-19 vaccination programme

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 coronavirus (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).

Information on the effectiveness of COVID-19 vaccination, which is being monitored by UKHSA, can be found on [the GOV.UK website](#).

Further information on COVID-19 disease, epidemiology and the vaccination programme can be found in the [Green Book COVID-19](#) chapter.

Further information on vaccine eligibility is described in the [Joint Committee on Vaccination and Immunisation \(JCVI\) advice](#), [Green Book COVID-19 chapter](#) and the UKHSA COVID-19 [PGDs](#) and [Protocols](#).

Patient information leaflets and resources can be ordered from the [Health Publications](#) website.

COVID-19 disease

Clinical symptoms

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.

In general, children appear to experience mild disease. 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 small respiratory droplets expelled from the nose and mouth through coughing, sneezing or speaking.

These droplets can also survive on objects and surfaces. People can become infected by touching these objects or surfaces, then touching their eyes, nose or mouth, although this risk is now generally considered to be low.

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 also associated with an increased risk of death, and obesity and [other underlying health conditions](#) can increase the risk for some people. Further information on high risk groups can be found on the NHS.UK webpage: [Who's at higher risk from coronavirus \(COVID-19\)](#). Deprivation and being from a black, Asian or minority ethnic 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.

COVID-19 vaccination programme

Aim of the programme

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

Vaccine development

Over 300 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. Whilst 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 safe and effective vaccines 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 COVID-19 vaccines which have been authorised for supply in the UK to date. The guidance will be updated as more information about these vaccines becomes 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.

COVID-19 vaccination eligibility

The JCVI consider the available epidemiological, microbiological and clinical information on the impact of COVID-19 in the UK and provide the government with advice to support the development of the COVID-19 vaccine strategy. Key published recommendations in chronological order are:

- Phase 1: [Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination 30 December 2020](#).
- Phase 2: [JCVI final statement on phase 2 of the COVID-19 vaccination programme: 13 April 2021](#).
- Children aged 12 to 17 years: [JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 4 August 2021](#).
- Third dose for immunosuppressed: [Joint Committee on Vaccination and Immunisation \(JCVI\) advice on third primary dose vaccination 1 September 2021](#).
- Children aged 12 to 15 years: The UK Chief Medical Officers recommendation: [Universal vaccination of children and young people aged 12 to 15 years against COVID-19 13 September 2021](#).
- Booster doses: [JCVI statement, September 2021: COVID-19 booster vaccine programme for winter 2021 to 2022 14 September 2021](#).
- Updated booster dose statement: [COVID-19 booster vaccine programme for winter 2021 to 2022: JCVI statement 15 November 2021](#).
- [JCVI advice on the UK vaccine response to the Omicron variant 29 November 2021](#).
- [JCVI statement on COVID-19 vaccination of children and young people aged 5 to 11 years and booster vaccinations in those aged 12 to 17 years 22 December 2021](#).
- [JCVI statement on vaccination of children aged 5 to 11 years old 16 February 2022](#)
- [JCVI statement on COVID-19 vaccinations in 2022 21 February 2022](#)

Full details on vaccine eligibility, with detail on the at-risk conditions are included in the [Green Book COVID-19 chapter](#) and have therefore not been detailed in this document.

COVID-19 vaccines

In the UK, the following COVID-19 vaccines are currently in use in the UK national COVID-19 vaccination programme:

1 COVID-19 Vaccine Pfizer BioNTech (Comirnaty 30 micrograms/dose)

Given authorisation for temporary supply by the MHRA on 2 December 2020 and then granted Conditional Marketing Authorisation on 9 July 2021. This vaccine is authorised for adults and adolescents from the age of 12 years.

2 COVID-19 Vaccine Pfizer BioNTech (Comirnaty 10 micrograms/dose)

Granted Conditional Marketing Authorisation by the MHRA on 22 December 2021. This vaccine is authorised for children from 5 to 11 years of age.

3 COVID-19 Vaccine AstraZeneca (Vaxzevria)

Given authorisation for temporary supply by the MHRA on 30 December 2020 and then granted Conditional Marketing Authorisation on 24 June 2021. This vaccine is authorised for adults from 18 years of age.

4 COVID-19 Vaccine Moderna (Spikevax)

Given authorisation for temporary supply by the MHRA on 8 January 2021 and then granted Conditional Marketing Authorisation on 1 April 2021. This vaccine is authorised from 12 years of age but it is not currently recommended it is given to those under 18 years of age.

Any other COVID-19 vaccines which are given regulatory approval and supplied in the UK will be added to this document when this occurs.

The Pfizer BioNTech (Comirnaty) and Moderna (Spikevax) COVID-19 vaccines use an mRNA platform and the COVID-19 Vaccine AstraZeneca (Vaxzevria) is an adenovirus vector vaccine.

All the currently UK-authorized vaccines are supplied in multi-dose vials and require completion of a 2-dose primary course. Using multi-dose vials can improve the efficiency of vaccine manufacture and distribution, enabling vaccine availability at the earliest opportunity.

Pfizer BioNTech and Moderna COVID-19 vaccines

The Pfizer BioNTech and Moderna COVID-19 vaccines are mRNA (messenger ribonucleic acid) vaccines. They contain 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.

AstraZeneca COVID-19 vaccine

The AstraZeneca COVID-19 vaccine 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 for the spike protein. The cells then process this genetic code to 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.

COVID-19 vaccines schedule

For both adenovirus vector and mRNA vaccines, there is evidence of better immune response and or protection where [longer intervals between doses](#) in the primary schedule are used

JCVI is therefore currently recommending an interval of 8 weeks between doses of all the available COVID-19 vaccines where a 2-dose primary schedule is used for adults and children at high risk. Operationally, using the same minimum interval for all of the COVID-19 vaccines will simplify supply and booking and will help to ensure a good balance between achieving rapid and long-lasting protection.

For those aged 12 to 17 who are not in a high-risk group, a 12-week interval is recommended. The longer interval in this age group reflects strong evidence of high levels of protection against severe disease from the first dose, although this interval could be shortened to 8 weeks in periods of high incidence or where there was concern about vaccine effectiveness (for example a new variant). Vaccinators would be advised when this interval should be shortened. Emerging evidence also suggests that countries with longer schedules (8 to 12 weeks) may have a lower

rate of myocarditis after the second dose. Although this latter evidence is limited, JCVI has taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis.

The main exception to the 8-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals (21 days for Pfizer BioNTech vaccines or 28 days for Moderna and AstraZeneca vaccines) may be followed to ensure that the vaccine is given while their immune system is better able to respond.

Previous incomplete vaccination

If the vaccine course is interrupted or delayed, it should be resumed using the same vaccine but the first dose should not be repeated. Evidence from [trials](#) suggest that those who receive mixed (heterologous) vaccine schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects in those who receive a different vaccine for their second dose are higher compared to those who received the same vaccine for both [doses](#). Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the [European Medical Agency](#).

For individuals who started the schedule and who attend for vaccination where the same vaccine is not suitable, is unknown or not available (for example, if the individual received their first dose abroad), one dose of the locally available product should be given to complete the schedule if that vaccine is suitable for age and not contraindicated (see [Appendix 1](#) and [Individuals who received COVID-19 vaccination overseas](#) section below). Individuals who experienced severe expected reactions after a first dose of AstraZeneca or Pfizer BioNTech vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine.

Individuals who received COVID-19 vaccination overseas

If a person aged 18 years and over has received a first dose of a COVID-19 vaccine overseas that is also available in the UK, they should receive the same vaccine for their second dose (unless contraindicated).

If the vaccine they received for their first dose is not available in the UK, the most similar alternative should be offered for their second dose (see table in [Appendix 1](#)). If the vaccine received overseas is not listed in the table, a full course of the appropriate vaccine recommended for the individual in the UK (which may depend on their age) should be given.

The various groups of vaccines are:

- Adenovirus (ChAdOx) vector – AstraZeneca (Vaxzevria), Covishield
- mRNA – Pfizer BioNTech (Comirnaty), Moderna (Spikevax)
- whole inactivated Coronavirus – Sinopharm, Sinovac, Covaxin

The other adenovirus-based vaccines (Janssen, Sputnik, CanSinoBio) use different vectors and so are not immunologically the same as either the AstraZeneca or Covishield adenovirus vector vaccines. However, as they, and the Novavax vaccine, are all based on spike protein, the vaccine course can be completed with any of the locally available vaccines as appropriate for the individual's age.

Those who are eligible to receive a booster dose should be given a full dose (30 micrograms) of the Pfizer BioNTech Comirnaty 30 micrograms/dose COVID-19 vaccine or a half dose (50 micrograms) of the Moderna vaccine. In this instance, the minimum interval of 3 months should be from their final primary dose. So for those considered fully vaccinated before arrival, the 3 months is taken from their final dose given overseas; for those requiring one or more UK doses, the 3-month interval is taken from the final 'additional' dose given in the UK.

The recommendations in this table will be reviewed regularly as more vaccines and information about the efficacy of these vaccines become available.

The above advice applies to individuals aged 18 years and older.

Children and young people aged 5 to 17 years

Children and young people aged 5 to 17 years who have commenced immunisation with an mRNA vaccine (Pfizer BioNTech or Moderna) overseas should continue their vaccine course as per the UK recommendations for their age and risk group. Those who received any other type of COVID-19 vaccine (not an mRNA vaccine) should be managed as per the advice in the table in Appendix 1 but using age-appropriate dosing and schedules for the UK. For those under 18 years who are eligible for a booster dose, any additional doses of vaccine given may count as a booster if given at least 3 months after the second dose.

Children and young people in both of the above groups should complete their schedule with the Pfizer BioNTech Comirnaty vaccine (10 microgram/dose vaccine or 30 microgram/dose vaccine as appropriate for age).

Booster doses received overseas

For individuals (aged 16 years and over) who have already received a booster dose of vaccine overseas, this dose would count as a valid booster dose if they had received:

- a homologous course (primary and booster doses) of AstraZeneca (or Institute of India Covishield) or mRNA vaccine (Pfizer BioNTech or Moderna)

- a heterologous course (primary and booster doses) that included at least one dose of AstraZeneca (or Institute of India Covishield) or mRNA vaccine (Pfizer BioNTech or Moderna)

If the booster dose received overseas was given less than 3 months after the last primary dose (regardless of which vaccine was given), the booster dose should be repeated in the UK using an mRNA vaccine (full dose Pfizer BioNTech or half dose Moderna (if over 18 years)) at least 3 months after the previous dose.

For those individuals eligible for the UK 2022 Spring booster (adults aged 75 years and over, residents in a care home for older adults, and individuals aged 12 years and over who are immunosuppressed), if they have already received a booster dose overseas which is being counted as a valid booster dose, they should be offered the Spring booster around 6 months after the previous dose. This interval may be brought forward to a minimum of 3 months to ensure they receive the booster during the spring campaign.

If an individual has not received any doses of either AstraZeneca (or Institute of India Covishield) or mRNA vaccine (Pfizer BioNTech or Moderna) as part of their previous course, then they should receive an additional booster dose of an mRNA vaccine in the UK at least 3 months after their last dose of COVID-19 vaccine.

If they are eligible for the Spring booster then this additional dose will count as their Spring booster and no further doses are currently recommended before the autumn.

Circumstances in which a different second vaccine to the first can be given

In addition to giving a different second vaccine where the first vaccine is unknown, or was a vaccine given abroad that is not available in the UK, there are certain other situations in which it may be appropriate to give a different second vaccine from the first, providing there are no contraindications. These are:

- people with prior anaphylaxis to a COVID-19 vaccine or a prior systemic allergic reaction to a component of the vaccine (but seek expert advice from a specialist first)
- after discussion with, and on the advice of, an allergy specialist, people with unexplained anaphylaxis or a history of anaphylaxis to multiple other medicines
- individuals who experience a clotting episode with concomitant thrombocytopenia or Guillain-Barré syndrome (GBS) following the first dose of AstraZeneca vaccine

If an individual experienced a severe adverse reaction to their first dose of COVID-19 vaccine, advice in the [Green Book COVID-19 chapter](#) regarding second doses should be followed and expert clinical opinion from a specialist should be sought if further advice is required.

Vaccine supply not available locally

If all efforts to enable an individual to receive the same vaccine at another time and or location have been exhausted, it may be necessary to use a different vaccine where the risk of not vaccinating is greater than the risk of further delay. However, age-specific recommendations on vaccine type as set out in the [Green Book COVID-19 chapter](#) should be followed.

Booster programme

To maintain high levels of protection against severe COVID-19 disease and specifically, hospitalisation and death through the winter, [the JCVI](#) initially advised that booster vaccines be offered to those most at risk from serious disease, and who were vaccinated during Phase 1 of the vaccine programme. However, after [extending the booster dose offer](#) to all aged 40 to 49 years, on 29 November 2021, in response to the emergence of the Omicron variant, the [JCVI advised](#) accelerating the booster programme and offering a booster dose to all adults aged from 18 years.

On 22 December 2021, the [JCVI recommended booster doses](#) for all those aged 16 and 17 years, children and young people aged 12 to 15 years who are at higher risk from COVID-19 (as set out in the Green Book [COVID-19 chapter](#)), and those aged 12 to 15 years who are household contacts of immunosuppressed individuals of any age.

Booster vaccination should be given at least 3 months after completion of the primary course.

Boosters in children and young people aged 12 to 15 years who are not at high risk and in those aged 5 to 11 years will be reviewed in due course.

On 21 February 2022, recognising the small decline in observed vaccine effectiveness against hospitalisation for COVID-19 after the booster dose, the [JCVI recommended](#) a Spring booster campaign for individuals at higher risk of severe COVID-19. In order to sustain protection, the JCVI recommended that a booster dose should be given around 6 months after the last vaccine dose to:

- adults aged 75 years and over
- residents in a care home for older adults, and
- individuals aged 12 years and over who are immunosuppressed

A further booster programme is expected in autumn 2022

Further information about the booster programmes is available in the JCVI statements and also in the [COVID-19 chapter](#) of the Green Book (which contains information about when the 6 month Spring booster interval may be reduced to 3 months for operational flexibility).

Vaccine to be used for booster doses

The JCVI have advised that a full dose (30 micrograms) of Pfizer BioNTech vaccine or a half dose (50 micrograms) of the Moderna vaccine should be offered as a booster dose. These 2 vaccines should be used with equal preference in the COVID-19 booster programme as both vaccines have been shown to substantially increase antibody levels when offered as a booster dose. A half dose of Moderna is advised for the booster dose as it is expected to have a lower rate of side effects (including myocarditis) than a full dose.

Where both the Pfizer and Moderna vaccines are clinically contraindicated, vaccination with the AstraZeneca vaccine may be considered for those who have received at least 1 dose of this vaccine previously. In exceptional circumstances, individuals aged 40 years or over who received a mRNA COVID-19 vaccine previously may be offered boosting with AstraZeneca vaccine following a decision by a health professional on a case-by-case basis. Where individuals have inadvertently received a third dose or booster of AstraZeneca vaccine, JCVI does not advise re-vaccination.

Pregnant women

The serious risks posed to women who become infected with the SARS-CoV-2 virus during pregnancy have becoming increasingly clear as the COVID-19 pandemic has progressed and data from recent studies has shown that clinical outcomes following COVID-19 in pregnant women have worsened over the course of the pandemic as the variant has changed.

There is an increased risk of hospitalisation, admission to an intensive care unit, invasive ventilation and extracorporeal membrane oxygenation in comparison to non-pregnant women of reproductive age, as well as an increased risk of stillbirth and preterm birth.

In December 2021, the [JCVI announced](#) that pregnant women should be considered a clinical risk group within the COVID-19 vaccination programme. Studies following the use of the COVID-19 vaccines in pregnant women have shown the vaccines to be safe and highly effective in preventing serious complications.

[Analysis by the UKHSA](#) looked at women who gave birth up to August 2021 and reassuringly found that there were similar rates of still birth, prematurity and low birth weight in vaccinated and unvaccinated women. It also found that pregnant women who are vaccinated are far more protected against serious COVID-19 than those who are unvaccinated.

There is no known risk associated with giving non-live vaccines during pregnancy. Since these vaccines cannot replicate, they cannot cause infection in either the woman or the unborn child.

There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines being given to pregnant women in the USA, with no safety signals being raised so far. Over 100,000 pregnant women have been vaccinated in England, Scotland and Wales. Because of more extensive experience with the Pfizer BioNTech and Moderna vaccines in pregnancy, these 2 vaccines are the preferred vaccines to offer to pregnant women aged 18 years and over. Pregnant women under 18 years of age should be offered the Pfizer BioNTech vaccine as that is the vaccine currently recommended for this age group. Pregnant women who

have already received a dose of AstraZeneca vaccine can complete with the same vaccine or with an mRNA vaccine (provided there are no contraindications to either).

Routine questioning about last menstrual period and or pregnancy testing is not required before offering COVID-19 vaccine. Women who are planning pregnancy or in the immediate postpartum can be vaccinated with a suitable product for their age and risk status.

If a woman finds out she is pregnant after she has started a course of COVID-19 vaccine, she should complete vaccination during pregnancy at the recommended intervals.

Further information about [the safety of COVID-19 vaccines when given in pregnancy](#) is available. Both the [Royal College of Obstetricians and Gynaecologists](#) and the [Royal College of Midwives](#) websites provide useful information and guidance about the COVID-19 vaccine.

Breastfeeding

There is no known risk associated with giving non-live vaccines whilst breastfeeding. [JCVI](#) advises that breastfeeding women should be offered vaccination with any suitable COVID-19 vaccine.

Emerging safety data is reassuring: [mRNA was not detected in the breast milk of recently vaccinated women](#) and [protective antibodies have been detected in breast milk](#).

The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19.

Children and young people

Children aged 5 to 11 years in at risk groups

On 22 December 2021, the [JCVI](#) recommended that children aged 5 to 11 years in the following 2 groups should be offered two 10 microgram doses of the Pfizer BioNTech Comirnaty vaccine with an interval of 8 weeks between the first and second doses. The groups are:

- children in a recognised clinical risk group who are at higher risk of severe COVID-19 (as defined in Table 4 of the [Green Book COVID-19 chapter](#)) – this includes children who are about to commence immunosuppressive treatment.
- children who are a household contact of someone who is immunosuppressed (defined as those who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals of any age who are immunosuppressed).

Eligible children aged 5 to 11 years should receive the Pfizer-BioNTech Comirnaty 10 micrograms/dose COVID-19 vaccine formulated for use in this age group.

Children aged 5 to 11 years not in an at-risk group

In February 2022, the [JCVI advised](#) a one-off, non-urgent programme to offer vaccination to all children aged five to 11 years of age who are not in a clinical risk group. This offer is intended to increase and broaden protection against severe COVID-19 in advance of a potential future wave of COVID-19.

Two doses of the Comirnaty 10 micrograms/dose vaccine should be offered to children age 5 to 11 years not in a risk group with an interval of at least 12 weeks between doses.

This one-off programme applies to those currently aged 5 to 11 years and children will continue to become eligible as they turn five years of age until the end of August 2022.

Aged 12 to 17 years not in an at-risk group

Aged 12 to 15 years

On 13 September 2021, the [Chief Medical Officers recommended a first dose of COVID-19 vaccination](#) for children aged 12-15 to reduce the chances of them catching COVID-19, reduce the number of outbreaks in schools, help avoid school absences and disruption to face-to-face education.

On 29 November 2021, the [JCVI recommended](#) that all young people in this age group be offered a second dose 12 weeks from the first dose.

Aged 16 to 17 years

On 4 August, the [JCVI recommended](#) that all 16 to 17 year olds should be offered a first dose of the Pfizer BioNTech vaccine. This was followed by a [further JCVI recommendation](#) on 15 November 2021 that those in this age group who are not in an at-risk group should be offered a second dose after an interval of 12 weeks.

On 22 December 2021, the [JCVI advised](#) that young people aged 16 to 17 years should be offered a booster dose of the Pfizer BioNTech COVID-19 vaccine at least 3 months from their last primary dose.

Interval between doses for 12 to 17 year olds not in at at-risk group

For 12 to 17 year olds not in an at-risk group, a 12 week interval between doses is preferred. This interval reflects the strong evidence of high levels of protection against severe disease from the first dose.

Emerging evidence also suggests that countries with longer schedules (8 to 12 weeks) may have a lower rate of myocarditis after the second dose. Although this latter evidence is limited, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis

Young people aged 12 to 17 years at higher risk

Young people aged 12 to 17 years with underlying conditions that put them at increased risk of complications from COVID-19 are recommended to receive 2 doses of vaccine 8 weeks apart, as are young people in this age group who are household contacts of immunosuppressed individuals or who work in health and social care.

- 1) Children and young people aged 12 years and over with specific underlying health conditions that put them at risk of serious COVID-19

Full details of the conditions included are listed in Table 4 in the [Green Book COVID-19 chapter](#)

- 2) Children and young people aged 12 years and over who are household contacts of immunosuppressed individuals

Those aged 12 years and above who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals of any age who are immunosuppressed.

On 22 December 2021, the [JCVI advised](#) that a booster dose of the Pfizer BioNTech COVID-19 vaccine should be offered to children and young people aged from 12 years in both of the above risk groups, at least 3 months from their last primary dose. Children in high risk groups who received primary vaccination as part of the 5 to 11 year cohort will be eligible for a booster dose when they turn 12 years of age.

Summary table of COVID-19 vaccine recommendations for children and young people aged 5 to 17 years

Group	Recommendation
Children aged 5 to 11 with specific underlying health conditions that put them at risk of severe COVID-19 or who are household contacts of an immunosuppressed person	<p>Offer two 10 microgram doses of the Pfizer BioNTech Comirnaty 10 micrograms/dose vaccine with an interval of 8 weeks between doses</p> <p>Offer a third primary dose to those who had severe immunosuppression at or around the time of their first or second primary COVID-19 vaccine doses at least 8 weeks after second dose</p>
Children aged 12 to 15 with specific underlying health conditions that put them at risk of severe COVID-19	Offer two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 micrograms/dose vaccine with an interval of 8 weeks between doses

	Offer a booster dose at least 3 months after completion of primary course
Children and young people aged 12 years and over who are severely immunosuppressed	<p>Offer two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 micrograms/dose vaccine with an interval of 8 weeks between doses</p> <p>Offer a third primary dose at least 8 weeks after second dose to those who had severe immunosuppression at or around the time of their first or second primary COVID-19 vaccine doses</p> <p>Offer a booster dose at least 3 months after completion of primary course</p>
Children and young people aged 12 and over who are household contacts of an immunosuppressed person	<p>Offer two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 micrograms/dose vaccine with an interval of 8 weeks between doses</p> <p>Offer a booster dose at least 3 months after completion of primary course</p>
Young people aged 16 and 17 in a clinical risk group or who work in health and social care	<p>Offer two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 micrograms/dose vaccine with an interval of 8 weeks between doses</p> <p>Offer a booster dose at least 3 months after completion of primary course</p>
All other children aged 5 to 11 not in an at risk group	Offer two 10 microgram doses of the Pfizer BioNTech Comirnaty 10 micrograms/dose vaccine with an interval of 12 weeks between doses
All other young people aged 12 to 15 not in an at risk group	Offer two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 micrograms/dose vaccine with an interval of 12 weeks between doses
All other young people aged 16 and 17 not in an at risk group	<p>Offer two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 micrograms/dose vaccine with an interval of 12 weeks between doses</p> <p>Offer a booster dose at least 3 months after completion of primary course</p>

Vaccine to give children and young people

Currently, the Pfizer BioNTech vaccines are the only vaccines recommended to be given to children and young people less than 18 years of age. Although the Moderna vaccine is also approved in children from 12 years, the Pfizer BioNTech vaccines are currently preferred due to a lower reported rate of myocarditis. The Pfizer BioNTech Comirnaty 30 micrograms/dose vaccine should be given to eligible children and young people from 12 years. The Pfizer BioNTech Comirnaty 10 micrograms/dose vaccine should be given to eligible children aged 5 to 11 years.

It is not recommended that the Comirnaty 30 micrograms/dose vaccine licensed for adults and adolescents from 12 years of age is used for children under 12 years other than in exceptional circumstances – for example where the Comirnaty 10 micrograms/dose vaccine is not available when protection is required rapidly. In this situation, 10 micrograms (0.1ml) of the Comirnaty 30 micrograms/dose vaccine may be used as an alternative. However, the use of a fractional dose of the Comirnaty 30 micrograms/dose vaccine would be off-label and healthcare providers need to have the necessary skills to deliver such fractional doses, with appropriate guidance, training and systems in place to support vaccine delivery. An appropriate legal mechanism would also need to be in place as a fractional dose could not be given using a Patient Group Direction or National Protocol.

Children aged 5 to 11 years who are given a fractional dose of the 30 micrograms/dose vaccine may complete their primary course with the 10 micrograms/dose vaccine formulation or vice versa.

Children aged 5 to 11 years who commence immunisation with the 10 microgram dose of the Pfizer BioNTech Comirnaty vaccine and then turn 12 years of age should complete vaccination with the 10 microgram dose. The 30 microgram adult or adolescent dose is an acceptable alternative if this is the only vaccine available.

In the USA, the safety experience with the Comirnaty 10 micrograms/dose vaccine suggests a lower rate of reactions in older children than after the adult dose, with a very low rate of reported myocarditis (1 to 2 cases per million doses). JCVI have therefore advised that the 10 microgram dose of vaccine is preferred for those aged 12 years when they are vaccinated with those aged 11 years in the same academic year (year 7 in England and Wales). Using the same vaccine dose for pupils in the same academic year should help simplify any school-based immunisations and increase overall safety. Children aged 12 years of age who have commenced vaccination with the 30 microgram dose who are being vaccinated alongside their peers from the same academic year may complete with the 10 microgram dose.

Young people aged 16 and 17 years who have already received a first dose of AstraZeneca vaccine can complete with the same vaccine or with an mRNA vaccine (provided there are no contraindications to either).

Vaccination of children and young people who have recently had SARS-CoV-2 infection

In children and young people under 18 years who are not in high risk groups, it is recommended that vaccination is deferred for 12 weeks from onset (or sample date) of SARS-CoV-2 infection. This is because, in this age group, protection from serious complications of COVID-19 infection is likely to be high for a period of months. Limited evidence suggests that countries with longer intervals between primary doses (8 to 12 weeks) may have a lower rate of myocarditis after the second dose. Based on extrapolation from this limited evidence, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis.

This 12 week recommendation includes children and young people who developed Paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 infection (PIMS-TS) – see section on [Vaccination of individuals with a current or previous history of COVID-19 disease](#) above.

It also applies to second doses for any individuals aged between 12 and 17 years not in an at-risk group who develop proven SARS-CoV-2 infection in the period between their first and second dose. For these individuals, the second dose of vaccine should be given 12 weeks following SARS-CoV-2 infection, or 12 weeks following the first vaccine dose, whichever is later.

This interval may be reduced to 8 weeks in healthy under 18 year olds during periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). Vaccinators will be informed when or if this interval should be reduced.

This 12 week recommendation does not apply to those aged 5 to 17 years in at-risk groups. These individuals should be offered COVID-19 vaccine if there has been a 4 week period following their positive test. This is because their individual risk of severe outcomes from COVID-19 is higher and so outweighs any potential benefit of delaying to 12 weeks. It also does not apply to those who are household contacts of immunosuppressed individuals or health and social care workers. Young people in these groups should also receive any vaccine doses due at a minimum interval of 4 weeks after a confirmed SARS-CoV-2 infection.

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, and so on. 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.

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 may 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 or 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 or treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or 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, 2021). The individual or 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.

The separate needles and syringes and the fixed-needle dose-sparing syringes being supplied for administration of the COVID-19 vaccines are suitable for use for vaccination of people with bleeding disorders or anticoagulation therapies.

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-19 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 limited evidence on response in immunosuppressed individuals there is also very little evidence upon which to base advice on the optimal timing of delivery. However, [one study](#) suggested immune responses were better in patients with cancer who received their chemotherapy at least 2 weeks earlier. 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-19 and the patient's likelihood of exposure.

The small number of patients (aged 5 years or above) who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least 2 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 (3 or 4 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.

As some individuals who are immunosuppressed due to underlying health conditions or medical treatment may not mount a full immune response to COVID-19 vaccination, [JCVI have recommended a third primary dose](#) for patients aged 5 years and over who were severely immunosuppressed at or around the time of their first or second primary COVID-19 vaccination.

Most individuals whose immunosuppression commenced at least 2 weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. Individuals who had received brief immunosuppression (≤ 40 mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. The specialist involved in the care of patients with immunosuppression should be involved in advising on the timing of a third dose.

If a third primary dose is required, ideally, it should be given at least 8 weeks after the second dose with special attention paid to the timing of any planned or current immunosuppressive therapy as vaccines administered during periods of minimum immunosuppression are more likely to generate better immune responses. Where possible the third dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum. [Advice for patients on chemotherapy](#) is available. The [general principles for the administration of a third dose](#) and the criteria for a third primary dose are described in the JCVI advice and the [Green Book COVID-19 chapter](#).

For those aged over 18 years, JCVI advises a preference for mRNA vaccines (a full dose of Pfizer BioNTech 30 micrograms/dose vaccine or a full dose of Moderna vaccine) for the third primary dose. The Pfizer BioNTech 30 micrograms/dose vaccine is preferred for 12 to 17 year olds and the Pfizer BioNTech 10 micrograms/dose vaccine for 5 to 11 year olds. AstraZeneca COVID-19 vaccine is an option for individuals aged 16 years and above who have received this vaccine previously where mRNA vaccines are clinically contraindicated. In exceptional circumstances, people aged 40 years or over who received a mRNA COVID-19 vaccine previously may be offered a third dose of AstraZeneca vaccine following a decision by a health professional on a case-by-case basis.

Those aged 12 years and above in this group will also require booster doses to extend protection from their primary course. Following the recognition of the Omicron variant, JCVI advised that a reinforcing (booster) dose should be offered from 3 months after the third primary dose. Those who have not yet received their third dose should be given their third dose immediately to avoid further delay (at least eight weeks after the second primary dose). A booster dose should then be given at least 3 months later, in line with the clinical advice on optimal timing in relation to the degree of immune suppression. As individuals in this group are also eligible for the Spring booster dose, a further booster should then be given during the spring campaign, provided there has been at least three months from the previous dose. Individuals who completed primary vaccination later, and so received their first booster (fourth dose) during the spring campaign, do not need an additional spring dose but are expected to next become eligible during the autumn booster campaign.

Although eligible for a third primary dose, advice on booster doses for children aged 5 to 11 years in this group is still under review by JCVI.

Individuals aged 5 years and over who are household contacts of immunosuppressed patients of any age should be offered COVID-19 vaccination to reduce the risks of exposure.

Information about post-vaccination antibody testing of individuals with severe immunosuppression is provided in the [Green Book COVID-19 chapter](#).

Period of observation following immunisation with COVID-19 vaccine

Following COVID-19 vaccine administration, vaccinated 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) and exiting the vaccination centre. They, or their carers, should also be informed where they can obtain further advice if they require it following vaccination.

According to the Summaries of Product Characteristics, it is recommended that all recipients of the Pfizer BioNTech and Moderna vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the [UK Chief Medical Officers](#) have recommended suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines.

The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination. Reporting of adverse events via the [Yellow Card Scheme](#) is strongly encouraged.

Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. A patient information leaflet [Waiting after your COVID-19 vaccination](#) is available to inform vaccinees about these. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.

Patients with a personal history of allergy will require a period of observation following vaccination (either 15 or 30 minutes depending on their clinical history). These individuals should be managed as described in table 5 of the [Green Book COVID-19 chapter](#). No specific management is required for patients with a family history of allergies.

There is no routine requirement for observation following the AstraZeneca vaccine. However, as fainting can occur following vaccination, all those vaccinated with any 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, vaccine recipients should be given information about possible reactions to the vaccine (see adverse reactions section below), how to treat these, and when and from whom to seek further advice if required. Vaccinators should ensure

they are familiar with the content of the latest version of the [What to expect after your COVID-19 vaccination](#) leaflet given to adult vaccine recipients (or [Information for children and young people on what to expect after COVID-19 vaccination](#) for children aged 12 years and over and [What to expect after your child's COVID-19 vaccination](#) for eligible at risk children aged 5 to 11 years).

Thrombosis with thrombocytopenia syndrome

A rare condition involving serious thromboembolic events accompanied by thrombocytopenia, has been reported after vaccination with the AstraZeneca COVID-19 vaccine. Vaccinated individuals should be advised to seek immediate medical attention if they develop new symptoms from around 4 days to 4 weeks after vaccination such as:

- new onset of severe headache, which is getting worse and does not respond to simple painkillers
- an unusual headache which seems worse when lying down or bending over, or may be accompanied by blurred vision, nausea and vomiting, difficulty with speech, weakness, drowsiness, confusion or seizures
- new onset of unexplained pinprick bruising or bleeding
- shortness of breath, chest pain, leg swelling or persistent abdominal pain

Further [information on blood clotting following COVID-19 vaccination](#) is available. This specific type of blood clot with low platelets is extremely rare and the MHRA continue to review all reported cases. All suspected cases should be reported using the [COVID-19 yellow card scheme](#) and to the [UKHSA clinical reporting system](#).

Myocarditis and pericarditis

Cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the pericardium) have been reported in people who have received COVID-19 vaccine. The reported rate appears to be highest in those under 25 years of age and in males, and after the second dose. Onset is within a few days of vaccination and most cases are mild, recovering within a short time following standard treatment and rest without any sequelae.

Vaccinated individuals should be advised to seek immediate medical attention if they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias.

As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, the current advice is that an individual's second or subsequent doses should be deferred pending further investigation and careful consideration of the risks and benefits. Details of antibody testing and how to proceed with further doses is described in the [Green Book COVID-19 chapter](#).

Further detailed information for healthcare professionals on [myocarditis and pericarditis following COVID-19 vaccination](#) is also available.

Guillain-Barré syndrome (GBS)

Very rare reports have been received of Guillain-Barré syndrome (GBS) following COVID-19 vaccination, so healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis, in order to initiate adequate supportive care and treatment and to rule out other causes.

[Guillain-Barré syndrome](#) is a very rare and serious condition that affects the nerves. It mainly affects the feet, hands and limbs, causing problems such as numbness, weakness and pain. In severe cases, GBS can cause difficulty moving, walking, breathing and or swallowing.

Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. Cases of GBS that occur following vaccination may occur by chance (the background rate of GBS is 2 per 100 000 per year in the population) and no causal mechanism with vaccination has been proven. There is evidence to suggest that having had a prior diagnosis of GBS does not predispose an individual to further episodes of GBS when immunised with other vaccines and for the Pfizer BioNTech COVID-19 vaccine. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within 6 weeks of an AstraZeneca vaccine, the Pfizer BioNTech or Moderna mRNA COVID-19 vaccines are preferred for any future doses. Where GBS occurs following either of the mRNA vaccines (Pfizer BioNTech or Moderna), further vaccination can proceed as normal, once recovered.

[Further information on GBS following COVID-19 vaccination](#) is available.

Immune thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) is a condition where the immune system does not function correctly and attacks and destroys platelets in the blood. Platelets help the blood to clot so this can lead to bruising and bleeding.

There is now emerging evidence of a small risk of ITP or ITP relapse following COVID-19 vaccination. To date, this has been reported extremely rarely and the [MHRA Yellow card summary](#) states that this is usually short-lived and of minor severity. In approximately 10 to 20% of the reports, patients had a history of ITP or an underlying condition known to be associated with ITP. Previous ITP is not a contraindication for vaccination but guidance produced by the UK ITP Forum Working Party advises discussing the potential for a fall in platelet count in patients with a history of ITP receiving any COVID-19 vaccine and recommends a platelet count check 2 to 5 days after vaccination ([British Society for Haematology COVID-19 updates](#)). Individuals who experience ITP in the four weeks after the first dose of AstraZeneca vaccine should be assessed by a haematologist and the risk benefit of further vaccination and with which product should be considered on an individual basis. If receiving further vaccination, the platelet count should be monitored.

Additional advice for vaccine recipients

Vaccine recipients should also be advised that it may take a few weeks for protection from their COVID-19 vaccination to develop and that they should continue to follow advice current at the time regarding social distancing, wearing a face mask and washing their hands thoroughly and frequently.

Vaccinees should also be advised to follow the current advice on testing and self-isolation if they develop any coronavirus symptoms. 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 polymerase chain reaction (PCR) test detects different genes of the virus than the one included in the vaccine.

As no vaccine is completely effective, some people may still become infected with coronavirus despite having been vaccinated (although this should be less severe). The vaccine cannot cause COVID-19 infection.

COVID-19 vaccine clinical trial participants

Individuals who are enrolled on, or have participated in a clinical trial of either primary or booster COVID-19 vaccine should be provided with written advice by the trial investigators as to whether and when any additional doses are required. Many of these individuals have already received the appropriate number of primary doses of a COVID-19 vaccine that has now been approved, or of another vaccine with proven efficacy and should therefore have equivalent levels of protection to those vaccinated routinely. People who have received a full course of an effective COVID-19 vaccine as part of a clinical trial should be offered a booster dose at least 3 months after their second primary COVID-19 vaccine. For those for whom additional primary doses are recommended by the trial investigators, boosters should be scheduled to be given at least 3 months after the final additional dose.

Whilst the UK recognises those who are in COVID-19 vaccine clinical trials as fully vaccinated for the purpose of certification, both domestic and international, many other countries currently require visitors to have been fully vaccinated with a vaccine that has been approved for deployment by the relevant medicines regulator. For this reason, to ensure they can travel abroad to countries which do not currently recognise trial vaccinations, clinical trial participants can now be offered 2 additional doses of an approved vaccine if they wish to receive them. Further information is available from the [participant's clinical trials team](#).

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 Pfizer BioNTech vaccine 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 (> 40%), 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 (for example paracetamol-containing products) may be used.

The types of reactions reported in adolescents aged 12 to 15 years who received the Pfizer BioNTech vaccine in clinical trials were the same as those reported in older individuals but they were reported slightly more frequently: injection site pain (> 90%), fatigue and headache (> 70%), muscle aches and chills (> 40%), joint pain and raised temperature (> 20%).

Compared to adults and older children, children aged 5 to 11 years in the clinical trials reported more injection-site redness (15-19% vs 5-7%) and local swelling (10-15% vs 5-8%), but less fever (3-7% vs 1-20%) and less chills (5-10% vs 6-42%). Children aged 5 to 11 years were just as likely as 12 to 15 year olds to experience swelling of local lymph glands (0.9% vs 0.8%).

More than 60% of AstraZeneca COVID-19 vaccine 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 AstraZeneca COVID-19 vaccine 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. Prophylactic use of paracetamol was found [not to affect the immune response](#) to this vaccine.

The most frequently reported adverse reactions to the Moderna COVID-19 vaccine were injection site pain (92%), fatigue (70%), headache (65%), myalgia (62%), arthralgia (46%) chills (46%), nausea or vomiting (23%), axillary swelling or tenderness (19.8%), fever (15.5%), injection site swelling (14.7%) and redness (10%). Adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. Older vaccinees experienced a slightly lower frequency of reactions. Overall, there was a higher incidence of some adverse reactions in younger age groups: the incidence of axillary swelling or tenderness, fatigue, headache, myalgia, arthralgia, chills, nausea or vomiting and fever was higher in adults aged 18 to < 65 years than in those aged 65 years and above. Local and systemic adverse reactions were more frequently reported after the second dose than after the first dose. If required, [symptomatic treatment with analgesic and or anti-pyretic medicinal products](#) (for example, paracetamol-containing products) may be used.

In clinical trials, booster doses of all 3 vaccines (Comirnaty 10 micrograms/dose not included) led to short term local and systemic reactions, similar to those seen after the primary course, including local pain, fatigue, headache and muscle pain. Rates of reactions were higher in

people who received a different vaccine for their booster (heterologous booster) than in those who received the same vaccine (homologous booster) and in those aged under 70 years when compared to older recipients.

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](#) (or call 0800 731 6789). Both vaccine recipients and healthcare providers can report any possible adverse reactions observed with these vaccines using the Yellow Card scheme. As new vaccine products, the MHRA have a specific interest in the reporting of adverse drug reactions for 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.

A [weekly summary of yellow card reporting](#) is published by MHRA which includes details of yellow card reports following the receipt of the UK-approved COVID-19 vaccines and analysis of the data.

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 1 to 2 days without treatment but analgesics and or anti-pyretics can be given if necessary to relieve any of these symptoms.

If someone experiences any of the initial key symptoms associated with COVID-19 infection (a high temperature, a new, continuous cough, or a loss or change to sense of smell or taste), or any other symptoms that make them think they might have COVID-19, 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

Relative contraindications to receiving a COVID-19 vaccine are:

- individuals who have had a previous systemic anaphylaxis reaction to a COVID-19 vaccine
- individuals with a prior allergic reaction to any component (excipient) of the COVID-19 vaccine, for example polyethylene glycol

The [Green Book COVID-19 chapter](#) provides full details about the contraindications and precautions to COVID-19 vaccine. Everyone involved in the COVID-19 vaccination programme should ensure they have read the latest online version of this Green Book chapter so that they are familiar with all the contraindications and precautions to the COVID-19 vaccines. 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.

Thrombosis and thrombocytopenia syndrome (TTS)

Following widespread use of the AstraZeneca COVID-19 vaccine, a rare condition involving serious thromboembolic events accompanied by thrombocytopenia, has been reported after receipt of this vaccine. The condition presents with unusual venous thrombosis, including cerebral venous sinus thrombosis, portal vein thrombosis, and sometimes arterial thrombosis, with low platelet count and high D-dimer measurements. The condition has similarities to heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) and patients usually have positive antibody to platelet factor 4. The majority of the events have occurred between [5 and 16 days](#) following vaccination.

The current reported rate of this event in the UK is around 15.5 cases per million after the first dose, although a higher incidence is seen in younger individuals (21.1 per million doses in those aged 18 to 49 years compared to 11.1 per million doses in those aged 50 years and over). After the second dose the reported rate is much lower, particularly in younger individuals (1.0 per million doses in those aged 18 to 49 years compared to 2.1 per million doses in those aged 50 years and over).

Individuals who experience a clotting episode with concomitant thrombocytopenia following the first dose of AstraZeneca vaccine should be properly assessed. If they are considered to have the reported condition, further vaccination should be deferred until their clotting has completely stabilised. Current evidence supports a decision to complete the primary course or boost patients with a history of TTS with an mRNA vaccine, provided at least 12 weeks has elapsed from the implicated dose.

Individuals who have received the first dose of AstraZeneca vaccine without developing this rare condition are advised to receive the second dose of the same vaccine at the currently recommended interval. To date, there is no signal of an increased risk of this condition after the

second dose and the rate of other reactions is lower at the second dose than after the first dose of this vaccine. Using an alternative product for the second dose is more likely to lead to common side effects.

Caution should also be used when vaccinating individuals who have a history of a previous episode of heparin induced thrombocytopenia and thrombosis (HITT or HIT type 2). The [Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca](#) advises that, as a precautionary measure, administration of the AstraZeneca vaccine in patients with a history of HITT or HIT type 2 should only be considered when the benefit outweighs any potential risks.

The contraindications and precautions to the AstraZeneca vaccine, including the age group recommendations for this vaccine, are detailed in the [COVID-19 chapter of the Green Book](#). Further detailed information is also available in the [Information for healthcare professionals on blood clotting following COVID-19 vaccination](#) document and a [COVID-19 vaccination and blood clotting](#) leaflet is available for patients. A [JCVI statement on the use of the AstraZeneca COVID-19 vaccine](#) has also been published.

Capillary Leak Syndrome

A small number of cases of capillary leak syndrome have been reported following vaccination with the AstraZeneca vaccine (16 reports in the context of more than 49 million doses given). 3 of those affected had a history of capillary leak syndrome.

Capillary leak syndrome causes fluid and proteins to leak out of the capillaries into surrounding tissues. This may lead to very low blood pressure, low blood albumin levels and thickened blood due to a decrease in plasma volume. Initial symptoms may include tiredness, nausea, abdominal pain, extreme thirst and sudden increase in body weight. Complications can include general swelling, compartment syndrome, kidney failure and stroke.

Individuals with a history of capillary leak syndrome should be carefully counselled about the risks and benefits of vaccination and may be offered an alternative COVID-19 vaccine (that is an mRNA vaccine instead of AstraZeneca).

Minor illness at time vaccination due

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

Although vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, people currently unwell and experiencing COVID-19 symptoms should not attend vaccination sessions to avoid infecting anyone else in the vaccination centre. As deterioration in some people with COVID-19 can occur up to 2 weeks after infection, ideally vaccination of adults and high risk children should be deferred until they have recovered to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive test in those who are asymptomatic to avoid confusing the differential diagnosis. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection. The four week interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Currently, the JCVI consider that, in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. These populations are likely to be highly vulnerable and will facilitate vaccination without the need for multiple visits.

In younger people, after natural infection or a single dose of vaccine, protection from serious complications of COVID-19 infection is likely to be high for a period of months. Limited evidence suggests that countries with longer intervals between primary doses (eight to twelve weeks) may have a lower rate of myocarditis after the second dose. Based on extrapolation from this limited evidence, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis. Therefore vaccination should ideally be deferred until twelve weeks from onset (or sample date) in children and young people under 18 years who are not in high risk groups. This interval may be reduced to eight weeks in healthy under 18 year olds when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Current advice in PIMS-TS cases also suggests that an interval of 12 weeks should be observed, although earlier administration can be considered in those at high risk of infection and/or who are fully recovered. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection.

There is no convincing evidence 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-containing or flu vaccines) can receive these vaccines once they have recovered and have completed the required isolation period for COVID-19. If they fulfil these 2 conditions, they do not have to wait 28 days but the

parent or 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.

Recent vaccination with other vaccines such as MMR and Td/IPV-containing vaccines do not affect testing for COVID-19 infection. The lateral flow device (LFD) test looks to detect a protein of the SARS-CoV-2 virus and the polymerase chain reaction (PCR) test looks for genes from the SARS-CoV-2 virus.

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.

Treatments for COVID-19 disease (for example monoclonal antibody, steroids or antiviral medicines) and vaccine administration

Monoclonal antibody preparations containing specific man-made antibodies which bind to the surface of the SARS-CoV-2 virus and stop it from attaching to the body's cells and replicating further have recently been licensed for the treatment and prophylaxis of COVID-19 infection. Primate data suggests that administration of the AstraZeneca combination monoclonal antibody product did not interfere with the subsequent response to active vaccination. Based on this limited evidence, therefore, no specific interval is required between receipt of these products and COVID-19 vaccination, or vice versa. As the use of these products is likely to be prioritised to those who are less able to respond to vaccination, for example immunosuppressed individuals, additional doses of vaccine may be required (see section on [administration of COVID-19 vaccine to individuals who are immunosuppressed](#)).

Steroid treatments such as dexamethasone may be given to patients experiencing severe COVID-19 symptoms to suppress the immune response and reduce inflammation. As the currently authorised COVID-19 vaccines are non-live vaccines, the response to these vaccines should not be affected by short-term steroid treatment. In addition, by the time a person who has received steroid treatment for COVID-19 infection is well enough to receive a COVID-19 vaccination, the suppressant effect of the steroid treatment should be gone.

Antiviral medicines prevent further replication of viruses. As none of the currently authorised COVID-19 vaccines contain live replicating virus, response to COVID-19 vaccine will not be affected by prior or recent receipt of anti-viral medication.

Therefore, none of these treatments would contraindicate COVID-19 vaccine. However, it is recommended that following infection, ideally vaccination of adults and children aged 12 to 17 years should be deferred to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen in those who are asymptomatic and for 12 weeks for those under 18 years not in high risk groups (see section on [vaccination of individuals with a current or previous history of COVID-19 disease](#)).

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. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by giving COVID-19 vaccine at the same appointment.

As the Pfizer BioNTech, AstraZeneca and Moderna COVID-19 vaccines are considered inactivated, where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring 2 or more vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. This includes, but is not limited to, vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). The only exceptions to this are the shingles vaccines, where a 7 day interval should ideally be observed. This is based on the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in Zostavax in the older population and because of the potential difficulty of attributing systemic side effects to the newer inactivated adjuvanted shingles vaccine, Shingrix.

A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity.

Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by 1 or 2 days will avoid confusion over systemic side effects.

If more than one vaccine is given at the same time, they should preferably be given in different limbs. Where this is not possible, they should be given at least 2.5cm apart and the site at which each vaccine was given should be clearly documented in the patient's records.

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 or 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 '[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.

The UKHSA are developing and updating PGDs for the COVID-19 vaccines as they are authorised. See '[Protocols and patient group directions \(PGDs\)](#)'.

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 protocols](#) allow 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 vaccine, a description of the vaccine, 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 or contractor must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The service provider or 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.

See also: [The legal mechanisms available for giving COVID-19 vaccines and their application](#) on the Specialist Pharmacy Service website.

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

In a [Phase I/II study of COVID-19 mRNA vaccine BNT162b1 in adults](#), different strength doses of the Pfizer BioNTech vaccine were given. The trial showed that a stronger dose (100 micrograms instead of the recommended 30 microgram dose) was not harmful but 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. The Moderna vaccine has also been given at higher dose levels in [clinical trials](#) than the dose recommended in the UK vaccination programme.

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.

Any subsequent doses due should still be given as per the recommended schedule.

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 risk assessment should be carried out to determine whether it is necessary to repeat the dose. Trial data for the Pfizer BioNTech and Moderna vaccines showed a good immune response was made to a lower dose of the vaccine than the recommended authorised dose, particularly in younger age groups and as a booster. For Pfizer, a third of the adult dose was as immunogenic in children aged 5 to 11 years as a full adult dose in those aged 16 to 25 years. A half dose of Pfizer vaccine also produced a similar antibody boost as a full dose when used as a booster in adults from a broad age range who had been primed with either AstraZeneca or Pfizer. For this reason, if at least half of the full dose of an mRNA vaccine was administered, the immune response to a primary dose in healthy younger people or to a booster in any age group would be considered adequate except for those with immunosuppression (as defined in the [Green Book COVID-19 chapter](#)).

Where the volume administered is thought to be less than a half dose of Pfizer or Moderna or in older individuals or those at higher risk, then a risk assessment should be undertaken. The risk assessment should consider how much of the dose it is estimated was given and the individual's age, whether they are immunosuppressed or have an underlying clinical risk condition, whether they have previously had confirmed COVID-19 infection and whether this is the first, second or booster dose. This risk assessment is recommended because of the increased reactogenicity and the risk of myocarditis and pericarditis following mRNA vaccination, notably in younger age groups, which should be weighed against the risk of a lower immune response to the vaccine.

Where the risk of under-dosing is considered substantial, it is recommended that a full additional recommended dose should be given immediately. If the error is only realised after the individual leaves the vaccination clinic, it is recommended that the repeat dose should be offered from 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, a further risk assessment will be required to decide on the optimal timing for a repeat dose, considering the individual risk and epidemiological context.

If the dose is repeated, the recipient should be advised of possible side effects and if this was the first primary dose, the 'second' dose of the 2 dose primary schedule (which will actually be the third dose in this case) should still be given at the recommended interval from the additional dose. If this was the second primary dose, the booster dose should still be given at the recommended interval (at least 3 months) from the additional dose.

Inadvertent administration of 10 microgram dose of Pfizer BioNTech vaccine instead of the recommended 30 microgram dose to those 12 years and over

If a young person aged 12 to 15 years is inadvertently given a 10 microgram dose of the Pfizer BioNTech vaccine instead of the recommended 30 microgram dose, this dose can still be counted as a valid dose and does not need to be repeated.

If this was the first dose, children aged 12 years should complete their primary vaccination course with the 10 microgram dose (although the 30 microgram dose is an acceptable alternative if this is the only vaccine available). Those aged 13 to 15 years should be given the 30 microgram dose for their second dose.

Please note that JCVI have advised that those aged 12 years may commence or complete with a 10 microgram dose to align with their peers in the same academic year (where those aged 12 years are being vaccinated alongside those aged 11 years in a school-based COVID-19 vaccination programme).

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, a further risk assessment will be required to decide on the optimal timing for a repeat dose, considering the individual risk and epidemiological context.

If a repeat dose is given, the recipient should be advised of possible side effects and if this was the first primary dose, the 'second' dose of the 2 dose primary schedule (which will actually be the third dose in this case) should still be given at the recommended interval from the additional dose. If this was the second primary dose, the booster dose should still be given at the recommended interval (at least 3 months) from the additional dose.

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

The diluent for the Pfizer BioNTech vaccines 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 properly reconstituted dose as soon as the error is realised.

Inadvertent administration of over-diluted vaccine

As the amount of active content in a dose of over-diluted vaccine will be less, it is recommended that a risk assessment is carried out to establish what the likely concentration of the vaccine given was and the individual's age, whether they are immunosuppressed or have an underlying clinical risk condition, whether they have previously had confirmed COVID-19 infection and whether this is the first, second or booster dose.

If the vaccine has been significantly over-diluted, the dose should be repeated as soon as the error is realised using a correctly reconstituted vaccine (or from 48 hours later if not repeated on the same day).

COVID-19 vaccine given to a young person less than 12 weeks after COVID-19 infection

Young people aged 12 to 17 years who have inadvertently received a COVID-19 vaccine less than 12 weeks after having COVID-19 infection can be reassured that they will produce an

adequate immune response to the vaccine. They should be made aware that they may be more likely to have side effects after receiving the vaccine. Most side effects are mild, start within hours of vaccination and resolve within a few days. Paracetamol can be used to manage symptoms.

Second dose inadvertently given at less than the minimum recommended interval

If the second dose of either of the Pfizer BioNTech vaccines are 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 or Moderna 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 the vaccine is inadvertently or unavoidably delayed beyond the recommended interval, for example because an individual is unable to attend their vaccination appointment, it is likely that their response to this second dose and their longer term protection will not be adversely affected.

[Data from clinical trials](#) shows that the efficacy of the AstraZeneca vaccine was higher when the second dose was given at, or after 12 weeks, and a [study](#) of people aged over 80 years found that extending the second dose interval to 12 weeks for the Pfizer BioNTech vaccine markedly increased the peak spike-specific antibody response by 3 and a half times compared to those who had their second vaccine at 3 weeks.

If an interval longer than that recommended is left between doses, there is no need to restart the course and the second dose should be given as soon as it can be arranged (preferably using the same vaccine to complete the course if no contraindications). Individuals should be encouraged to receive their second dose on time as this will significantly boost their protection and prevent further hospitalisations and deaths. Timely administration of the second dose is especially important when COVID-19 community infection rates are high or increasing, although deferral after COVID-19 infection is advised (see [Vaccination of individuals with a current or previous history of COVID-19 disease](#) above).

Different COVID-19 vaccine inadvertently given for second primary dose than was given for first dose at correct interval

Evidence from trials suggest that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines, make a good immune response, although rates of side effects at the second dose are higher. Reactogenicity and safety data from the [Com-COV clinical trial](#) showed that mixed schedule recipients were more likely to experience feverishness, chills, fatigue, headache, joint pain, malaise, and muscle ache. Therefore, if an individual is inadvertently given a different vaccine for their second dose than for their first dose, they should be informed that they may experience more side effects than they did following their first dose but that a further dose is not required.

Inadvertent administration of a different COVID-19 vaccine at a short interval after the first dose

If a dose of a different COVID-19 vaccine is inadvertently given a few days after the first dose was given, the person should be offered a third dose of vaccine at the currently recommended interval for second doses (8 weeks from when the second dose was given).

If different COVID-19 vaccines are given a minimum of 21 days apart, these doses should be counted as a completed course and no further doses are needed.

Half dose of Moderna vaccine given as third dose to an immunosuppressed individual in error

It is recommended that individuals who were immunosuppressed at or around the time they received their first or second primary dose should be offered a third primary dose of vaccine at least 8 weeks after their second dose and that, preferably, the Pfizer BioNTech vaccine or a full dose of the Moderna vaccine should be given for this third dose. However, if a half dose of Moderna vaccine is inadvertently given to an immunosuppressed individual in error, the dose does not need to be repeated as it is expected that a half dose will still produce a good immune response and is expected to be equivalent to that of a full dose of Pfizer. A study by [Choi et al](#) using a half dose of Moderna (50 micrograms) in those who had received a primary course of Moderna (100 micrograms) showed good immunogenicity and a rate of reactions similar to the second dose of Moderna.

Moderna vaccine given in error to child or young person under 18 years

Although the Moderna Spikevax vaccine has been approved for use in children from 12 years of age, the Pfizer BioNTech Comirnaty vaccine is currently preferred due to a lower reported rate of myocarditis.

If a child or young person under 18 years of age receives a dose of Moderna vaccine in error, they should complete the course with the Pfizer BioNTech vaccine.

Administration of a booster dose less than 3 months after the second dose

The JCVI recommend that booster vaccination should not be given within 3 months of completion of the primary course.

Where the booster dose is inadvertently given earlier than 3 months (12 weeks) from the final primary dose, it should not be counted as a valid booster dose and a further booster dose should be scheduled around 3 months from the dose inadvertently given early.

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. See also NHS E&I [Management of COVID-19 vaccination clinical incidents and enquiries SOP](#).

COVID-19 vaccine inadvertently administered to a pregnant woman should be reported to the [UKHSA Immunisation and Vaccine Preventable Disease Division](#).

Useful links

British Society of Immunology. [A guide to vaccinations for COVID-19](#) and [other useful coronavirus resources](#).

[GOV.UK Coronavirus \(COVID-19\) in the UK](#) The official UK government website for data and insights on coronavirus (COVID-19).

[Green Book COVID-19 chapter](#)

[Health Publications](#) website – to order COVID-19 vaccine programme leaflets, posters, record cards, stickers and also download BSL videos to support people who are deaf. You can also order braille, large print, translated resources in 19 languages and Easy read versions

[LSHTM COVID-19 vaccine tracker](#)

[MHRA weekly summary of Yellow Card reports](#)

[Product information for the COVID-19 mRNA Vaccine BNT162b2](#)

[Product information for the COVID-19 Vaccine AstraZeneca \(Vaxzevria\)](#)

[Product information for the COVID-19 Vaccine Moderna \(Spikevax\)](#)

Royal College of Nursing [COVID-19 vaccination page](#)

Royal College of Midwives [Guidance for maternity staff on COVID-19 vaccination](#)

Royal College of Obstetricians and Gynaecologists [COVID-19 vaccines, pregnancy and breastfeeding](#)

Specialist Pharmacy Services [COVID-19 Vaccines](#)

UKHSA [Coronavirus vaccination programme resources](#)

[Vaccine update: issue 315, December 2020, COVID-19 special edition and Vaccine update: issue 322, June 2021, COVID-19 phase 2 special edition](#)

[WHO COVID-19 Worldwide Dashboard](#)

Appendix 1. Vaccine interchangeability guidance

(For those over 18 years. See advice on page 17 for children under 18 years)

Vaccine manufacturer	Vaccine names (if applicable)	Type	Efficacy (whole course)*	Approval	Manufacturer's authorised schedule	UKHSA advice	UK alternative
AstraZeneca	Vaxzevria AZD1222	Recombinant adenovirus vector (ChAdOx) vs spike	80% ¹	MHRA EMA WHO	18yrs+, 2 doses, 4 to 12 weeks apart	If partial primary vaccination: <ul style="list-style-type: none"> complete course with same vaccine if possible (or closest alternate) with at least 8 week interval from previous dose if more than 8 weeks since first dose, complete course as soon as possible If complete primary course given less than 3 months ago: <ul style="list-style-type: none"> no further immediate vaccine 	Any suitable locally available alternative
Pfizer BioNTech	Comirnaty BNT162b2	mRNA vs spike	95% ²	MHRA EMA, FDA WHO	12yrs+, 2 doses, at least 3 weeks apart		Moderna**
Institute of India	Covishield	Identical to AstraZeneca	80%	WHO	18yrs+, 2 doses, 4 to 12 weeks apart		AstraZeneca
Moderna	Spikevax COVID-19 Vaccine mRNA-1273	mRNA vs spike	94.1% ³	MHRA EMA, FDA WHO	12yrs+**, 2 doses, 4 weeks apart		Pfizer
Novavax	Nuvaxovid NVX-CoV2373	Recombinant spike protein with novel adjuvant	89.7% ⁴	MHRA EMA WHO	18yrs+, 2 doses, 3 weeks apart		Any suitable locally

Vaccine manufacturer	Vaccine names (if applicable)	Type	Efficacy (whole course)*	Approval	Manufacturer's authorised schedule	UKHSA advice	UK alternative
	Covovax					needed unless severely immunosuppressed at or around time 1 st or 2 nd dose given in which case 3 rd primary dose should be given from 8 weeks after 2 nd dose Booster dose for both groups: <ul style="list-style-type: none"> enrol for booster in UK if eligible and give minimum 3 months after final primary dose 	available alternative
Janssen/ Johnson and Johnson	COVID-19 Vaccine Janssen JNJ-78436735 Ad26.COV2.S	Recombinant adenovirus (Ad26) vector vs spike	66.9% ⁵	MHRA EMA, FDA WHO	18yrs+, single dose		Not required as single dose schedule
Gamaleya National Centre of Epidemiology and Microbiology	Sputnik V Gam-COVID-Vac	Recombinant adenovirus (Ad26 and Ad5) vector vs spike	91.6% ⁶	-	18yrs+, 2 doses, 3 weeks apart		Any suitable locally available alternative
Bharat Biotech	Covaxin	Whole inactivated coronavirus	77.8% ⁷	WHO	2 doses, 4 weeks apart	Any suitable locally available alternative	

Vaccine manufacturer	Vaccine names (if applicable)	Type	Efficacy (whole course)*	Approval	Manufacturer's authorised schedule	UKHSA advice	UK alternative
Gamaleya National Centre of Epidemiology and Microbiology	Sputnik Light	Recombinant adenovirus (Ad26) vector vs spike	79.4% ⁸	-	18yrs+, single dose	If vaccinated with 1 dose: <ul style="list-style-type: none"> provide 1 dose of UK approved vaccine 8 weeks after previous dose enrol for booster in UK if eligible and give minimum 3 months after final primary dose If vaccinated with 2 doses and 2 nd dose was less than 3 months ago: <ul style="list-style-type: none"> provide 1 dose of UK approved vaccine 8 weeks after previous dose enrol for booster in UK if eligible and give minimum 3 months after final primary dose 	Any suitable locally available alternative
CanSino Biologics	Ad5-nCoV Convidecia	Recombinant adenovirus vector (Ad5) vs spike	65.7% ⁹	-	18yrs+, single dose		Any suitable locally available alternative
Sinopharm (Beijing)	COVID-19 vaccine BIBP BBIBP-CorV	Whole inactivated coronavirus	78.1% ¹⁰	WHO	18yrs+, 2 doses (3 in some cases), 3 to 4 weeks apart		Any suitable locally available alternative
Sinopharm (Wuhan)	WIBP-CorV	Whole inactivated coronavirus	72.8% ¹⁰	-	18yrs+, 2 doses 3 to 4 weeks apart		Any suitable locally available alternative
Sinovac Biotech	CoronaVac	Whole inactivated coronavirus	50 to 83.5% ¹¹	WHO	18yrs+, 2 doses, 2 to 4 weeks apart		Any suitable locally available alternative

Vaccine manufacturer	Vaccine names (if applicable)	Type	Efficacy (whole course)*	Approval	Manufacturer's authorised schedule	UKHSA advice	UK alternative
						<p>If vaccinated with 2 doses and 2nd dose was more than 3 months ago:</p> <ul style="list-style-type: none"> • give an additional dose of UK approved vaccine now. For those eligible for a booster, this will count as their booster dose and no further doses are currently recommended <p>If vaccinated with 3 primary doses:</p> <ul style="list-style-type: none"> • enrol for booster in UK if eligible and give minimum 3 months after final primary dose 	

*All trials use different criteria for what counts as an infection which can lead to variations in results for effectiveness so trials should not be compared. However, all vaccines will reduce hospitalisations and deaths. Effectiveness will also vary by country depending on virus strain circulating at the time.

**although authorised for use from 12 years, Moderna vaccine is not currently recommended for individuals under 18 years in the UK

If the vaccine received overseas is not listed in the table, a full course of the appropriate vaccine recommended for the individual in the UK (which may depend on their age) should be given.

References for table

- 1 [Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca \(Vaxzevria\)](#) 25 June 2021
- 2 [Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine](#) 4 June 2021
- 3 [Summary of Product Characteristics for COVID-19 Vaccine Moderna \(Spikevax\)](#) 19 April 2021
- 4 [Safety and Efficacy of NVX-CoV2373 COVID-19 Vaccine](#) New England Journal of Medicine 23 September 2021; 385:1172-1183
- 5 [Summary of Product Characteristics for COVID-19 Vaccine Janssen](#) 28 May 2021
- 6 [Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia](#) The Lancet 20 February 2021; 397(10275):671-681
- 7 [Efficacy, safety, and lot to lot immunogenicity of an inactivated SARS-CoV-2 vaccine \(BBV152\): a, double-blind, randomised, controlled phase 3 trial](#) 2 July 2021
- 8 [Russia authorises use of single-dose COVID-19 vaccine Sputnik Light](#) Pharmaceutical Technology 7 May 2021
- 9 [CanSinoBio's COVID-19 vaccine 65.7% effective in global trials, Pakistan official says](#) Reuters 8 February 2021
- 10 [Effect of 2 Inactivated SARS-CoV-2 Vaccines on Symptomatic COVID-19 Infection in Adults: A Randomized Clinical Trial](#). JAMA. 2021;326(1):35-45
- 11 [Interim recommendations for use of the inactivated COVID-19 vaccine, CoronaVac, developed by Sinovac](#) WHO 24 May 2021

Further information about the current approval or authorisation status of different COVID-19 vaccines available in other countries is available from the Regulatory Affairs Professionals Society (RAPS) [COVID-19 vaccine tracker](#).

Appendix 2. Storage and preparation of the COVID-19 Pfizer BioNTech Comirnaty 30 micrograms/dose vaccine

Vaccine composition

In addition to the highly purified messenger RNA (tozinameran), the Pfizer BioNTech (Comirnaty) COVID-19 vaccine 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
- sodium hydroxide (for pH-adjustment)
- hydrochloric acid (for pH-adjustment)

Vaccine presentation

The Pfizer BioNTech COVID-19 vaccine 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 the [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. Information leaflets for vaccine recipients will also be provided with each vaccine pack. Patient vaccination record cards should be ordered directly from the [Health Publications website](#).

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 -90°C to -60°C
- the vaccine should be kept upright, in its original packaging and away from prolonged light exposure
- shelf-life is 9 months at -90°C to -60°C

Thawing

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.

Frozen vials may be thawed at temperatures up to 30°C for 30 minutes for immediate use. They must not be kept at room temperature (up to 30°C) for any longer than 2 hours prior to dilution.

Once thawed, the vaccine should not be re-frozen.

Delivery in a thawed state

The Pfizer BioNTech COVID-19 30 micrograms/dose vaccine may 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 thawed, unopened, undiluted vaccine has a maximum shelf life of up to 1 month at +2 and +8°C
- the vaccine pack has a space on the label on the front which should state the expiry date on it
- 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 Pfizer BioNTech Comirnaty 30 micrograms/dose COVID-19 vaccine 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 equipment is required for reconstitution is:

- one Pfizer BioNTech Comirnaty 30 micrograms/dose COVID-19 vaccine multidose vial (purple cap)
- one plastic ampoule of Sodium Chloride 0.9% Solution for Injection – this will be supplied separately in multiple presentations (different manufacturers and different sized ampoules); it does not need to be kept in the fridge
- an alcohol swab, needle and syringe to reconstitute – combined needles and syringes are being supplied at the same time as the vaccine

Reconstituting the vaccine

- clean hands with alcohol-based gel or soap and water
- assemble 1 ampoule of Sodium Chloride 0.9% Solution for Injection, a single use alcohol swab, and the combined needle and syringe provided for dilution
- from cold storage, remove 1 vial of vaccine
- if removing the multidose vaccine vial directly from a ULT freezer, allow the vaccine to thaw as described above
- 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 1 month
- allow the vaccine to come to room temperature, then 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
- clean the vial stopper with the single use antiseptic swab and allow to air dry fully
- invert the ampoule containing the Sodium Chloride 0.9% Solution for Injection diluent and withdraw 1.8ml slowly to avoid formation of bubbles
- discard the diluent ampoule and any remaining diluent in it – do not use any other type of diluent
- add diluent slowly 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
- after the needle has been removed from the vial, dispose of the dilution needle and syringe into a yellow sharps bin
- 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
- the date and time of discard should be clearly recorded on the vial label

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

Reconstituted vaccine can be stored between 2°C and 30°C but must be used within 6 hours following dilution.

You can find out more about the [Comirnaty vaccine](#) and watch a video showing how to reconstitute and prepare the vaccine for use.

Vaccine dose preparation

- if the vaccine has previously been reconstituted, check that it is still within the 6 hour allowed time period from when it was reconstituted
- visually inspect the vaccine for appearance and particles each time a dose is drawn up
- clean top of vial with a single use antiseptic swab and allow to air dry fully
- unwrap one of the 1ml 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)
- insert the needle vertically into the centre ring of the vaccine vial stopper. Non-vertical insertion of the needle into the stopper can result in the needle scraping rubber off the inner wall of the small channel of the stopper
- do not twist or rotate the needle once inserted as this may cause a particle to be cored out of the stopper
- 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

The dose of Pfizer BioNTech Comirnaty 30 micrograms/dose COVID-19 vaccine for adults and eligible adolescents for the priming and booster doses is 0.3 ml.

The primary course consists of 2 doses with a minimum 21 day interval between doses (but see [COVID-19 vaccines schedule](#) section above).

The booster dose should be given to eligible individuals at least 3 months after the final primary dose.

Appendix 3. Storage and preparation of the AstraZeneca COVID-19 vaccine (Vaxzevria)

Vaccine composition

The AstraZeneca COVID-19 vaccine 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.

Presentation

COVID-19 Vaccine AstraZeneca 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).

AstraZeneca COVID-19 vaccine is delivered in packs that contain 10 vials.

2 different presentations of the AstraZeneca vaccine will be provided:

- 80 dose packs (10 4ml vials with at least 8 doses per vial)
- 100 dose packs (10 5ml 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 also be provided. 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 0.5ml dose cannot be extracted, the remaining contents should be discarded.

Ordering

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

Combined 1ml 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 should be ordered directly from the [Health Publications website](#).

Vaccinators are advised to [read the latest administration instructions in the product information](#).

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 1ml 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.

2 doses of AstraZeneca vaccine are required for the primary course with a minimum 28 day interval between doses (but see [COVID-19 vaccines schedule](#) above).

Appendix 4. Storage and preparation of the Moderna COVID-19 vaccine (Spikevax)

Vaccine composition

The Moderna COVID-19 vaccine (Spikevax) contains single-stranded RNA embedded in lipid nanoparticles.

It also contains:

- lipid SM-102
- cholesterol
- 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
- 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG)
- trometamol (Tris)
- trometamol hydrochloride (Tris HCl)
- acetic acid
- sodium acetate trihydrate
- sucrose
- water for injections

The vaccine does not contain preservative and it does not contain any animal products.

Presentation

The Moderna COVID-19 vaccine is presented in a multidose vial containing a solution which should be white to off-white and may contain white or translucent product-related particulates. It does not require reconstitution. The vial has a chlorobutyl rubber stopper and is sealed with an aluminium overseal. There is no latex in the vial stopper (bung).

The Moderna vaccine is delivered in cartons which each contain 10 multidose vials.

Ordering

NHS Trusts should order the Moderna (Spikevax) COVID-19 vaccine via the ImmForm platform. PCN designated sites need to use the Foundry system to order vaccines. Ordering is only available for pre-authorized sites.

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

Patient Information leaflets are also provided with each vaccine pack. Patient vaccination record cards should be ordered directly from the [Health Publications website](#).

Delivery in frozen state

The Moderna COVID-19 vaccine will be delivered frozen to healthcare facilities with the appropriate freezers to store the vaccine vials between -25°C to -15°C until ready for use.

Thaw in refrigerated conditions between +2°C to +8°C for 2½ hours. Let each vial stand at room temperature for 15 minutes before administering. To note: whilst this is the thawing advice stated in the Moderna (Spikevax) vaccine's [Summary of Product Characteristics](#), in practice it has been found to take significantly longer than this to thaw. The [Specialist Pharmacy Service Standard Operating Procedure 'Unpacking of frozen Moderna \(Spikevax\) COVID-19 Vaccine and transfer to fridges to thaw'](#) states that the vials may take up to 24 hours to thaw in a fridge.

Alternatively, thaw at room temperature between +15°C to +25°C for one hour.

Once thawed, the vaccine cannot be re-frozen and may be stored refrigerated at +2°C to +8°C, protected from light, for up to 30 days if not used (if it has not been opened and the bung has not been punctured by a needle).

Shelf-life is 9 months at -25°C to -15°C.

Delivery in thawed state

The COVID-19 Vaccine Moderna (Spikevax) may be delivered to where it is going to be administered thawed but refrigerated between +2°C 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°C and +8°C.

Once thawed, the unopened vaccine may be stored refrigerated at +2°C to +8°C, protected from light, for up to a maximum of 30 days.

The vaccine pack should have a label on the front stating the time it was removed from the freezer into storage at +2°C to +8°C and the date and time by which it must be discarded 30 days later if it has not been used.

The unopened vaccine may be stored at +8°C to +25°C for up to 24 hours after removal from refrigerated conditions.

Use of the vaccine once bung punctured

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 +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

Moderna COVID-19 vaccine (Spikevax) does not require reconstitution. The vaccine comes ready to use once thawed.

- 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 white to off-white and may contain white or translucent product-related particulates. If other particulate matter or discolouration are present, the vaccine should not be administered
- swirl the vial gently after thawing and between each dose withdrawal. Do not shake the vaccine vial
- the vial bung should be wiped with an alcohol swab and allowed to air-dry fully.
- a 1ml dose-sparing syringe with a 23g, 25mm fixed-needle should be used to draw up and administer the Moderna (Spikevax) vaccine (these will be provided with the 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 0.5ml for each primary vaccination or 0.25ml for a booster vaccination. Take particular care to ensure the correct dose is drawn up
- pierce the stopper at a different site each time a dose is withdrawn from the vial.
- 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

The priming dose of Spikevax is 0.5ml.

The primary course consists of 2 doses with a minimum 28-day interval between doses (but see [COVID-19 vaccines schedule](#) above).

The dose of Spikevax for booster vaccination is 0.25ml and this should be given to eligible individuals at least 3 months after the final primary dose.

Appendix 5. Storage and preparation of the Pfizer BioNTech Comirnaty 10 micrograms/dose COVID-19 vaccine

Vaccine composition

The Pfizer BioNTech Comirnaty 10 micrograms/dose COVID-19 vaccine contains messenger RNA (tozinameran) embedded in lipid nanoparticles. Tozinameran is a single-stranded mRNA which encodes the viral spike (S) protein of SARS-CoV-2.

In addition to the highly purified mRNA, the Pfizer-BioNTech COVID-19 vaccine also contains:

- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
- 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
- 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
- cholesterol
- trometamol
- trometamol hydrochloride
- sucrose
- water for injections

The first 4 components listed are used to form the lipid nanoparticles which encapsulate the mRNA.

The vaccine does not contain preservative and it does not contain any animal products.

Presentation

The Comirnaty 10 micrograms/dose COVID-19 vaccine is supplied in packs containing 10 vials of vaccine.

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

Each vial contains 1.3ml of vaccine and should be diluted with 1.3ml of Sodium Chloride 0.9% Solution for Injection (also referred to as normal saline). Once diluted, each reconstituted vaccine vial will supply 10 doses of 0.2 ml. The diluent is supplied separately to the vaccine.

The dose-sparing needles and syringes being provided with the vaccine should be used in order to extract 10 full doses from the vial. If standard syringes and needles are used, there may not

be sufficient volume to extract 10 doses from a single vial. Care should be taken to ensure a full 0.2 ml dose will be administered to the child from the same vial. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Storage

Whilst the Comirnaty 10 microgram/dose Pfizer-BioNTech COVID-19 vaccine can be stored frozen for 6 months at -90°C to -60°C , it will be delivered to vaccinators in a thawed state. Once thawed, the vaccine should not be re-frozen.

When removed from the freezer, the thawed, unopened, undiluted vaccine has a maximum shelf life of up to 10 weeks at $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$ within the 6 month shelf life.

Upon moving the vaccine from the freezer to 2°C to 8°C storage (thawing), the vaccine will have been re-labelled with an updated expiry date on the outer carton and the vaccine should be used or discarded by this date.

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.

Thawed vials

When received thawed and refrigerated at 2°C to 8°C , the vaccine must be transferred immediately to a vaccine fridge on arrival and stored in a carefully monitored temperature range of $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$.

The expiry date on the outer carton should have been updated to reflect the refrigerated expiry date for the thawed, unopened, undiluted vaccine.

Prior to use, the unopened vaccine can be stored for up to 12 hours at temperatures up to 30°C .

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. Thawed vials can be handled in room light conditions.

Vaccine reconstitution

- Comirnaty 10 micrograms/dose should be prepared using aseptic technique to ensure the sterility of the prepared 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 and one of the 2ml combined needle and syringes supplied for dilution

- remove one vial of vaccine from the vaccine fridge. Ensure it is the orange-capped 10 micrograms/dose formulation and check the expiry date
- 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 appearance of the vaccine. Prior to dilution, the thawed vaccine may contain white to off-white opaque amorphous (of no particular defined shape) particulates. Return the vial to the manufacturer if the appearance of the vaccine does not match this description
- clean the vial stopper with the single use alcohol-swab and allow to air dry fully
- invert the ampoule containing the Sodium Chloride 0.9% Solution for Injection diluent and withdraw 1.3ml slowly to avoid formation of bubbles
- 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 1.3 ml of air into the empty diluent syringe before removing the needle from the vial
- remove the needle from the vial and dispose of dilution needle and syringe into yellow sharps bin
- gently invert the diluted solution 10 times. One inversion means turning the vial upside down and back again. Do not shake – this could affect the potency of the vaccine
- the diluted vaccine should be a white to off-white solution with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present
- the diluted vial should be clearly labelled with the date and time of discard which should be 12 hours from the time of dilution
- discard any unused vaccine within 12 hours after dilution
- after dilution the vaccine should be used as soon as is practically possible
- Reconstituted vaccine can be stored between 2°C and 30°C but must be used within 12 hours following dilution

Vaccine dose preparation

- if the vaccine has previously been reconstituted, check the discard time on the label to ensure that it is still within the 12-hour allowed time period from when it was reconstituted
- visually inspect the vaccine for appearance and particles each time a dose is drawn up
- do not shake the diluted vaccine. If refrigerated, allow the diluted vaccine to come to room temperature prior to use
- using aseptic technique, clean the top of the vial with a single-use alcohol swab and allow to air dry fully

- unwrap one of the 1 ml combined 23 g/25 mm blue hub needle and syringes provided (recommended needle length depends on body mass. Longer length (38 mm) needles are available for morbidly obese children to ensure the vaccine is injected into muscle)
- insert the needle vertically into the centre ring of the vaccine vial stopper.
- do not twist or rotate the needle once inserted as this may cause a particle to be cored out of the stopper
- withdraw a dose of 0.2 ml of diluted product for each vaccination. Take particular care to ensure the correct dose is drawn up
- 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
- the needle should only be changed between the vial and the patient if it is contaminated or damaged

Dose and schedule

The amount to be given for each dose of the Pfizer BioNTech Comirnaty 10 microgram COVID-19 vaccine to eligible children aged 5 to 11 years is 0.2 ml.

The primary course consists of 2 doses with a minimum 21-day interval between doses. However, the JCVI have recommended that the second primary dose of COVID-19 vaccine should be routinely scheduled 8 weeks after the first dose unless there is a specific reason to give it earlier.

Third doses for 5- to 11-year-old children who were severely immunosuppressed at the time of their first or second primary dose are recommended. Booster doses are not currently recommended.

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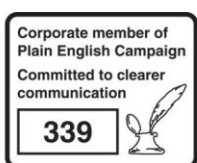
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