Public Health England

Protecting and improving the nation's health

COVID-19 vaccination programme

Information for healthcare practitioners

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About Public Health England

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Document information

This document is being published provisionally, ahead of authorisation of any COVID-19 vaccine in the UK, to provide information to those who will be involved in the COVID-19 national vaccination programme which is expected to start being delivered in December 2020 **subject to regulatory approval.**

The information in this document was correct at time of publication. As COVID is an evolving disease, a lot is still being learned about both the disease and the vaccines which have been developed to prevent it and the knowledge base is still being developed. For this reason, **some of the information may change.** Updates will be made to this document as new information becomes available. Please use the online version to ensure you are accessing the latest version.

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Background

On 31 December 2019, the World Health Organization (WHO) was informed of a cluster of cases of pneumonia of unknown cause detected in Wuhan City, China.

On 12 January 2020, it was announced that a novel coronavirus was identified as the cause of the illnesses being detected. This virus is referred to as SARS-CoV-2, and the associated disease as COVID-19.

On 30 January 2020, the WHO Emergency Committee agreed that the outbreak met the criteria for a Public Health Emergency of International Concern and on 11 March 2020, the WHO declared COVID-19 as a pandemic.

The Coronavirus (COVID-19) in the UK dashboard shows the UK summary of the daily number of cases and deaths from COVID-19. The dashboard also shows the number of virus tests processed daily and healthcare figures including the daily number of patients admitted to hospital, patients in hospital and patients in ventilator beds.

Further information on COVID-19 disease, epidemiology, the vaccination programme and vaccine efficacy can be found in the Green Book COVID-19 chapter.

Further information on vaccine eligibility is described in the JCVI advice, Green Book chapter and will be included in the PHE COVID-19 PGD and Protocol once available.

Patient information leaflets and resources can be ordered from the Health Publications website

COVID-19 disease

Clinical symptoms

COVID-19 is an emerging disease and complications can be severe and fatal, particularly for those in risk groups.

Asymptomatic infection has been reported but those who do develop symptoms report a range of symptoms which include fever, a new and continuous cough, shortness of breath, fatigue, loss of appetite, anosmia (loss of smell) and ageusia (loss of taste). Other symptoms include: myalgia, sore throat, headache, nasal congestion, diarrhoea, nausea and vomiting.

Around 40% of people who develop symptoms report mild symptoms and typically present without hypoxia or pneumonia. A further 40% present with moderate symptoms which may include non-severe pneumonia and 15% present with severe pneumonia and significant disease.

Critical disease can lead to life threatening complications and is reported in around 5% of cases. Patients with critical disease may experience acute respiratory distress syndrome (ARDS), sepsis, septic shock, cardiac disease, thromboembolic events such as pulmonary embolism and multi-organ failure.

Evidence is growing that the longer-term consequences of more severe complications associated with the inflammatory response may be considerable in those who experience critical and life-threatening illness. Rare neurological and psychiatric complications, which can also occur in patients without respiratory symptoms, include stroke, meningo-encephalitis, delirium, encephalopathy, anxiety, depression and sleep disturbances.

Fewer than 5% of SARS-CoV-2 infection cases are amongst children and in general they appear to experience milder symptoms than adults. Further evidence is needed about the association between underlying conditions and risk of COVID-19 disease in children. A rare presentation of multisystem inflammatory syndrome temporarily associated with COVID-19 in children and adolescents has been noted.

Transmission

SARS-CoV-2 virus is primarily transmitted between people through respiratory droplets expelled from the nose and mouth through coughing, sneezing or speaking or when

people touch their eyes, nose or mouth following contact with contaminated objects and surfaces.

Groups affected by COVID-19

Increasing age and male gender are thought to be significant risk factors for severe disease and infection fatality ratios are highest in the oldest age groups. Co-morbidities such as diabetes and severe asthma are associated with an increased risk of death and obesity and other underlying health conditions can increase the risk for some people[1]. Further information on high risk groups (those who are clinically extremely vulnerable) and moderate risk groups (those who are clinically vulnerable) can be found on the NHS.UK webpage: Who's at higher risk from coronavirus (COVID-19). Deprivation and being from a black, ethnic and minority group also results in an increased risk of death from COVID-19. Additionally, health and social care workers are at increased risk of acquiring infection in their work setting and they may potentially transmit the virus to their families and to those in their care.

[1] Williamson EJ, Walker AJ et al. Factors associated with COVID-19-related death using OpenSAFELY. Nature 2020 July 8. 584:430–436 https://doi.org/10.1038/s41586-020-2521-4

COVID-19 vaccination programme

Aim of the programme

The aim of the COVID-19 vaccination programme is to protect those who are at most risk from serious illness or death from COVID-19.

Vaccine history and development

Over 250 different COVID-19 vaccines are in various stages of development. Some have been made using currently used vaccine technology, whilst others have been made using completely new approaches. While it normally takes several years to develop a vaccine, scientists across the world have worked collaboratively and rapidly to achieve the same amount of work in a few months in order to make a safe and effective vaccine available as soon as possible. Although clinical trials have been carried out more rapidly than they have for other vaccines, this has been achieved by conducting some of the steps in parallel rather than sequentially and vaccine safety has not been compromised. The vaccine trials have been subject to all of the usual strict trial and regulatory requirements.

For more information about COVID vaccines in development, see the LSHTM COVID-19 vaccine tracker.

This document will discuss the first two vaccines which are expected to be authorised for supply in the UK. The guidance will be updated as more information about these vaccines become available and will include other vaccines as they become available for use. **As each vaccine will be presented and prepared differently, immunisers must ensure they are familiar with the specific details of the vaccine that they will be working with.**

Duration of protection

As COVID-19 vaccines have only been given in clinical trials in recent months, there is currently no data available to describe how long protection from vaccination will last. Post-authorisation surveillance and continued follow-up of trial participants may indicate the need for booster doses but they are not currently recommended.

COVID-19 vaccination eligibility

Vaccine priority groups – provisional list

The objectives of the COVID immunisation programme is to protect those who are at highest risk from serious illness or death. The Joint Committee on Vaccination and Immunisation (JCVI) therefore considered the available epidemiological, microbiological and clinical information on the impact of COVID-19 in the UK and provided the Government with advice to support the development of a vaccine strategy.

Full details on vaccine eligibility, with detail on the at-risk conditions and the eligibility of health and social care and laboratory staff groups, are included in the Green Book COVID-19 chapter.

Pregnant women

There is no known risk associated with giving inactivated, recombinant viral or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding. Since inactivated vaccines cannot replicate they cannot cause infection in either the mother or the fetus. Although one of the vaccines which may be authorised for use (AstraZeneca COVID-19 vaccine) contains a live adenovirus vector, this virus does not replicate so will not cause infection in the mother or the fetus. As with most pharmaceutical products, specific clinical trials of COVID-19 vaccine in pregnant women have not been carried out.

Although the available data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. Vaccination should be postponed until completion of pregnancy. Pregnant women at high risk (including health care workers) should be offered vaccine as soon as possible after completion of pregnancy.

If a woman finds out she is pregnant after she has started a course of vaccine, she should complete her pregnancy before finishing the recommended schedule. Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine.

In the event of an inadvertent administration of COVID-19 vaccine to a pregnant woman, reassurance should be given as the vaccine is not a live vaccine and cannot cause infection in the mother or the baby. Termination of pregnancy following inadvertent immunisation should not be recommended. Surveillance of inadvertent administration in pregnancy is being conducted by the PHE Immunisation Department, to whom such cases should be reported (Tel: 020 8200 4400).

For a small number of women who cannot avoid exposure, and who have underlying conditions that put them at very high risk of serious complications of COVID-19, clinicians may consider discussing vaccination with the woman. These conditions would include Down's syndrome, cerebral palsy, homozygous sickle cell disease, motor neurone disease, chemotherapy, and chronic kidney disease. The woman should be told about the absence of safety data for these vaccines.

Children

SARS-CoV-2 vaccine trials have only just begun in children and therefore, there are, very limited data on safety and immunogenicity in this group. Children and young people have a very low risk of COVID-19, severe disease or death due to SARS-CoV-2 compared to adults and so COVID-19 vaccines are not routinely recommended for children and young people under 18 years of age.

There are currently very limited data on clinical risk factors in childhood, but children with neurological comorbidities are over-represented in those who develop severe COVID-19 requiring intensive care and those who die of COVID-19. Given the increased risk of exposure to infection and outbreaks in institutional settings, vaccination may be considered for children with serious neuro-disabilities (including cerebral palsy, severe autism and Down's syndrome) who spend regular time in institutional settings. As there are limited data on the use of COVID-19 vaccines in children, vaccination should be mainly restricted to older children (for example, those aged 12 years and older), who have higher risk of acquiring and becoming sick from infection.

Recommendations on vaccinating children with other underlying conditions will be reviewed after the initial roll-out phase by which time additional data on use of the vaccines in adults should allow a better assessment of risks and benefits.

Immunosuppression and HIV

Individuals who have immunosuppression and HIV infection (regardless of CD4 count) should be given COVID vaccine in accordance with the recommendations and contraindications stated in the PGD or Protocol and Green Book COVID-19 chapter. These individuals may not make a full antibody response and should therefore continue to follow advice to avoid exposure unless they are advised otherwise by their doctor.

Consideration should also be given to vaccinating the adult household contacts of immunocompromised individuals, ie individuals who share living accommodation or those who provide care for whom continuing close contact is unavoidable.

Vaccination of health and social care workers under 18 years of age

JCVI have recommended vaccination for health and social care workers as they have been identified as a group at risk of acquiring SARS-Cov-2 infection. Please see detailed recommendations by staff group in the Green Book COVID-19 chapter.

Young people under the age of 18, who are employed in, studying or in training for health and social care work should be offered vaccination alongside their colleagues. As the vaccine is expected to have a similar safety profile and immune response in this age group, extending the offer of vaccination to these staff is considered reasonable. Young people who are taking part in health and social care work as volunteers, interns or for the purposes of work experience, should make all efforts to avoid exposure to infection. Vaccination could be considered for those in longer term placements and for those individuals where future employment in that setting is likely.

Vaccination of individuals under the age of 18 is likely to be considered to be outside of regulatory approval and so these individuals will require a patient specific prescription for the vaccine.

COVID-19 vaccines

In the UK, two COVID-19 vaccines are expected to be considered first for regulatory approval for supply within the UK national vaccination programme. More vaccines may become available at a later date. The Pfizer BioNTech COVID-19 vaccine uses an mRNA platform and the AstraZeneca COVID-19 vaccine is an adenovirus vector vaccine.

Both vaccines are presented in multi-dose vials and require completion of a two-dose course. Using multi-dose vials can improve the efficiency of vaccine manufacture and distribution, enabling vaccine availability for those eligible at the earliest opportunity.

Pfizer BioNTech COVID-19 vaccine

The Pfizer BioNTech COVID-19 vaccine is an mRNA (messenger ribonucleic acid) vaccine. It contains the genetic sequence (mRNA) for the spike protein which is found on the surface of the SARS-CoV-2 virus, wrapped in a lipid envelope (referred to as a nanoparticle) to enable it to be transported into the cells in the body.

When injected, the mRNA is taken up by the host's cells which translate the genetic information and produce the spike proteins. These are then displayed on the surface of the cell. This stimulates the immune system to produce antibodies and activate T-cells which prepare the immune system to respond to any future exposure to the SARS-CoV-2 virus by binding to and disabling any virus encountered.

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

Clinical trials

The safety and immunogenicity of the Pfizer BioNTech COVID-19 vaccine has been evaluated in clinical trials in six countries: US, Germany, Brazil, Argentina, South Africa and Turkey.

The clinical trials looked at the safety and immunogenicity of the vaccine in two different age groups (18 to 55 years and 65 to 85 years) and at different dose levels.

Over 43 500 participants have taken part in the clinical trials of the Pfizer BioNTech COVID-19 vaccine. Half of the participants received the COVID-19 vaccine and the other half received a placebo vaccine. Results from the phase three clinical trials suggested the vaccine can prevent 95% of vaccinated adults from getting COVID-19 and that the vaccine works equally well in people of all ages, races and ethnicities. The observed efficacy in adults over 65 years of age was over 94%.

AstraZeneca COVID-19 vaccine

AstraZeneca COVID-19 vaccine is a viral vector vaccine which uses a weakened adenovirus as a carrier to deliver the SARS-CoV-2 antigen. The adenovirus has been modified so that it cannot replicate (grow and multiply by making copies of itself) in human cells and therefore cause any disease.

The genes that encode for the spike protein on the SARS-CoV-2 virus have been inserted into the adenovirus's genetic code to make the vaccine. When the vaccine is injected, it enters the host's cells which then manufacture the spike protein. This then stimulates the immune system which reacts by producing antibodies and memory cells to the SARS-CoV-2 virus without causing disease.

Clinical trials

Trials of the AstraZeneca COVID-19 vaccine showed that it produced neutralising antibodies in Rhesus macaques as well as a reducing the amount of detectable virus in the lower respiratory tract following challenge with SARS-CoV-2[2]. In human trials, the vaccine was compared with a placebo vaccine in healthy adults aged between 18-55 years. Preliminary findings show that neutralising antibodies were induced at day 14 and 28 after the first vaccination and that levels of these increased after a second dose. Specific T cell responses were also induced after a single immunisation and were maintained after the second dose. Data showed that spike antibody responses and neutralising antibody 28 days after the second dose were similar across the three age cohorts (18–55 years, 56–69 years, and ≥70 years). More than 99% (20/209) of the participants had neutralising antibody responses two weeks after the booster dose. Peak T-cell responses were seen 14 days after the first dose and were broadly equivalent in the three age groups[3].

Further clinical trial data for both of these vaccines will be added when this becomes available.

Details about storing and preparing these vaccines will be added here when this information becomes available.

[2] Van Doremalen, N et al. ChAdOx1 nCoV-19 vaccination prevents SARS-CoV-2 pneumonia in rhesus macaques. Nature 2020 July 30. 586: 578–582 https://doi.org/10.1038/s41586-020-2608-y

[3] Ramasamy M et al. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. Lancet 2020 Nov18. https://doi.org/10.1016/S0140-6736(20)32466-1

Interchangeability of different COVID-19 vaccines

There is no evidence as to the interchangeability of the different COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete with the same vaccine.

For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or where the first product received is unknown, it is reasonable to offer a single dose of the locally available product. This option is preferred if that individual is likely to be at immediate high risk or is considered unlikely to attend again. In these circumstances, as both of the vaccines are based on the spike protein of the virus, it is likely that the second dose will help to boost the response to the first dose. Further doses of vaccine are not required unless additional information becomes available.

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. See www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-non-aerosol-generating-procedures

Hand hygiene is critical to prevent the spread of disease and hands should be cleaned with alcohol-based gel or soap and water before vaccine preparation, between patients, etc. Those preparing and administering the vaccine should maintain good hand hygiene throughout and should take care not to touch the vial bung with their fingers.

Injection technique

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

Individuals who have minimal muscle mass in the deltoid area of the upper arm, or a particular reason to avoid immunisation in the deltoid muscle, can be given their vaccine in the vastus lateralis muscle in the thigh if necessary.

The area for injection should be clearly visible and accessible. Garments with long or tight sleeves may need to be removed. The injection site does not need to be cleaned unless visibly dirty. If cleaning is required, water should be used and the area dried with a gauze swab. It is not necessary to disinfect the skin.

Insert the needle into the injection site far enough to ensure it will deliver the vaccine into the muscle and depress the plunger. There is no need to pull back on the plunger (aspirate) before the plunger is depressed to release the vaccine into the muscle because there are no large blood vessels at the recommended injection sites.

Ensure the full dose is administered as a partial dose will not evoke a full immune response. Remove the needle and if there is any visible blood at the injection site, the patient can apply pressure to the site with a piece of gauze/cotton wool.

Administering COVID-19 vaccine to individuals with a bleeding disorder

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes (ACIP, 2019). The individual/carer should be informed about the risk of haematoma from the injection.

Administering COVID-19 vaccine to individuals taking anticoagulants

Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual’s anticoagulant therapy.

Period of observation following immunisation with COVID-19 vaccine

Recipients of COVID-19 vaccine should be observed for any immediate reactions during the period they are receiving any post-immunisation information and subsequent appointment if required. There is no evidence to support the practice of keeping patients under longer observation.

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Adverse reactions following vaccination

Possible adverse reactions following vaccination

Local reactions at the injection site were found to be fairly common after vaccination with the Pfizer BioNTech COVID-19 vaccine during clinical trials. Participants reported pain at the injection site usually without redness or swelling. Systemic events reported were generally mild and short lived[4]. In a safety analysis of at least 8,000 participants 18 years and older, the most common events reported were fatigue in around 4% and headache in 2%. Older adults tend to report fewer adverse events following vaccination.

Mild pain and tenderness at the injection site was also common with AstraZeneca COVID-19 vaccine, occurring in 88% of 18-55 year olds, 73% of 56-69 year olds and 61% of people aged 70 years or over; similar levels were reported after each dose. Short lived systemic symptoms including fatigue and headache were also common but decreased with age. These reactions were unusual after the second dose[3]. Mild fever (>38°C) was recorded in the first 48 hours for around a quarter of younger participants and but was not reported in those over 55 years of age or in any age group after the second dose[3]. Prophylactic use of paracetamol was found not to affect the immune response to this vaccine[5].

Reporting adverse reactions

Suspected adverse reactions following administration of COVID-19 vaccine should be reported to the MHRA using the specially established Coronavirus Yellow Card reporting scheme (coronavirus-yellowcard.mhra.gov.uk/ or call 0800 731 6789). Both patients and healthcare providers can and should report any possible adverse reactions observed with these vaccines using the Yellow Card scheme. As a new vaccine product, MHRA have a specific interest in the reporting of adverse drug reactions for the new COVID-19 vaccines.

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[4] Walsh, E et al. RNA-Based COVID-19 Vaccine Pfizer BioNTech COVID-19 vaccine Selected for a Pivotal Efficacy Study. New England Journal of Medicine. 2020 Oct 14 www.nejm.org/doi/10.1056/NEJMoa2027906
[5] Folegatti, P et al. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2 single-blind, randomised controlled trial. Lancet 2020 August 15, 396(10249): 467-478

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

Differentiating between a reaction to the vaccine and symptoms of COVID-19 disease

Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 is suspected.

Feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally these symptoms were found to resolve within one to two days without treatment but paracetamol can be given if necessary to relieve any of these symptoms.

The most commonly reported COVID-19 symptoms are: a high temperature, a new, continuous cough, or a loss or change to sense of smell or taste. If someone experiences any of these symptoms they should get tested. The COVID-19 vaccine will not interfere with testing for COVID-19 infection.

As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS 111.

COVID-19 vaccine contraindications and precautions

COVID-19 vaccine contraindications

The COVID-19 chapter of the Green Book advises that there are very few individuals who cannot receive the Pfizer BioNTech or AstraZeneca COVID-19 vaccines. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local screening and immunisation team or health protection team.

The vaccine should not be given to those who have had:

- a confirmed anaphylactic reaction to a previous dose of COVID-19 vaccine
- a confirmed anaphylactic reaction to any components of the vaccine

COVID-19 vaccine precautions

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms of the illness as being possible reactions to the vaccine.

Current or previous history of COVID-19 disease

People currently unwell and experiencing COVID-19 symptoms should not receive COVID-19 vaccine until they have recovered. This is to avoid wrongly attributing any new symptom or the progression of symptoms to the vaccine. As deterioration in some people with COVID-19 can occur up to two weeks after infection, ideally vaccination should be deferred until they have recovered and at least four weeks after onset of symptoms or four weeks from the first PCR positive specimen in those who are asymptomatic.

There is no evidence from clinical trials of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19

antibody so people who have had COVID-19 disease (whether confirmed or suspected) can still receive COVID-19 vaccine. This is because it is not known how long antibodies made in response to natural infection persist and whether immunisation could offer more protection. If antibodies have already been made to the disease following natural infection, receiving COVID-19 vaccine would be expected to boost any pre-existing antibodies.

Vaccination of people experiencing prolonged COVID-19 symptoms ('Long COVID')

Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if there is evidence of current deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

Time interval between treatments for COVID-19 disease (for example dexamethasone, convalescent plasma, monoclonal antibody or antiviral medicines) and vaccine administration

Dexamethasone is a steroid treatment given to patients experiencing severe COVID-19 symptoms to suppress the immune response and reduce inflammation.

Convalescent plasma is a preparation of pooled antibodies taken from people who have recently recovered from COVID-19. The antibodies bind to the surface of the SARS-CoV-2 virus and stop it from attaching to the body's cells and replicating further.

Monoclonal antibody treatment works in the same way as convalescent plasma but is a specific preparation containing two specific man-made antibodies.

As the COVID-19 vaccines that may become available are non-live vaccines, it is not anticipated that these treatments would contraindicate the vaccine. Although theoretically, high levels of antibodies in the convalescent plasma could interfere with the immune response to the vaccine, passively acquired antibodies from the plasma treatment are not thought to persist for long so by the time a person who has received this is well enough to receive a COVID-19 vaccination, these antibodies are likely to have gone.

Antivirals prevent the further replication of viruses. As the COVID-19 vaccines that may become available for use do not contain live virus, response to the vaccine will not be affected by prior or recent receipt of anti-viral medication.

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

Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated (weaker) immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult.

Because of the absence of data on co-administration with COVID-19 vaccines, COVID-19 vaccine should not be routinely offered at the same time as other vaccines. Based on current information about the first COVID-19 vaccines which may be used, scheduling of COVID-19 vaccine and other vaccines should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events.

As both of the COVID-19 vaccines which may be authorised for use first are considered inactivated, where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first. In many cases, vaccination should proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.

Legal aspects of vaccine administration

All vaccines are classified as prescription only medicines (POMS). This means that they are subject to legal restrictions and in order to give them, there needs to be an appropriate legal framework in place before they can be supplied and/or administered to eligible people. Additionally, any person who supplies and administers a vaccine must have a legal authority to do so. This legal authority may be in the form of a written patient specific prescription, a Patient Specific Direction (PSD), a Patient Group Direction (PGD) or another process such as a Written Instruction or a Protocol.

Using a Patient Group Direction (PGD) to give COVID-19 vaccine authorised under regulation 174

In response to certain public health threats, such as the current pandemic, the UK Medicines and Healthcare products Regulatory Agency (MHRA) can temporarily authorise the supply of an unlicensed medicine or vaccine for use, under regulation 174 of The Human Medicines Regulations 2012, when it is satisfied that there is robust evidence to show the safety, quality and effectiveness of the medicine/vaccine.

In October 2020, new legislation amending The Human Medicines Regulations 2012 was passed. Prior to this, PGDs could only be used for licensed medicines. The change to legislation allows medicines which have been temporarily authorised for supply in the UK under regulation 174 to be administered in accordance with a PGD. So registered healthcare professionals who are allowed to work to a PGD may supply and administer COVID-19 vaccines, temporarily authorised under Regulation 174, using a PGD. The workforce that can administer under PGDs has not changed (see www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them).

PHE will develop and publish PGDs for COVID-19 vaccines.

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. Such a national protocol may 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 will specify: the classes (that is characteristics and training required) of 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 will also include information similar to that commonly found in PGDs, for example, who is eligible for vaccination under the protocol and who is not, actions to be taken if the patient is excluded or declines the medicine, a description of the vaccine(s), route of administration, dose, frequency, reporting of adverse reactions, recording, storage and disposal.

It is expected that the protocol will allow flexibility for different delivery models. It 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 must ensure that all elements of the protocol are complied with in the provision of vaccination to each patient. The service provider is responsible for ensuring that health care workers are trained and competent to safely deliver the activity they are employed to provide under this protocol.

Accountability

When working to some or all of the protocol, registered healthcare workers are responsible and accountable for their practice. They are accountable to their regulatory body and to their employer.

When administering vaccines under the protocol, non-registered healthcare workers are accountable to their employer. Their employer is responsible for ensuring they are suitably trained, have completed the necessary competency assessment and are provided with an appropriate level of supervision when carrying out their duties under the protocol.

Inadvertent vaccine administration errors

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

The diluent for the Pfizer BioNTech COVID-19 vaccine is sodium chloride, which is purified water with a very small amount of salt in it. This diluent is commonly used to dilute other medicines and no adverse reactions would be expected if it was inadvertently administered alone. However, the diluent alone will not evoke an immune response so the person should be given a dose of properly reconstituted Pfizer BioNTech COVID-19 vaccine as soon as the error is realised.

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

In a Phase I/II study of COVID-19 mRNA vaccines in adults, different strength doses of Pfizer BioNTech COVID-19 vaccine were given. This means that some people in the trials have already received higher doses of a similar vaccine (BNT162b1) than the currently recommended dose. The trial showed that although a stronger dose was not harmful, the recipients experienced more local reactions with very painful arms being reported. If a person is given more than the recommended dose, they should be reassured that this is not harmful but that they may be more likely to experience pain in their injected arm. The second dose of vaccine should still be given as per the recommended schedule.

Inadvertent administration of over-diluted vaccine

As the amount of active content in a dose of over-diluted vaccine will be less, the vaccine dose should be repeated as soon as the error is realised using a correctly reconstituted vaccine.

Second dose given at less than the minimum recommended interval

If the second dose of the Pfizer BioNTech COVID-19 vaccine is given less than 19 days after the first dose, the dose should be discounted and another dose (a third dose) should be given at least 21 days after the dose given too early. The 19 day interval is the minimum interval that was used in the clinical trials.

If the second dose of the AstraZeneca COVID-19 vaccine is given at less than the recommended 28 day interval, but at least 21 days after the first dose, it does not need

to be repeated. If the second dose is given less than 21 days after the first, it should be discounted and another dose (a third dose) should be given at least 28 days after the dose given too early.

Longer than recommended interval left between doses

If an interval longer than the recommended interval is left between doses, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted.

Different COVID-19 vaccine given for second dose than was given for first dose

There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete the course with the same vaccine. However, as both of the vaccines which may be used are based on the spike protein, it is likely that even if the vaccine given for the second dose is different to the first, it will help to boost the response to the first dose. For this reason, until additional information becomes available, further doses are not required.

COVID-19 vaccine administered to a person not in an eligible cohort

If COVID-19 vaccine is inadvertently administered to a person not in an eligible cohort and the person is aged 50 or over, they should be offered a second dose as per the recommended schedule. If the person is under 50 years of age, they should be advised to wait for their second dose until their age group is invited to attend for vaccination. They can be reassured that the longer interval between doses should not affect vaccine efficacy.

Reporting vaccine errors

Errors or incidents in vaccine storage, preparation or administration should be reported to the vaccination session team leader or the local Screening and Immunisation team. As some errors will require immediate action, they should be reported as soon as possible after they are realised.

They should also be reported to the MHRA, CQC or HSE as appropriate and recorded on STEIS, the NRLA or any locally-established reporting systems.

COVID-19 vaccine inadvertently administered to a pregnant woman should be reported to the PHE Immunisation Department (Tel: 020 8200 4400).

Useful links

Green Book COVID-19 chapter www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

Public Health England Coronavirus resources
www.gov.uk/government/collections/immunisation

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

WHO COVID-19 Worldwide Dashboard
https://covid19.who.int/?gclid=EAIaIQobChMInr6P36Dc7AIVBWHmCh3IswIXEAAYASAAEgIPT_D_BwE

LSHTM COVID-19 vaccine tracker https://vaclshtm.shinyapps.io/ncov_vaccine_landscape/

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

Royal College of Nursing - COVID-19 vaccination page www.rcn.org.uk/clinical-topics/public-health/immunisation/covid-19-vaccination