



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 	3 February 2021

Version number	Change details	Date
	174 Information for UK healthcare 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 	6 August 2021

Version number	Change details	Date
	<ul style="list-style-type: none"> - GBS and Capillary Leak syndrome - vaccination of 12 to 17 year olds - consent for children and young people <p>2. Appendix 2 revised to detail transition from use of the Pfizer BioNTech (Comirnaty) vaccine under Reg 174 to use under Conditional Marketing Authorisation</p>	
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

Version number	Change details	Date
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
5.0	<ol style="list-style-type: none"> 1. Updated throughout to align with the revised (4 September) Green Book COVID-19 chapter, including details of the Autumn 2022 Booster programme and the currently recommended or supplied vaccines 2. Substantially revised text and Appendix 1 – guidance about ‘Individuals who received COVID-19 vaccination overseas’ 3. Table summarising ‘Children and Young People’ offer updated and moved to Appendix 2 4. Removed reference to Regulation 174 in legal section 5. Added new sections within ‘Inadvertent vaccine administration errors’ to support recent programme or vaccine changes 6. ‘Storage and preparation’ appendices extended, renumbered and revised to reflect the latest product SPCs and newly licensed or supplied vaccines; deleted Astra Zeneca COVID-19 vaccine appendix 	10 October 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.

It has been updated to provide specific information about the storage and preparation of each newly introduced vaccine, following its authorisation by the UK Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA). 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 the 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 only access this document online to ensure that you are using the latest version.

Background to the COVID-19 vaccination programme

COVID-19 disease first emerged as a presentation of severe respiratory infection in Wuhan, China in late 2019. In January 2020 a novel coronavirus, SARS-CoV-2, was identified as the cause, and in March the World Health Organisation (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 number of cases and deaths from COVID-19 as well as: the number of virus tests processed; healthcare figures including the number of patients admitted to hospital, patients in hospital and patients in ventilator beds; and the number of people vaccinated.

[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.

[The NHS Specialist Pharmacy Service \(SPS\) publishes comprehensive guidance](#) regarding storage, transportation and all aspects of medicines management relating to the vaccines.

NHS England publishes a regularly updated [Current Cohort Eligibility Operational Status](#) document.

COVID-19

Clinical symptoms

In adults, the clinical picture varies widely. A significant proportion of individuals are likely to have mild symptoms and may be asymptomatic at the time of diagnosis. Symptoms are commonly reported as a new onset of cough and fever but may include headache, loss of smell, nasal obstruction, lethargy, myalgia (aching muscles), rhinorrhoea (runny nose), taste dysfunction, sore throat, diarrhoea, vomiting and confusion.

Fever may not be reported in all symptomatic individuals.

Patients may also be asymptomatic.

Progression of disease, multiple organ failure and death will occur in some individuals.

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. Cough and fever are the main symptoms; gastrointestinal symptoms are common. 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, male gender and pregnancy have been shown to be significant risk factors for severe disease and infection fatality ratios are highest in the oldest age groups; a disproportionate number of deaths are reported for individuals resident in a care home. Co-morbidities such as cancer, diabetes and poorly controlled 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 or Asian 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 main aim of the COVID-19 vaccination programme is to protect those who are at highest risk from serious illness or death from COVID-19. The objective of occupational immunisation of health and social care staff is to protect workers at high risk of exposure who may also expose vulnerable individuals whilst providing care.

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 and are in current use. The guidance will be updated as more information about these vaccines becomes available, to include other vaccines as they are added to the programme and to remove information about vaccines that are no longer being supplied.

As each vaccine is presented, stored and prepared differently, immunisers must ensure they are familiar with the specific details of the vaccine with which they are working.

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. The programme therefore has changed and will continue to change over time in response to the most up to date information.

All staff involved in delivering the programme need to understand who is eligible to receive COVID-19 vaccination, which vaccine they should receive, and the reasons why.

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.

Knowledge of the progression of the programme from its commencement will assist staff when deciding upon the requirements for every individual in their care. This is covered in the [training materials](#) and the [Green Book chapter 14a](#).

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 [Regulatory approval of Pfizer/BioNTech vaccine for COVID-19](#). This vaccine is authorised for adults and adolescents from the age of 12 years. It is also referred to as **Comirnaty 30 Concentrate** to distinguish it from the new Pfizer BioNTech bivalent vaccine (number 5 in this list) and, sometimes, as the ‘adult/adolescent’ product or dose.

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 [Regulatory approval of Pfizer/BioNTech vaccine for COVID-19](#). It is also referred to as **Comirnaty 10 Concentrate** and, sometimes, as the ‘paediatric’ product or dose.

3. 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 [Regulatory approval of Spikevax \(formerly COVID-19 Vaccine Moderna\)](#). This vaccine is authorised from 6 years of age but it is not currently recommended that it is given to those under 18 years of age. It is now also referred to as **Spikevax Original** to distinguish it from the new Moderna bivalent vaccine (see below).

4. COVID-19 Vaccine Moderna (Spikevax Bivalent Original/Omicron)

Granted Conditional Marketing Authorisation on 15 August 2022 [Regulatory approval of Spikevax bivalent Original/Omicron booster vaccine](#). It is more commonly referred to as **Spikevax Bivalent**.

5. COVID-19 Vaccine (Comirnaty Bivalent Original/Omicron)

Granted Conditional Marketing Authorisation on 3 September 2022 [Regulatory approval of Pfizer/BioNTech bivalent Original/Omicron booster vaccine](#). It is more commonly referred to as Comirnaty Bivalent.

6. COVID-19 vaccine Novavax (Nuvaxovid)

Granted Conditional Marketing Authorisation on 3 February 2022 [Regulatory approval of COVID-19 vaccine Nuvaxovid](#). It is licensed from age 12 years.

Many adults have received primary doses of the Astra Zeneca vaccine, Vaxevria. This is not licensed for boosting and is not being supplied from 1 September 2022.

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

All the currently UK-authorized vaccines in use are supplied in multi-dose vials. 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.

Comirnaty 30 Concentrate, Spikevax Original, and Comirnaty 10 Concentrate are all monovalent; they contain only the mRNA that encodes for the spike protein of the original (wildtype) virus. They are licensed for primary and booster dosing.

Spikevax Bivalent and Comirnaty Bivalent are bivalent; they contain mRNA that encodes for the spike protein of the original (wildtype) virus and mRNA that encodes for the spike protein of the BA.1 sub-lineage of the Omicron variant.

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

Novavax COVID-19 vaccine (Nuvaxovid)

Nuvaxovid is a recombinant, adjuvanted vaccine for individuals aged 12 years or older when mRNA vaccines are not considered clinically suitable. Very few individuals will require a dose of Nuvaxovid, and it will therefore only be made available at a limited number of designated,

accessible sites throughout the country, with locally agreed referral and assessment pathways developed and put in place.

Nuvaxovid contains a laboratory produced form of the SARS-Cov-2 spike protein which stimulates the immune response, and an adjuvant to help strengthen that response. It should not be co-administered with flu vaccine (there must be an interval of at least 7 days).

Either a prescription or a Patient Specific Direction is required for legal administration; the prescriber should be familiar with the information in the product's [summary of product characteristics](#) and in the [Green Book COVID-19 chapter](#).

COVID-19 vaccines indications and schedule

Primary doses

For the available mRNA vaccines licensed for primary dosing, 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 the COVID-19 vaccines simplifies supply and booking and helps 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 is concern about vaccine effectiveness (for example a new variant). Vaccinators will be advised if 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 is for those about to commence immunosuppressive treatment. In these individuals, the minimal intervals (21 days for Pfizer BioNTech vaccines Comirnaty 30 Concentrate and Comirnaty 10 Concentrate, or 28 days for Moderna vaccine Spikevax Original) 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 preferably using the same vaccine, but the first dose should not be repeated.

Circumstances in which different vaccines may be given for the first and second primary doses

Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines (for example, Astra Zeneca Covid-19 vaccine Vaxevria), make a good immune response, although rates of side effects with a heterologous second dose are higher.

Accumulating evidence now supports the use of heterologous schedules for primary immunisation (these are now recognised by the [European Medicines Agency](#)).

For individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available, one dose of the locally available product should be given to complete the primary course.

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.

Age-specific recommendations on vaccine type as set out in the [Green Book COVID-19 chapter](#) should be followed.

Individuals who received COVID-19 vaccination overseas

Emerging evidence on a wide range of COVID-19 vaccines, based on a range of different platforms and including the vaccines licensed in the UK, suggest that protection against mild disease declines rapidly - particularly against more recently emerged variants. Although protection against severe disease is maintained for longer, individuals at higher risk of severe COVID-19 are offered boosting at regular intervals. There is also clear evidence that many different heterologous primary schedules and/ or different heterologous boosters tend to provide higher or equivalent immune responses to homologous courses. Most vaccines in use, including those approved under the WHO EUL and others undergoing approval, are based either on the spike protein or whole inactivated vaccine, and this wealth of evidence suggests that, regardless of vaccine received, most vaccinated individuals will be primed for a spike antibody response. Based on first principles, this implies that administration of a single dose of any UK approved vaccine is likely to boost immunity in all of those individuals who received a

previous vaccination abroad. Similarly, this also means that re-vaccination may result in a higher rate of known side effects. The overall balance of risk and benefit is not therefore in favour of routinely repeating a full course.

Therefore, the guidance for immunocompetent individuals who move to the UK has been simplified. This is presented in a table as [Appendix 1](#). In order to use the table it is important to first establish whether the individual is eligible for vaccination according to UK recommendations and, whenever possible, ascertain which vaccines - if any – they have previously received.

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 recommended 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.

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

Autumn 2022 booster campaign

Following on from the spring campaign, the JCVI has recommended a move to regular, planned and targeted boosting as the most important strategy to control COVID-19. For the [2022 autumn booster programme](#), the primary objective is to augment immunity in those at higher risk from COVID-19 and thereby optimise protection against severe COVID-19, specifically hospitalisation and death, over winter 2022 to 2023.

The following groups should be offered a COVID-19 booster vaccine in the autumn of 2022:

- residents in a care home for older adults and staff working in care homes for older adults
- frontline health and social care workers
- all adults aged 50 years and over
- persons aged 5 to 49 years in a clinical risk group, as set out in Tables 3 and 4 of the Green Book chapter 14a
- persons aged 5 to 49 years who are household contacts of people with immunosuppression (as defined in Tables 3 and 4)
- persons aged 16 to 49 years who are carers (as defined in [Table 3](#))

The booster should ideally be offered from September, allowing a minimum of 3 months from the previous dose. The programme should prioritise delivery to those aged over 75 years and in care homes for older adults but recognising the need for operational flexibility based on the likely delivery models. The aim should be to complete the campaign before December to provide additional protection in time for the expected winter peak of other seasonal viruses. Someone in the eligible groups above who has received a full course of primary vaccination (2 or 3 doses) but has not received a booster before September 2022, may be given the autumn booster in the campaign provided there is at least 3 months from the previous dose. Additional doses are not then required.

JCVI considered evidence around the differences in neutralising antibody after vaccination with the bivalent vaccines compared to the original boosters. The Committee considered that the improvement in neutralising antibody levels were modest and likely to translate to only small improvements in protection against the BA.1 strain, with no clear advantage against other variants. This marginally improved protection against one variant was considered insufficient to justify any substantial delay in offering boosters to those at highest risk. On this basis the committee concluded that the Moderna and Pfizer BioNTech bivalent vaccines should be offered in the autumn booster programme, but only if the supply was sufficient to avoid delays in the planned implementation timetable. Individuals should be clearly advised that boosting is required to ensure timely protection over the winter, and therefore to accept whichever booster vaccine they are offered. Otherwise, the vaccines offered should follow the age-appropriate advice for reinforcing doses.

Further information about the booster programmes is available in the JCVI statements and also in the [COVID-19 chapter](#) of the Green Book.

Vaccine to be used for adult booster doses

The JCVI have advised that, from September 2022, one of the following should be offered as a booster dose to eligible adults:

- a full dose (30 micrograms) of Pfizer BioNTech Comirnaty 30 Concentrate vaccine, or
- a half dose (50 micrograms) of the Moderna Spikevax Original vaccine (a half dose is advised for the booster dose as it is expected to have a lower rate of side effects (including myocarditis) than a full dose), or
- a full dose (25/25 micrograms) of the Moderna Spikevax Bivalent vaccine, or
- a full dose (15/15 micrograms) of the Pfizer-BioNTech Comirnaty Bivalent vaccine

Study data indicates that mRNA vaccines provide a strong booster effect regardless of which vaccine was used for the primary course.

Timeliness of vaccination is more important than the type of booster vaccine used. The key priority of the autumn programme should be for eligible individuals to be offered a booster vaccine dose to increase their immunity against severe COVID-19 (hospitalisation and death). Individuals offered vaccination should be advised that timely boosting is desirable to increase protection over the winter, and therefore to accept whichever booster vaccine is offered.

When mRNA vaccines are not considered clinically suitable, COVID-19 vaccine Nuvaxovid may be given as a booster, of-label, following the age-appropriate advice for reinforcing doses. Access to this vaccine will be at designated sites, via locally agreed referral and assessment pathways.

Pregnant women

COVID-19 vaccines can be given to pregnant women.

Pregnancy is considered a clinical risk group. Pregnant women are eligible for primary doses and for the autumn 2022 booster programme.

The serious risks posed to women who become infected with the SARS-CoV-2 virus during pregnancy have become 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.

Pfizer BioNTech and Moderna vaccines are the preferred vaccines for eligible pregnant women (for those under 18 years, Pfizer BioNTech vaccines are preferred), because of more extensive experience of their use in pregnancy. When mRNA vaccines are not considered clinically suitable, Novavax COVID-19 vaccine Nuvaxovid may be used for primary vaccination of pregnant women, including to complete a course or as a booster, although experience in pregnancy is relatively limited.

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

COVID-19 vaccines can be given to breastfeeding women.

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

A table summarising the recommendations for children and young people is presented in [Appendix 2](#).

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 2 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)

These children are additionally eligible for an autumn 2022 booster.

Eligible children aged 5 to 11 years should receive the Pfizer-BioNTech Comirnaty 10 Concentrate (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 5 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 Concentrate (10 micrograms/dose) vaccine should be offered to children aged 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 5 years of age until the end of August 2022. These children are not eligible for a booster dose.

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 to 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, Comirnaty 30 Concentrate. 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 a Pfizer BioNTech COVID-19 vaccine at least 3 months from their last primary dose.

Interval between doses for 12 to 17 year olds

Young people aged 12 to 17 years not in an 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.

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](#).

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 Comirnaty 30 Concentrate 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.

They are all now eligible for an autumn 2022 booster.

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 Spikevax Original vaccine is also approved in for primary doses 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 Concentrate (30 micrograms/dose) vaccine should be given to eligible children and young people from 12 years for primary doses. The full dose of Pfizer BioNTech vaccines Comirnaty 30 Concentrate (30 micrograms) or Comirnaty Bivalent (30 micrograms) are the recommended booster vaccines for this age group. Note that the Moderna bivalent booster vaccine (Spikevax Bivalent) is not licensed for use in under 18-year-olds. Nuvaxovid is an alternative from age 12 when mRNA vaccines are clinically unsuitable.

The Pfizer BioNTech Comirnaty 10 Concentrate (10 micrograms/dose) vaccine should be given to eligible children aged **5 to 11 years** for primary and booster doses. The JCVI has recommended off-label use of Comirnaty 10 Concentrate vaccine for boosting in this age group.

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 an mRNA vaccine (provided there are no contraindications).

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 the 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 Comirnaty 30 Concentrate (30 micrograms/dose) vaccine or a full dose of Moderna Spikevax Original 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. When mRNA vaccines are not considered

clinically suitable, COVID-19 vaccine Nuvaxovid may be given as a primary dose. Access to this vaccine will be at designated sites, via locally agreed referral and assessment pathways.

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 8 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. Individuals in this group were also eligible for the Spring booster dose, provided there had been at least 3 months from the previous dose. Individuals who completed primary vaccination later, and so received their first booster (fourth dose) during the spring campaign, did not need an additional spring dose. These young people are now eligible for an autumn booster dose, again at a minimum interval of 3 months since their previous dose. If they have completed their primary course but not yet received any booster doses they will require just one booster during the autumn programme.

Those in the 5 to 11 year age group have more recently become eligible for primary immunisation. As JCVI has now recommended a booster dose, care should be taken to ensure that there is a minimum 3-month interval between their last primary dose and this booster, particularly when a third primary dose is indicated. A full (0.2ml) dose of Comirnaty Concentrate 10 should be given (off-label use).

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 any Pfizer BioNTech and Moderna vaccine 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](#) recommended suspension of this requirement. This 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.

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 (TTS)

A rare condition involving serious thromboembolic events accompanied by thrombocytopenia, has been reported after vaccination with the AstraZeneca COVID-19 vaccine, which, from 1 September 2022 is no longer being supplied. Guidance about subsequent dosing is covered in the cautions and precautions section of this document.

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 has occurred 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 4 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 have participated in a clinical trial of either primary or booster COVID-19 vaccination should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least 3 months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes).

Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification.

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 Pfizer BioNTech Comirnaty 30 Concentrate 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 Comirnaty 30 Concentrate 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 to 19% versus 5 to 7%) and local swelling (10 to 15% versus 5 to 8%), but less fever (3 to 7% versus 1 to 20%) and less chills (5 to 10% versus 6 to 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% versus 0.8%).

The most frequently reported adverse reactions to the Spikevax Original 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 under 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 Comirnaty 30 Concentrate and Spikevax Original vaccines 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.

The reactogenicity profile of Spikevax Bivalent and Comirnaty Bivalent were found to be similar to that of the Spikevax Original and Comirnaty 30 Concentrate respectively.

Reporting adverse reactions

Suspected adverse reactions following administration of COVID-19 vaccine should be reported to the MHRA. 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. Both vaccine recipients and healthcare providers can report any possible adverse reactions observed with these vaccines using the Yellow Card scheme. The MHRA is planning to merge the specially established Coronavirus Yellow Card reporting scheme with its standard scheme and so the link to the standard scheme should now be used and supplied to vaccinees: <https://yellowcard.mhra.gov.uk> (or call 0800 731 6789).

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)

A recently recognised condition involving serious thromboembolic events accompanied by thrombocytopenia, has been reported after AstraZeneca vaccination. There is no evidence of any underlying risk factors in the individuals affected by this condition who have mainly been previously healthy. The condition is rare, tends to present with unusual forms of clotting and the mechanism is believed to be an idiosyncratic reaction related to an immune response to the AstraZeneca vaccine.

Individuals who experienced a clotting episode with concomitant thrombocytopenia following the first dose of AstraZeneca vaccine should be properly assessed. If they are considered to have had 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 had received the first dose of AstraZeneca vaccine without developing this rare condition were advised to receive the second dose of the same vaccine as there is no signal of an increased risk of this condition after the second dose. Eligible individuals who did not take up the offer of a second primary dose of Astra Zeneca vaccine, and now wish to complete their prior course, should be offered an mRNA vaccine.

Although the Astra Zeneca vaccine is not being supplied from 1 September 2022, individuals may still have questions and concerns that relate to this. It is therefore helpful for staff to have some knowledge about TTS – see [Information for healthcare professionals on blood clotting following COVID-19 vaccination](#).

Capillary Leak Syndrome

Extremely rare reports of capillary leak syndrome have been reported after AstraZeneca and Moderna Spikevax Original vaccines in individuals with a prior history of this condition. 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 advice from a specialist should be sought

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 4 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 4-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 (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. Therefore vaccination should ideally be deferred until 12 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 8 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

Initially data on co-administration of COVID-19 with other vaccines was limited. 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.

A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. In contrast, a study of co-administration of Novavax COVID-19 vaccine Nuvaxovid with inactivated influenza, did show some attenuation of the antibody response to COVID-19 and, although the clinical significance of this is unclear, administration of Novavax COVID-19 vaccine should be separated from administration of influenza vaccine by at least 7 days.

With the exception of this, as COVID-19 vaccines are considered inactivated (including the non-replicating adenovirus vaccine), 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.

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

The MHRA's guidance [Patient group directions: who can use them](#) is a good overview and includes links to additional resources from the Specialist Pharmacy Service (SPS) and the National Institute for health and Care Excellence (NICE).

The UKHSA are developing and updating PGDs (and protocols – see below) 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: dosing

The following tables are provided to aid understanding of the management of dosing errors.

Table 1. Moderna vaccines and their doses showing antigen (mRNA) content

Vaccine	Spikevax Original primary dose	Spikevax Original booster dose	Spikevax Bivalent booster dose
Recommended ages	18 years and above	18 years and above	18 years and above
COVID-19 mRNA (total)	100 micrograms Original virus	50 micrograms Original virus	50 micrograms (25 micrograms of the original virus and 25 micrograms of the Omicron BA.1 variant)
Dose volume	0.5ml	0.25ml	0.5ml

Table 2. Pfizer adult or adolescent vaccines and their doses and antigen (mRNA) content

Vaccine	Comirnaty 30 Concentrate (primary and booster dose)	Comirnaty Bivalent booster dose
Recommended ages	12 years and above	12 years and above
COVID-19 mRNA (total)	30 micrograms	30 micrograms (15 micrograms of the original virus and 15 micrograms of the Omicron BA.1 variant)
Dose volume	0.3ml	0.3ml

Inadvertent administration of a larger than recommended dose

For example:

- a full 100 microgram (0.5ml) dose of Spikevax Original given as a booster dose to an adult (the recommended dose is 50 micrograms (0.25ml))
- a 30 microgram dose of Pfizer BioNTech vaccine instead of the recommended 10 microgram dose to individuals aged less than 12 years

- a vial of Pfizer BioNTech Comirnaty 30 Concentrate or Comirnaty 10 Concentrate is first diluted, and the entire contents of the multi-dose vial are then drawn up and administered to one individual
- the entire contents of a vial of a 'ready to use' vaccine (Comirnaty Bivalent, Spikevax Original or Spikevax Bivalent) is drawn up and administered to one individual

In this situation the individual will have received additional antigen. Studies have indicated that they may be more likely to experience pain in their injected arm but that this is not generally otherwise harmful.

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 an individual is given more than the recommended dose:

- the individual should be monitored and treated for any symptoms as required. They should be reassured that this is not generally harmful but that they may be more likely to experience pain in their injected arm
- all individuals in receipt of vaccination should be provided with the advice within the leaflet [What to expect after your COVID-19 vaccination](#), and it is important that the advice it contains about heart inflammation is brought to their and, if applicable, their parents or carers attention
- any subsequent doses due should still be given as per the recommended schedule

Inadvertent administration of incomplete dose of vaccine

There are 2 scenarios that occur when under-dosing is noticed immediately:

1. The vaccine and/or dose selected and administered are incorrect but the amount of vaccine given is known.
2. Less than the full dose of COVID-19 vaccine is inadvertently given, for example, if some vaccine leaks out as it is being administered, and the quantity administered is uncertain.

Other common scenarios occur where a number of people are vaccinated before it is noticed that some vaccine remains, or where a lower dose is recorded but it is not clear whether this is

a true under-dosing or a recording error. In these scenarios, where individuals have experienced a possible under-dosing, an overall assessment of the risks and benefits of re-vaccination for the population need to be considered alongside an assessment of the feasibility and operational complexity of a lookback.

Risk assessment

Where the volume administered is thought to be less than a half the recommended dose of Moderna vaccine or less than a full dose of Pfizer vaccine then a risk assessment should be undertaken. This risk assessment should consider how much of the dose it is estimated was given and take account of 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 a booster dose.

This risk assessment is recommended because of the increased reactogenicity and the risk of myocarditis and pericarditis following mRNA re-vaccination, notably in younger age groups, which should be weighed against the risk of a lower immune response to the vaccine.

For the purposes of this assessment, if an incomplete dose of a bivalent vaccine has been administered, consider the likely total dose in micrograms that they have received rather than the amount of mRNA for each variant.

In many cases a duty of candour exists to inform the individual of the dose error. However, if the dosing error is not considered to be of clinical significance – for example, if the response is expected to be **equivalent to another approved vaccine**, or if it is unclear whether there was a genuine error, then a local decision may be made regarding whether to inform those exposed.

The UKHSA publication [Vaccine incident guidance: Responding to errors in vaccine storage, handling and administration](#) includes sections about Duty of Candour and incident management.

The [table](#) below summarises the recommended default minimum response, however this does not preclude an operational decision to inform patients and/ or to advise additional action to manage specific incidents.

Supporting information

Recommended doses of mRNA vaccines produce high short term antibody responses, higher than seen with most other approved vaccines and much higher than those generated after natural infection. Antibody responses are substantially higher in vaccinated individuals with evidence of natural infection, even after a single dose of vaccine. By September 2022, around 75% of adults have been naturally infected ([COVID-19 vaccine surveillance report: week 35](#)).

The strong evidence of a prime-boost response, including with heterologous schedules with other vaccines, means that a single episode of under-dosing with an mRNA product is unlikely to be clinically significant in virtually all individuals.

Trial data for primary vaccination with the Pfizer BioNTech (Walsh and others, 2020) and Moderna (Jackson and others, 2020) vaccines showed a good immune response was made to 2 doses of the vaccines at a lower dose than the subsequently recommended and authorised dose, even in older individuals. Initial studies with 2 25 microgram doses of Moderna vaccine (one quarter of the recommended 100 microgram dose) and 20 microgram of Pfizer BioNTech vaccine (two-thirds of the recommended 30 microgram dose) gave antibody levels higher than seen in convalescent cases. [Mateus and others found that a low-dose \(25 micrograms\) of Moderna Spikevax Original vaccine](#) produced similar antibody and T cell responses as naturally acquired immunity. Based on this evidence, a half of the recommended primary dose of Moderna vaccine (50mcg instead of 100mcg) is likely to be at least as immunogenic as a full dose (30 micrograms) of Pfizer vaccine and better than other approved vaccines including Novavax, AstraZeneca and Janssen. One half dose of either Pfizer or Moderna vaccines given as part of a 2 dose primary schedule is unlikely to lead to inadequate antibody levels, and the full course of 2 doses is likely to be at least as protective as other approved vaccines.

For Pfizer vaccine, a third (10 micrograms) 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 UK study underway suggests that this low dose is also highly immunogenic in older teenagers.

For boosters, a study by [Choi and others](#) using a half dose of Moderna Spikevax Original (50 micrograms) in those who had received a primary course of Moderna Spikevax Original (100 micrograms) showed good immunogenicity and a rate of reactions similar to the second dose of Moderna Spikevax Original. This suggests that most individuals are well primed after a primary course of UK vaccines and will make a good booster response with smaller doses of mRNA.

This was confirmed in the [COV-BOOST](#) study, where a half dose (15 micrograms) of the Pfizer BioNTech monovalent vaccine, given as a third dose booster to fully primed individuals, boosted antibody and neutralising responses with only a minimal decrease in immunogenicity as compared to a full (30 micrograms) dose, including in individuals aged 75 years and above.

Antibody levels after boosting were higher in those boosted with this 15 micrograms dose compared to most other boosters with the exception of a full dose of Moderna vaccine. Based on this evidence, a half of the recommended booster dose of Moderna vaccine (25mcg instead of 50mcg) is likely to be or similar immunogenicity as a full dose (30 micrograms) of Pfizer vaccine, better than half a dose (15mcg) of Pfizer vaccine and better than other vaccines (including Novavax and AstraZeneca).

[Table 3](#) summarises the actions to be taken when under-dosing occurs.

Repeat doses

Where, following a risk assessment, the risk of under-dosing is considered substantial, and it is recommended that a full additional dose should be given, it is preferable to do this immediately (Note the option in [Table 3](#) to immediately give a half dose of Moderna Spikevax Original when a known dose of at least 50 micrograms of Moderna Spikevax Original or 50 micrograms of Spikevax Bivalent has been administered for priming and this is realised at once; this option applies only in this situation.)

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 assessment will be required to decide on the optimal timing for a repeat dose, considering the individual risk and epidemiological context (for example, time of year), plus the risk of side-effects.

If the dose is repeated, the recipient should be advised of possible side effects. The interval required before the next scheduled dose should be calculated from the date of the additional dose.

Table 3. Summary of actions to be taken in response to an under-dosing error

Indication	Dose administered	Action	Additional information
Primary dose (including a third primary dose for people with immunosuppression)	At least half a primary dose (50mcg) of Moderna Spikevax Original or a full booster dose (50mcg) of Spikevax Bivalent*	None	If noticed immediately the remaining half dose can be given on the same day. Use Spikevax Original (licensed for priming). Otherwise, no action is required.
	Less than half a primary dose (50 mcg) of Moderna Spikevax Original or a full booster dose (50 mcg) of Spikevax Bivalent*	A risk assessment should be carried out (see page 43)	If additional vaccine is given, administer a full dose of a vaccine licensed for priming. This should ideally be given on the same day. If this is not possible, allow 48 hours to elapse and then administer the dose ideally within 7 days of the original (incomplete) dose (see ' Repeat doses ')
	Less than a full dose (30 mcg) of Pfizer Comirnaty 30 or Comirnaty Bivalent*		
Administered as a booster dose	At least half a booster dose (25 mcg) of Moderna Spikevax Original or Spikevax Bivalent	None	
	At least half a dose (15 mcg) of Pfizer vaccine given to an individual known to be immunocompetent	None	
	Less than a full dose (30mcg) of Pfizer Comirnaty 30 Concentrate or Comirnaty Bivalent	A risk assessment should be carried out (see page 43). Note that if the individual is assessed as immunocompetent and has received at least a half dose (15 micrograms) of Pfizer vaccine this is considered adequate for boosting	If additional vaccine is given, administer a full dose. This should ideally be given on the same day. If this is not possible, allow 48 hours to elapse and then administer the dose ideally within 7 days of the original (incomplete) dose (see ' Repeat doses ')
	Less than half a dose (<25mcg) of Moderna Spikevax Original or Spikevax Bivalent		

* This is an additional error as this vaccine is not licensed or recommended as a primary dose.

Inadvertent administration of 10 microgram dose of Pfizer BioNTech monovalent 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).

Inadvertent administration of a ready to use vaccine that has been diluted

COVID-19 vaccines Moderna Spikevax Original, Spikevax Bivalent and Comirnaty Bivalent are ready to use and do not require dilution. If they are in error diluted prior to administration the amount of antigen in each dose will be less. In the event that these vaccines are diluted and administered in error 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).

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

Although the Spikevax Original vaccine is approved in children from 12 years, the Pfizer BioNTech Comirnaty vaccines are currently preferred due to a lower reported rate of myocarditis. However, up to 27 July 2022, the MHRA has not received any reports of these adverse events for individuals under the age of 18 having had a Moderna vaccine.

Moderna Spikevax Bivalent is not licensed for use in individuals of less than 18 years of age

All individuals in receipt of vaccination should be provided with the advice within the leaflet [What to expect after your COVID-19 vaccination](#). If a Spikevax Original or Spikevax Bivalent is administered to a child or young person, it is important that the advice it contains about heart inflammation is brought to their and their parent or carers attention.

Use the [MHRA weekly summary of Yellow Card reports](#) to check the latest information. The dose will be effective and does not need repeating. If further doses are indicated an age appropriate vaccine should be administered.

Inadvertent vaccine administration errors: scheduling

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 primary dose inadvertently given at less than the minimum recommended interval

If the second dose of either of the Pfizer BioNTech Comirnaty Concentrate 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 Moderna Spikevax Original 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.

If an individual attends having had a second dose of the AstraZeneca vaccine 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 has been 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. Unless contraindicated, this should be an mRNA vaccine as the Astra Zeneca

product is no longer being supplied. They should be informed that they may experience more side effects than they did following their first dose and reassured that evidence supports the use of a mixed schedule.

Longer than recommended interval left between primary 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 Comirnaty 30 Concentrate 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).

Administration of a booster dose less than 3 months after completion of the primary course, or a previous booster dose

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

Where the booster dose is inadvertently given earlier than 3 months (12 weeks) from the final primary dose, or the previous booster 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, taking operational requirements into consideration. For example, for the autumn 2022 booster, opportunities for vaccination will be available up to the end of January 2023.

Longer than recommended interval left between completion of either the primary course, or a previous booster dose and the next booster dose

If the interval since completion of the primary course, or since a previous booster dose was received has exceeded 3 months, the booster should be offered as soon as possible within the current booster campaign. However, the purpose of booster doses is to offer timely protection for those at greatest risk of serious disease and hospitalisation during periods of known or anticipated high infection rates, and in some cases, the offer may therefore be time-limited – that is, no longer available once the risk has lessened. In this situation individuals should be encouraged to promptly take up any further offer(s) of vaccination and be reminded of current advice about other measures they can employ to minimise their risk of becoming infected and when and how to seek medical advice if they think that have become ill with COVID-19.

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

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. However, data also indicates that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines, make a good immune response, and there is accumulating evidence to support the use of heterologous schedules for primary immunisation (these [heterologous schedules are now recognised by the European Medicines Agency](#)).

For individuals who have started the primary course and who attend for vaccination where the same vaccine is not available, or if the first product received is unknown or not available, or is not clinically unsuitable, a heterologous second dose is the only option and should be offered. Therefore, if an individual is inadvertently given a different vaccine for their second dose than that given for their first dose, they should be informed that they may experience more side effects than they did following their first dose, reassured that evidence supports the use of a mixed schedule, and advised that the dose does not need to be repeated.

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

If a dose of a different COVID-19 vaccine is inadvertently given a few days after the first primary dose was given, the person should be offered a third dose of vaccine at the currently

recommended interval for second primary 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.

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 England [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](#)

[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 British Sign Language (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 Comirnaty 30 Concentrate and Comirnaty 10 Concentrate vaccines](#)

[Product information for the Spikevax Original vaccine](#)

COVID-19 vaccination programme: Information for healthcare practitioners

[Product information for the Spikevax Bivalent vaccine Regulatory approval of Spikevax bivalent Original/Omicron booster vaccine](#)

Product information for Comirnaty Bivalent vaccine [Regulatory approval of Pfizer/BioNTech bivalent Original/Omicron booster vaccine](#)

Product information for Nuvaxovid vaccine [Regulatory approval of COVID-19 vaccine Nuvaxovid](#)

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 COVID-19 special edition](#), December 2020; [Vaccine update: issue 322 COVID-19 phase 2 special edition](#), June 2021 and [Vaccine update: issue 330 COVID-19 spring special edition](#), June 2022

[WHO COVID-19 worldwide dashboard](#)

Appendix 1. Immunisation of individuals who received COVID-19 vaccination overseas

Vaccine previously administered	UKHSA advice	UK vaccine to administer
Two or more vaccine doses, at least one of which was a dose of any vaccine approved and used in the UK/ EU, or is approved by another recognised regulator or is on the WHO EUL list (see References)	Further primary doses not required. If eligible, boost as per UK recommendations, a minimum of 3 months after administration of the last dose	Follow UK recommendations regarding clinical suitability and indications
A single dose of any vaccine approved and used in the UK/ EU, or is approved by another recognised regulator or is on the WHO EUL list (see References)	Administer a single dose of vaccine to complete the primary course, a minimum of 8 weeks after the first dose was administered (or 12 weeks if the individual is less than 18 years of age and not in a risk group) If eligible, boost as per UK recommendations, a minimum of 3 months after administration of the above dose	
One or more doses of vaccine received, none of which are approved and used in the UK/ EU, or are approved by another recognised regulator or are on the WHO EUL list (see References) or Previously vaccinated with one or more doses of COVID-19 vaccine but the specific product is unknown	Administer a single dose of vaccine, a minimum of 8 weeks after the last dose was administered (or 12 weeks if the individual is less than 18 years of age and not in a risk group) If eligible, boost as per UK recommendations, a minimum of 3 months after administration of the above dose	Follow UK recommendations regarding clinical suitability and indications
One or more doses of vaccine received, none of which are approved and used in the UK/ EU, or are approved by another recognised regulator or are on the WHO EUL list (see References) and the individual is immunosuppressed	Administer 2 doses of vaccine, starting a minimum of 4 weeks after the last dose was administered and a minimum of 8 weeks apart. If eligible, boost as per UK recommendations, that is a minimum of 3 months after administration of the second UK dose	
Unvaccinated	Offer primary course and, if eligible, a booster dose as per UK recommendations or schedules	

Links for this table

- [Status of COVID-19 vaccines within WHO EUL/ PQ evaluation process](#)
- [List of Stringent Regulatory Authorities \(WHO\)](#)
- [Regulatory Affairs Professionals Society \(RAPS\) COVID-19 vaccine tracker](#)

Appendix 2. summary of COVID-19 vaccine recommendations for individuals 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>Two 10 microgram doses of the Pfizer BioNTech Comirnaty 10 Concentrate vaccine with an interval of 8 weeks between doses.</p> <p>A third primary dose of Comirnaty 10 Concentrate at least 8 weeks after the second dose to those who had severe immunosuppression at or around the time of their first or second primary doses.</p> <p>An autumn 2022 booster of Comirnaty 10 Concentrate (off-label) at least 3 months after completion of the primary course.</p>
Children aged 12 to 15 with specific underlying health conditions that put them at risk of severe COVID-19	<p>Two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 Concentrate vaccine with an interval of 8 weeks between doses.</p> <p>A booster dose at least 3 months after completion of the primary course</p> <p>An autumn 2022 booster dose at least 3 months later. Note: if they have completed their primary course but not yet had their booster dose, only a single booster dose is now required.</p> <p>Either a full dose of Comirnaty 30 Concentrate or a full dose of Comirnaty Bivalent can be administered for any required booster doses.</p>
Children and young people aged 12 years and over who are severely immunosuppressed	<p>Two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 Concentrate vaccine with an interval of 8 weeks between doses.</p> <p>A third primary dose of Comirnaty 30 Concentrate at least 8 weeks after the 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>A booster dose at least 3 months after completion of the primary course.</p> <p>These individuals should also have been offered a spring 2022 booster dose and they are now eligible for an autumn 2022 booster at an interval of 3 months since completion of the primary course or their last booster. Note: if they have completed their primary course but not yet had any or all their booster doses, only a single booster dose is now required.</p> <p>Either a full dose of Comirnaty 30 Concentrate or a full dose of Comirnaty Bivalent can be administered for any required booster doses.</p>
Children and young people aged 12 and over who are household contacts of an immunosuppressed person	<p>Two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 Concentrate vaccine with an interval of 8 weeks between doses.</p> <p>A booster dose at least 3 months after completion of the primary course.</p> <p>They are now eligible for an autumn 2022 booster at an interval of 3 months since completion of the primary course or their booster. Note: if they have completed their primary course but not yet had their first booster dose, only a single booster dose is now required.</p> <p>Either a full dose of Comirnaty 30 Concentrate or a full dose of Comirnaty Bivalent can be administered for any required booster doses.</p>
Young people aged 16 and 17 in a clinical risk group (which includes	<p>Two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 Concentrate vaccine with an interval of 8 weeks between doses.</p>

Group	Recommendation
informal carers) or who work in health and social care	<p>A booster dose at least 3 months after completion of primary course.</p> <p>They are now eligible for an autumn 2022 booster at an interval of 3 months since completion of the primary course or their last booster. Note: if they have completed their primary course but not yet had their first booster dose, only a single booster dose is now required.</p> <p>Either a full dose of Comirnaty 30 Concentrate or a full dose of Comirnaty Bivalent can be administered for any required booster doses.</p>
All other children aged 5 to 11, on or before 31 August 2022, not in an at-risk group	<p>Two 10 microgram doses of the Pfizer BioNTech Comirnaty 10 Concentrate vaccine with an interval of 12 weeks between doses.</p> <p>Boosters in young people aged 5 to 11 years who are not at high risk are not currently recommended by JCVI.</p>
All other young people aged 12 to 15 not in an at-risk group	<p>Two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 Concentrate vaccine with an interval of 12 weeks between doses.</p> <p>Boosters in young people aged 12 to 15 years who are not at high risk are not currently recommended by JCVI.</p>
All other young people aged 16 and 17 not in an at-risk group	<p>Two 30 microgram doses of the Pfizer BioNTech Comirnaty 30 Concentrate vaccine with an interval of 12 weeks between doses.</p> <p>Offer a booster dose at least 3 months after completion of the primary course.</p> <p>Either a full dose of Comirnaty 30 Concentrate or a full dose of Comirnaty Bivalent can be administered for any required booster doses.</p>

Appendix 3. Storage and preparation of the Pfizer BioNTech Comirnaty 30 micrograms/dose (Comirnaty 30 Concentrate) COVID-19 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 0.45ml of vaccine and should be diluted with 1.8ml of Sodium Chloride 0.9% Solution for Injection (also referred to as normal saline). Once diluted, each reconstituted vaccine will supply 6 doses of 0.3ml.

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 0.3ml 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 0.3ml, 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 2ml 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 1.8ml 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 15 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 1.8ml 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 0.3ml 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 0.3ml.

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 4. Storage and preparation of the Moderna Spikevax Original and Spikevax Original/Omicron (Spikevax Bivalent) COVID-19 vaccines

Vaccine composition

The Moderna COVID-19 vaccines (Spikevax Original and Spikevax Bivalent) contain single-stranded RNA embedded in lipid nanoparticles. Spikevax Original is monovalent: it contains mRNA from just one variant, that of the original (wildtype) virus. Spikevax Bivalent contains mRNA from 2 variants of the virus: the original (wildtype) and the BA.1 sub-lineage of the Omicron variant.

They also both contain:

- 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 vaccines do not contain preservative and do not contain any animal products.

Presentation

The Moderna COVID-19 vaccines are both presented in a multidose vial containing a solution which should be white to off-white and may contain white or translucent product-related particulates. They do not require reconstitution. The vials have a chlorobutyl rubber stopper and are sealed with an aluminium overseal. There is no latex in the vial stoppers (bungs). The Moderna vaccines are 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-authorised sites.

Combined 1ml dose-sparing syringes with a safety retractable needle 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

Spikevax Original 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. Spikevax Bivalent will be delivered frozen to healthcare facilities with the appropriate freezers to store the vaccine vials between **-50 °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.

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 (Spikevax Original), 9 months at -50C to -15°C (Spikevax Bivalent)

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 vaccines do 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 safety retractable should be used to draw up and administer the Moderna vaccines (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 of Spikevax Original; withdraw a dose of 0.5ml for each booster dose of Spikevax Bivalent. 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 Original 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 Original for booster vaccination is 0.25ml and this should be given to eligible individuals at least 3 months after the final primary dose or last booster dose that they received.

The booster dose of Spikevax Bivalent is 0.5ml; this should be given to eligible individuals at least 3 months after the final primary dose or last booster dose or last booster dose that they received.

Appendix 5. Storage and preparation of the Pfizer BioNTech Comirnaty 10 micrograms/dose (Comirnaty 10 Concentrate) 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 0.2ml. 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 0.2ml 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 0.2ml, 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

Instructions for 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 1.3ml 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

Instructions for 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 1ml combined 23g/25mm 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 0.2ml 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 0.2ml.

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.

Appendix 6. Storage and preparation of the Pfizer BioNTech Comirnaty Original/Omicron (Comirnaty Bivalent) COVID-19 vaccine

Vaccine composition

The Pfizer BioNTech Comirnaty Original/Omicron 15/15 micrograms/dose (Comirnaty Bivalent) COVID-19 vaccine contains 15 micrograms of Tozinameran and 15 micrograms of Riltazinameran per dose, embedded in lipid nanoparticles. Tozinameran is a single-stranded mRNA which encodes the spike (S) protein of the original (wildtype) SARS-CoV-2 virus and Riltazinameran, is a single-stranded mRNA which encodes for the viral spike protein of the BA.1 sub-lineage of the Omicron variant. In addition to the highly purified mRNA, Comirnaty Bivalent 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 Bivalent 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 a grey flip-off plastic cap. Bromobutyl is a synthetic rubber – it does not contain latex.

Each vial contains 2.25ml of 'ready to use' vaccine that does NOT require dilution prior to administration.

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

Storage

Comirnaty Bivalent vaccine can be stored frozen for 12 months at -90°C to -60°C . It may be delivered frozen to healthcare facilities with ultra low temperature (ULT) freezers.

When required, frozen vials of vaccine should be transferred to $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ to thaw; a 10 vial pack of Comirnaty Bivalent will take 6 hours to thaw. Individual vials of vaccine may be thawed at temperatures up to $+30^{\circ}\text{C}$ for 30 minutes for immediate use.

Once thawed, the vaccine should not be refrozen.

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 12 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.

Vials may be delivered thawed to sites that have no facility for the storage of frozen vaccine.

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 dose preparation

Check that the vaccine has been stored correctly. If the vaccine has already been removed from the vaccine fridge, check that the maximum permissible time and temperatures have not been exceeded. Then:

- 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 1ml combined 1/25mm needle and syringes provided (recommended needle length depends on body mass. Longer length (38mm) 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 0.3ml of 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

Dose and schedule

The amount to be given for each dose of the Pfizer BioNTech Comirnaty Bivalent COVID-19 vaccine to eligible individuals aged 12 years and above is 0.3ml.

The vaccine is only licensed and recommended for boosting, for individuals who have completed at least a primary course of vaccination and allowing a minimum interval of 3 months since their previous dose was given.

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