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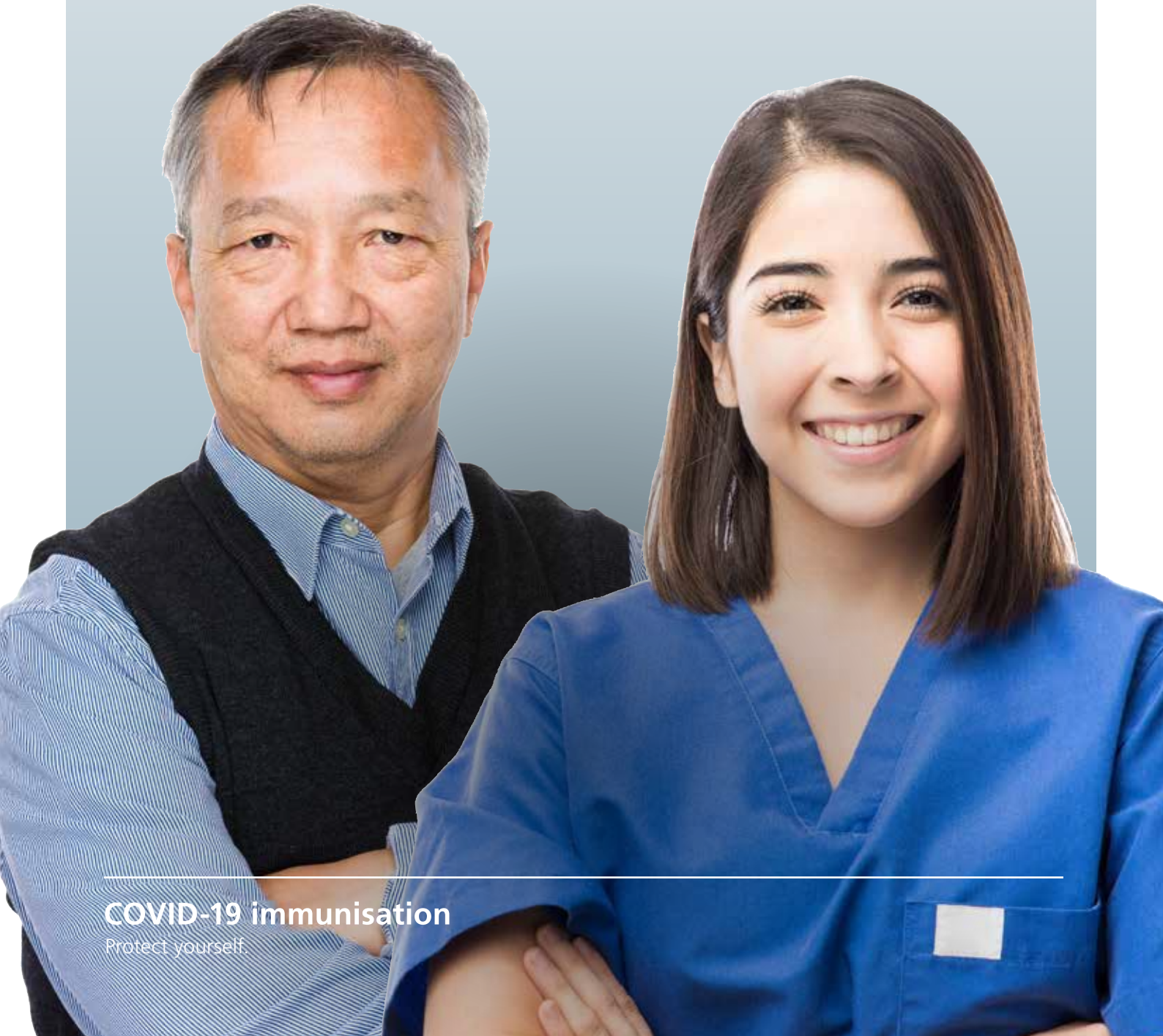
COVID-19 vaccination programme

Information for healthcare practitioners



COVID-19 immunisation
Protect yourself.

Acknowledgement

The information in this document was adapted from a variety of COVID-19 resources produced by Public Health England (PHE). PHE granted permission to use their materials in Northern Ireland, this is gratefully acknowledged.

Document information

The information in this document was correct at time of publication. As COVID-19 is an evolving disease, a lot is still being learned about both the disease and the vaccines that 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.

This document includes specific information about the storage and preparation of the COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech and the COVID-19 Vaccine AstraZeneca), following the authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency (MHRA) given on 2 December 2020 and 30 December 2020, respectively.

This document has been updated to provide information about the storage and preparation of the COVID-19 Vaccine Moderna, given authorisation for temporary supply on 8 January 2021.

The guidance will be updated as more information about these vaccines becomes available and will include other vaccines as they become available for use. **As each vaccine is presented, stored and prepared differently, immunisers must ensure they are familiar with the specific details of the vaccine that they are working with.**

COVID–19 disease

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

What are the symptoms of COVID-19?

Asymptomatic infection has been reported but those who do develop symptoms report a range of symptoms, including fever, a new and continuous cough, anosmia (loss of smell) and ageusia (loss of taste), shortness of breath, fatigue and loss of appetite. 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.

How is COVID-19 spread?

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 or direct human contact.

Who is 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. Comorbidities 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. 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 nidirect website Coronavirus (COVID-19): definitions of 'clinically extremely vulnerable' and 'vulnerable'. 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.

COVID-19 vaccination programme

What is the aim of the vaccination 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 and to protect the health and social care staff and system.

How was the vaccine developed?

Over 300 different COVID-19 vaccines are in various stages of development. Some have been made using existing 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.

There is more information about COVID-19 vaccines in development, at https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/

This document will discuss the first COVID-19 vaccines to be authorised for supply in the UK. The guidance will be updated as more information about these vaccines becomes available and may include other vaccines as they are authorised for use in the UK.

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.

How long does the vaccine offer protection and will booster doses be needed?

It is not yet known how long protection will last, whether regular booster doses will be needed and to what extent the vaccine stops people from catching and spreading the virus or just prevents them from becoming ill.

On 30 June 2021, the JCVI issued interim advice which stated that any potential COVID-19 booster programme should be offered in 2 stages from September 2021, starting with those most at risk from serious disease. This includes care home residents, people aged over 70, frontline health and Social care workers, clinically extremely vulnerable adults and those who are immunosuppressed.

The JCVI will continue to review emerging scientific data over the next few months, including data relating to the duration of immunity from the current vaccines. Final advice on booster vaccination may change as a result of this.

COVID-19 vaccination eligibility

Vaccine priority groups – provisional list

The objectives of the COVID immunisation programme are 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 and Devolved Administrations with advice to support the development of a vaccine strategy. This is available at https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020

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.

Can pregnant women receive the vaccine?

Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. There is now extensive post-marketing experience of the use of the Pfizer-BioNTech and Moderna vaccines in the USA with no safety signals so far (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/ vsafepregnancyregistry.html). These vaccines are therefore the preferred vaccines to offer to pregnant women. Clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy.

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

If a woman finds out she is pregnant after she has started a course of vaccine, she may complete vaccination during pregnancy using the same vaccine product (unless contraindicated). Alternatively, vaccination should be offered as soon as possible after pregnancy.

The Royal College of Obstetricians and Gynaecologists (RCOG) and Royal College of Midwives (RCM) have a decision guide and other useful information on COVID-19 vaccines and pregnancy (www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnancy/covid-19-vaccines-pregnancy-and-breastfeeding/).

See also https://www.health-ni.gov.uk/news/statement-uk-chief-medical-officers-prioritisation-first-doses-covid-19-vaccines

Can breastfeeding women receive the vaccine?

There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunisation against COVID-19; at the same time, women should be informed about the emerging safety data for the vaccine in breastfeeding.

Can children receive the vaccine?

Following careful consideration of the risks and benefits of vaccinating children and young people aged 12 to 17 years, the JCVI has recommended vaccination of the following groups:

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

   These conditions include:

   - severe neurodisabilities and/or neuromuscular conditions that compromise respiratory function. This includes conditions (such as cerebral palsy, autism and muscular dystrophy) that may affect swallowing and protection of the upper airways, leading to aspiration, and reduce the ability to cough and resulting overall in increased susceptibility to respiratory infections;

   - a learning disability, including those with Down's syndrome, profound and multiple learning disabilities (PMLD) or severe learning disabilities and those who are on the learning disability register;

   - immunosuppression due to disease or treatment. Further detail about this group is provided in the Green Book COVID-19 chapter.

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

3) JCVI has also recommended that all 16 to 17 year olds should be offered a first dose of the Pfizer BioNTech vaccine. This is in addition to the existing offer of 2 doses of vaccine to 16 to 17 year-olds who are in 'at-risk' groups above. Pending further evidence on effectiveness and safety in this age group, a second vaccine dose is anticipated to be offered later to increase the level of protection and contribute towards longer term protection. Further information about second doses will be given before these are due. This does not include those turning 18 years of age in the next three months who should be offered two doses 8 weeks apart in accordance with recommendations for those aged 18 to 29 years.

4) On 13 September 2021, the Chief Medical Officers recommended that, in addition, all healthy 12 to 15 year olds should be offered a first dose of COVID-19 vaccine to reduce the chances of them catching COVID-19, reduce the number of outbreaks in schools and help avoid school absences and disruption to face-to-face education. Pending further evidence on effectiveness and safety in these age groups, a second vaccine dose is anticipated to be offered later to increase the level of protection and contribute towards longer term protection. Further information about second doses will be given before these are due.

Can someone with immunosuppression and HIV receive the vaccine?

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 and the 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.

The small number of patients who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the two-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID-19 and from their underlying condition.

On 1 September 2021, the JCVI advised that a third primary dose be offered to individuals aged 12 years and over who were severely immunosuppressed at the time of their first or second primary COVID-19 vaccine doses. Definitions of severe immunosuppression and details of timings are described in the JCVI statement and in the COVID-19 chapter of the Green Book. https://www.gov.uk/government/publications/third-primary-covid-19-vaccine-dose-for-people-who-are-immunosuppressed-jcvi-advice/joint-committee-on-vaccination-and-immunisation-jcvi-advice-on-third-primary-dose-vaccination

Further advice is pending regarding any further booster dose following completion of this 3-dose primary vaccine course.

Can someone with a history of COVID-19 disease receive the vaccine?

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.

Can someone experiencing prolonged COVID-19 symptoms ('Long COVID') receive the vaccine?

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.

Is there a 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 currently authorised COVID-19 vaccines 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 neither of the above mentioned COVID-19 vaccines contain live virus, response to the vaccine will not be affected by prior or recent receipt of anti-viral medication.

Can individuals with a bleeding disorder receive the COVID-19 vaccine?

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 two minutes*. The individual/carer should be informed about the risk of haematoma from the injection.

Can individuals taking anticoagulants receive the COVID-19 vaccine?

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

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

COVID-19 vaccines

In the UK, three COVID-19 vaccines have been approved by MHRA for use within the UK national vaccination programme. These are the COVID-19 mRNA Vaccine BNT162b2 (Comirnaty, manufactured by Pfizer-BioNTech), COVID-19 Vaccine Moderna (Spikevax) and COVID-19 vaccine AstraZeneca (Vaxzevria). Information about other COVID-19 vaccines which are given regulatory approval will be added when this occurs.

The COVID-19 mRNA Vaccine BNT162b2 and COVID-19 Vaccine Moderna use an mRNA platform and the COVID-19 vaccine AstraZeneca is an adenovirus vector vaccine.

*www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020

All the currently authorised 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.

COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech) and COVID-19 Vaccine Moderna

The COVID-19 mRNA Vaccine BNT162b2 and COVID-19 Vaccine Moderna are mRNA (messenger ribonucleic acid) vaccines. They contain the genetic sequence (mRNA) for the spike protein which is found on the surface of the SARS-CoV-2 virus, wrapped in a lipid envelope (referred to as a nanoparticle) to enable it to be transported into the cells in the body.

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

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

How do we know the COVID-19 mRNA Vaccine BNT162b2 is safe?

During clinical trials, local reactions at the injection site were found to be fairly common after vaccination with the COVID-19 mRNA Vaccine BNT162b2. Over 80% of trial participants reported pain at the injection site. This occurred within seven days after the injection and resolved after a few days.

The safety of COVID-19 mRNA Vaccine BNT162b2 was also evaluated in participants 16 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. The most frequent adverse reactions in participants 16 years of age and older were pain at the injection site (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 30%), chills (> 30%), arthralgia (> 20%) and pyrexia (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (eg paracetamol-containing products) may be used. Further information can be found in the Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 Vaccine.

How do we know the COVID-19 mRNA Vaccine BNT162b2 is effective?

The immunogenicity of the COVID-19 mRNA Vaccine BNT162b2 has been evaluated in clinical trials in six countries: US, Germany, Brazil, Argentina, South Africa and Turkey.

Over 44,000 participants have taken part in the clinical trials of this 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 disease 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%.

How do we know the COVID-19 Vaccine Moderna is safe?

The safety of COVID-19 Vaccine Moderna was evaluated in ongoing phase 3 clinical trials in the United States involving 30,351 participants 18 years of age and older.

The most frequently reported adverse reactions were injection site pain (92%), fatigue (70%),

headache (65%), myalgia (62%), arthralgia (46%), chills (46%), nausea/vomiting (23%), auxillary swelling/tenderness (19.8%), fever (15.5%), injection site swelling (14.7%) and redness (10%). Adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers.

How do we know the COVID-19 Vaccine Moderna is effective?

The immunogenicity of the COVID-19 Vaccine Moderna has been evaluated in clinical trials in the United States with over 30,000 participants. In phase 1 testing of the Moderna mRNA-1273 vaccine, all patients seroconverted to IgG after the first dose of vaccine. Phase 3 placebo controlled testing in participants, showed a vaccine efficacy of 94.1%. Efficacy was similar in those over 65 years. Vaccine efficacy against severe COVID-19 was 100%. The cumulative case numbers in the phase 3 study showed a clear divergence between the vaccine and placebo groups from about 14 days days after the first dose.

COVID-19 Vaccine AstraZeneca

COVID-19 Vaccine AstraZeneca is a viral vector vaccine that 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.

How do we know the COVID-19 Vaccine AstraZeneca is safe?

The overall safety of COVID-19 Vaccine AstraZeneca is based on an interim analysis of pooled data from four clinical trials conducted in the United Kingdom, Brazil, and South Africa. At the time of analysis, 12,021 participants received at least one dose of COVID-19 Vaccine AstraZeneca.

Reactions reported were similar to those seen following other vaccines and there were no serious adverse reactions to the vaccines seen in the trial participants who received them. The most frequently reported adverse reactions were injection site tenderness (>60%), injection site pain, headache, fatigue (>50%), myalgia, malaise (>40%), pyrexia, chills (>30%), and arthralgia, nausea (>20%). These symptoms were usually mild or moderate in intensity and resolved within a few days after vaccination. Further information can be found in the Information for Healthcare Professionals on Covid-19 Vaccine AstraZeneca at www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca

A recently recognised condition involving serious thromboembolic events accompanied by thrombocytopaenia has been reported after AstraZeneca vaccination (see Precautions to COVID-19 vaccines on page 13).

For more information, see https://www.publichealth.hscni.net/publications/covid-19-astrazeneca-vaccine-and-very-rare-blood-clots

How do we know the COVID-19 Vaccine AstraZeneca is effective?

Prior to approval by the MHRA, manufacturers of the COVID-19 vaccines need to show evidence that they will be effective. They can do this by showing a reduction in virus levels in animal studies where

the vaccines were used and that people in the trials have made an antibody response to the vaccine. COVID-19 Vaccine AstraZeneca elicited increased neutralisation antibodies in Rhesus macaques as well as a reduction in detectable virus in the lower respiratory tract following challenge with SARS-CoV-2.

Final data in human trials showed that IgG spike antibody responses and neutralising antibody 28 days after the booster dose were similar across the three age cohorts (18–55 years, 56–69 years and ≥70 years). More than 99% (208/209) of the participants had neutralising antibody responses two weeks after the booster dose. In analysis of over 11,000 patients in the phase 3 clinical trials, overall vaccine efficacy against symptomatic disease was 70·4%. High protection against hospitalisation was seen from 21 days after the first dose until two weeks after the second dose, suggesting that a single dose will provide high short-term protection against severe disease.

Can a different vaccine be used for the 2nd dose?

Evidence from trials suggest that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines, make a good immune response, although rates of side effects following the second dose are higher compared to those who received the same vaccine for both doses. Initial reactogenicity and safety data from the Com-COV clinical trial showed that mixed schedule recipients were more likely to experience feverishness, chills, fatigue, headache, joint pain, malaise, and muscle ache. Because of this increased risk of side effects, every effort should be made to determine which vaccine the individual received for their first dose and to complete the 2-dose course with the same vaccine (unless contraindicated).

Individuals who do receive a different vaccine for their second dose should be informed that they may experience more reactions to the second dose.

For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, for example, if the individual received their first dose abroad, or where the first product received is unknown, it is reasonable, in these circumstances, to offer one dose of a locally available product to complete the schedule if suitable for age and not contraindicated. This option is preferred if that individual is likely to be at immediate high risk or is considered unlikely to attend again.

For information relating to individuals who received their COVID-19 vaccination overseas, please refer to Public Health England (PHE) COVID-19 vaccination programme Information for healthcare practitioners: https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners

Booster programme

On 14 September 2021, JCVI advised that adults who received a primary course in Phase 1 of the COVID-19 vaccination programme (priority groups 1-9) should be offered a COVID-19 booster vaccine. Information on priority groups and the booster programme can be found in the COVID-19 chapter of the Green Book.

In general, younger individuals may be expected to generate stronger and more durable immunity from a primary course of vaccination compared to older individuals and will have only received their second COVID-19 vaccine dose in late summer or early autumn. Advice on reinforcing doses for younger people, including children under 16 years and healthy pregnant women are therefore under further consideration.

The booster dose should be offered no earlier than six months after completion of the primary vaccine course. The Pfizer-BioNTech vaccine is the recommended vaccine to be given for the booster dose. As an alternative, a half dose of the Moderna vaccine can be given instead.

https://www.gov.uk/government/publications/jcvi-statement-september-2021-covid-19-booster-vaccine-programme-for-winter-2021-to-2022

Can the vaccine be administered 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.

As the Pfizer-BioNTech, AstraZeneca and Moderna COVID-19 vaccines are considered inactivated, where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring 2 vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. An exception to this is shingles vaccination, where a 7 day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to reduce the response to the live virus.

A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects.

Inadvertent vaccine administration errors

Does the vaccine dose need to be repeated if only the diluent is administered?

The diluent for the COVID-19 mRNA Vaccine BNT162b2 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 COVID-19 mRNA Vaccine BNT162b2 as soon as the error is realised.

What should you do if you inadvertently administer 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 COVID-19 mRNA Vaccine BNT162b2 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.

What should you do if you inadvertently administer an incomplete dose of vaccine or a dose that may have been affected by a storage or preparation error?

If less than the full dose of COVID-19 vaccine is inadvertently given, for example, if some vaccine leaks out as it is being administered or if the vaccine has been over-diluted, a full dose should be drawn up and given as soon as possible after the error is realised.

If a dose of COVID-19 vaccine is given following an incident in which the potency may have been affected, for example by a storage or preparation error, seek expert advice from the local health protection team (Duty Room 0300 555 0119) and if recommended repeat the dose of vaccine. This should either be given on the same day as the potentially affected dose was given, or from 48 hours after the potentially affected dose was given.

If a full dose is not given on the same day as the partial dose, for example if the error is realised after the individual has left the vaccination centre, or if it is suspected but not known for certain whether an individual received a partial dose, a full 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, seek expert advice.

If this was the first dose, the 'second' dose of the 2 dose schedule (which will actually be the third dose in this case) should still be given at the recommended interval from the additional dose.

What should you do if the second dose is given at less than the minimum recommended interval?

If the second dose of the COVID-19 mRNA Vaccine BNT162b2 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 or Moderna COVID-19 vaccine is given at less than the recommended 28 day interval, but at least 21 days after the first dose, it does not need to be repeated. If the second dose is given less than 21 days after the first, it should be discounted and another dose (a third dose) should be given at least 28 days after the dose given too early, up to an interval of 12 weeks.

What should you do if longer than recommended interval is 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.

What if a different COVID-19 vaccine is given inadvertently for second dose than was given for first dose?

Evidence from trials suggest that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines, make a good immune response, although rates of side effects at the second dose are higher. Reactogenicity and safety data from the Com-COV clinical trial showed that mixed

schedule recipients were more likely to experience feverishness, chills, fatigue, headache, joint pain, malaise, and muscle ache. Therefore, if an individual is inadvertently given a different vaccine for their second dose than for their first dose, they should be informed that they may experience more side effects than they did following their first dose, but that a further dose is not required.

What if a different COVID-19 vaccine is inadvertently given at a short interval after the first dose?

If a dose of a different COVID-19 vaccine is inadvertently given a few days after the first dose was given, the person should be offered a third dose of vaccine a minimum of 28 days after the second dose was given. As clinical trials showed that compared with the first dose, adverse reactions reported after the second dose of the AstraZeneca vaccine were milder and reported less frequently, it is recommended that the AstraZeneca vaccine is given for this third dose where possible and only if suitable for age, as it is likely to be less reactogenic as an additional dose.

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

COVID-19 vaccine contraindications

COVID-19 vaccine should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- a previous dose of the same COVID-19 vaccine
- any components of the vaccine.

The COVID-19 chapter of the Green Book also provides full details about the contraindications to COVID-19 vaccine. Where there is any doubt as to whether the vaccine can be given, appropriate advice should be sought from the relevant specialist in the first instance.

A very small number of individuals have experienced anaphylaxis when vaccinated with the Pfizer-BioNTech vaccine and anaphylaxis events have also been reported after the Moderna vaccine. Following close national surveillance, the MHRA is no longer advising that individuals with a history of anaphylaxis to any vaccine, medicine or food do not get the vaccine. Anyone with a previous history of allergic reactions to the ingredients of the vaccine should not receive it, but those with any other allergies (such as a food allergy) can now have the vaccine. Please refer to the Green Book COVID-19 vaccine chapter for management of individuals with a history of allergy.

Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 Vaccine for full list of excipients). Further information on COVID-19 Vaccine AstraZeneca is in Information for Healthcare Professionals on Covid-19 Vaccine AstraZeneca at www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca

Product information for the COVID-19 Vaccine Moderna at www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna/information-for-healthcare-professionals-on-covid-19-vaccine-moderna

Polyethylene glycol (PEG)

The Pfizer-BioNTech and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products

and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of the Pfizer-BioNTech and Moderna vaccines. It is unclear whether PEG is the only cause of allergic reactions in patients with systemic allergic symptoms after the first dose of these vaccines.

Polysorbate 80

The AstraZeneca vaccine does not contain PEG but does contain a related compound called polysorbate 80. Some people with PEG allergy may also be allergic to polysorbate 80.

However, polysorbate 80 is widely used in medicines and foods, and is present in many medicines including monoclonal antibody preparations. Some injected influenza vaccines (including the main vaccine used in over 65 year olds) contain polysorbate 80. Individuals who have tolerated injections that contain polysorbate 80 (such as certain influenza vaccines) are likely to tolerate the AstraZeneca vaccine. Please see table 4 in the Green Book COVID-19 vaccine chapter.

Thrombosis and thrombocytopaenia occurring after COVID-19 AstraZeneca vaccination

A recently recognised condition involving serious thromboembolic events accompanied by thrombocytopaenia, has been reported after AstraZeneca vaccination.

The condition is very rare, tends to present with unusual forms of clotting and the mechanism is believed to be an idiosyncratic reaction related to an immune response to the AstraZeneca vaccine. Because of this likely immune mechanism, there is no reason to believe that individuals with a past history of clots or of certain thrombophilic conditions would be at increased risk of this very rare condition.

Caution should be used when vaccinating individuals who have a history of a previous episode of heparin-induced thrombocytopaenia and thrombosis (HITT or HIT type 2). These individuals may be offered vaccination with an alternative COVID-19 vaccine.

Individuals who experience a clotting episode with concomitant thrombocytopaenia following the first dose of AstraZeneca vaccine should be properly assessed. If they are considered to have the reported condition, further vaccination should be deferred until their clotting has completely stabilised, and they should then be considered for a second dose of an alternative (mRNA) COVID-19 vaccine at least 12 weeks after their first dose of AstraZeneca vaccine.

Individuals who have received the first dose of AstraZeneca vaccine without developing this rare condition are advised to receive the second dose of the same vaccine at the currently recommended interval of around 12 weeks. To date, there have been no confirmed cases of this condition after the second dose and the rate of other reactions is lower at the second dose than after the first dose of this vaccine. Using an alternative product for the second dose may be more likely to lead to common side effects.

Based on current evidence JCVI is advising a preference for an alternative vaccine for healthy people under 40 years of age, including health and social care workers, unpaid carers and household contacts of immunosuppressed individuals.

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. There is no evidence that those with a prior history of thrombosis or known risk factors for thrombosis are more at risk of developing this immune-mediated condition of thrombosis in combination with thrombocytopaenia after the AstraZeneca vaccine.

For most of these individuals, the risk of recurrent thrombosis due to COVID-19 infection, remains far greater than the risk of this syndrome. Therefore individuals with such a history should be vaccinated with any of the available vaccines (provided they are not otherwise contra-indicated). The same consideration applies to those who experience common clotting episodes after the first dose of AstraZeneca vaccine but without concomitant thrombocytopaenia.

Extremely rare reports of capillary leak syndrome have been reported after AstraZeneca vaccine in individuals with a prior history of this condition. These individuals may be offered vaccination with an alternative COVID-19 vaccine.

For further information, see https://www.publichealth.hscni.net/publications/blood-clotting-following-covid-19-vaccination-information-health-professionals

Precautions to COVID-19 vaccines

Other precautions

It is recommended that individuals are observed for a minimum of 15 minutes following administration of the Pfizer-BioNTech and Moderna vaccines. There is no requirement for 15 minutes observation following the AstraZeneca vaccine. However, as fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should either be driven by someone else or should not drive for 15 minutes after vaccination.

Patients with undiagnosed PEG allergy often have a history of immediate onset-unexplained anaphylaxis or anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis. Such individuals should not be vaccinated with the Pfizer-BioNTech or Moderna vaccine, except on the expert advice of an allergy specialist. The AstraZeneca vaccine can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. The vaccine should be administered in a setting with full resuscitation facilities (e.g. a hospital), and a 30 minute observation period is recommended.

The British Society for Allergy and Clinical Immunology (BSACI) has advised that individuals who have a reaction to the first dose of a COVID-19 vaccine may be able to receive a 2nd dose of vaccine. Please see the flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine in the Green Book COVID-19 vaccine chapter for further information.

Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting.

Further information can be found on the RCUK publishes, including hypersensitivity to the active substance or to any of the excipients, anaphylaxis guidance for vaccination settings | Resuscitation Council UK

Myocarditis and pericarditis

Worldwide, there have also been recent, rare cases of myocarditis or pericarditis (inflammation of the heart) reported after the Pfizer-BioNTech and Moderna COVID-19 vaccines. The reported rate appears to be highest in those under 25 years of age and in males, and after the second dose. Onset is within a few days of vaccination and most cases are mild, recovering within a short time following standard treatment and rest without any sequalae.

Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Those who develop myocarditis or pericarditis following the first COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. Subsequent doses should be deferred until further information becomes available.

Additional advice for recipients

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

Vaccine recipients should also be advised to follow the current advice on testing and self-isolation if they develop any coronavirus symptoms or undergo regular testing as a health or social care worker. Vaccination will not affect testing. The lateral flow device (LFD) test detects a different protein of the virus than the one encoded in the vaccine, and the polymerase chain reaction (PCR) test detects different genes of the virus than the one included in the vaccine.

It is not yet known whether vaccination will stop people from catching and passing on the virus and as no vaccine is completely effective, some people may still become infected with COVID-19 despite having been vaccinated (although this should be less severe). The vaccine cannot cause COVID-19 infection.

Postponing immunisation

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.

Useful links

Northern Ireland COVID-19 Vaccination Programme:
www.publichealth.hscni.net/covid-19-coronavirus/northern-ireland-covid-19-vaccination-programme

Northern Ireland COVID-19 - Daily Dashboard Updates:
www.health-ni.gov.uk/articles/covid-19-daily-dashboard-updates

Green Book COVID-19 chapter:
www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

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://vac-lshtm.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

Product information for the COVID-19 mRNA Vaccine BNT162b2: Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 Vaccine

Liu, X, Shaw, RH, Stuart, ASV and others. Safety and Immunogenicity Report from the Com-COV Study – a Single-Blind Randomised Non-Inferiority Trial Comparing Heterologous And Homologous Prime-Boost Schedules with An Adenoviral Vectored and mRNA COVID-19 Vaccine. Available at SSRN: https://ssrn.com/abstract=3874014 or http://dx.doi.org/10.2139/ssrn.3874014

Shaw, RH and others. Heterologous prime-boost COVID-19 vaccination: initial reactogenicity data. Lancet 2021 May 12, https://doi.org/10.1016/S0140-6736(21)01115-6

Regulation 174 Information for UK healthcare professionals on COVID-19 Vaccine AstraZeneca: https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca-regulation-174

Guidance for healthcare practitioners on the COVID-19 vaccination programme - see Appendix 1 for vaccine interchangeability guidance: https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners

Vaccination, helping to protect those most vulnerable.

If you need more information on the COVID-19 vaccination please visit: www.nidirect.gov.uk/covid-vaccine

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