UK Health Security Agency

COVID-19 vaccination programme

Information for healthcare practitioners

Republished 03 October 2024
Version 7.0

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Document history

Version number	Change details	Date
1.0	Document created	27 November 2020
2.0	Vaccine specific information about the coronavirus (COVID-19) mRNA Vaccine BNT162b2 (Pfizer BioNTech) added	4 December 2020
2.1	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

Version number	Change details	Date
	174 Information for UK healthcare professionals on Pfizer/BioNTech COVID-19 vaccine	
3.3	Advice added regarding inadvertent administration of a different COVID-19 vaccine at a short interval after the first dose	11 February 2021
3.4	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
7.0	1. Updated to align with the revised Green Book chapter 14a published on 16 September 2024 and the recommendations for the autumn 2024 vaccination campaign 2. Extensively revised: information available in other sources removed and content about common issues in clinical practice and links to resources retained	03 October 2024

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 does not replace the Green Book COVID-19 chapter, the Summaries of Product Characteristics (SPCs) nor the Patient Group Direction (PGD) and national protocol for the COVID-19 vaccines, all of which should be available to and actively consulted by those delivering this programme.

As the COVID-19 vaccination programme is well established, this document has been extensively revised and now focuses predominantly on common issues encountered in clinical practice. Links to additional resources are provided.

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.

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 2020 the World Health Organisation (WHO) declared COVID-19 as a pandemic.

Transmission of SARS-CoV-2 has been widespread and sustained and the disease is associated with significant morbidity and mortality within certain groups. Collaborative scientific effort led to the rapid development of safe and effective vaccines and, on 8 December 2020, the COVID-19 vaccination programme began in the UK.

Resources

UKHSA resources

The primary resource is Immunisation against infectious diseases: the green book, including chapter 14a: COVID-19.

This chapter is also available via the UKHSA COVID-19 vaccination programme document collection.

Other resources within the UKHSA collection include:

- the Joint Committee on Vaccination and Immunisation (JCVI) advice and minutes
- a template PGD and national protocol which are developed for NHS England by UKHSA; they require local sign-off before use and each document clearly sets out which staff can work to it (which section(s) of it, for the national protocol) and the training that is required in order to do so
- links to comprehensive e-learning (published on the e-Learning for Health platform, log-in required) and other training resources including recommendations; use of the competency assessment is recommended for all staff in all healthcare settings
- patient information leaflets and resources for the public to order and download from Health Publications; these are also available in a wide range of languages and in Braille, easy-read and audio formats
- published Vaccine effectiveness monitoring reports

Other resources

Coronavirus (COVID-19) in the UK dashboard provide details of the latest UK disease, healthcare impact and vaccination statistics.

The Summary of Product Characteristics (SPC or SmPC) documents (and Patient Information Leaflets (PILs) for the vaccines are available from the Electronic Medicines Compendium (emc).

The NHS Specialist Pharmacy Service (SPS) provides guidance about storage, transportation and all aspects of medicines management relating to the vaccines.

Further information about legal mechanisms (PGDs, PSDs, National Protocols) and who can use them is available from NHS England, the NHS Specialist Pharmacy Service and the MHRA.

NHS England circulates operational guidance to commissioners and providers and publishes information on the FutureNHS Collaboration Platform (log-in required). Enquiries about this should be sent to NHS England (for providers this should be via their local or regional Public Health/Screening and Immunisation commissioning team).

Suspected adverse reactions following administration of COVID-19 vaccine should be reported to the MHRA using the Yellow Card scheme. The MHRA publishes details of yellow card reports following the receipt of the UK-approved COVID-19 vaccines.

COVID-19 vaccination programme

Overview

This programme has, since it began in December 2020, been implemented against a background of newly emerging variants, and via a number of primary vaccination phases and booster campaigns, to protect individuals at highest risk from serious illness or death and to protect the NHS by reducing the risks of hospitalisation and critical care admission.

As it also does for other vaccination programmes, the Joint Committee on Vaccination and Immunisation (JCVI) considers the available epidemiological, microbiological and clinical information about the disease and its impact on the UK population and provides the government with advice to support the development of the vaccination strategy. The COVID-19 vaccination programme has therefore changed and will continue to change over time in response to the most up to date information.

COVID-19 vaccination is now a targeted offer for those at higher risk of severe COVID-19 disease and is offered during planned seasonal campaigns. These campaigns are currently bi-annual: an autumn campaign (part of overall winter health preparedness), and an additional spring campaign for those at the highest risk – individuals who will be especially vulnerable over the later summer months as their immunity wanes.

COVID-19 vaccines given in the UK

The JCVI recommendations for vaccine type, dose and schedule – which are set out in the Green Book COVID-19 chapter – should be followed at all times, including when this differs from the vaccine products' Summaries of Product Characteristics (often referred to as SPCs or SmPCs).

The supplied vaccines differ in both their presentation and in their requirements for preparation and vaccinators must be familiar with the specific product information for the vaccines that they will be administering during the current campaign. The SPCs are provided with each vaccine pack and are also available from the Electronic Medicines Compendium.

COVID-19 vaccine indications and schedules: autumn 2024 campaign

This section provides brief information about the autumn 2024 vaccination campaign. Staff should consult the Green Book COVID chapter for the full details and use the resources, listed above, including the e-learning, to fully update their knowledge of the programme.

Eligibility

During the 2024 autumn campaign the following groups should be offered a COVID-19 vaccine:

- all adults aged 65 years and over including individuals aged 64 who will have their 65th birthday before the campaign ends (31st March 2025)
- residents in a care home for older adults
- individuals aged 6 months and over who are in a clinical risk group, as defined in tables 3 and 4 of the Green Book chapter 14a

Recommended vaccines

The recommended vaccines for the autumn 2024 campaign are all monovalent products containing mRNA for the spike protein of the JN.1 sub-lineage of the Omicron variant strain of the SARS-CoV-2 virus.

Eligible adults aged 18 years or over

- a 0.3ml dose of Pfizer BioNTech 30 micrograms/dose COVID-19 vaccine (Comirnaty 30 JN.1)

The Comirnaty 30 micrograms/dose product will be supplied as multi-dose vials containing ready-to-use vaccine; a maximum of six doses of 0.3ml may be drawn up and administered from each vial. Any excess vaccine in the vial should be discarded.

- a 0.5ml dose of Moderna 50 micrograms/dose COVID-19 vaccine (Spikevax JN.1)

The Spikevax 50 micrograms/dose product will be supplied as multi-dose vials containing ready-to-use vaccine; a maximum of five doses of 0.5ml may be drawn up and administered from each vial. Any excess vaccine in the vial should be discarded.

Eligible children and young adults aged 12-17 years

- a 0.3ml dose of Pfizer BioNTech 30 micrograms/dose COVID-19 vaccine (Comirnaty 30 JN.1)

The Comirnaty 30 micrograms/dose product will be supplied as multi-dose vials containing ready-to-use vaccine; a maximum of six doses of 0.3ml may be drawn up and administered from each vial. Any excess vaccine in the vial should be discarded.

Eligible children aged 5 to 11 years

- a 0.3ml dose of Pfizer BioNTech 10 micrograms/dose COVID-19 vaccine (Comirnaty 10 JN.1)

The Comirnaty 10 micrograms/dose product will, from the start of the autumn 2024 campaign, be supplied as single-dose vials; a 0.3ml dose should be drawn up and administered and any excess solution in the vial should be discarded.

Eligible children aged 6 months to 4 years

- a 0.3ml dose of Pfizer BioNTech 3 micrograms/dose COVID-19 vaccine (Comirnaty 3 JN.1)

The Comirnaty 3 micrograms/dose concentrate vaccine will, from the start of the autumn 2024 campaign, be supplied as three-dose vials. Once correctly diluted (with 1.1ml of normal saline) a maximum of three doses of 0.3ml may be drawn up and administered from each vial. Any excess vaccine should be discarded.

Doses and schedules

Number of doses

The JCVI has advised that the UK approved COVID-19 vaccines should routinely be offered to eligible individuals aged 5 years and over as a single vaccine dose per campaign. This is irrespective of previous vaccination history: see section on 'Missed' doses and previous incomplete courses below.

Eligible children aged 6 months to 4 years of age who have not been previously vaccinated may require a second dose.

Information about doses for individuals with immunosuppression is included in the Special population groups section below and the Green Book provides full details.

Intervals between doses

The JCVI has recommended that a minimum interval of 3 months is routinely left between all doses of any COVID-19 vaccine, to help to maximise the duration of protection.

Information about vaccination intervals for individuals with immunosuppression is included in the Special population groups section below. and the Green Book has further information.

‘Missed’ doses and previous incomplete courses

Doses offer time-limited protection (protection increases after each dose but then wanes over the following few months). Individuals who have not taken up previous offers of vaccination therefore cannot be ‘caught-up’ as any doses they missed were intended to protect them during a period of time that has now elapsed:

- If currently eligible they should be vaccinated during the present campaign and encouraged to take up any future offers that apply
- If they are not currently eligible, they may become eligible for vaccination during a future seasonal campaign and should be encouraged to come forward again when they are next called.

If an individual commenced but did not complete a previously recommended primary vaccination course and is eligible for the present campaign they should receive a single dose of an age-appropriate vaccine, and any previous primary dose(s) should not be repeated. If they are not currently eligible, they may be included in a future campaign and should be encouraged to come forward for vaccination at that time.

Individuals who received COVID-19 vaccination overseas

It is important to first establish whether the individual is eligible for vaccination according to UK recommendations.

It is not necessary to know which vaccine(s) an individual has previously received unless they indicate that they had an adverse event to a COVID-19 vaccine that would either contradict or be a precaution for a further dose.

All eligible individuals should be vaccinated irrespective of their previous COVID-19 vaccination history. Observe a minimum interval of 3 months since any previous dose. If the date of any previous dose cannot be established, follow the Unknown vaccination history guidance below.

COVID-19 vaccine clinical trial participants

Individuals who have previously participated in a clinical trial for any COVID-19 vaccine and who are eligible for the autumn 2024 campaign should be offered vaccination in line with the general population, that is a single dose should be administered at least 3 months after their previous dose (including if this was a dose given as part of the clinical trial).

Individuals who have received a dose of COVID-19 vaccine privately

If they are eligible for the autumn 2024 campaign, these individuals should be offered an NHS dose of an appropriate COVID-19 vaccine, observing a minimum 3 months' interval since their previous dose.

Unknown vaccination history

If the previous COVID-19 immunisation history of an individual eligible for a dose during the present campaign is unknown, it is preferable, rather than delaying vaccination, to administer a dose of any suitable COVID vaccine. If upon further investigation this dose is discovered to have been given within 3 months of the previous dose, it should still be counted and, for the purposes of calculating the interval to any future recommended doses, the date on which it was administered is 'day 0'.

Specific population groups

Immunosuppression

The advice of their specialist should be obtained for individuals who are immunosuppressed. Full details are provided in the Green Book chapter 14a and what follows is a summary of the key issues to be considered.

Individuals who are eligible for a vaccination due to severe immunosuppression but miss vaccination during the campaign period, may be considered for a booster at a later date based on individual clinical judgement, balancing their immediate level of risk against the advantages of waiting till the next seasonal campaign.

Additional doses

Individuals who become or have recently become severely immunosuppressed (those commencing immunosuppressive therapy or those who have developed an immunosuppressive condition) should be considered for additional doses.

Further information is provided in the Green Book chapter 14a but specialist clinical judgement is required to determine which individuals should be given additional doses and when they should optimally receive them, both with regard to the appropriate interval between doses and to whether they should be administered within or between seasonal campaigns (which is permitted if immediate administration of a dose or doses is indicated).

Timing of administration of these additional doses

Where indicated, the additional dose(s) may be administered 8 to 12 weeks after the previous dose.

Individuals with immunosuppression may not make a full immune response to vaccination. As there is limited evidence on response for each specific immunosuppressing therapy or condition then general principles are needed to inform the optimal timing of delivery. It is expected that vaccines administered during periods of minimum immunosuppression are more likely to generate better immune responses. Therefore, vaccination should be given, ideally, with special attention paid to current or planned immunosuppressive therapies. 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.

Administration of doses prior to planned immunosuppressive treatment

Vaccination should preferably be administered (and ideally completed if an additional dose is indicated) a minimum of 2 weeks before planned immunosuppressive therapy and allowing a minimum interval of 3 weeks between doses to optimise the benefits.

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.

Selective revaccination

Individuals who receive bone marrow transplants, and many individuals who receive CAR-T therapy for certain conditions, may lose immunological memory from vaccination received prior to the treatment and the development of the underlying condition. After treatment and recovery, these individuals should be considered for a full course of revaccination for **all** vaccines used in the routine programme (see chapter 7 of the Green Book). Specialist advice should be followed on which vaccines can be safely given and on the optimal timing for commencing revaccination.

Individuals who have recovered from a bone marrow transplant should be considered for a first dose of COVID-19 vaccine, regardless of the time of year. A subsequent dose should then be offered ideally at an interval of 8 to 12 weeks, to extend the duration of protection. This interval may be reduced to a minimum of three weeks on specialist clinical advice. Those who remain immunosuppressed will then continue to be eligible for seasonal campaigns.

Assessing the requirement for additional doses or revaccination

Those with immunosuppressive conditions, particularly those where the condition or treatment has changed over time, should discuss with their specialist regarding their best options for

vaccination. General principles are outlined below and should be taken alongside specialist advice.

A suggested clinical approach is to consider this in terms of the patient pathway, respecting that the mutability of “immunosuppression” adds complexity.

When the JCVI recommends including, in a seasonal campaign, the vaccination of individuals with immunosuppression as defined in Tables 3 and 4 of the Green Book chapter 14a this refers to individuals who are ***currently*** considered to be immunosuppressed and therefore eligible during that campaign. These are normally offered at least three months after a previous dose.

All eligible individuals should be offered a single dose regardless of prior vaccination history. Individuals who are ***severely*** immunosuppressed (as defined in Boxes 1 and 2 of the Green Book chapter 14a) should also be considered for additional dose(s) – and, if required, these may be administered between seasonal campaigns. These additional doses are normally offered two to three months from a previous dose.

Individuals with a haematological malignancy may, especially during the acute stage of their illness may also be severely immunosuppressed (Boxes 1 and 2 of the Green Book chapter 14a).

But they may also, with treatment (with or without bone marrow transplant (BMT)) over time improve and become either less severely immunosuppressed (Tables 3 and 4 but not Boxes 1 and 2 of the Green Book chapter 14a) or no longer immunosuppressed (neither Table 3 nor Box 1 or Table 4 nor Box 2).

Individuals who have recently had a BMT are considered severely immunosuppressed but, if the BMT is successful they may over time move from a state of severe immunosuppression to immunosuppression and – if they no longer require immunosuppressive treatment and haven’t suffered graft versus host disease (GVHD) – to no longer being immunosuppressed. >Most cases of GVHD occur with 2 years of BMT so, by 24 months post-successful BMT, individuals who are not receiving immunosuppressive treatment (for whatever reason) and who have not had GVHD would not usually be classed as immunosuppressed.

There will therefore be a time after their BMT when they are immunologically able to respond to vaccination and it is at this point that they should be considered for re-vaccination because they are considered naïve for any of the antigens encountered before they had their BMT. COVID-19 is just one of the vaccinations that they should be offered.

As some vaccines will constitute a specific risk in this group, specialists should take responsibility for issuing advice on the need for additional doses and the timing of revaccination, taking account of an individual’s degree of immunosuppression and ability to respond to vaccination. This may then lead to COVID-19 vaccination being offered at a shorter interval of three weeks, as advised in some of the specialist guidance, but the balance between

any immediate risk, the expected more durable protection from using a longer interval and providing vaccination at a point where immune status has recovered further should be considered.

Women who are pregnant or breastfeeding

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

Being pregnant is an indication for the autumn 2024 campaign.

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

As COVID-19 vaccine can be given at any stage of pregnancy, its administration should not be delayed so that it can be given during the same appointment as pertussis or RSV vaccine. (The same advice applies to flu vaccination; flu vaccine can be given at any stage of pregnancy and can be co-administered with COVID-19 vaccine).

Additional resources for healthcare professionals and for pregnant and breastfeeding women are available from the UKHSA and the Royal College of Obstetricians and Gynaecologists (RCOG).

Administration of COVID-19 vaccine

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.

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.

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.

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 receiving anticoagulation therapies.

Administering COVID-19 to individuals with a history of allergy

A previous systemic anaphylactic reaction to a COVID-19 vaccine or a prior allergic reaction to any component (excipient) of the COVID-19 vaccine e.g. polyethylene glycol (PEG) are relative contraindications to receiving an mRNA COVID-19 vaccine but, following an assessment, there are likely to be very few individuals who cannot safely receive these vaccines. Comprehensive guidance about the assessment and management of individuals with a history of allergy are contained within Chapter 14a of the Green Book. Specialist advice may be required.

Observation following immunisation with COVID-19 vaccine

Individuals with a personal history of allergy 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.

Individuals without a personal history of allergy, or with only a family history of allergy, do not need a period of observation.

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.

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.

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 individuals, or their carers, the manufacturer's patient information leaflet for the vaccine that they have received and an age appropriate UKHSA information leaflet in an accessible format.

What to advise an individual who develops possible COVID-19 symptoms after receiving COVID-19 vaccine

All vaccine recipients should be advised that it may take a few days for protection from their COVID-19 vaccination to develop (longer if the vaccine they have received is their first dose and they have not previously had COVID-19 infection) 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 (see How to avoid catching and spreading COVID-19 infection. - NHS (www.nhs.uk).

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.

Some individuals may have already become infected and be incubating the disease at the time of their vaccination, and thus become symptomatic in the post-vaccination period.

It is often possible to differentiate between symptoms following vaccination that are part of the immune system's response to the vaccine ('vaccine reaction') and symptoms caused by the disease:

- 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 and myalgia (aching muscles). The Omicron COVID variant is less likely to cause loss of sense of smell (anosmia) and more likely to cause a sore throat than previous variants.

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 (or any other recent vaccination) will not interfere with testing for COVID-19 infection should this be required.

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.

Rarely reported adverse events

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.

Spikevax JN.1 50 micrograms/dose is **not** recommended for use in young people (aged 12 to 17 years of age); a dose of Comirnaty JN.1 30 micrograms/dose vaccine is preferred due to a slightly lower reported rate of myocarditis.

Limited data indicate that the risk of myocarditis and pericarditis after vaccination with an age-appropriate dose of Comirnaty vaccine in children aged 5 to 11 years is lower than in ages 12 to 17 years and that in children from 6 months to 4 years of age the risk is similar to, or lower than, that in 5 to 11-year-olds.

Onset of myocarditis and pericarditis post-COVID-19 vaccination is within a few days of vaccine administration 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 14a.

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 receiving any future doses they are eligible for. 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.

Erythema multiforme

Erythema multiforme (EM) is a hypersensitivity reaction which tends to develop suddenly. The trigger is most often an infection but can be a medicine. The main symptom is a rash which usually disappears on its own, but sometimes treatment may be required. It can occur in any age group but is seen mainly in young adults and is slightly more common in men. EM is usually mild - 'erythema multiforme minor' – with only the skin affected and clearing up in days to weeks. Some individuals become generally unwell with a high temperature and headache and develop blisters (erythema multiforme major). More information about this condition is available at British Association of Dermatologists (bad.org.uk).

A number of cases of erythema multiforme (EM) have been reported after the Pfizer and Moderna mRNA vaccinations. These reports appear to be consistent with EM minor. Recurrence has been reported after re-challenge with the Pfizer vaccine. MHRA have consulted dermatology experts who consider EM an uncommon, benign and self-limiting condition which could plausibly be triggered by COVID-19 vaccination, although over reporting due to misdiagnosis was possible. A past history of erythema multiforme is not a contraindication to COVID-19 vaccination.

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.

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 COVID-19 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 continue to vaccinate eligible individuals 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, but are eligible for a dose of vaccine during the present campaign 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 currently experiencing symptoms 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.

There is no need to defer immunisation in individuals after recovery from a recent episode of compatible symptoms, whether or not they are tested for COVID-19. 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.

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 for 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 .

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.

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

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 individual 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 their 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 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 RSV vaccine (Abrysvo)

Pregnant women

A COVID-19 vaccine can be given at any stage of pregnancy and administration should not be delayed so that it can be given during the same appointment as RSV vaccine (Abrysvo). However, if a woman presents for her RSV vaccine and has not yet received a COVID-19 vaccine the COVID-19 vaccine can be administered at the same appointment.

Older adults

Some data shows that co-administration of COVID 19 vaccination and RSV vaccination may reduce the immune response to the RSV vaccine. The clinical significance of any reduced response is unknown, but there is emerging data that RSV immune response also correlates with clinical protection. It is therefore recommended that these vaccines should not routinely be scheduled to be given on the same day to older adults who are eligible to receive both vaccines. No specific interval is required between administering the vaccines.

If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, the vaccines can be administered at the same time.

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

See above regarding co-administration with RSV vaccine. For all other vaccines, if they are due at the same time as the COVID-19 vaccine, they can be given.

Initially, 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 and Comirnaty 30 JN.1 and Spikevax 50 JN.1 are now licensed for co-administration with some specified antigens.There is no evidence of any safety concerns from co-administration, although it 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 individual 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 COVID-19 vaccine.

Where co-administration does occur, individuals and, when applicable, their parents or 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.

Inadvertent vaccine administration errors: dosing

Administration of a larger than recommended dose

For example:

- a full dose of Pfizer BioNTech Comirnaty monovalent 30 micrograms/ 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 3 micrograms/dose vaccine is first diluted, and the entire contents of the multi-dose vial are then drawn up and administered to one child aged 6 months to 4 years
- the entire contents of a vial of Pfizer BioNTech Comirnaty 30 micrograms/ dose or Modern Spikevax 50 micrograms/dose vaccine are drawn up and administered to one individual of the correct age
- the entire contents of a vial of Pfizer BioNTech Comirnaty 10 micrograms/ dose are drawn up and administered to a child aged 5 to11 years
- a dose of Comirnaty 10 micrograms/ dose vaccine is given to a child aged 6 months to 4 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 vaccine given in error to a person of less than 18 years of age

Although now licensed from 6 months of age, Moderna Spikevax COVID-19 vaccines 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 Moderna Spikevax COVID-19 vaccine is inadvertently administered to a child or young person under 18 years, 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.

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.

Pfizer Comirnaty 30 micrograms/ dose 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. Follow up should be as per Administration of a larger than recommended dose.

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

This is not a licensed use of this vaccine. A child of this age requires just a 3 microgram dose to produce effective immunity. Follow the advice for ‘Administration of a larger than recommended dose.

Pfizer Comirnaty 3 micrograms/ dose vaccine given in error to a child aged 5 or older

This is not a licensed use of this vaccine. A child aged 5 to11 years requires a 10 microgram dose of Comirnaty vaccine; 3 micrograms is less than half of the recommended dose. Follow the advice for Inadvertent administration of an incomplete dose below.

Pfizer Comirnaty 10 micrograms/ dose vaccine given in error to an individual aged 12 years or older

This is not a licensed use of this vaccine. The Comirnaty 30 micrograms/dose vaccine is the recommended vaccine for individuals aged 12 years and above. If they are inadvertently given Comirnaty 10 micrograms/dose, this is less than half the recommended dosage. Follow the advice for Inadvertent administration of an incomplete dose below.

0.2ml of the Pfizer 3 micrograms/dose vaccine given to a child aged 6 months to 4 years

The correct dose for the Pfizer 3 micrograms/dose vaccine product is now 0.3ml. A 0.2ml dose of correctly reconstituted product is therefore two-thirds of the required dose. For immunocompetent individuals, follow the advice below for “Immunocompetent individuals who have received at least half of the recommended dose of an age-appropriate COVID-19 vaccine”. For those who are immunosuppressed, a risk assessment is required so the advice for Inadvertent administration of an incomplete dose below should be followed.

Inadvertent administration of an incomplete dose

This may be that:

- 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 any of the above scenarios, where individuals have experienced a possible under-dosing, an overall assessment of the risks and benefits of re-vaccination need to be considered alongside an assessment of the feasibility and operational complexity of a lookback.

Risk assessment

Where less than the recommended dose of 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)
- 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, there is an increased risk of myocarditis and pericarditis following re-vaccination with an mRNA vaccine, 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 involved.

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.

Immunocompetent individuals who have received at least half of the recommended dose of an age-appropriate COVID-19 vaccine

No further action is required if it can be established that at least half of the recommended dose of an age-appropriate COVID-19 vaccine has been administered and that the individual is immunocompetent.

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 has left 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
- the administered vaccine has been exposed to temperatures outside the manufacturer's recommended range (a breach of the cold chain) or the expiry date or the post-puncture expiry time has been exceeded

In these scenarios expert advice should be sought as it is it is important to consider 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 'Inadvertent administration of an incomplete dose' (above) 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 3 micrograms/ dose (a concentrate vaccine that requires reconstitution) and 10 micrograms/ dose (which is supplied 'ready to use') Pfizer products.

Inadvertent administration of the Comirnaty 3 micrograms/dose diluent only

The diluent for the Pfizer BioNTech Comirnaty 3 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 child 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

With the exception of the Pfizer Comirnaty 3 micrograms/ dose vaccine, the mRNA vaccines are all 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 vaccine administration errors: scheduling

Administration of a dose less than 3 months after the previous dose

The JCVI recommend that vaccination should not be routinely given within 3 months of a previous dose. This is to maximise the benefit from extending the period of protection on top of that remaining from the previous dose until the next seasonal campaign. Where a dose is inadvertently given earlier than 3 months (12 weeks) from the previous dose, but within the seasonal campaign period, it can still count as a seasonal dose.

Shorter intervals between doses may be clinically indicated for individuals who are, or who are about to become, immunosuppressed. Refer to the Green Book chapter 14a for details.

Reporting vaccine errors

Errors or incidents in vaccine storage, preparation or administration should be reported as per the employing organisation's policy and contractual requirements and standard operating procedures (for example, the commissioner of the vaccination service (the local NHS England public health/screening and immunisation team) may expect to be notified). 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.

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 vaccines

Product information for the Spikevax vaccine

Royal College of Nursing COVID-19 vaccination page

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

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

Published: October 2024
Publishing reference: GOV-17400

UKHSA supports the UN Sustainable Development Goals