UK Health Security Agency

COVID-19 vaccination programme

Information for healthcare practitioners

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Contents

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	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 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	11 December 2020
3.0	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	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	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

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	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	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	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	1. Updated the following sections in line with revisions made to the Green Book COVID-19 chapter: - 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	1. Updated to include: - revisions to the Green Book COVID-19 Chapter	6 August 2021

Version number	Change details	Date
	- GBS and Capillary Leak syndrome - vaccination of 12 to 17 year olds - consent for children and young people 2. Appendix 2 revised to detail transition from use of the Pfizer BioNTech (Comirnaty) vaccine under Reg 174 to use under Conditional Marketing Authorisation	
3.11	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	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	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	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
6.0	1. Updated to align with the revised Green Book chapter 14a published on 27 April 2023, the recommendations for the spring 2023 vaccination campaign and the introduction of a primary immunisation for children aged 6 months to 4 years at higher risk 2. Revised 'Inadvertent vaccine administration errors' section including new content to support recent programme and vaccine changes 3. Storage and preparation appendices removed	3 May 2023

Document information

This document has been published to provide information to those involved in the COVID-19 national vaccination programme since its commencement in 2020.

It has been and will continue to be updated to provide specific information about the storage and preparation of each newly introduced vaccine and changes to the programme as detailed in the Green Book chapter 14a.

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, the information in this document was correct at the time of publication. Please only access this document online to ensure that you are using the latest version.

This document does not replace the Green Book COVID-19 chapter nor the PGDs and national protocols for COVID-19 vaccines, all of which should be available and actively consulted by those delivering this programme.

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 the latest 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

Common symptoms include headache, fatigue, cough and myalgia (aching muscles). Compared to previous variants, Omicron is less likely to cause loss of sense of smell (anosmia) and more likely to cause a sore throat. In severe cases, COVID-19 can lead to pneumonia, acute respiratory distress syndrome, multiple organ failure and death.

The long-term consequences of COVID-19 infection, known as Long COVID or Post-Acute Sequelae of SARS-CoV-2 (PASC) infection, are an area of ongoing study. Reported long-term symptoms (12-16 weeks after the initial infection) are varied, involving most organ systems and affecting both physical and mental health.

In general, children remain asymptomatic or develop mild disease, often with upper respiratory symptoms, but symptoms may be non-specific and atypical, affecting other organ systems. The majority of children recover completely and any persistent symptoms improve with time and serious long-term complications are rare.

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 route appears to play only a minor role in transmission.

Secondary attack rates within households are high and each strain has been more infectious than its predecessor.

Groups affected by COVID-19

The risk of poorer outcomes from COVID-19 infection increases dramatically with age in both healthy adults and in adults with underlying health conditions. Those over the age of 65 years have by far the highest risk, and the risk increases steeply with age. Residents in care homes for older adults have been disproportionately affected by the COVID-19 pandemic.

Pregnant women with COVID-19 infection are more likely to be admitted to an intensive care unit and the maternal mortality ratio, stillbirth rate and the number of neonatal deaths amongst pregnant women with COVID-19 infection all increased between the wildtype SARS-CoV-2 dominant period to the Delta strain dominant period. Although the likelihood of these events has decreased since the Omicron strain achieved dominance, severity of COVID-19 infection remains higher in unvaccinated than vaccinated pregnant women.

Severe COVID-19 requiring hospitalisation is rare in children and deaths even more so but for a small proportion of children with pre-existing health conditions, the risk of severe illness is greater. Longitudinal follow-up studies are ongoing to assess risks and outcomes in children. The incidence of the rare temporally associated presentation of paediatric multisystem inflammatory syndrome (PIMS-TS) has declined as the virus has mutated and natural and vaccine-induced immunity has increased.

COVID-19 vaccination programme

Phases and aims of the programme

Primary immunisation

The primary immunisation programme was introduced in 2 phases. Its main aim was to protect those who were at highest risk from serious illness or death. In Phase 1, individuals were ranked based on the risk of COVID-19 specific mortality (priority groups 1-9) and this included occupational immunisation of health and social care staff. In Phase 2 the offer of primary vaccination was extended (in descending order of age) to all adults, and then incrementally further extended to children aged 5 and above, to protect those at risk from serious illness or death, and to protect the NHS by reducing the risks of hospitalisation and critical care admission, against a background of newly emerging variants.

Reinforcing doses

A completed primary course of vaccine was found to greatly reduce the risk of severe illness and hospitalisation but was less effective at preventing infection due to the heavily mutated Omicron variant and protection declined to very low levels 6 months after the primary course. Reinforcing (‘first booster’) doses were therefore offered to individuals in priority groups 1-9

from autumn 2021. However, protection again declined during the following months and additional booster doses were advised for the groups at most risk of severe illness, resulting in a number of booster dose campaigns and, from 2022, a recommendation by the JCVI that regular, planned and targeted boosting is the most important control strategy.

The ‘Living with COVID-19’ programme

During 2023 there will be a transition towards a proportionate, focussed, and sustainable programme which aims to reduce severe disease (hospitalisation and mortality) and thus also to protect NHS capacity, with a particular focus on winter preparedness (autumn campaigns) but with additional (spring) campaigns for those at the highest risk, who will be especially vulnerable over the later summer months as their immunity wanes.

The primary course of vaccination will become a targeted offer available only to those at higher risk of severe COVID-19 and only during the planned seasonal booster campaigns.

Exceptionally, based on clinical judgement, individuals who develop severe immunosuppression (Boxes 1 and 2 of the Green Book COVID-19 chapter) may be at high risk of severe COVID-19 and less able to sustain any protection from previous vaccination or exposure and should be considered for catch-up primary vaccination or additional dose(s) of vaccination before the next seasonal campaign.

COVID-19 vaccination eligibility

The JCVI considers the available epidemiological, microbiological and clinical information on the impact of COVID-19 in the UK and provides 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 of 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

Vaccine development

In response to the emergence of a new virus, scientists across the world worked collaboratively and rapidly to accelerate the development of safe and effective vaccines, using both existing vaccine technologies and new approaches. Some of the clinical trial steps were conducted in parallel rather than sequentially in order to make these vaccines more quickly available without compromising vaccine safety. The vaccine trials and vaccine licensing have been subject to all of the usual strict regulatory requirements.

This document discusses the COVID-19 vaccines which have been authorised for administration in the UK to date and that are currently 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.

UK vaccines

The following COVID-19 vaccines are both licensed and currently supplied for use in the UK national COVID-19 vaccination programme (click on the hyperlinks to view their Summary of Product Characteristics documents (SPCs) or search for these in the Electronic Medicines Compendium). Additional details about each vaccine are provided in the appendices.

Pfizer BioNTech Comirnaty COVID-19 vaccines

Comirnaty bivalent Original/Omicron BA. 4-5 (15/15 micrograms)/dose is the ‘adult/adolescent’ Comirnaty vaccine. It’s a bivalent vaccine licensed and recommended for primary and booster doses for eligible individuals aged 12 years and above. It is also referred to in this document as Comirnaty bivalent BA.4-5 15/15. Comirnaty bivalent Original/Omicron BA.1 (15/15 micrograms)/dose may alternatively be supplied.

Comirnaty 10 micrograms/dose is the ‘paediatric’ Comirnaty vaccine. It is a monovalent vaccine licensed and recommended for primary and booster doses for eligible individuals from 5 to 11 years of age, and for completing primary doses for eligible individuals aged 12 years old who commenced primary vaccination when aged 11. It is also referred to in this document as Comirnaty 10 Concentrate.

Comirnaty 3 micrograms/dose is the ‘infant/pre-school children’s’ Comirnaty vaccine. It is a monovalent vaccine licensed for primary doses for eligible individuals from 6 months to 4 years of age. In certain circumstances it may be administered as a primary dose to children aged 5 years old. It is also referred to in this document as Comirnaty 3 (three) Concentrate.

Moderna Spikevax COVID-19 vaccines

Spikevax bivalent Original/Omicron BA.4-5 (25/25 micrograms)/dose is licensed for booster doses for individuals aged 12 years and above but is recommended for primary and booster doses, however only for eligible individuals aged 18 years and above. It is also referred to in this document as Spikevax bivalent BA.4-5 25/25. Spikevax bivalent Original/Omicron BA.1 (25/25 micrograms)/dose may alternatively be supplied.

Novavax COVID-19 vaccine

Nuvaxovid is a monovalent recombinant, adjuvanted vaccine licensed for primary doses from age 12 years and for booster doses from aged 18 years but may be used for boosting from aged 12 years. It is available at selected sites to individuals for whom an mRNA vaccine is clinically unsuitable (only). The current stock has been granted a shelf-life extension until 31 May 2023.

Sanofi COVID-19 vaccine

VidPrevtyn Beta is a monovalent recombinant adjuvanted vaccine licensed for booster doses for individuals aged 18 years and above. It is recommended for booster doses for eligible individuals aged 75 years and above and, in defined operational circumstances, for some eligible individuals aged 65 years and above and for primary doses from that age.

Other licensed vaccines

The following vaccine is licensed by the MHRA but **not currently being supplied**:

- Pfizer BioNTech Comirnaty bivalent Original/Omicron BA.4-5 (5/5micrograms)/dose licensed for 5 to 11 years of age

The following vaccines are **no longer being supplied**:

- Vaxevria (Astra Zeneca)
- Comirnaty 30 Concentrate (Pfizer BioNTech)
- Spikevax Original (Moderna)

All the currently UK-authorised 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 mRNA 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 3 (three) Concentrate and Comirnaty 10 Concentrate are monovalent; they contain only the mRNA that encodes for the spike protein of the original (wildtype or 'ancestral') virus.

Comirnaty Original/Omicron BA.4-5 15/15 (and Comirnaty Original/Omicron BA.1 15/15) and Spikevax Original/Omicron BA.4-5 25/25 (and Spikevax Original/Omicron BA.1 25/25) 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.4-5 (or 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.

Sanofi COVID-19 vaccine (VidPrevtyn Beta)

VidPrevtyn Beta is recombinant adjuvanted vaccine. The genes (DNA) that encode for the spike (S) surface protein on the Beta variant (B.1.351 strain) of the SARS-CoV-2 virus are inserted into bacterial cells in the laboratory. These cells then produce ('express') the S protein, which is then purified to produce the antigen component of the vaccine.

The vaccine uses the AS03 adjuvant system. The role of the adjuvant is to hold the antigen at the injection site for longer so that the immune system can better recognise the antigen and to produce a stronger response by stimulating certain components of the innate immune system. There is no whole or live virus involved so the vaccine cannot cause disease.

Novavax COVID-19 vaccine (Nuvaxovid)

Nuvaxovid is a recombinant, adjuvanted vaccine for individuals aged 12 years or older when mRNA vaccines are considered clinically unsuitable. 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. It is not therefore available to individuals who prefer not to receive one of the other suitable vaccines, only to those who are contraindicated.

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.

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. Training materials have been produced by the manufacturer.

COVID-19 vaccine indications and schedules

Primary doses

Eligibility

Individuals aged 5 years and above

Anyone who is eligible for a spring 2023 booster dose but has not yet commenced or completed a primary course should first receive their outstanding primary dose(s).
The 'evergreen' offer of primary immunisation remains in place during the spring 2023 campaign for all individuals aged 5 years and above who have yet to start or complete a primary course, including those in a clinical risk group from their 5th birthday. Note, however, that healthy children aged 5 (not in any clinical risk group) are only eligible if their 5th birthday occurred on or before 31st August 2022.

The offer of primary immunisation is expected to cease at the end of this campaign for healthy individuals, whilst those in clinical risk groups (except those who are severely immunosuppressed) will not be able to receive any outstanding primary doses until the next seasonal campaign.

Children aged 6 months to 4 years of age

The offer of primary immunisation for children aged 6 months to 4 years of age in recognised clinical risk groups (as defined in Table 4 of the Green Book COVID-19 chapter) will be implemented during the spring and summer 2023.

Third primary doses for those aged 6 months and over with severe immunosuppression

Individuals aged 6 months and above who were severely immunosuppressed (as defined in Boxes 1 and 2 of the Green Book COVID-19 chapter) at or around the time of their primary immunisation should be offered an age-appropriate third primary dose a minimum of 8 weeks after receiving their second dose. See additional information about third primary doses in the immunosuppression section under 'Specific population groups'.

Vaccines for primary doses

For adults, the Comirnaty bivalent Original/Omicron 15/15 and Spikevax bivalent Original/Omicron 25/25 mRNA COVID-19 vaccines are now recommended, off-label, for all primary doses. The Sanofi Pasteur COVID-19 vaccine VidPrevtyn Beta may be used off-label as a primary dose in those aged 65 years and over if there would otherwise be a delay in vaccination and when an mRNA vaccine is clinically unsuitable.

For young people aged 12 years and above (but not yet 18 years of age) only the Pfizer BioNTech Comirnaty bivalent Original/Omicron 15/15 mRNA COVID-19 vaccines may be used. Comirnaty 10 micrograms/ dose is recommended for all 5 to 11 year olds and for 12 year olds who, having commenced primary immunisation with this vaccine, had their 12th birthday between doses.

Comirnaty 3 micrograms/dose is licensed for primary doses for eligible individuals from 6 months to 4 years of age. Children below 6 years of age, including those who commenced immunisation with the 3 microgram infant dose before turning 5, may commence and complete primary vaccination with the 3 micrograms/dose vaccine if that is the only vaccine readily available in the clinic.

Nuvaxovid is licensed for primary doses from age 12 years and may be used for individuals in whom an mRNA vaccine is clinically unsuitable. Once Nuvaxovid is no longer being supplied, an individual clinical judgement will be required regarding vaccination of individuals under 65 years of age for whom an mRNA vaccine is clinically unsuitable: expert advice should be obtained and, if a decision is made to administer an mRNA vaccine, it should be given in hospital under medical supervision.

Vaccination of those aged 6 months to 11 years in whom mRNA vaccines are unsuitable requires an individual clinical judgement.

Schedules

There is evidence of a 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 from aged 6 months 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.

Although Comirnaty 3 micrograms/dose is licensed as a 3 dose primary course, the JCVI has recommended a 2-dose schedule for eligible children aged 6 months to 4 years of age. The minimum interval is 8 weeks.

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 or Novavax vaccines or 28 days for Moderna Spikevax vaccines) may be followed to ensure that the vaccine is given while their immune system is better able to respond; see: 'Timing of administration of COVID-19 vaccine to individuals who are or who are about to become immunosuppressed'.

Individuals commencing their primary course during the present vaccination campaign

Many eligible individuals who receive their first primary dose 8 weeks or less before the end of the present campaign will not be able to complete their primary course before this campaign ends. The only exception is individuals about to start immunosuppressive therapy who may be considered for a second dose at a shorter interval and those who develop severe immunosuppression who may be considered for an additional dose of vaccination between seasonal campaign (see the Green Book COVID-19 chapter).

All approved COVID-19 vaccines produce high short term antibody responses. Antibody responses are substantially higher in vaccinated individuals with evidence of natural infection, even after a single dose of vaccine. Seroprevalence studies indicate that most of the adult and childhood population have now been naturally infected, and therefore response to a single dose of vaccine is likely to be as good or better than a full primary course in a naïve individual. It is therefore not recommended to shorten the minimum intervals in order to complete the course. Unvaccinated individuals who are eligible for a booster should be encouraged to receive their first dose during the campaign. Clinicians should, as part of the consent process, explain why they do not need a second dose at this time.

Individuals in a clinical risk group may be able to receive a 2nd dose with the latest recommended vaccine during the next campaign (anticipated to be in the autumn of 2023) if

they remain eligible. JCVI will be reviewing the disease epidemiology, the prevalent variants and the expected vaccine effectiveness and announce details of who needs protection and will therefore be eligible during that campaign later this year.

The primary offer to healthy individuals (not in a clinical risk group) will end when the spring 2023 campaign is completed.

As above, those who develop severe immunosuppression may, on the basis of individual assessment, be considered for vaccination between campaigns, to accommodate optimal timing and ensure that they are best protected.

Previous incomplete vaccination

If the vaccine course is interrupted or delayed, it should be resumed preferably using the same vaccine, but any previous primary dose(s) 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 and any mRNA vaccine can be used to complete a primary course.
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.

Children aged 5 to 12 years who have commenced immunisation with the paediatric dose of Pfizer BioNTech Comirnaty 10 micrograms/dose vaccine should ideally complete vaccination with the paediatric dose but an adult/adolescent dose of a Comirnaty bivalent 15/15 micrograms/dose vaccine is an alternative in those who turn 12 years of age between doses. Those who present for the second dose over the age of 12 years should be given an adult/ adolescent dose of vaccine.

Children below 6 years of age, including those who commenced immunisation with the infant dose of Pfizer BioNTech Comirnaty 3 micrograms/dose vaccine before turning 5, may commence and complete primary vaccination with the 3 microgram product if that is the only vaccine readily available in the clinic.

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 individuals who have received at least one dose of vaccine 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.

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. 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).

Booster doses

Spring 2023 booster campaign

To provide additional protection for the most vulnerable over the spring and summer months, the JCVI has recommended that a booster dose should be given to:

- adults aged 75 years and over
- residents in a care home for older adults
- individuals aged 5 years and over who are immunosuppressed (defined as immunosuppressed in the Green Book COVID-19 chapter Tables 3 and 4)

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

As primary vaccination of children aged 6 months to 4 years at high clinical risk was only advised in early 2023, severely immunosuppressed children under 5 years of age will not be eligible for a booster in spring 2023. These children may be considered for additional doses at a later time point.

Limits to vaccination offers and ‘missed’ booster doses

Booster doses offer time-limited protection (protection increases after each dose but then wanes over the following few months). Individuals who have not taken up the offer of additional doses therefore cannot be ‘caught-up’ as the dose(s) they missed were intended to protect them during a period of time that has now elapsed. If eligible they should be vaccinated during the current campaign and encouraged to take up any future offers that apply.

Booster doses are recommended on the basis of the current epidemiology of the disease and the specific risks to individuals and, therefore, may not be required for all individuals during every campaign. Sub-groups of individuals at highest risk may be selected for additional doses that are not offered to everyone in a clinical risk group. Only those individuals who are eligible for a spring 2023 booster should now receive a booster dose.

The routine ‘first booster’ offer for all other eligible cohorts formally ended on 12th February 2023 with the closure of the Autumn 2022 booster campaign.

The JCVI will announce its recommendations for booster doses for autumn 2023 in due course.

Vaccines to be used for spring 2023 booster doses

Full details of the recommended vaccines for each cohort for the spring 2023 campaign are set out in the Green Book COVID-19 chapter.

The evidence is that heterologous schedules are non-inferior, or in some cases superior, to single vaccine schedules, that mRNA vaccines provide a strong booster effect regardless of which vaccine was used for the primary course and that any mRNA vaccine can be used as a booster.

The bivalent mRNA COVID-19 vaccines are licensed for boosting. The Pfizer BioNTech Comirnaty bivalent Original/Omicron 15/15 vaccines may be given to anyone aged 12 years and above. The Moderna Spikevax bivalent Original/Omicron 25/25 vaccines may be given to anyone aged 18 years and above.
Sanofi COVID-19 vaccine VidPrevtyn Beta is an additional option for those aged 75 years and above. It is anticipated that the inclusion of an adjuvant in this vaccine will strengthen the immune response in these older individuals, who are at greatest risk of serious illness if they have a COVID-19 infection. In defined operational circumstances, this vaccine may also be administered to some eligible individuals aged 65 years and above.

Nuvaxovid is licensed for booster doses from aged 18 years but is recommended from age 12 years as a booster dose when an mRNA vaccine is clinically unsuitable (contraindicated). Access to this vaccine will be at designated sites, via locally agreed referral and assessment pathways. It is not therefore available to individuals who prefer not to receive one of the other suitable vaccines.

When Nuvaxovid is no longer available, a dose of VidPrevtyn Beta may be considered for individuals aged 65 years and above. Vaccination of individuals of less than 65 years in whom mRNA vaccines are unsuitable will require an individual clinical judgement: expert advice should be obtained and if a decision is made to administer an mRNA vaccine this should be given in hospital under medical supervision.

Comirnaty 10 micrograms/dose is licensed for boosting for individuals aged 5 to 11 years. Vaccination of those aged 5 to 11 years in whom mRNA vaccines are unsuitable requires an individual clinical judgement.

Timeliness of vaccination is more important than the type of booster vaccine used. For those aged 12 and above, if the age appropriate bivalent mRNA vaccine containing the latest variant (currently Omicron BA.4-5) is not available, a bivalent with a previous variant (such as Omicron BA.1) may be used if there would otherwise be a delay in vaccination.

The key priority of the 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 reinforce

their waning protection over the spring and summer months, and therefore to accept whichever booster vaccine is offered.

Unknown vaccination history

If the primary immunisation history of an individual eligible for a booster dose during the spring 2023 is unknown, it is preferable, rather than delay vaccination, to administer a dose of any suitable vaccine. If upon further investigation this is discovered to have been their first primary dose then a second dose can be given, within the same vaccination campaign, after a minimum 8 week interval. If the campaign ends before these 8 weeks have elapsed and they remain eligible, they can receive this dose during the next campaign. If they are severely immunosuppressed clinical judgment should be used to determine the timing of this second dose, which may, if necessary, be administered between campaigns.

Specific population groups

Immunosuppression

Timing of administration of COVID-19 vaccine to individuals who are or are about to become 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.

Individuals aged 6 months and 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 primary 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.

Third primary doses

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, a third primary dose is recommended for individuals aged 6 months and over who were severely immunosuppressed at or around the time of their first or second primary COVID-19 vaccination (Boxes 1 and 2 in the Green Book chapter 14a). 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 (≤40mg prednisolone per day) for an acute episode (for example, asthma, COPD or 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.

The JCVI advises a preference for an age-appropriate mRNA vaccine for the third primary dose. When mRNA vaccines are not considered clinically suitable, COVID-19 vaccine Nuvaxovid may be given as a primary dose to those aged 12 years and above. Individual clinical assessment is required for children aged 6 months to 11 years who are contraindicated to receiving an mRNA vaccine.

Reinforcing doses

Emerging evidence suggests that many patients with immunosuppression do derive protection after 2 doses of vaccination. However, just as it does for immunocompetent individuals, protection from primary vaccination does decline over time. As those with immunosuppression remain at higher risk of serious complications from COVID-19 infection, this group of individuals

have been eligible for a booster in the spring and autumn 2022 campaigns and are expected to be eligible for future seasonal campaigns. Those aged 5 years and above in this group will also require booster doses to extend protection from their primary course.

A reinforcing (booster) dose should be offered from 3 months after the third primary dose (or last booster dose), ideally during a designated/seasonal vaccination campaign. 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. If they have completed their primary course but not yet received any booster doses, they will require just one booster during the spring 2023 programme. Some children with immunosuppression who turned 5 years of age after August 2022 may have been offered a booster during the autumn 2022 programme (provided there was at least 3 months since their final primary dose); they are eligible for a spring 2023 booster dose after a further minimum interval of 3 months has elapsed.

Pregnant women

COVID-19 vaccines can be given to pregnant women.

Pregnancy is clinical risk group (see ‘Groups affected by COVID-19’). Covid-19 vaccines can be administered at any stage of pregnancy to those who are eligible. 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.

Vaccination against COVID-19 can take place at the same time as, or at any interval before or after, other vaccines offered in pregnancy (pertussis, influenza).

During the spring 2023 campaign, **pregnant women may be offered primary vaccination as part of the ‘Evergreen’ offer** as this remains in place for everyone already eligible who has yet to start or complete a primary course.

Pregnant women who have already received a dose of AstraZeneca or Moderna vaccine can complete with any mRNA vaccine (provided there are no contraindications).

If a woman finds out she is pregnant after she has started a course of COVID-19 vaccine, she should complete vaccination during pregnancy using the same vaccine product (unless contraindicated).

Although pregnancy is a clinical risk group, not all clinical risk groups are being offered a spring 2023 booster. Therefore, if they have previously completed their primary course, **pregnant women are only eligible for a spring 2023 booster if they are also immunosuppressed**, as defined in Tables 3 and 4 of the Green Book COVID-19 chapter.

Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the COVID-19 vaccine. Eligible women who are planning pregnancy or are in the immediate postpartum can be vaccinated.

Resources for pregnant and breastfeeding women are available from the UKHSA and on the RCM website. Professional resources are available from the RCM and the RCOG.

Breastfeeding women

COVID-19 vaccines can be given to eligible breastfeeding women.

Those eligible for the spring 2023 campaign are women who require a primary dose as part of the 'Evergreen' offer or who are immunosuppressed - as defined in Tables 3 and 4 of the Green Book COVID-19 chapter - and require a spring 2023 booster dose.

There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that eligible 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

Interval between doses for 5 to 17 year olds who are not in a clinical risk group

For those aged 5 to 17 who are not in a high-risk group, a 12-week interval is preferred but an 8 week interval is acceptable and may be necessary for operational reasons or in order to complete the course during the campaign. As the programme is moving to only offer vaccination to children and young people at clinical risk an eight-week interval will now be the most common schedule in all age groups.

Previous guidance recommended a 12 week interval in healthy children, which reflected the balance of risk-benefit in these individuals. Emerging evidence suggested that countries with longer schedules (8 to 12 weeks) may have a lower rate of myocarditis and high levels of protection against severe disease were seen after the first dose. JCVI took a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis, but the benefits in those at clinical risk were deemed more in favour of completing primary vaccination earlier.

Vaccination of children and young people who have recently had COVID-19 infection

There is no longer any requirement for vaccination to be deferred for a prescribed interval following COVID-19 infection. Follow the guidance provided under 'Vaccination of individuals with a current or previous history of COVID-19 disease'.

For eligible children who have developed Paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 infection (PIMS-TS) the advice of the paediatrician treating them should be sought with regard to the timing of their COVID-19 vaccination(s).

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. **Wearing gloves is not recommended**.

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 densest part of 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.

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 parent/carer, 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 COVID-19 vaccine are kept for observation and monitored for a minimum of 15 minutes, however the Commission on Human Medicines (CHM) has suspended this requirement in individuals **without a history of allergy**. The advice to suspend the routine 15 minute observation period therefore applies to all currently available COVID-19 vaccines in all age groups.

Reporting of adverse events including anaphylaxis via the Yellow Card Scheme is strongly encouraged and the MHRA will continue to monitor and report on these.
Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. 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 offer the manufacturer's patient information leaflet for the vaccine that they have received and an age appropriate UKHSA information leaflet in an accessible format.

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 has not been supplied since September 2022. 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 rarely 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 sequalae. 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.

Thrombocytopenia

Cases of thrombocytopenia (without thrombosis) have been reported rarely following receipt of Astra Zeneca and other COVID-19 vaccines. Some of these cases have occurred in individuals with a history of immune thrombocytopenia (ITP) (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).

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 experienced 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 days for protection from their COVID-19 booster vaccination to develop (longer if they have received a primary dose) and that they should continue to follow advice current at the time regarding infection prevention and control measures such as washing their hands thoroughly and frequently.

If a vaccine recipient experiences any symptoms or there is any other reason that makes them or their parent/carer think that may have COVID-19, they stay at home and avoid contact with other people, especially with anyone who is at higher risk of getting seriously ill from COVID-19.The latest advice is available on the NHS website.

Some individuals are still eligible for testing. The COVID-19 vaccine will not interfere with testing for COVID-19 infection should this be required. 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.

Adverse reactions following vaccination

Possible adverse reactions following vaccination

The types and rates of local and systemic reactions vary by vaccine product, dose number and the age of the recipient. The Summary of Product Characteristics (SPC) for the vaccine being administered should therefore always be consulted. However, commonly reported reactions following COVID-19 vaccination include:

Local reactions: injection site pain, redness and localised swelling; these usually occur - and resolve - within a few days of the injection.

Systemic reactions: tiredness, headache, muscle aches, chills, joint pain, and a raised temperature (pyrexia); nausea or vomiting and axillary lymph gland swelling or tenderness are also reported. Symptoms are usually mild or moderate in intensity and resolve within a few days after vaccination.

Rates of reactions are higher in people when mixed (heterologous) vaccine schedules are received.

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.

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

The MHRA publishes details of yellow card reports following the receipt of the UK-approved COVID-19 vaccines.

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 and other 'flu-like' symptoms are common, expected reactions and will generally resolve within a few days without treatment, but if required, symptomatic treatment with analgesic and or anti-pyretic medicinal products (for example paracetamol-containing products) may be used.

Commonly reported COVID-19 symptoms include headache, fatigue, cough myalgia (aching muscles), Omicron is less likely to cause loss of sense of smell (anosmia) and more likely to cause a sore throat.

If someone experiences any of these or any other symptoms or any other reason that makes them think they may have COVID-19, they should try to stay at home and avoid contact with other people, especially with anyone who is at higher risk of getting seriously ill from COVID-19. The latest advice is available on the NHS website. Some individuals are still eligible for testing. The COVID-19 vaccine will not interfere with testing for COVID-19 infection should this be required.

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 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.

Because of this likely immune mechanism, there is no reason to believe that individuals with a past history of clots or of certain thrombophilic conditions (including pregnancy or taking the contraceptive pill) would be at increased risk of this very rare condition. There have been no confirmed cases reported in pregnant women to date.

Individuals with past clotting episodes and those diagnosed with thrombophilia, whether or not they are on long term anti-coagulation, remain at risk of COVID-19 disease.

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 no longer supplied, 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 vaccines in individuals with a prior history of this condition. 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.

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.

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

Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, but anyone currently experiencing symptoms of COVID-19 disease should not attend for vaccination until they have recovered, to avoid infecting others at the vaccination clinic.

Although it was previously advised to wait a certain period of time following confirmed or suspected COVID infection, this is no longer the case, however, as some individuals with COVID-19 disease can continue to develop new symptoms or experience worsening of their symptoms for up to 2 weeks after infection, vaccination should ideally be deferred until clinical recovery.

Individuals with a previous history of COVID-19 disease (confirmed or suspected)

These people can – and should - still receive COVID-19 vaccine. Vaccination in these circumstances would be expected to boost any pre-existing antibodies. It is not known how long antibodies made in response to natural infection persist and it is known that hybrid immunity – a combination of natural immunity and vaccine-induced immunity – enhances protection against severe disease (which is the aim of the booster programme).

There is no evidence of any safety concerns from receiving a COVID-19 vaccine if antibodies have already been made to the disease following natural infection.

During care home outbreaks, vaccination of residents with confirmed COVID-19 may go ahead, provided the residents are clinically stable and infection control procedures can be maintained. These populations are likely to be highly vulnerable and this policy should help to maximise vaccination coverage without the need for multiple visits.

There is no minimum interval between COVID-19 infection and receipt of any vaccination as long as the individual is recovered.

Recent vaccination with other vaccines does not affect testing for COVID-19 infection in the event that this is required.

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. No specific interval is required between receipt of these products and COVID-19 vaccination. 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.

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

This is not a reason to defer any COVID-19 vaccination but should be taken into account when providing advice.

Based on what is known about how vaccines and the immune system work, it was thought when any COVID-19 vaccine was co-administered with another vaccine there would be limited interference and that any potential interference was most likely to result in a slightly attenuated (weaker) immune response to one of the vaccines. A few studies have more recently been conducted and indicate that co-administration does not clinically diminish vaccine effectiveness. There is no evidence of any safety concerns, although co-administration may make the attribution of any adverse events more difficult.

Based on the available evidence, therefore:

- where individuals in an eligible cohort present having recently received one or more vaccines, whether inactivated or live, COVID-19 vaccination should still be given
- the same applies for 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 all vaccines commonly administered around the same time or in the same settings to anyone who is eligible to receive a Comirnaty 10 Concentrate COVID-19 vaccine.

Where co-administration does occur, children/parents/carers 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.

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

Administration of a larger than recommended dose

For example:

- a full dose of Pfizer BioNTech Comirnaty bivalent Original/Omicron BA.4-5 (or Comirnaty bivalent Original/Omicron BA.1) 15/15 micrograms per dose vaccine is administered instead of the recommended Comirnaty 10 micrograms/dose vaccine to individuals aged less than 12 years
- a vial of Pfizer BioNTech Comirnaty 10 micrograms/dose vaccine 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 Original/Omicron BA.4-5, Comirnaty bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4-5 (or Spikevax bivalent Original/Omicron BA.1) are drawn up and administered to one individual
- a full vial of correctly mixed Sanofi VidPrevtyn Beta is administered to one individual
- a dose of Comirnaty 10 micrograms/ dose vaccine is given to a child aged 6 months to less than 5 years instead of the recommended Comirnaty 3 micrograms/ dose vaccine

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.

If an individual is given more than the recommended dose:

- they should be monitored and treated for any symptoms as required. They should be reassured that this is not 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

Moderna Spikevax bivalent Original/Omicron BA.4-5 or BA.1 vaccine given in error to a person of less than 18 years of age

Moderna Spikevax bivalent vaccines although licensed (from age 12 years for Spikevax Original/Omicron BA.4-5 and 6 years for Spikevax bivalent Original/Omicron BA.1) are not recommended for use in individuals of less than 18 years of age because of the slightly higher risk of myocarditis/pericarditis compared to Pfizer vaccines.

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 bivalent Original/Omicron BA.4-5 (or Spikevax bivalent Original/Omicron BA.1) 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 parents' or carers' attention.

The dose will be effective and does not need repeating. If further doses are indicated an age-appropriate vaccine should be administered.

Sanofi VidPrevtyn Beta vaccine given in error to a person of less than 65 years of age

Although this use is not recommended by the JCVI, Sanofi VidPrevtyn Beta vaccine is licensed from age 18 years. The dose does not need repeating.

Inadvertent administration of Sanofi VidPrevtyn Beta vaccine as a primary dose

VidPrevtyn Beta is licensed for individuals 18 years of age and older. Provided the individual does not have any underlying health conditions that would contraindicate receiving the vaccine, or an allergy to any of the excipients, any immediate issues will relate to the adverse effects for routine administration as detailed in the SPC.

VidPrevtyn Beta is licensed only for booster doses. Although the study data provided to support its authorisation by the MHRA relate to its use as a booster following a primary course, in the initial clinical trials it was found to generate antibodies when given as a primary dose. Therefore, although not licensed for priming this dose does not need to be repeated.
If this was a first primary dose a vaccine recommended for priming should be used to complete the primary course, after the recommended minimum interval of 8 weeks, and in line with current operational arrangements. There is strong evidence that individuals receiving a mixed

primary schedule make a good immune response, although rates of side effects with a heterologous second dose are higher.

Local reporting procedures should be followed and, in order to minimise the risk of this occurring again, operational processes should be in place to ensure that prior vaccination history is reviewed before vaccine administration.

Pfizer Comirnaty bivalent Original/Omicron BA.4-5 or BA.1 vaccine given in error to a child aged 5 to 11 years

This is not a licensed use of this vaccine. A child of this age requires just a 10 microgram dose to produce effective immunity. A dose of Comirnaty bivalent Original/Omicron BA.4-5 or Comirnaty bivalent Original/Omicron BA.1 contains a total of 30 micrograms (15 micrograms of each of 2 COVID-19 strains). This dose does not need repeating. Follow up should be as per ‘Administration of a larger than recommended dose’.

Pfizer Comirnaty 10 micrograms/ dose given in error to a child aged 6 months to 4 years of age

Follow the advice for ‘administration of a larger than recommended dose’.

Pfizer Comirnaty 3 micrograms/ dose given in error to a child aged 7 years or older

Follow the advice for inadvertent administration of an incomplete dose

Inadvertent administration of an incomplete dose

This may be noticed immediately:

- the vaccine and/or dose selected and administered are incorrect, but the amount of vaccine given is known
- 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 less than the recommended dose vaccine has been administered a risk assessment should be undertaken. This risk assessment should consider:

- the level of certainty around the dosing error (is the amount that has been given known or estimated?)
- the suspected level of underdosing (how much of the recommended dose was given?)
- the risk profile of the individual (for example: their age, whether they are immunosuppressed or have an underlying clinical risk condition, whether they have previously had a confirmed COVID-19 infection)
- type of dose (primary or booster dose; previous COVID-19 vaccination history)

This risk assessment is recommended because there is a possibility of increased reactogenicity following receipt of an additional dose. In addition, following mRNA re-vaccination, there is an increased risk of myocarditis and pericarditis following mRNA re-vaccination, notably in younger age groups. These factors should be weighed against the risk of a lower immune response to less than the recommended dose of vaccine.

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.

Effectiveness of COVID-19 vaccines

All approved COVID-19 vaccines produce high short term antibody responses. Antibody responses are substantially higher in vaccinated individuals with evidence of natural infection, even after a single dose of vaccine. Seroprevalence studies indicate that most of the adult and childhood population have been naturally infected.

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. There is less information to support decisions about under-dosing with VidPrevtyn, but as the vaccine includes an adjuvant, and those receiving it are likely to have been primed by vaccine, natural infection or both, smaller doses may well lead to an effective boost.

Note that there is no longer a different dose recommendation for primary and reinforcing doses for any of the available mRNA vaccines.

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.

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.

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

For example:

- inadvertent administration of incorrectly diluted Comirnaty 3 micrograms/dose vaccine or Comirnaty 10 micrograms/dose vaccine

In these scenarios expert advice should be sought as it is it is important to include, as part of the assessment, a calculation of the dose administered and what the available potency data indicate for that dose. The guidance for risk assessment and repeat doses for ‘Underdosing’ also applies and should be followed. The UKHSA publication Vaccine incident guidance:

Responding to errors in vaccine storage, handling and administration includes guidance for the management of these incidents.

Staff vaccinating children should be aware of the differences between the concentrate and diluent volumes for the infant and paediatric Pfizer products as mixing these up will result in either giving too much or too little antigen:

	Comirnaty 3 Concentrate	Comirnaty 10 Concentrate
Concentrate for dispersion in each vial	0.4ml	1.3ml
Volume of diluent (0.9% sodium chloride) to be added to each vial	2.2ml	1.3ml
Volume of each dose	0.2ml	0.2ml
Number of doses per vial	10	10
Strength of each dose	3 micrograms	10 micrograms

If 2.2ml of diluent is incorrectly added to the Comirnaty 10 Concentrate vial, in each 0.2ml dose will contain too small a dose. Follow the guidance in the ‘Inadvertent administration of an incomplete dose’ section regarding risk assessment and, if then indicated, repeat dosing.

If 1.3ml of diluent is incorrectly added to the Comirnaty 3 (three) Concentrate vial, each 0.2ml dose will contain too large a dose. Follow the advice for ‘administration of a larger than recommended dose’ regarding advice, monitoring and management of post-vaccination symptoms.

Administration of a dose of VidPrevtyn Beta that has not been refrigerated after mixing

Once mixed, VidPrevtyn Beta can be kept for a maximum of 6 hours, after which it must be discarded.

Ideally, the vaccine should be returned to storage (vaccine fridge or cool box) between doses at a temperature of +2°C to +8°C. If for some reason it has remained at room temperature but is used within 6 hours of mixing then no action will need to be taken in respect of any doses that have already been given, nor would we advise that the unused vaccine is discarded before 6 hours have elapsed.

There is no requirement to remove the mixed vaccine from the fridge for a specific period of time before administration. The product will quickly come up to a comfortable temperature for administration whilst the dose is being drawn up.

Inadvertent administration of the Comirnaty 3 micrograms/dose or Comirnaty 10 micrograms/dose diluent only

The diluent for the Pfizer BioNTech Comirnaty 3 micrograms/dose and Comirnaty 10 micrograms/dose 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 a ready to use vaccine that has been diluted

COVID-19 vaccines Moderna Spikevax bivalent Original/Omicron BA.4-5 and Moderna Spikevax bivalent Original/Omicron BA.1 and Comirnaty bivalent Original/Omicron BA.4-5 and Comirnaty bivalent Original/Omicron BA.1 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).

Inadvertent administration of the Sanofi VidPrevtyn Beta antigen (only)

For example:

- a full vial of antigen has been administered
- 0.5ml of antigen has been administered

Sanofi's trial data indicates that without the addition of the adjuvant, the antigen is unlikely to stimulate a sufficiently strong immune response, even when a larger than recommended amount of antigen has been administered. The recipient and/or their carer(s) should be advised about possible local and systemic reactions and they should be monitored and treated for any symptoms as required. They should be reassured that this is not generally harmful. A dose of correctly prepared vaccine should be administered following the 'repeat dose' guidance in the 'Inadvertent administration of an incomplete dose' section above.

Inadvertent administration of Sanofi VidPrevtyn Beta adjuvant (only)

The advice is the same whether a full vial or 0.5ml of adjuvant has been administered. The role of the adjuvant is to hold the antigen at the injection site for longer so that the immune system can better recognise the antigen and to produce a stronger response by stimulating certain components of the innate immune system. In the absence of the antigen any reactions should be minimal, however, as with any injected substance, the adjuvant may cause some local inflammation, and particularly if a large volume (the full vial) has been injected. However, the adjuvant alone will not evoke an immune response so the person should be given a dose of any suitable vaccine as soon as the error is realised. If VidPrevtyn Beta is administered it must be correctly prepared (adjuvant + antigen). It would be preferable (if possible) to use a different administration site to avoid additional discomfort.

Inadvertent vaccine administration errors: scheduling

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 unlikely that their response to this second dose and their longer term protection will be adversely affected.

There is no need to restart the course and the second dose should be given as soon as it can be arranged using any age-suitable mRNA vaccine (unless contraindicated) to complete the course. If the second dose is given during a seasonal booster campaign this counts as the booster and an additional booster is not required.

Vaccination of an individual who has not received a primary course

If an individual is given a booster dose but is then discovered not to have a received a primary course the booster dose should be counted as a primary dose. If the dose is given during a seasonal booster campaign this counts as the booster and an additional booster is not required. If this was their first primary dose then a second dose can be given, within the same vaccination campaign, after a minimum 8 week interval.

However, as the programme has moved to a pattern of lime-limited campaigns, individuals in a clinical risk group may not be able to receive their 2nd dose until the next campaign period during which they are eligible (with the exception of severely immunosuppressed individuals who may, on the basis of individual assessment, be considered for vaccination between campaigns). The primary offer to healthy individuals (not in a clinical risk group) will end when the spring 2023 campaign is completed.

Administration of a booster dose less than 3 months after a previous 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. This is to maximise the benefit from extending the period of protection on top of that remaining from the previous doses.

Where the booster dose is inadvertently given earlier than 3 months (12 weeks) from the final primary dose, but within the seasonal campaign period up to the end of June 2023, it can still count as a seasonal 2023 booster.

Longer than recommended interval left between previous dose and currently recommended booster dose

As long as 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 within the current booster campaign. The purpose of booster doses is to extend protection for those at greatest risk of serious disease and hospitalisation during periods of known or anticipated high infection rates, and the offer may therefore be time-limited – that is, no longer available once the risk has lessened. Individuals who are longer from their previous dose may be at higher risk and should therefore be encouraged to promptly take up the offer of vaccination.

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 other COVID-19 vaccine reporting systems that have been established. See also NHS England Management of COVID-19 vaccination clinical incidents and enquiries SOP.

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).

elearning for healthcare COVID-19 vaccination e-learning

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.

MHRA Yellow Card reports

Product information for the Comirnaty 10 Concentrate and Comirnaty 3 Concentrate vaccines

Product information for the Spikevax bivalent vaccines

Product information for the Comirnaty bivalent vaccines

Product information for Nuvaxovid vaccine

Product information for Sanofi VidPrevtyn Beta vaccine

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

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) Note that individuals who were vaccinated with a single dose of Janssen vaccine have completed their primary course and do not require additional doses unless they are eligible for a booster	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 Note that, unless contraindicated, the WHO recommends that booster doses for eligible individuals who the received single dose primary course of Janssen vaccine should be an mRNA vaccine.	
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	
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	Follow UK recommendations regarding clinical suitability and indications
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 transitional WLAs (who.int) (WHO; these are replacing the previously referenced Stringent Regulatory Authorities)

About the UK Health Security Agency

UKHSA is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation's health secure.

UKHSA is an executive agency, sponsored by the Department of Health and Social Care.

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