Public Health England

Protecting and improving the nation's health

COVID-19 Vaccination programme

Core training slideset for healthcare practitioners 08 January 2021

Note to trainers

This slide set contains a collection of core slides for use or adaptation during the delivery of COVID-19 immunisation training. Trainers should select the slides required depending on the background and experience of the immunisers they are training and according to the role they will have in delivering the COVID-19 vaccine programme.

The information in this slide set was correct at time of publication. As COVID is an evolving disease, much is still being learned about both the disease and the vaccines which have been developed to prevent it. For this reason, some of the information may change. Updates will be made to this slide set as new information becomes available. Please check online to ensure you are accessing the latest version. Trainers may need to update data and any information that changes between republications of this slide set.

Slides containing vaccine specific details (such as storage and reconstitution) on the first two COVID-19 vaccines to receive regulatory approval have been added to the end of this slide set. Details for other vaccines will be added here as they receive regulatory approval. They are available at the end of the slide set so that trainers can specifically select those they need for the vaccine(s) for which they are delivering training.

Content

Learning objectives

By the end of this session, you should be able to:

- explain what COVID-19 is and be aware of the UK epidemiology
- understand the policy behind the COVID-19 vaccination programme
- describe how vaccines work and how they are developed and trialled
- identify the groups who are at high risk for COVID infection and who should be prioritised to receive the COVID-19 vaccine
- describe the process of consent and how this applies when giving vaccines
- understand the legal mechanisms by which immunisers can supply and administer COVID-19 vaccine
- recognise the differences between a prescription, a PSD, a PGD and a Protocol and understand which staff can use each of these
- describe the key principles of how to correctly store, prepare and administer COVID-19 vaccines
- communicate key facts in response to questions from patients and direct them to additional sources of information

Pre-requisites to administering COVID-19 vaccine

Before administering COVID-19 vaccine, you should have:

- undertaken training in the management of anaphylaxis and Basic Life Support as specified by policy for your local area
- undertaken any additional statutory and mandatory training as required by your employer
- received COVID-19 vaccine training through attending a taught session and/or the eLearning for Healthcare COVID-19 vaccine elearning programme
- received practical training in COVID-19 vaccine preparation and administration
- completed the COVID-19 vaccinator competency assessment tool
- an appropriate legal framework to supply and administer COVID-19 vaccine in place e.g. patient specific prescription, Patient Specific Direction (PSD), Patient Group Direction (PGD) or Protocol
- accessed and familiarised yourself with the following key documents: Green Book COVID-19 chapter, the PHE ‘COVID-19 immunisation programme information for healthcare practitioners’ document and the vaccine product information in the ‘Information for healthcare professionals’ document (MHRA website)

Key messages

- the ongoing global COVID-19 pandemic continues to cause millions of infections and over a million deaths across the world
- a vaccine to prevent COVID-19 is likely to be the most effective way to control the pandemic
- scientists across the world have worked to develop vaccines which have then been rigorously tested for safety and efficacy
- it is crucial that the COVID-19 vaccines are safely and effectively delivered to as many of those eligible as possible
- those with a role in delivering the COVID-19 vaccine programme need to be knowledgeable, confident and competent in order to promote confidence in the vaccination programme and deliver the vaccine safely

Introduction

- a new virus emerged in Wuhan, China during December 2019
- this virus, which causes respiratory disease, was identified as being part of the Coronavirus family and it rapidly spread to many other countries around the world
- by 30/12/20, 2,432,888 people had tested positive for the virus and 72, 548 people had died within 28 days of a positive test in the UK
- common symptoms of COVID-19 include a high temperature, a continuous dry cough and loss or change to sense of smell and taste
- about 80% of infected people have no or mild symptoms; 1 in every 6 people who gets COVID-19 becomes seriously ill
- older people and those with underlying medical problems are more likely to develop serious illness or die from COVID-19
- measures to contain the virus have included the introduction of social distancing measures, travel restrictions, closure of public spaces and the wearing of face coverings in shops
- despite these measures, the number of positive cases and deaths have continued to increase on a daily basis

International and UK COVID-19 timeline – the first 7 months

31/12/19	27 cases of pneumonia of unknown aetiology reported in Wuhan
13/01/202	First case outside China (Thailand)
21/01/2020	293 cases in mainland China, including 15 healthcare workers and 6 deaths
25/01/202	First confirmed case in Europe (France)
30/01/2020	WHO declares Public Health Emergency of International Concern (PHEIC)
31/01/202	UK nationals repatriated from Wuhan. First two UK cases confirmed in England
01/03/202	35 UK cases in total
05/03/20	CMO of England announced first UK death
11/03/2020	WHO declares COVID-19 as a pandemic
12/03/20	UK Government announce move from contain phase into delay. UK CMOs raised the risk to UK population from moderate to high
23/03/20	FCO asks all British travellers to return to the UK and advises against non-essential international travel for 30 days. UK Government introduces new social distancing measures. i) all persons to stay at home, except for very limited purposes; ii) all non-essential businesses and venues to close; iii) no gatherings of more than two people in public
16/04/20	Decision to maintain social distancing measures for further three weeks
13/05/20	UK Government announce 5 level COVID-19 alert system. UK CMOs set alert to level 4
18/05/20	Loss of or change in normal sense of taste or smell added to case definition
19/06/20	UK CMOs lower the UK COVID-19 alert level to 3 following recommendation of Joint Biosecurity Centre
04/07/20	Further relaxation of national restrictions (travel restrictions, social distancing, closure of public spaces updates)
24/07/20	Face coverings are now compulsory for customers in shops in England

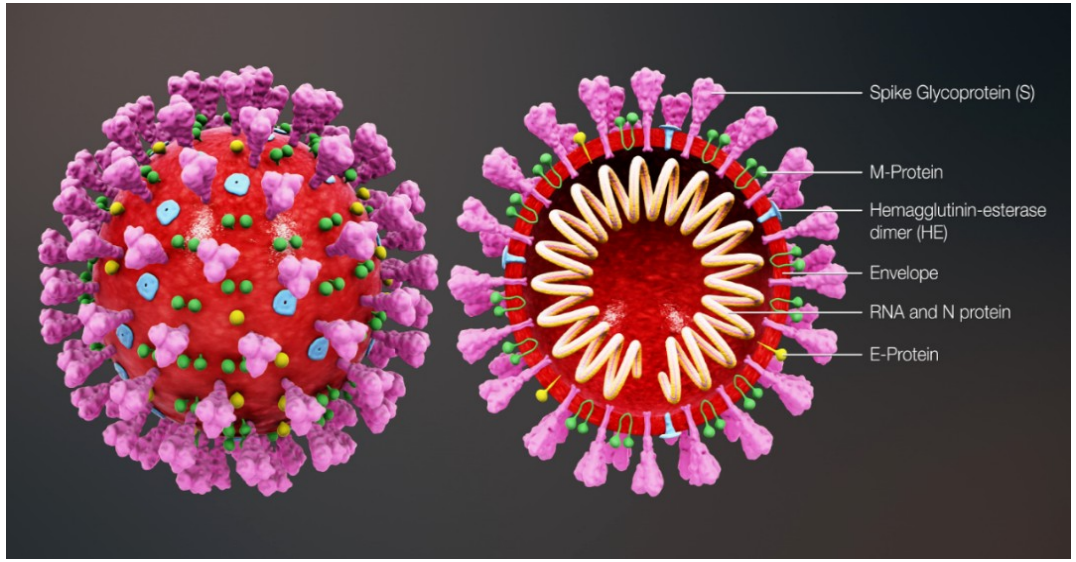
COVID-19 and Coronavirus

- COVID-19 is the disease that is caused by infection with the SARS-CoV-2 virus which belongs to the Coronavirus family
  - SARS-CoV-2 stands for Severe Acute Respiratory Syndrome (SARS) and CoV for coronavirus
  - COVID-19 stands for Coronavirus Disease and 19 is from the year 2019 when it was first seen
- Coronaviruses may cause illness in animals or humans and they are responsible for causing infections ranging from the common cold to more severe disease such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) which have been responsible for two outbreaks during the last twenty years
- SARS-CoV-2 virus is the most recently discovered coronavirus and has now affected many countries globally
- because of the global spread and the substantial number of people affected, the World Health Organisation (WHO) declared COVID-19 as a pandemic on 11/03/2020 (Pan (all) demos (people))

Viral infection

- viruses are much smaller than bacteria and consist of a small amount of either DNA or RNA surrounded by a protein coat called a capsid
- viruses cannot replicate themselves, but need to seek out the replication mechanism contained within a host cell
- examples of vaccine preventable viral diseases include measles, mumps, rubella, influenza, hepatitis A and B
- Influenza viruses, which are RNA viruses, are constantly mutating into slightly different forms, which is why we need to produce and give different flu vaccines every year
- SARS-CoV-2 is an RNA virus

Coronavirus structure



- the key parts of the coronavirus are the RNA and the spike proteins
- the RNA is surrounded by an **envelope** which has different roles in the life cycle of the virus. These may include the assembly of new virus and helping new virus to leave the infected cell
- the **spike proteins** (S) are anchored into the viral **envelope** and form a crown like appearance, like the solar corona, hence the name coronavirus. The spike proteins attach to the target cell and allow the virus to enter it
- the **RNA** is inside the envelope and acts as a template so that once it is inside the host cell, the coronavirus can replicate itself and be released into the body
- the spike protein and the RNA have been used to develop and make different vaccines to protect against SARS-CoV-2

Transmission of COVID-19 infection

For transmission to occur, the SARS-CoV-2 virus needs to be transported to a susceptible person. To do this, it needs to have:

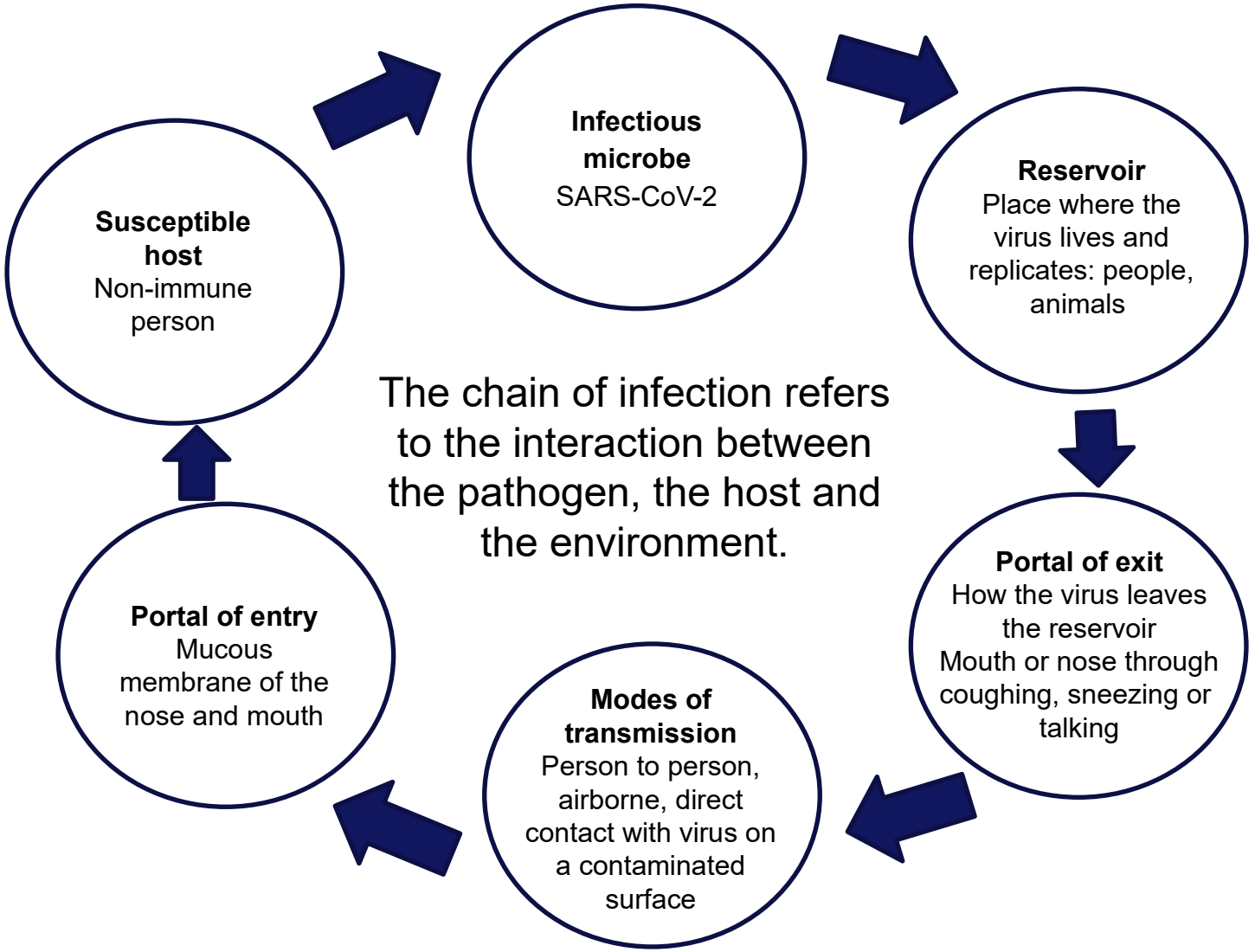
- a portal of exit (from the place where it is living and replicating)
- a mode of transmission (such as coughing or sneezing) and
- a portal of entry (to the susceptible host)

COVID-19 spreads primarily from person to person through small droplets from the nose or mouth which are expelled when a person with COVID-19 coughs, sneezes, or speaks.

These droplets can also survive on objects and surfaces such as tables, doorknobs and handrails.

People can catch COVID-19 if they breathe in these droplets from a person infected with the virus or by touching contaminated objects or surfaces, then touching their eyes, nose or mouth.

COVID-19 Chain of infection



COVID-19 symptoms

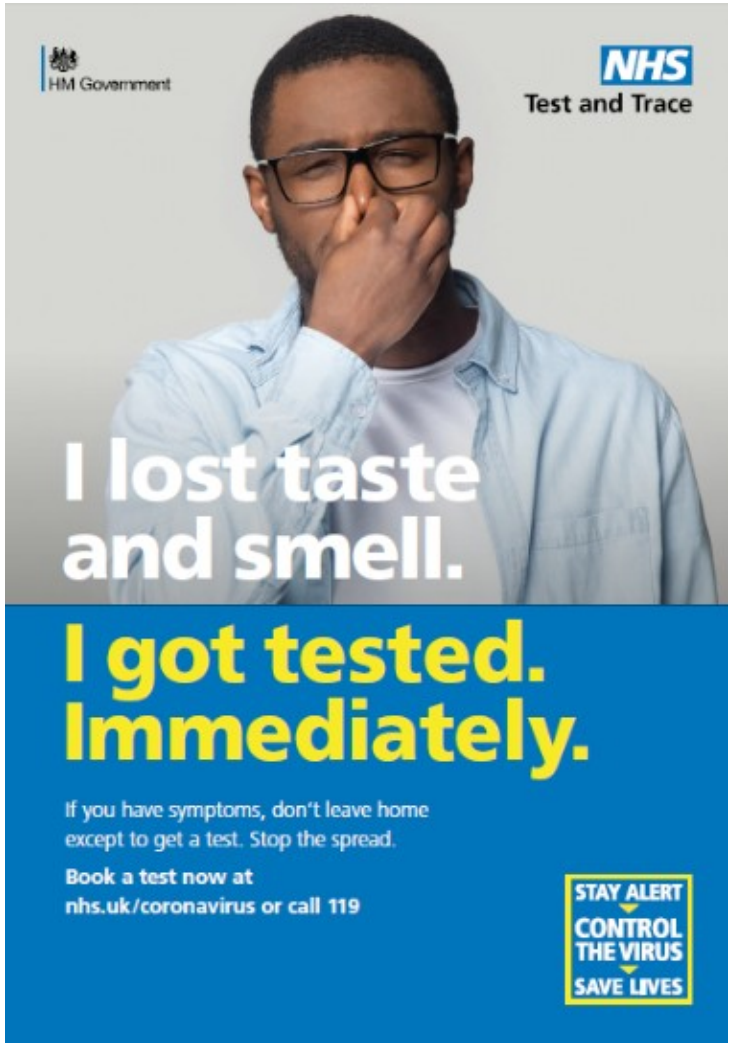
The estimated incubation period is 3 to 6 days but can vary between 1 and 11 days.

Symptoms may vary by age but the main symptoms of coronavirus are:

- **a new, continuous cough** – coughing for more than an hour, or 3 or more coughing episodes in 24 hours
- **a high temperature**
- **a loss or change to sense of smell or taste**

Other symptoms reported include:

- fatigue and lethargy
- shortness of breath
- headache
- sore throat
- aching muscles
- diarrhoea and vomiting



COVID-19 symptom progression

Symptoms may begin gradually and are usually mild.

- the majority of people (around 80%) have asymptomatic to moderate disease and recover without needing hospital treatment
- around 15% may get severe disease including pneumonia
  - older people and those with underlying medical problems such as high blood pressure, heart and lung problems, diabetes, or cancer are more likely to develop serious illness
- around 5% become critically unwell. This may include septic shock and/or multi-organ and respiratory failure

The infection fatality rate (the proportion of deaths among all infected individuals) is estimated to be 0.9% but it varies according to age and sex. It is lower in younger people (0.5% for those 45-64 years) and higher in those over 75 years of age (11.6%).

Complications of COVID-19 disease

Complications from COVID-19 can be severe and fatal.
The risk of developing complications increases with age and is greater in those with underlying health conditions.

The type of complication that can develop may include:

- venous thromboembolism
- heart, liver and kidney problems
- neurological problems
- coagulation (blood clotting) failure
- respiratory failure
- multiple organ failure
- septic shock

COVID-19 complications in pregnancy

- maternal morbidity is similar to that of other women of reproductive age and the outcome for women infected during pregnancy is usually good
- however, pregnant women with pre-existing comorbidities such as chronic hypertension or diabetes, those with higher maternal age, and high body mass index may experience severe COVID-19 disease
- they may also require intensive care unit admission and invasive ventilation and around 6% of pregnant women may experience a spontaneous pre-term delivery
- neonates born to mothers with COVID-19 have an increased risk of admission to a neonatal unit
- although stillbirths have been reported, perinatal deaths are rare and occur in less than 1% of cases

Symptoms in children and young people

- children comprise only 1 to 2% of cases of COVID-19 worldwide and are more likely to have mild symptoms or asymptomatic infection

- a study of children and young people aged less than 19 years admitted to hospital with laboratory confirmed SARS-CoV-2 reported that the median age of those enrolled in the study was 4.6 years

- other clinical features included age, sex and ethnicity: 35% (225/651) of them were under 12 months old; 56% (367/650) were male; 57% (330/576) were white; 12% (67/576) were South Asian and 10% (56/576) were Black

- of the 651 children and young people in the study, 42% had at least one other medical condition (co-morbidity). These included neurological conditions (11%), haematological, oncological or immunological conditions (8%) and asthma (7%)

Complications from COVID-19 in children and young people

- an extremely rare but severe multisystem inflammatory syndrome (MIS-C) occurring 2 to 4 weeks after the onset of COVID-19 has been identified in children and adolescents
- cardiac complications were documented in 57% (21/37) of MIS-C cases. These were more frequent in post-acute / antibody positive cases (75% 15/20) than in the acute phase 35% (6/17)
- of the children admitted to hospital, 18% required critical care. This was associated with:
  - age, particularly for those less than one month old and for those age 10 -14 years
  - black ethnicity and
  - admission to hospital for more than five days before symptom onset
- other complications from COVID-19 in children and young people include fever, cardiac symptoms (myocarditis, heart failure) and GI symptoms (abdominal pain, diarrhoea, vomiting)

Coronavirus (COVID-19) epidemiology

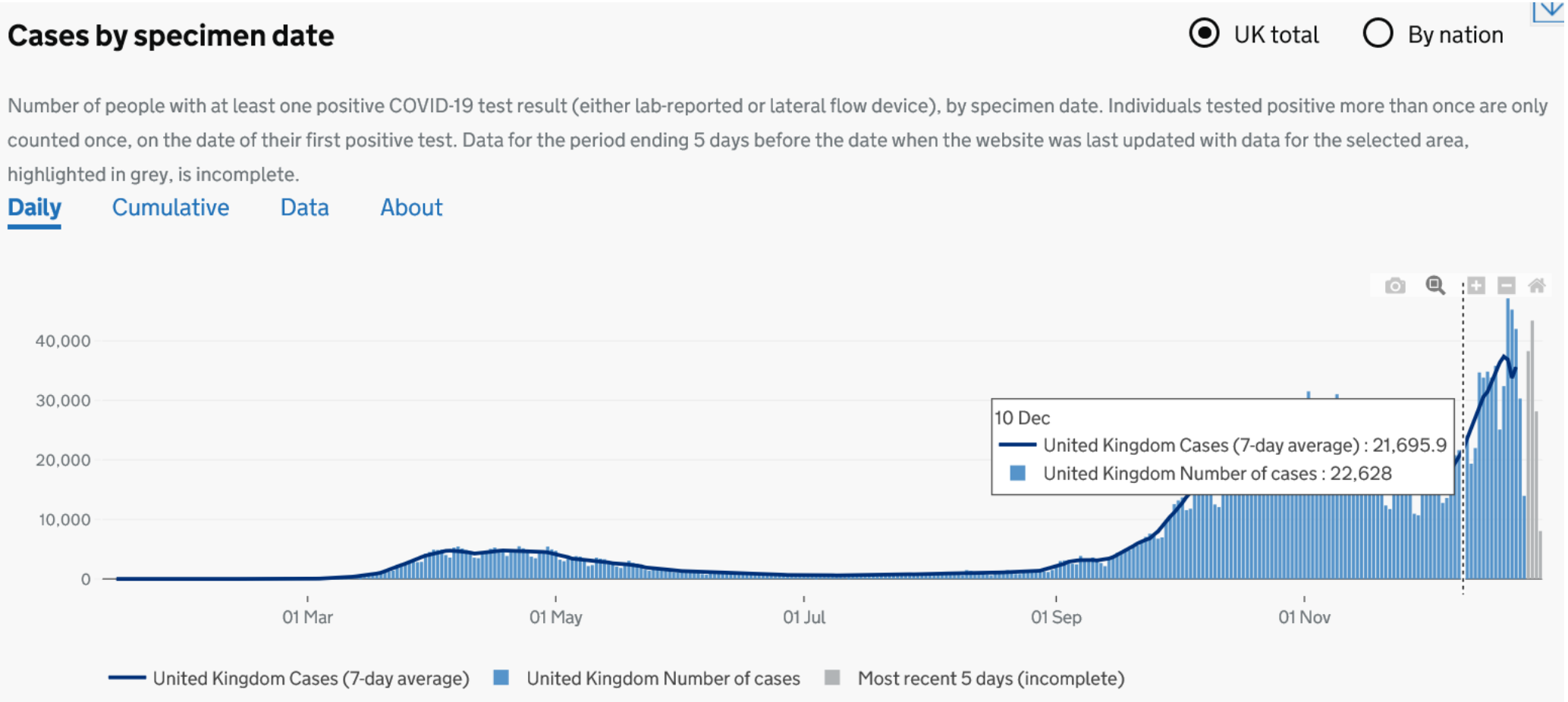
The current UK epidemiology can be seen on the GOV.UK website at: https://coronavirus.data.gov.uk/

This UK COVID-19 dashboard shows current trend information for:

- virus testing capacity
- virus tests processed
- people tested positive
- deaths within 28 days of positive test
- death from COVID-19 on death certificate
- patients in hospital
- patients in ventilator beds
- patients admitted

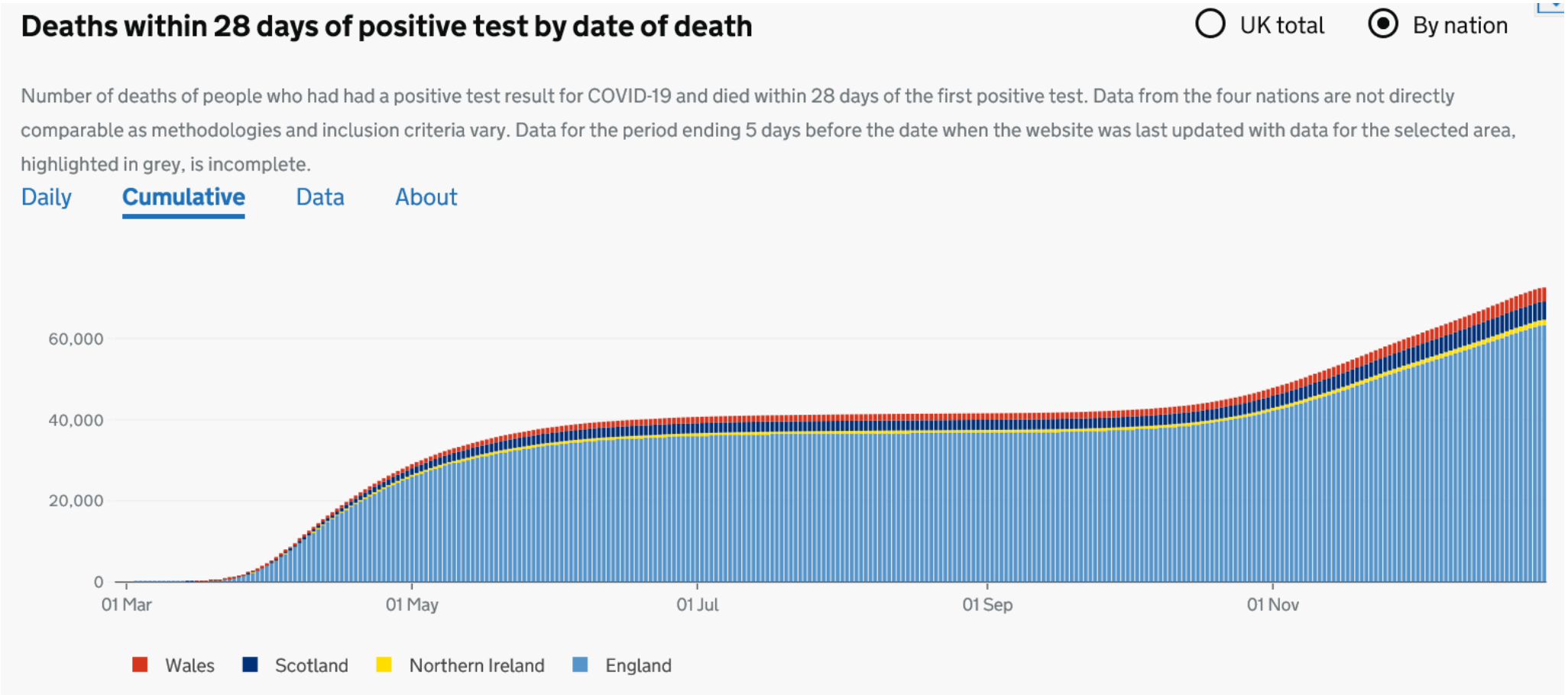
UK Coronavirus (COVID-19) positive tests by nation

2,432,888 people tested positive for Coronavirus (COVID-19) in the UK between 14/01/2020 and 30/12/2020



UK deaths within 28 days of a positive test

72, 548 deaths within 28 days of a positive test were recorded between 05/03/2020 and 30/12/2020



COVID-19 vaccine taskforce

- as the majority of the population are still susceptible (non-immune) to the SARS-CoV-2 virus and the virus spreads easily, it is clear that a safe and effective vaccine is needed to prevent further cases

- a COVID-19 vaccine prepares the immune system so that in the event of an exposure to the virus, it is able to respond and prevent or reduce the severity of infection

- during April 2020, a UK vaccine taskforce was set up to support the development of a SARS-CoV-2 vaccine

- the taskforce supported research and industry to rapidly develop and scale up the manufacture of a vaccine to protect the population

COVID-19 vaccine development

- scientists, industry and other organisations have worked collaboratively across the globe to complete the different phases of vaccine development in parallel, rather than sequentially to make a safe and effective vaccine available as soon as possible
- by knowing the genetic code for the SARS-CoV-2 virus, various methods to create vaccines can be used such as using the code itself (mRNA vaccines) or inserting part of this code into existing viruses (viral vector vaccines)
- by 30 December 2020, over 280 different COVID-19 vaccines were in early development, over 50 of these were being given to people in clinical trials and 11 were being trialled in large phase 3 trials
- some vaccines have been made using currently used vaccine technology, others have been made using new approaches or methods used during previous emergencies such as the SARS pandemic and west African Ebola

Properties of an ideal vaccine

Ideally, a vaccine will:

- produce the same immune protection which usually follows natural infection but without causing disease
- generate long lasting immunity so that the person is protected if they are exposed to the antigen several years after vaccination
- interrupt the spread of infection by preventing carriage of the organism in the vaccinated person

Vaccines need to be safe and the risk from any side effects should be much lower than the benefit of preventing deaths and serious complications of the disease.

For the COVID-19 vaccines, many of these properties can be confirmed from the clinical vaccine trials.

Longer term ongoing surveillance of the disease and of those vaccinated will show whether:

- vaccine protection is long lasting or booster or annual doses are needed
- the vaccine prevents a vaccinated person from carrying and spreading the virus

Stages of vaccine trials

Vaccines are extensively tested through several different phases of trials.

- **pre-clinical studies** using tissue-culture, cell-culture or animal studies. At this stage, safety and immunogenicity (the ability of the vaccine to produce an immune response) are assessed. If pre-clinical studies are successful, the vaccine then goes through several different phases of vaccine trials in humans
- **phase I clinical trials** are small-scale trials in healthy adult volunteers (generally 20-100) to assess whether the vaccine is safe in humans and type and extent of immune response it induces
- **phase II clinical trials** are larger (several hundred healthy volunteers) and usually carried out in the target age group(s) the vaccine is likely to be used in. They are looking mainly to assess the efficacy of the vaccine against artificial infection and clinical disease. Vaccine safety, side-effects and immune response are also studied
- **phase III clinical trials** involve the vaccine being studied on a large scale in many hundreds or thousands of subjects across several sites to evaluate efficacy under natural disease conditions and make sure that there are no unintended side effects not detected in phase II studies

Safety

- before any of the COVID vaccines can be authorised for widespread use in the population, the manufacturers have to demonstrate that they are safe and effective
- tens of thousands of people across the world have already received COVID-19 vaccines in clinical trials
- no serious adverse reactions to the vaccines were seen in the trial participants who received them
- any reactions reported were similar to those seen following other vaccines such as pain and tenderness at the injection site and fever, headache, muscle aches and fatigue

Effectiveness

- 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
- vaccine effectiveness can be calculated by comparing the number of cases of COVID-19 disease in trial participants who received the COVID-19 vaccine with the number of trial participants who received the placebo or alternative (non-COVID-19) vaccine

Those running clinical trials will also look at antibody response:

- after one dose and two doses
- at different dosages of the vaccine
- with different time intervals between vaccine doses
- in different age groups

Over time, they will look at:

- how long the antibodies last and the effect on antibody levels if a booster dose is given.
- whether the vaccine only stops people from becoming severely ill or if it also stops them spreading the virus too

Regulatory approval and licencing

- in the UK, vaccine manufacturers apply to the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA) for a product licence but they may issue a temporary authorisation ahead of the full UK product licence

- in exceptional situations, the MHRA may enact Regulation 174. This enables them to temporarily authorise the supply of an unlicensed medicinal product in response to certain identified public health risks, such as the SARS-CoV-2 pandemic

- the MHRA assess all of the available safety, quality and efficacy data and considers whether the evidence supports the use of the medicine or vaccine under the legal basis of regulation 174 until it can be licensed

- the process involves the same level of scrutiny as the usual licensing process and this exception is only used when strictly necessary to speed up access to a potentially life-saving intervention

Post authorisation surveillance

On-going studies of vaccines continue after the vaccine has been authorised for use. These studies aim to assess long term efficacy and to detect any rare adverse effects because in real life administration, compared to pre-licensure trials, there will be:

- some variability in preparation of the vaccine as vaccines will come from different batches
- possible variability in stability and storage, for example the cold chain may not be as rigidly maintained in practice as it was in a clinical trial
- use of the vaccines in different groups than in pre-authorisation studies, for example they will be given to people with underlying medical conditions who would not necessarily have been included in a pre-licensure/pre-authorisation clinical trial

COVID-19 Vaccines

On 2 December 2020, the following vaccine was given authorisation for temporary supply by the UK DHSC and the MHRA:

- **COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech)** is a messenger ribonucleic acid (mRNA) that contains the genetic sequence of the antigens found on the surface of the SARS-CoV-2 virus

On 30 December 2020, the following vaccine was also authorised for temporary supply in the UK:

- **COVID-19 Vaccine AstraZeneca** which is a non-replicating viral vector vaccine. It uses a weakened adenovirus as a carrier to deliver the genetic sequence for part of the SARS-CoV-2 virus into the body

COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech)

The COVID-19 mRNA Vaccine BNT162b2 vaccine is a messenger ribonucleic acid (mRNA) 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.

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.

Additional COVID-19 vaccines

If more COVID vaccines are considered for authorisation in the UK, information about these will be added to this slide set.

Further details about presentation, storage and preparation of the Pfizer-BioNTech see slides from 108 to 125 and the AstraZeneca COVID-19 vaccines are available on slides 126 to 136 at the end of this slide set.

Vaccine interchangeability

- data is not yet available on the interchangeability of different COVID-19 vaccines
- 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
- as the Pfizer-BioNTech BNT162b2 vaccine and the AstraZeneca vaccine are both 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

Key factors that inform UK vaccination policy

The Joint Committee on Vaccines and Immunisation (JCVI) consider the following before making vaccination policy recommendations to the Department of Health and Social Care (DHSC):

1. Availability of a safe and effective vaccine:

- there are currently over 280 COVID-19 vaccines in development and being trialled
- vaccines undergo extensive and vigorous testing before they are licensed and authorised for use as they have to be able to demonstrate quality, efficacy and safety

2. Whether there is a need for a vaccination programme:

- SARS-CoV-2 has caused a significant public health problem, transmission is widespread and has been sustained despite various interventions
- the virus affects all age groups and there have been frequent outbreaks in nursing and residential homes, schools and communities
- there is significant morbidity and mortality in certain groups. There are multi-system complications from having the disease and there have been tens of thousands of deaths from COVID-19 in the UK

Designing and implementing a vaccination programme

Other national bodies involved in the design and implementation of vaccination programmes include:

- **the Department of Health and Social Care (DHSC)** is responsible for vaccine policy decisions and finance for vaccine programmes
- **the Medicines and Healthcare products Regulatory Agency (MHRA)** is responsible for independent oversight of all aspects of vaccine manufacture and regulation including the licensing of vaccines and the Yellow Card adverse event reporting scheme
- **Public Health England (PHE)** is responsible for the national planning, leadership, procurement and supply of vaccines used for the national vaccination schedule and for on-going surveillance to inform the programmes
- **the National institute for Biological Standards and Control (NIBSC)** is responsible for evaluating the quality and biological activity of vaccines and for official batch release testing as required by EU law before release
- **NHS England** is responsible for the commissioning, implementation and delivery of immunisation programmes through local teams

Other agencies

Many other agencies have a key role in the design, development and implementation of vaccination programmes at a national, regional and local level to ensure the key components of a successful vaccination programme come together.

These components include:

- vaccine development
- vaccine supply and delivery
- surveillance of vaccine coverage
- surveillance of population susceptibility to the disease
- surveillance of disease in the population
- adverse events and vaccine safety surveillance
- monitoring attitudes to vaccination
- communication
- modelling to predicting the future impact of vaccination programmes

COVID-19 vaccine programme considerations

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

In order to advise which groups of patients to vaccinate and in which order to prioritise vaccination of these groups, the JCVI consider all the available relevant information on:

- vaccine efficacy and/or immunogenicity and the safety of administration in different age and risk groups
- the effect of the vaccine on acquisition of infection and transmission
- the epidemiological, microbiological and clinical characteristics of COVID-19

From this, they then make recommendations to the DHSC and planning to deliver vaccine and maximise uptake in these groups can begin.

Priority groups for COVID-19 vaccination

- JCVI have identified provisional priority groups for vaccination
- these groups are under regular review and prioritisation may change as more information about the vaccines becomes available
- prioritisation will ensure that those at highest risk of severe illness and death are vaccinated early
- the priority groups have been selected based on the epidemiology of the infection observed since the start of the pandemic: their risk of severe disease, mortality and other considerations such as ethnicity, deprivation and occupation
- evidence from the UK indicates that the risk of poorer outcomes from COVID-19 infection increases dramatically with age in both healthy adults and in adults with underlying health conditions
- those over the age of 65 years have by far the highest risk, and the risk increases with age
- full details on vaccine eligibility, with detail on the at-risk conditions, are included in the Green Book COVID-19 chapter

Vaccine priority groups: JCVI advice 30 December 2020

1	Residents in a care home for older adults and their carers
2	All those 80 years of age and over Frontline health and social care workers
3	All those 75 years of age and over
4	All those 70 years of age and over Clinically extremely vulnerable individuals (not including pregnant women and those under the age of 16 years)
5	All those 65 years of age and over
6	All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
7	All those 60 years of age and over
8	All those 55 years of age and over
9	All those 50 years of age and over

Older adults resident in a care home

- there is clear evidence that those living in residential care homes for older adults have been disproportionately affected by COVID-19
- those living in care homes have a high risk of exposure to infection due to their close contact with staff (including bank staff) and other residents including those residents returning to the care home from hospital
- the closed setting of the care home also increases the risk of outbreaks occurring as any asymptomatic residents and staff could be potential reservoirs for on-going transmission
- given the increased risk of outbreaks, morbidity and mortality in these closed settings, older adults in care homes are considered to be at very high risk
- JCVI have advised that this group should be the highest priority for vaccination
- vaccination of residents and staff at the same time is considered to be a highly efficient strategy within a mass vaccination programme with the greatest potential impact

Older adults

- older adults are considered to be at very high risk if they develop COVID-19 infection
- current evidence strongly indicates that the single greatest risk of mortality from COVID-19 is increasing age and that the risk increases exponentially with age
- disease severity, risk of hospitalisation and mortality increase from age 50 upwards, with the highest risk in those aged 80 years and above
- data indicate that the absolute risk of mortality is higher in those over 65 years than that seen in the majority of younger adults with an underlying health condition

Health and Social care workers

- frontline health and social care workers are a priority for vaccination as they are at higher risk of acquiring COVID-19 infection and developing serious disease
- as well as the risk to themselves, they can carry and transmit the virus to their families, friends and colleagues as well as to vulnerable patients in health and social care settings (including those in residential and care homes)
- this group includes those working in hospice care and those working temporarily in the COVID-19 vaccination programme who provide face-to-face clinical care
- the Green Book COVID-19 chapter contains details about the different groups of health and social care workers who may be offered COVID-19 vaccine

Clinically extremely vulnerable

- people who are defined as clinically extremely vulnerable are considered to be at very high risk of severe illness from COVID-19

- there are two ways an individual may be identified as clinically extremely vulnerable:
  - they have one or more of the conditions listed on the GOV.UK website, or
  - a hospital clinician or GP has added them to the Shielded patients list because they consider them to be at higher risk of serious illness from COVID-19

- many of those who are clinically extremely vulnerable are in the oldest age groups and will be among the first to receive vaccine -the remainder of this group should be offered vaccine alongside those aged 70-74 years of age

- the overall risk of mortality for clinically extremely vulnerable younger adults is estimated to be roughly the same as the risk to persons aged 70-74 years

- see Green Book COVID-19 chapter for more information about vaccination of this group

Groups with underlying health conditions

As well as age, other risk factors have been identified that place individuals at risk of serious disease or death from COVID-19. These include groups with certain underlying health conditions and may include people who have:

- chronic (long-term) respiratory disease
- chronic heart disease
- chronic kidney disease
- chronic liver disease
- chronic neurological disease
- diabetes
- a weakened immune system due to disease or treatment
- asplenia or dysfunction of the spleen
- morbid obesity (defined as BMI of 40 and above)
- severe mental illness

Detailed information giving examples of conditions in each of the clinical risk groups which would make individuals aged 16 years and over eligible for vaccination is provided in the COVID-19 Green Book chapter.

Pregnancy

- although the currently available data do not indicate any safety concerns or harm to pregnancy, there is currently insufficient evidence to recommend the use of COVID-19 vaccines during pregnancy
- however, the JCVI has advised that vaccination in pregnancy should be considered where the risk of exposure to SARS-CoV-2 infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19
- in these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnancy
- those who are trying to become pregnant do not need to avoid pregnancy after vaccination
- 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
- termination of pregnancy following inadvertent immunisation should **not** be recommended. Surveillance of inadvertent administration in pregnancy is being conducted by the PHE Immunisation Department Please report inadvertent administration in pregnancy to them (www.gov.uk/guidance/vaccination-in-pregnancy-vip)

Breastfeeding

- there is no known risk associated with giving non-live vaccines whilst breastfeeding
- JCVI advises that breastfeeding women may be offered vaccination with the Pfizer-BioNTech or COVID-19 AstraZeneca vaccines
- the developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19
- the woman should be informed about the absence of safety data for the vaccine in breastfeeding women

Deprivation and ethnicity

- there is clear evidence that certain Black, Asian and minority ethnic (BAME) groups have higher rates of infection, and higher rates of serious disease, morbidity and mortality from SARS-Cov-2 infection
- there is no strong evidence that ethnicity by itself (or genetics) is the sole explanation for observed differences in rates of severe illness and deaths
- certain health conditions are associated with increased risk of serious disease, and these health conditions are often overrepresented in certain BAME groups
- good vaccine coverage in BAME groups is therefore really important
- societal factors, such as occupation, household size, deprivation, and access to healthcare can increase susceptibility to COVID-19 and worsen outcomes following infection

How vaccination works

Vaccines deliver components known as antigens. These usually consist of inactivated, attenuated (weakened), modified viruses or bacteria or genetic material from the virus and they are used to prime the immune system against specific infections.

Once a vaccine enters the body, and delivers the antigen, the immune system recognises the antigens as ‘foreign’ to the body and responds to them by making antibodies and memory cells.

When memory cells meet the antigen again (either as a natural infection or in a booster dose of vaccine), specific antibodies are produced much more quickly and in greater numbers than during the first response.

This response is similar to the response made to natural infection but without the risks of the disease itself as the microorganism used in a vaccine is artificially weakened (attenuated), modified or inactivated (killed).

Innate and adaptive immunity

Immunity is generally described as being either innate or acquired.

Innate immunity is the body's first line of defense. It is present from birth and includes physical barriers, chemical barriers, phagocytic cells and the complement system. Innate immunity has no memory so doesn't provide protection against future exposure to the pathogen.

Acquired immunity (also called adaptive immunity) is the body's second line of defense. The immune system learns to recognise specific pathogens and challenge them if they meet them again later on. This capacity is called immunological memory.

A series of short videos has been produced by PHE to help to provide a basic understanding of the immune system and how vaccines work.

These can be accessed at: https://immunologyanimation.phe.org.uk/

PPE and infection prevention and control

- health care practitioners should follow the recommendations for Personal Protective Equipment (PPE) that are current at the time of vaccination
- hand hygiene is critical to prevent the spread of disease and hands should be cleansed 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

Preparing the vaccine

Some of the COVID-19 vaccines may require reconstitution and are supplied in two parts: the active component and the diluent.

If a vaccine requires reconstitution:

- only use the diluent specified by the manufacturer
- use the correct volume of diluent
- write the date and time of reconstitution on the reconstituted vaccine vial
- store and use any reconstituted vaccine within the time period specified by the manufacturer

Before administration, check:

- which diluent to use, the amount needed for reconstitution and the ‘use within’ time
- that the colour and composition of vaccine is as specified in description in vaccine manufacturer’s instructions
- when the vaccine was reconstituted and expiry date
- you have drawn up the correct dose

Before administering a vaccine

Before administering a vaccine, the individual should be assessed to ensure that:

- there are no contraindications to the vaccine being given
- they or their carer is fully informed about the vaccine to be given and understand the vaccination procedure
- they or their carer are aware of possible adverse reactions to the vaccine and how to treat them
- they have consented to having the vaccine

Immunisers should ensure that:

- they have the appropriate knowledge and legal authority to administer the vaccine
- the vaccine has been properly stored and prepared for use and that they know where and how to administer it

Vaccine contraindications and precautions (1)

A **contraindication** is when an individual has a health condition that increases the likelihood of them having a serious adverse reaction to a vaccine. A vaccine should not be administered when the individual has a valid contraindication.

A **precaution** to a vaccine is when an individual has a condition that may increase the risk or severity of an adverse reaction following immunisation, that may compromise their ability to make an immune response to the vaccine or that may confuse a diagnosis.

Where there is any doubt whether it is safe to give a vaccine, seek expert advice.

Vaccines are contraindicated in 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**

There may be additional contraindications specific to each COVID-19 vaccine. Ensure you check these before administering the vaccine

Vaccine contraindications and precautions (2)

As the COVID-19 vaccine could not be trialled in every patient group, there may be some temporary contraindications or precautions until more is known about the vaccine and it has been given more widely to more people.

COVID-19 vaccines are currently not recommended in pregnancy or for people aged under 16 years of age.

Before administering a COVID-19 vaccine, it is important to check for any relevant medical history including any allergies and any previous history of severe reaction to a vaccine or anaphylaxis with an unidentified cause.

If any specific contraindications or precautions to a COVID-19 vaccine have been listed in the Green Book COVID-19 chapter or the information provided about the vaccine by the manufacturer, you must check whether any of these apply to the person to be vaccinated before any vaccine is given.

Consent

Before giving COVID-19 vaccine, immunisers must ensure that they have obtained informed consent from the patient or that a best interest decision has been made if the patient does not have mental capacity at the time of vaccination.

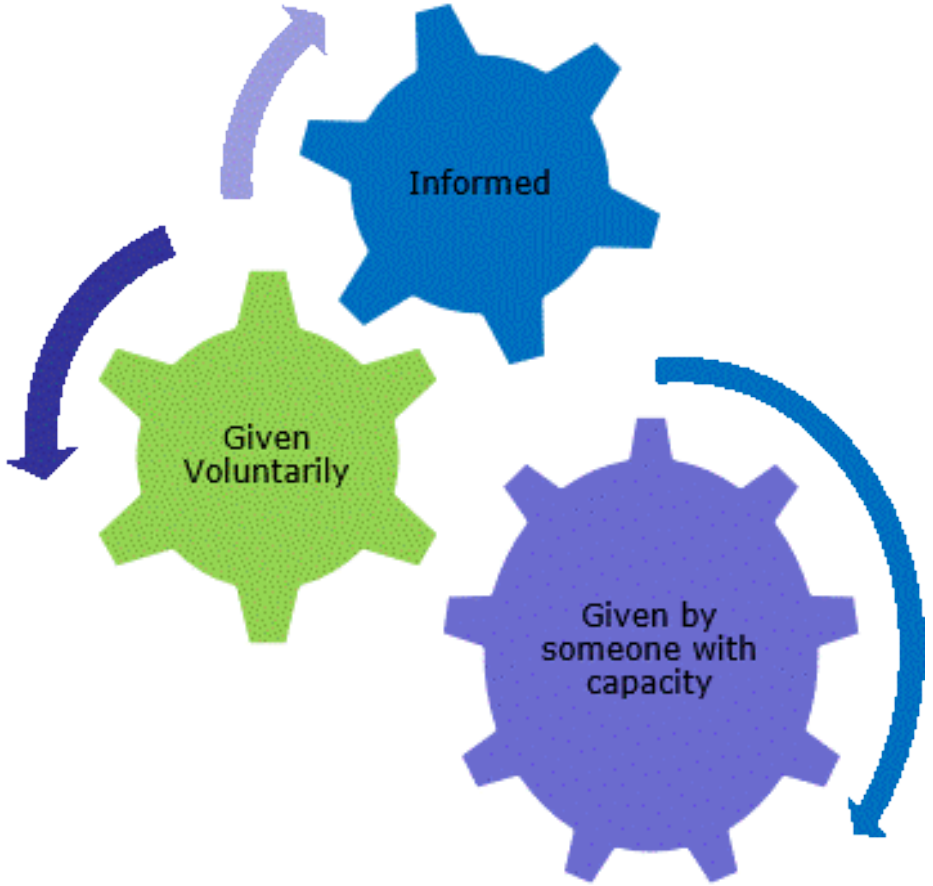
In order to be able to consent to vaccination, the vaccinee should receive an explanation of the treatment and its benefits and risks, either verbally from a clinician, or in the form of a leaflet and letter.

When assessing capacity to consent, the immuniser should be guided by the principles of the Mental Capacity Act.

Consent

Consent is a process, not a one-off discussion and must consider three factors:

- the person giving consent must be appropriately informed: they must have the necessary information in order to make the decision
- consent must be voluntary by the individual without undue pressure or coercion
- the person consenting must have the capacity to make the decision



Consent

Information to be given includes:

- vaccine to be given and the disease that will be prevented
- benefits/risks of immunisation versus risks of the disease
- any new information that has become available since consent to previous doses of this vaccine were given if applicable
- any possible vaccine reactions and how to treat these
- follow-up/information as to any further doses required
- how any personal data will be stored and kept (information governance)

How much information should you give?

This will be personal to the individual at the time, and will depend on their previous knowledge and discussions with others.

- give people as much information as they need and/or want to make an informed decision
- some people will just ‘trust’ what you say while others want lots of information; either is fine
- how much each individual needs is up to them, no one is obliged to seek full information

Informed consent

- the need for ‘informed consent’ is a legal requirement and the patient’s views must be respected and consent sought
- sufficient evidence-based information must be provided to the person to enable them to make a balanced and informed decision about their care and treatment
- consent can be given verbally, in writing, or it can be implied
- however consent is given, the person must understand what they are consenting to
- if there are any issues or uncertainties with seeking or gaining consent, ask for advice from an experienced colleague rather than abandon the offer of immunisation

Mental capacity and best interest decisions

All adults are considered to have capacity to consent to receiving vaccinations unless there is evidence to suggest that capacity is limited.

If an adult is able to do the following three things, then they should be considered to have capacity and their decision should be respected:

1. Understand the information that you are giving them about the vaccine and any potential risks from it or from the disease it protects against
2. Consider the information you have given them and retain it for long enough to make a decision on whether to accept or decline the offer of vaccination
3. Communicate their decision to you

Actions to support decision making

There are some actions that can be taken to support and optimise a person's ability to make a decision. These include:

- making reasonable adjustments to facilitate decision making or accommodate individual needs
- using communication tools such as 'Easy Read' leaflets
- speaking with them at their best time of day
- asking someone who the person knows and trusts to speak to them

If an adult does not have capacity, a best interest decision will need to be made by the decision-maker, considering all relevant circumstances.

This is not the same as consenting on behalf of another adult so

- a GP cannot consent on behalf of their patient
- a husband or wife cannot consent on behalf of their spouse
- a family member cannot consent to a relative's treatment if they lack capacity

Making a best interest decision

To make a best interest decision, the following must be considered:

- the person who lacks capacity should be involved in the decision-making process if possible, particularly if their capacity fluctuates. If capacity does fluctuate, the healthcare professional would accept consent given at the time
- any previously expressed wishes or behaviours such as previously consenting to vaccination should be acknowledged
- the offer of vaccination should be discussed with those close to the patient such as their carer, relatives or anyone appointed as a Lasting Power of Attorney (LPA) for Health and Welfare, or those named by the person to be consulted on vaccination if practical
- the person's actual interests at the time the vaccine is offered

This process should be documented and the decision recorded.

It is good practice to inform nursing or care home management teams of any plans to vaccinate residents in advance of the scheduled date to allow time to address any potential issues.

Documenting informed consent

- it is best practice to document on the vaccine recipient's healthcare record that informed consent has been obtained

- providers of an immunisation service may decide, for operational purposes or in accordance with their local consent policy, that written consent should be obtained for each vaccine recipient

- operational purposes may include assessing the numbers of vaccines required for a clinic or venue, enabling data capture for patient records or obtaining consent from someone other than the vaccinee (such as a parent or an Attorney)

- national consent forms and letters for local adaptation have been provided on the **GOV.UK COVID-19 vaccination programme** page to support those providers who do wish to obtain written consent

Legal requirements for the Supply and Administration of Vaccines

- the regulation of medicines is defined under the Human Medicines Regulations 2012
- 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

Legal requirements for the supply and administration of vaccines

Vaccines are Prescription Only Medicines (POMs). This means a legal framework to supply and/or administer a vaccine must be in place and can be in the form of:

- a written patient specific prescription
- a Patient Specific Direction (PSD): a written instruction, signed by a doctor, dentist, or non-medical prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis
- a Patient Group Direction (PGD): allows some registered specified health care professionals to supply and/or administer a POM directly to a patient with an identified clinical condition rather than needing an individual prescription or an instruction from a prescriber. PGDs are often used for the administration of vaccines
- or another process such as a Protocol or Written Instruction

Patient Group Directions (PGD)

- PGDs set out the core requisites of those people who can have the medicine under the direction and those who should not
- the document will also include details of any additional training that should have been undertaken, actions to be taken if the patient is excluded or declines the medicine, a description of the medicine(s), route of administration, doses, frequency, reporting of adverse reactions, recording, storage and disposal
- the HCP working under a PGD is responsible for assessing that the patient fits the criteria set out in the PGD. The healthcare professional operating under the PGD may not delegate the role to others
- PGDs must be authorised before use by a doctor and a pharmacist and by an appropriate body e.g. NHS EI, PHE, NHS Trust, CCG etc
- health professionals who will be using the PGD must be named and authorised before they use it to provide care

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 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/vaccines which have been temporarily authorised for supply in the UK under regulation 174 to be administered in accordance with a PGD
- registered HCPs who are allowed to work to a PGD may supply and administer COVID-19 vaccines, as temporarily authorised vaccines under Regulation 174, using a PGD
- the workforce that can administer under PGDs has not changed
- PHE will develop and publish PGDs for COVID-19 vaccines

Protocols for the supply and/or administration of COVID-19 vaccine

- the changes to the Human Medicines Regulations 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 against coronavirus in accordance **with a protocol** that is approved by ministers
- a national protocol has been published which allows trained and competent non-registered healthcare workers as well as registered healthcare professionals, to administer COVID-19 vaccine
- the protocol specifies who can use it and includes information similar to that commonly found in PGDs
- the protocol allows flexibility for different COVID-19 vaccine delivery models.
- it may be followed wholly from patient assessment through to post-vaccination by a single person. Alternatively, multiple HCWs may undertake different roles or stages in the patient vaccination pathway in accordance with the protocol
- the service provider is responsible for ensuring that HCWs are trained and competent to safely deliver the activity they are employed to provide under the protocol

Vaccine storage, preparation and administration

Vaccine storage, preparation and administration are critical components of a successful vaccination programme and are key to ensuring that vaccination is as safe and effective as possible.

If specific requirements are not followed, vaccinees may not make a response to the vaccine and so remain unprotected or, they may be at higher risk of developing a vaccine reaction.

To minimise the risk of vaccine failures and reactions:

- the storage conditions of the vaccine should always be checked before administration
- the vaccine must be reconstituted according to the manufacturer's instructions
- the correct equipment should be used to prepare the vaccine
- the correct technique must be used to deliver the injection and
- the vaccine must be administered in the correct anatomical site

Vaccine storage

- as vaccines are biological products, they are temperature sensitive so must be stored and transported within the recommended temperature range
- the system of transporting and storing vaccines is called **the cold chain**
- a cold chain breach occurs when vaccines have been stored outside of this temperature range
- vaccines that have not been stored or transported correctly can lose potency and may not evoke a full or lasting immune response, leaving the vaccinee at risk of the disease the vaccine should have prevented
- for vaccines in the national vaccination programme, the recommended vaccine storage temperature range is usually between +2˚C to +8˚C

Vaccine storage (continued)

- vaccine storage recommendations are set out by the manufacturer and are part of the licensing or authorisation conditions

- vaccines that have not been stored in the recommended temperature range are outside of those conditions. Any apparent failure of the vaccine and responsibility and liability for their use will therefore lie with the immunisation provider

- vaccines that are not stored and transported correctly may need to be disposed of which leads to increased wastage and programme costs

- adhering to the temperature recommendations will ensure that vaccines are in optimum condition for those individuals they are given to

General principles of vaccine storage

- all vaccines must be stored in a lockable dedicated vaccine/medicine fridge between 2°C and 8°C (**unless other storage requirements have been specified**)
- systems to prevent accidental interruption of the power supply to the fridge must be in place
- fridges should be situated away from radiators and other sources of heat that could affect how they work
- records should be kept of regular fridge servicing and thermometer calibration
- the temperature in the fridge must be continually monitored using a current/minimum/maximum thermometer
- fridge temperatures should be monitored and recorded on a designated chart ideally twice every working day
- fridge alarm parameters should be set appropriately to alert to any deviations from the 2°C to 8°C range
- vaccines must be kept upright and stored in their original packaging
- vaccines with shorter expiry dates should be placed at the front of the fridge
- expired stock should be removed from the fridge and destroyed
- **take immediate action if the temperature goes outside recommended range**

Storage and transportation of COVID-19 vaccines

All those involved in the delivery of the COVID-19 vaccination programme have a professional responsibility to ensure that the cold chain is maintained and must be aware of the recommended storage requirements for the different COVID-19 vaccines.

Be very clear about your specific responsibilities for maintaining the cold chain and at what point e.g. transporting it, receiving a delivery, daily fridge monitoring, reconstitution, etc.

COVID-19 vaccine must not be given if you are not confident that it has been stored or reconstituted as recommended by the manufacturer or as advised by a vaccine expert

Temperature monitoring systems

- there should be a named person and a deputy responsible for COVID-19 vaccine storage
- those responsible should be familiar with the fridge digital display readings, the functioning of the thermometer reset button and the manufacturer's user guidelines
- data loggers can be useful in the event of a cold chain breach as the data can be used to calculate cumulative exposure to out of range temperatures. However, they should always be used in conjunction with the integral fridge thermometer and should not be used to replace the daily temperature monitoring and recording
- a visual check of the actual temperature should also be made each time a vaccine is removed from the fridge

Temperature monitoring equipment

- most vaccine and medicine fridges have integral thermometers with a digital display. Ideally, a second thermometer, independent of the main power source (for example, battery operated) should be available to monitor the temperature in the event of a power failure
- temperature probes with cables should be correctly positioned in the fridge, ensuring that the cable does not interfere with the door seal and that the probe is not up against the back or sides of the fridge
- data loggers are recommended as a back up to visual temperature reading from integral thermometers
- vaccines being stored or transported in portable cool bags or refrigeration devices should be monitored to the same standard as vaccines stored in vaccine fridges
- vaccine fridges and temperature-monitoring equipment should be regularly serviced and calibrated

Action to take if vaccines are stored incorrectly

If COVID-19 vaccines are stored incorrectly:

- label & isolate affected vaccines and do not use until further notice
- inform your team leader / manager and other vaccinators in the clinic
- make alternative arrangements for immunisation clinics until resolved
- seek advice from the manufacturer or a source of expert advice
- be able to provide them with the following information:
    - what monitoring has taken place (max/min/current thermometer readings)
    - when the cold chain was last guaranteed
    - what time period/s are involved (hours/days)
    - what the temperature range has been during this period
    - identify all vaccines stored in the fridge, the time they have been stored there and expiry dates

Portable refrigeration

- a medical grade cool box or bag purchased from a medical supplier must be used for storage and transportation of vaccines being used for home visits or community clinics
- all vaccines should be kept in their original packaging until use and the cool box or bag should be packed following the manufacturer’s instructions and not overfilled
- the minimum and maximum temperatures in the cool box or bag should be recorded
- if the temperature has gone out of range, a risk assessment should be conducted before using or disposing of the vaccines

Vaccination site

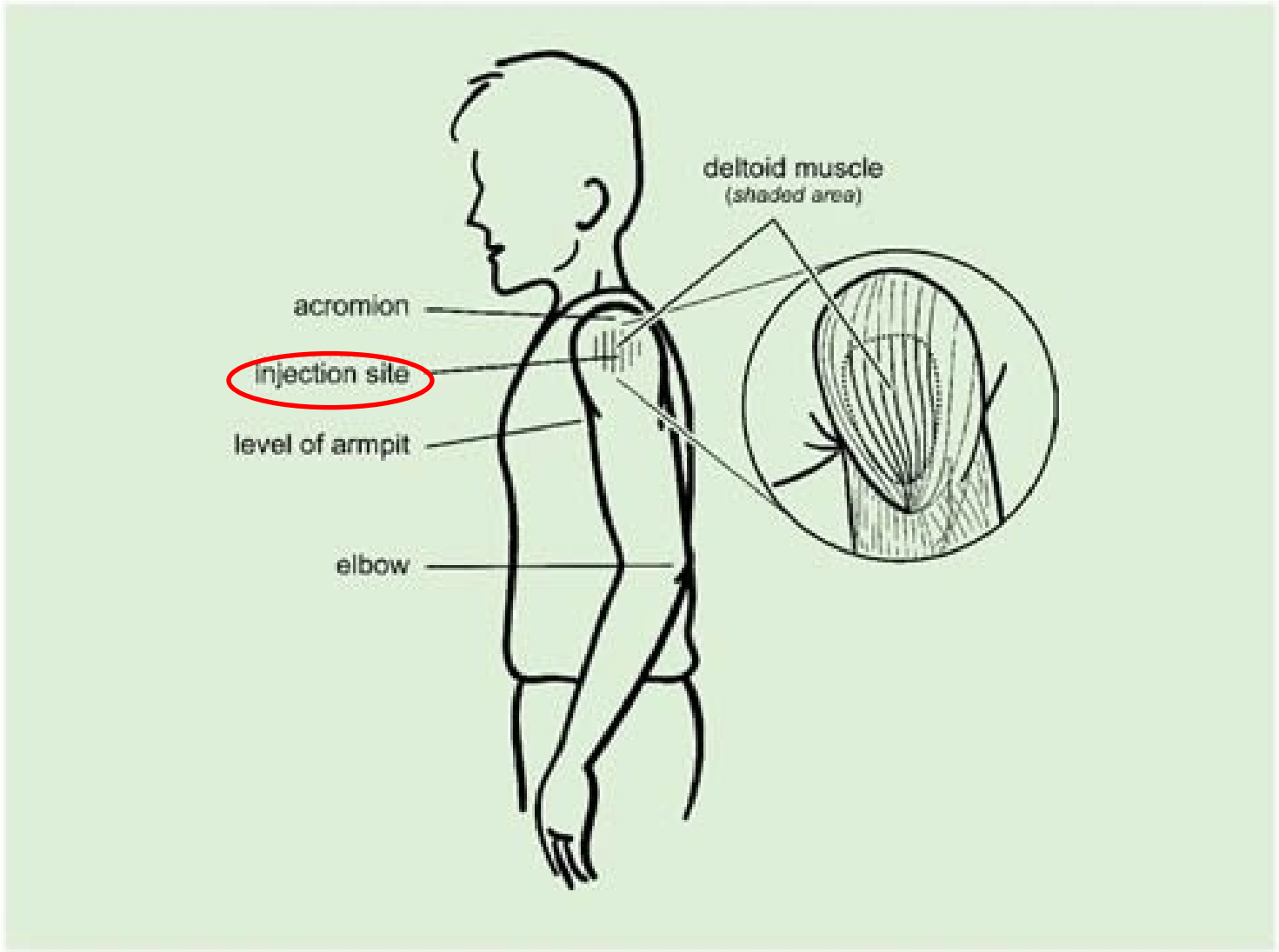
Giving vaccine into the muscle:

1. leads to a better immune response to the vaccine (as the muscle contains the appropriate cells necessary to initiate the immune response) and
2. is less likely to cause local reactions than if the vaccine is given into the skin (subcutaneously)

The needle needs to be long enough to ensure vaccine is injected into the muscle. For this reason, a 25mm needle is being provided for administration of the COVID-19 vaccine. A 38mm length needle is available if required for adults who have more fat covering their muscles.

The COVID-19 vaccine should be injected into the deltoid muscle in the upper arm or, if there is insufficient muscle mass in the area of the deltoid or a particular reason the deltoid muscle is otherwise unsuitable, into the vastus lateralis muscle in the anterolateral aspect of the thigh.

The deltoid muscle (upper arm)



https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/147915/Green-Book-Chapter-4.pdf
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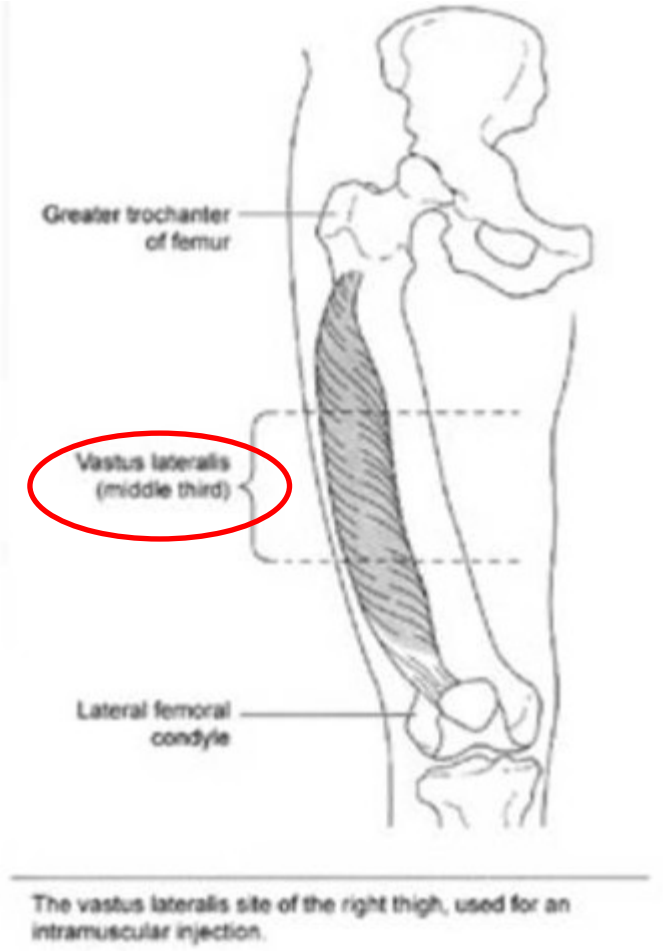
The Vastus lateralis muscle (anterolateral aspect of the thigh)



The vastus lateralis site of the right thigh, used for an intramuscular injection.

www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

Infants under one year receive their immunisations into the anterolateral aspect of the thigh because the deltoid muscle is not sufficiently well enough developed at this age.

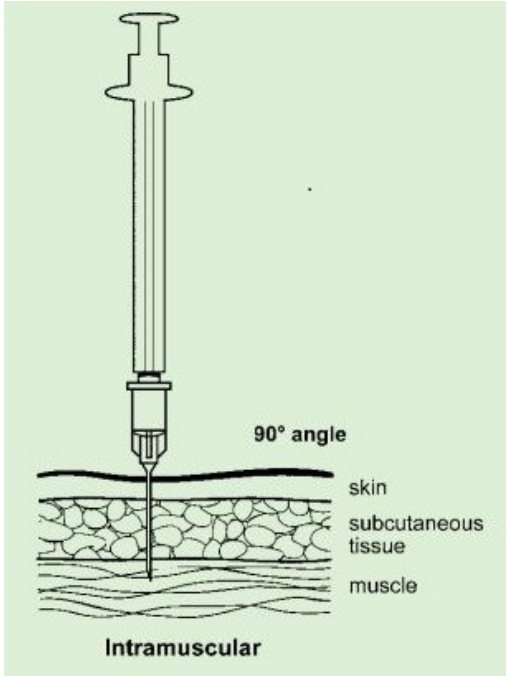
Although the deltoid muscle is more commonly used in older children and adults as it is quicker and easier to access, the vastus lateralis muscle in the thigh can be used in these age groups if necessary.

Vaccine administration continued

Skin does not need to be specially cleaned prior to vaccination. If it is visibly dirty then water is sufficient to clean it.

Intramuscular process:

- identify the correct site for IM injection
- stretch the skin at the site
- insert the needle at a 90 degree angle far enough to ensure vaccine is delivered into muscle
- depress the plunger
- gently remove the needle
- apply light pressure using gauze or cotton wool if bleeding occurs



Consequences of incorrect injection technique

- it is essential that the correct site and injection technique is used to administer vaccines
- injecting too high into the upper arm might result in a shoulder injury or a frozen shoulder. This leads to pain, weakness and a limited range of motion that can last for months
- injecting too far to the side of the arm or too low on the arm risks injecting into the axillary nerve or the radial nerve
- to avoid shoulder injury, always assess the limb before administering the vaccine to identify the correct site for injection

Individuals with bleeding disorders or taking anticoagulation therapy

- 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, e.g. treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/ treatment is administered
- individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination
- 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
- the individual/parent/ carer should be informed about the risk of haematoma from the injection

Post vaccination advice and observation

- those vaccinated should be observed for any immediate adverse effects for a minimum of 15 minutes following immunisation with the Pfizer BioNTech vaccine (longer if deemed necessary after clinical assessment)
- there is no requirement for 15 minutes observation following the AstraZeneca COVID-19 vaccine
- vaccinees should be given a copy of the patient information leaflet and/or any other relevant written information and informed how that they can obtain further advice if required
- they should also be given a vaccination record card and an appointment for any further dose required
- inform the vaccinee 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. Those advised to shield should continue to do so until told otherwise.

Disposal of consumables

- **needles should not be re-sheathed following vaccination under any circumstances**
- the needle and syringe should be disposed of immediately after use in a puncture resistant yellow sharps bin
- the yellow sharps bin should be sealed when it is two thirds full and replaced with a new one
- vaccine cardboard packaging should be placed in a yellow clinical waste bag for incineration
- any blood stained gauze or cotton wool should be placed in a bin for clinical waste
- local policy should be followed for the disposal of PPE

Adverse reactions following vaccination

Some people can feel unwell following an injection and some people may experience an adverse reaction.

Vaccinees should be informed of the potential expected reactions to COVID-19 vaccines.

There are three main types of adverse reaction following immunisation:

1. local reactions at the injection site such as redness, swelling or pain at the injection site
2. systemic reactions (reaction affecting the whole body) such as fever, headache, loss of appetite
3. allergic reaction such as anaphylaxis or a severe systemic allergic reaction

Adverse reactions following vaccination

Adverse events following vaccination may occur for various reasons. These include:

- inappropriate practices in the provision of vaccinations such as giving the wrong dose of vaccine or poor injection technique

- reactions caused by the vaccine or its component parts. These may be a direct effect of the vaccine or due to an underlying medical condition in the individual

An individual may report an event following vaccination that may be coincidental rather than a true adverse event, for example when a vaccinee develops cold-like symptoms after receiving the flu vaccine. The vaccination and the symptoms are linked because of the timing, but the vaccine did not cause the symptoms

Anaphylaxis

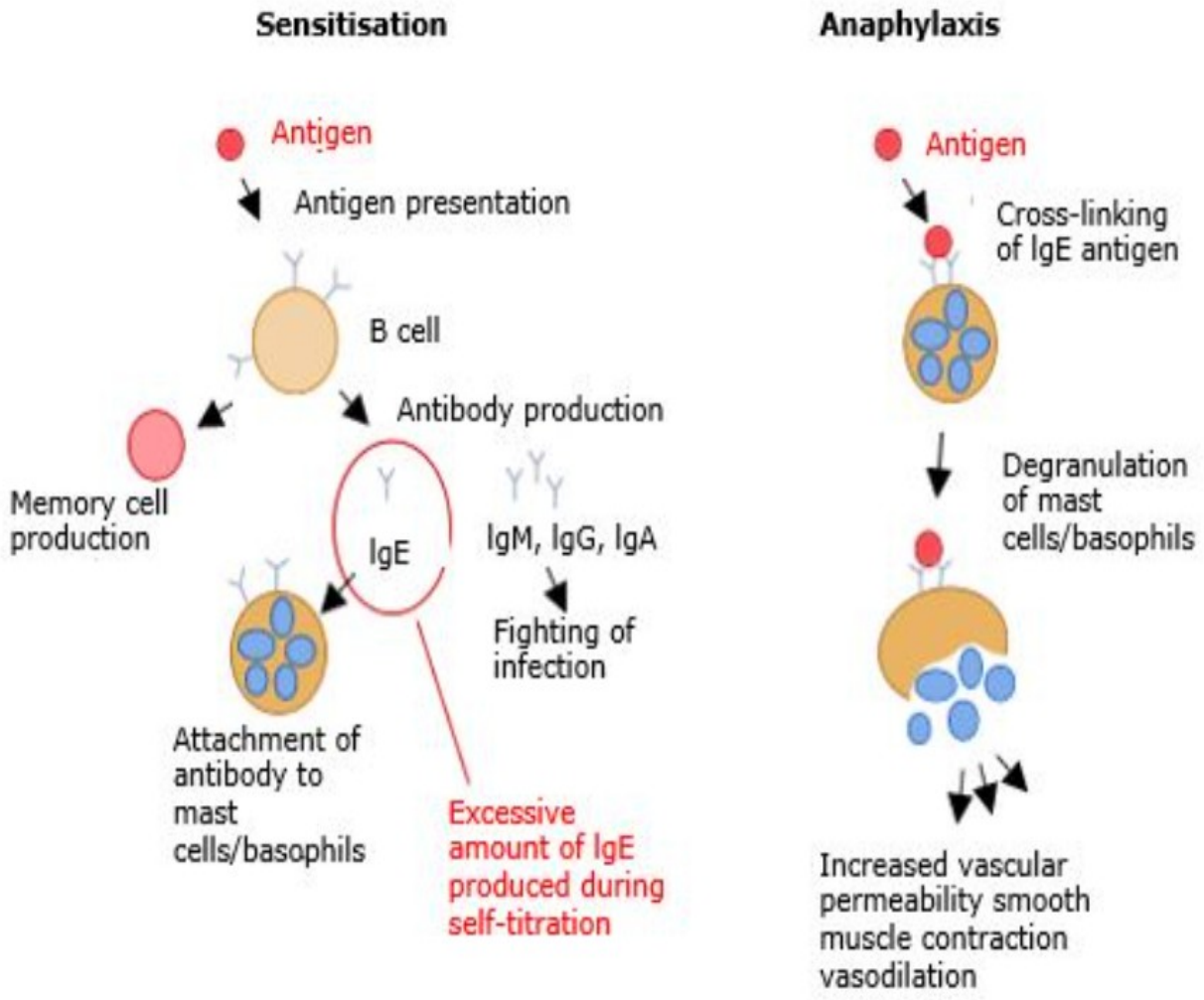
- common causes of anaphylaxis include food, eggs, and nuts but it can also be caused by medicines or vaccines
- anaphylaxis is a rare, potentially life-threatening event
- confirmed anaphylaxis following vaccination is extremely rare
- data from the UK, Canada and the US indicate rates of 0.65 to 3 anaphylaxis events per million doses of vaccine given
- onset is typically rapid, within minutes, with variable severity
- it is critically important that immunisers know how to treat anaphylaxis should it occur and equipment for treating anaphylaxis must always be available in all vaccination settings
- **you must have completed Basic Life Support and anaphylaxis training prior to giving any vaccinations**

Anaphylaxis

Anaphylaxis occurs as a result of exposure to an allergen to which a person has been sensitised and previously made specific immunoglobulin E (IgE).

On re-exposure to the antigen, explosive amounts of histamine and other chemical mediators are released following the binding of the antigen to IgE coated mast cells.

This causes bronchospasm, angioedema, pulmonary oedema, cardiovascular collapse and loss of consciousness.



Reporting adverse reactions

Suspected adverse reactions following administration of COVID-19 vaccine should be reported to the MHRA using the specific Coronavirus Yellow Card reporting scheme (coronavirus-yellowcard.mhra.gov.uk/ or call 0800 731 6789). As new vaccines, MHRA have a specific interest in the reporting of adverse drug reactions for these vaccines.

- vaccines are carefully monitored to ensure they are safe, not causing untoward side effects and are suitable for the immunisation programme
- MHRA promotes the collection and investigation of adverse reactions through the Yellow Card scheme which is a voluntary reporting system for suspected adverse reactions
- anyone (patients and HCWs) can make a Yellow Card report, even if they are uncertain as to whether a vaccine caused the condition

Suspected reactions following vaccination should be reported to the MHRA via the Yellow Card scheme

Documentation and record keeping

- it is essential that the information in Box 1 is recorded for all doses of vaccine given to ensure complete and accurate patient vaccination records and to enable extraction of the correct data for surveillance and vaccine coverage purposes
- if not administered at the patient's GP surgery, a record of the vaccination given should be sent to the patient's GP to avoid duplicate vaccination and so that data can be submitted to the national COVID-19 vaccine uptake data survey

BOX 1. Following vaccination, the following information should be recorded

- vaccine name
- product name
- batch number
- expiry date
- dose administered
- date immunisation given
- route/site used
- name and signature of vaccinator

Examples of patient records where vaccination details may need to be recorded

- patient's GP record (or other patient record, depending on location)
- practice computer system
- occupational health record/employer's record

Communicating with patients

There are many sources of information available relating to COVID-19. Since the virus was first identified in January 2020, there have been thousands of publications globally.

When considering the information contained in written materials, there are some key points to consider:

- the author and their expertise/background
  - if the author is not named, or the source is not clear, this should raise your suspicion about the quality of the information
  - does the author have a vested interest in presenting an unbalanced view?

- the way the information is presented
  - is it presented in an unbiased manner, or is it selected to provide only one viewpoint when there are other equally valid views?
  - is the information dated? If so, there may be more recent information that is different
  - if there are any uncertainties, are they mentioned?
  - is it possible to follow up any information by going to the original data, e.g. a trial of a vaccine?

Addressing concerns and providing information to those being vaccinated

- the COVID-19 vaccines are new vaccines. Patient information leaflets will be provided in advance but many patients will want additional verbal reassurance or answers
- it is important to read the information being made available to vaccinees so the information you give is consistent with this and so you know what information they have already had
- it is also important to know where to direct patients to for further information
- **if people's questions and concerns are answered accurately and appropriately, they are more likely to accept vaccination**

General principles for addressing concerns

- give the patient/parent/carer time to ask questions
- find out the basis for their concerns
- explore the nature and sources of information they have already gathered
- check the patient/parents'/carers' personal experience
- provide them with other sources of information such as valid and reliable websites
- check their understanding of the information that you provide
- ask them if there are any more concerns
- if they decline to be vaccinated, suggest talking again in a couple of days/weeks if appropriate
- recommend immunisation

Knowledge and skills

- a high level of knowledge and a positive attitude to immunisation helps to achieve and maintain high vaccine uptake

- those being vaccinated need to feel confident that the person giving them the vaccine or advising them knows what they are doing and has the appropriate knowledge, skills and ability

- immunisers who do not feel confident should discuss their concerns with a mentor or supervisor

Knowledge and skill check

Statutory and mandatory training – should be completed as specified by your employer (including basic life support and anaphylaxis). This may also include additional sessions on infection prevention and control, information governance and other relevant topics to the patient group(s) you will be vaccinating

Vaccine specific training (knowledge) – through elearning, classroom-based training or a webinar

Vaccine specific training (practical) - preparing a vaccine and intramuscular (IM) injection technique

Competency assessment - for formal assessment and sign-off of clinical competency.

Supervision is recommended for new immunisers until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to administer vaccines safely and competently

Competency assessment tool

The competency assessment tool is divided into three areas

1. Knowledge
2. Core clinical skills
3. The clinical process/procedure for vaccine administration

It should be completed by those who are new to or returning to immunisation before sharing with their supervisor. Experienced immunisers should use it as a self-assessment tool.

The supervisor carrying out the assessment should:

i. review the self-assessment, discussing any areas identified as ‘need to improve’
ii. observe performance in the provision of immunisations/advice and indicate whether each competency is ‘met’ or ‘needs to improve’ in the ‘supervisor review’ column
iii. if improvement is needed, help to develop an action plan to enable the achievement of the required level of competence and plan a further assessment
iv. sign off the section at the bottom of the assessment when competency is agreed

COVID-19 vaccinator competency assessment tool

	Competency assessment tool for heatlh care workers administering COVID-19 vaccine	Not applicable to role assigned (NA)	Self-assessment Record: met (M) or needs to improve (NI) (initial & date)	Supervisor review Record: met (M) or needs to improve (NI) (initial & date)	Record action plan for any assessed as 'needs to improve' (as agreed with supervisor)
	Part 1: Knowledge		**Self-Assessment**	**Supervisor review**	
1a	Can provide evidence of completion of the COVID-19 vaccine e-learning programme or attendance at a specific, comprehensive COVID-19 vaccine training course.				
1b	Has successfully completed and passed a knowledge assessment – either the e-learning course assessment or an end of course test.				
1c	Able to access the online Green Book and other relevant COVID-19 vaccine guidance e.g. DHSC/PHE/NHS E&I letters (or Scotland, Wales and Northern Ireland equivalents), Vaccine Update, PHE Information for Healthcare Practitioners on the COVID-19 vaccine programme document, COVID-19 vaccine PGD and Protocol, etc				
1d	Knows who to contact for advice if unsure about issues such as eligibility for vaccination or action to take if a vaccine error occurs.				
1e	Able to explain the basics of how the vaccine works, what it contains and why, how it has been trialled, any contraindications or precautions and possible side effects and how to treat them.				

	Part 2: Core Skills for immunisation	Not applicable to role	Self-Assessment	Supervisor review	Record action plan for any assessed as 'needs to improve'
2a	Is up to date with requirements for anaphylaxis and basic life support (BLS) training (has undertaken within past year or as per employers' stipulations).				
2b	Aware of how to respond to an immediate serious adverse event following vaccination and knows the whereabouts of anaphylaxis and emergency care equipment and how and when to use it.				
2c	Can explain incident response and reporting process in case of a procedural error, needlestick injury, breach of infection control measure, etc. as per local protocol.				
2d	Knows how to put on and take off personal protective equipment (PPE) as required and demonstrates good practice in infection prevention and control. Uses aseptic technique when preparing vaccines and handling injection equipment (e.g. syringes, needles) to prevent contamination and infection.				
2e	Disposes of sharps, vaccine syringes and vials and other vaccine equipment safely in line with local protocol.				
2f	Demonstrates knowledge and understanding of the rationale for and importance of maintaining the vaccine cold chain. Familiar with local protocols for cold chain management and the action to be taken in case of cold chain failure and who to contact.				
	Part 3: Clinical process and procedure	**Not applicable to role**	**Self-Assessment**	**Supervisor review**	**Record action plan for any assessed as 'needs to improve' (as agreed with supervisor)**
3a	Checks patient's identity and patient's records prior to vaccination to ascertain suitability for COVID-19 vaccination.				

Supervision and accountability

Supervision

- supervision for new immunisers is critical to the safe and successful delivery of the COVID-19 immunisation programme
- supervisors must be registered, appropriately trained, experienced and knowledgeable practitioners in immunisation

Accountability

- all staff involved in immunisation are accountable for their own practice, both to their employer and to their professional regulator (where applicable)
- employers are responsible and accountable for ensuring that employees have the required training and competency and are provided with an appropriate level of supervision to safely and effectively carry out the role they have been contracted to provide

Delegation

If immunisation is delegated, patient safety must be considered and not compromised in any way.

The delegation must be appropriate, safe and in the best interests of the patient

When delegating immunisation, the delegating healthcare professional (whether nursing, medical or other independent prescriber) must ensure that:

- the person they are delegating to has undergone training, has the appropriate knowledge, skills and competency
- there is adequate supervision and support in place

If these conditions have been met and the role of administering an immunisation is delegated, the delegatee is accountable to the patient for their actions and decisions, and for any errors they make through civil law and to their employer.

Maximising vaccine uptake

As COVID-19 vaccine may be offered in different settings, different methods of promoting the vaccine to maximise uptake may be required.

This may include:

- displaying posters in areas of high footfall such as waiting rooms, train stations, shopping centres
- having leaflets available for patients to read before their appointment
- signposting people to online resources or resources in a suitable format, for example Easy Read, BSL, large text and translated versions
- speaking confidently and positively about the vaccines and encouraging others in the vaccination clinic to do so as well
- confirming an appointment has been made for the second dose
- offering flexible appointments, including evening and weekend clinics
- ensuring mobile staff are able to locate patient's homes

Further information

UK vaccine policy can be found in the online publication commonly referred to as the "**Green Book**". This can be found on the Immunisation page of the GOV.UK website.

Green Book recommendations are based upon JCVI's expert opinion and should always be followed, even when they differ from those made by the vaccine manufacturer.

PHE COVID-19 immunisation programme Information for healthcare practitioners

This document provides additional information, answers to frequently asked questions and actions to take in the event of inadvertent errors.

It is important to read this document before you start vaccinating and also to refer to the online version regularly as it will be updated as more information becomes available and to address any issues or frequently arising questions as COVID-19 vaccines are delivered more widely.

Vaccine product information

Licensed vaccines have a Summary of Product Characteristics (SPC).

Initially, the COVID-19 vaccines will be given authorisation for temporary supply rather than a product license.

This means they will not have an SPC but all the information about the vaccine that would usually be found in an SPC is presented in an “Information for Healthcare Professionals” document.

1. the Information for healthcare professionals document provides a description of the vaccine, how to use it and the conditions attached to its use
2. an “Information for UK recipients” document is also available which provides information for patients about the vaccine

For both of these documents, see: MHRA guidance on coronavirus (COVID-19)
www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19#vaccines-and-vaccine-safety

Action plan

To consolidate learning, the following actions should be completed:

- undertake the COVID-19 vaccine, vaccine administration, storage and legal aspects elearning sessions if required after this training session
- undertake Basic Life Support/anaphylaxis training if not undertaken in the past year
- complete any additional statutory and mandatory training required by your employer
- undertake practical training in immunisation if required e.g. IM injection technique
- complete the COVID-19 competency assessment tool
- visit the GOV.UK Immunisation web pages and familiarise yourself with the resources available on this site
- read the PHE “COVID-19 immunisation programme Information for healthcare practitioners” document
- read the vaccine product information in the “Information for healthcare professionals” document on the MHRA website
- access the Green Book online and read the COVID-19 vaccine chapter and any other chapters that are relevant e.g. vaccine administration, vaccine storage
- subscribe to Vaccine Update to ensure that you receive this free monthly newsletter as it is published. It contains details of immunisation programme updates and changes
- find out and make a note of who you can contact if you have an immunisation query or incident. This may be your local NHS England Screening and Immunisation Team or lead consultant (if working in Occupational Health, etc)

Learning objectives

By the end of this session, you should be able to:

- explain what COVID-19 is and be aware of the UK epidemiology
- understand the policy behind the COVID-19 vaccination programme
- describe how vaccines work and how they are developed and trialled
- identify the groups who are at high risk for COVID infection and who should be prioritised to receive the COVID-19 vaccine
- describe the process of consent and how this applies when giving vaccines
- understand the legal mechanisms by which immunisers can supply and administer COVID-19 vaccine
- recognise the differences between a prescription, a PSD, a PGD and a Protocol and understand which staff can use each of these
- describe the key principles of how to correctly store, prepare and administer vaccines
- communicate key facts in response to questions from patients and direct them to additional sources of information

Resources

- 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://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/
- Royal College of Nursing. COVID-19 vaccination resources www.rcn.org.uk/clinical-topics/public-health/immunisation/covid-19-vaccination
- 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

Public Health England

Protecting and improving the nation's health

COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech)

Contraindications to COVID-19 mRNA Vaccine BNT162b2

The COVID-19 mRNA Vaccine BNT162b2 should not be given to people who have had a confirmed anaphylactic reaction to a previous dose of the same vaccine or to any components of the vaccine

In addition to the highly purified BNT162b2 messenger RNA, the vaccine also contains:

- ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium hydrogen phosphate dihydrate
- sucrose
- water for injections

Polyethylene glycol (PEG) is from a group of known allergens commonly found in medicines and also in household goods and cosmetics. Known allergy to PEG is rare but would contraindicate receipt of this vaccine.

Precautions to COVID-19 mRNA Vaccine BNT162b2 (1)

- a very small number of individuals have experienced anaphylaxis when vaccinated with the COVID-19 mRNA Vaccine BNT162b2 vaccine

- following close surveillance of the initial roll-out, the MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to a component (excipient) of the vaccine

- all recipients of this vaccine should be kept for observation and monitored for a minimum of 15 minutes

- facilities for management of anaphylaxis should be available at all vaccination sites

Precautions to COVID-19 mRNA Vaccine BNT162b2 (2)

The British Society for Allergy and Clinical Immunology (BSACI) has advised that:

- individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated)
- individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital)
- individuals with non-allergic reactions (vasovagal (fainting) episodes, non-urticarial skin reaction or non-specific symptoms) can receive the second dose of vaccine in any vaccination setting

COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech)

- the vaccine contains BNT162b2 messenger RNA embedded in lipid nanoparticles
- the vaccine does not contain preservative
- no animal products are contained in the vaccine product
- full product information about the COVID-19 mRNA Vaccine BNT162b2 is available at https://coronavirus-yellowcard.mhra.gov.uk/productinformation
- further useful information about this vaccine available on the Specialist Pharmacy Service website at www.sps.nhs.uk/articles/excipients-information-for-pfizer-biontech-covid-19-vaccine/

Adverse reactions following COVID-19 mRNA Vaccine BNT162b2

The following reactions were reported by the vaccine clinical trial participants

Local reactions

Over 80% reported pain at the injection site. Redness and swelling was also commonly reported.

Systemic reactions

The most frequently reported systemic reactions (reactions affecting the whole body) were

tiredness (> 60%) headache (> 50%)

muscle aches (> 30%) chills (> 30%)

joint pain (> 20%) raised temperature (pyrexia)(> 10%)

- these symptoms were usually mild or moderate in intensity and resolved within a few days after vaccination
- medicines such as paracetamol can be given for post-vaccination pain or fever if required.
- inform vaccinees these symptoms normally last less than a week but if their symptoms get worse or they are concerned, they should speak to their GP or call NHS 111

COVID-19 mRNA Vaccine BNT162b2 presentation

- the vaccine packs contain 195 vials of vaccine
- the vaccine is contained in a multidose clear glass vial. The vial has a rubber (bromobutyl) stopper, aluminium seal and a flip-off plastic cap. The stopper does not contain latex
- each vial contains 0.45 ml of vaccine and should be diluted with 1.8 ml of Sodium Chloride 0.9% Solution for Injection (normal saline). Once diluted, each reconstituted vaccine will supply 5 or 6 doses of 0.3 ml (30 mcg)
- after withdrawing 5 full 0.3ml doses from the vial, it may be possible to withdraw a sixth full dose if the dose-sparing needles and syringes being provided with the vaccine are being used
- care should be taken to ensure a full 0.3 mL dose will be administered to the patient from the same vial. Where a full 0.3 ml dose cannot be extracted, the contents should be discarded

Diluent for COVID-19 mRNA Vaccine BNT162b2

- only Sodium Chloride 0.9% Solution for Injection (normal saline) should be used as a diluent for this vaccine
- a separate ampoule containing a minimum of 2ml of normal saline is required for vaccine reconstitution
- each ampoule of diluent is single use and any remaining diluent must be discarded after 1.8 ml has been withdrawn, regardless of the ampoule volume
- there are no special storage requirements for the diluent and this can be stored with other ambient products (needles and syringes) in a dry environment away from direct sunlight

Ordering COVID-19 mRNA Vaccine BNT162b2

- COVID-19 mRNA Vaccine BNT162b2 should be ordered via PHE's ImmForm platform
- each pack of vaccine ordered should automatically generate an order for the required number of the following for that vaccine pack:
  - ✓ diluent
  - ✓ syringes and needles for dilution
  - ✓ syringes and needles for vaccine administration*
  - ✓ vaccination record cards
  - ✓ patient information leaflets

*Longer length (38mm) needles are recommended for morbidly obese individuals to ensure the vaccine is injected into muscle. These can be ordered from ImmForm when ordering vaccine if required in addition to the 25mm needles and syringes that will be supplied

COVID-19 mRNA Vaccine BNT162b2 dose and schedule

- a single dose is 0.3 ml (30 mcgs)
- two doses of COVID-19 mRNA Vaccine BNT162b2 are required with a minimum 21-day interval between doses
- operationally, it is recommended that the second dose of COVID-19 vaccine should be routinely scheduled between four and 12 weeks after the first dose
- this will allow more people to benefit from the protection provided from the first dose during the roll out phase and will have a greater impact in reducing mortality, severe disease and hospitalisation
- longer term protection will then be provided by the second dose

Storage and transportation of mRNA Vaccine BNT162b2

For information only as those handling vaccines at ultra low temperatures should have received specific additional training for this and should be working to detailed standard operating procedures:

- the vaccine will be delivered frozen **to healthcare facilities with ultra low temperature (ULT) freezers**
- vaccine packs will be shipped inside isothermic boxes (validated boxes which will maintain a constant temperature for a specified period of time) inside a cardboard box
- the isothermic box will also contain dry ice which should be disposed of carefully following local protocols
- upon delivery, the vaccine packs should be removed from the isothermic box and transferred to a suitable ULT freezer to ensure ongoing storage between -80°C and -60°C
- the vaccine should be kept upright, in its original packaging and away from prolonged light exposure
- when removed from the freezer, the undiluted vaccine can be stored for up to 5 days at 2°C to 8°C, and an additional 2 hours at temperatures up to 25°C in preparation for dilution
- once thawed, the vaccine cannot be re-frozen
- shelf-life is 6 months at -80°C to -60°C

Storage and transportation of COVID-19 mRNA Vaccine BNT162b2 in a thawed state

- the vaccine may then be delivered to where it is going to be administered thawed but refrigerated between +2 and +8°C
- refrigerated vaccine must be transferred immediately to a vaccine fridge on arrival and stored in a carefully monitored temperature range of +2 and +8°C
- when removed from the freezer, the undiluted vaccine has a maximum shelf life of up to 5 days (120 hours) at +2 and +8°C and an additional 2 hours at temperatures up to 25°C in preparation for dilution
- the vaccine pack will have a yellow label on the front stating the time it was removed from the freezer into storage at +2 to +8°C and the date and time by which it must be discarded 5 days (120 hours) later if it has not been used
- vaccine should be stored in the original package to protect it from light. Exposure to room light should be minimised and exposure to direct sunlight and ultraviolet light should be avoided

Storage and use of mRNA Vaccine BNT162b2

- the mRNA Vaccine BNT162b2 has very specific storage, reconstitution and 'use within' requirements
- all those involved in the delivery of the COVID-19 vaccination programme must be aware of the recommended storage requirements

The vaccine must not be given if you are not confident that it has been stored or reconstituted as recommended by the manufacturer or as advised by a vaccine expert

If the vaccine is stored incorrectly:

- Label and isolate affected vaccines in the fridge and do not use until further notice
- Seek advice from the manufacturer or a source of expert advice

COVID-19 mRNA Vaccine BNT162b2 reconstitution

The following equipment is required for reconstitution:

- one COVID-19 mRNA Vaccine BNT162b2 vaccine multidose vial
- one plastic ampoule of Sodium Chloride 0.9% Solution for Injection - this will be supplied in multiple presentations (different manufacturers and different sized ampoules)
- an alcohol swab, a green hubbed needle and a 2 ml syringe to reconstitute - needles and syringes will be supplied together in boxes of 100

After dilution the vaccine should be used as soon as is practically possible
Reconstituted vaccine can be stored between +2°C and +25°C **but must be used within 6 hours following dilution**

Reconstituting COVID-19 mRNA Vaccine BNT162b2 (1)

1. clean hands with alcohol-based gel or soap and water
2. assemble one ampoule of Sodium Chloride 0.9% Solution for Injection, a single use alcohol swab, a needle with a green hub and a 2ml syringe
3. from cold storage, remove one vial of vaccine
4. if removing the multidose vaccine vial directly from a ULT freezer, allow the vaccine to thaw at temperatures up to 25°C and reconstitute within 2 hours
5. if removing the multidose vaccine vial from cold storage between +2 and +8°C, check that it has not been stored there for longer than 5 days (120 hours)
6. when the thawed vaccine is at room temperature, gently invert the vial 10 times prior to dilution. **Do not shake**
7. check the expiry date and the appearance of the vaccine. Prior to dilution, the vaccine should be an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present
8. connect the needle with a green hub to the 2 ml syringe

Reconstituting COVID-19 mRNA Vaccine BNT162b2 (2)

9. clean the vial stopper with the single use alcohol swab and allow to air dry fully

10. draw up 1.8 ml of Sodium Chloride 0.9% Solution for Injection, then discard the diluent ampoule and any remaining diluent in it. Do not use any other type of diluent

11. add diluent to the vaccine vial. You may feel some pressure in the vial as you add the diluent. Equalise the vial pressure by withdrawing 1.8 ml of air into the empty diluent syringe before removing the needle from the vial

12. gently invert the diluted solution 10 times. **Do not shake**

13. the diluted vaccine should be an off-white solution with no particulates visible. Return the vial to the manufacturer if particulates or discolouration are present

14. dispose of green hub needle and syringe into yellow sharps bin

15. the diluted vial should be clearly labelled with the dilution time and date

Reconstituted vaccine should ideally be used immediately and must be used within 6 hours following dilution

Dose preparation of COVID-19 mRNA Vaccine BNT162b2

- if the vaccine has previously been reconstituted, check that the time of reconstitution was within the last 6 hours
- clean top of vial with a single use alcohol swab and allow to air dry fully
- unwrap one of the 1ml combined 23g/25mm blue hub needle and syringes provided (recommended needle length depends on body mass of patient. Longer length (38mm) needles are recommended for morbidly obese individuals to ensure the vaccine is injected into muscle)
- withdraw a dose of 0.3 ml of diluted product for each vaccination. **Ensure correct dose is drawn up**
- any air bubbles should be removed before removing the needle from the vial in order to avoid losing any of the vaccine dose
- the same needle and syringe should be used to draw up and administer the dose of vaccine to prevent under dosing of the vaccine to the person
- the needle should only be changed between the vial and the patient if it is contaminated or damaged

Disposal

Needles should not be re-sheathed under any circumstances following vaccine administration

- needles, syringes, used vials and ampoules should be disposed of immediately after use in a yellow puncture-resistant sharps bin
- the yellow sharps bin should be sealed when it is two-thirds full and replaced with a new one
- any blood-stained gauze or cotton wool should be placed in a bin for clinical waste
- vaccine cardboard packaging should be placed in a yellow clinical waste bag for incineration
- local policy should be followed for disposal of PPE

Public Health England

Protecting and improving the nation's health

COVID-19 Vaccine AstraZeneca

Contraindications

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

- a previous dose of this COVID-19 vaccine
- any component~~s~~ of this vaccine

Adverse reactions following COVID-19 Vaccine AstraZeneca

The following reactions were reported by the vaccine clinical trial participants:

Local reactions

More than 60% reported tenderness at the injection site with redness, swelling, pain also being reported.

Systemic reactions

The most frequently reported systemic reactions (reactions affecting the whole body) were:

tiredness (> 50%)	headache (> 50%)
muscle aches (> 40%)	feeling generally unwell (>40%)
chills (> 30%)	raised temperature (pyrexia)(> 30%)
joint pain (> 20%)	nausea (> 20%)

- these symptoms were usually mild or moderate in intensity and resolved within a few days after vaccination
- medicines such as paracetamol can be given for post-vaccination pain or fever if required
- inform vaccinees these symptoms normally last less than a week but if their symptoms get worse or they are concerned, they should speak to their GP or call NHS 111

Vaccine composition

The COVID-19 Vaccine AstraZeneca contains recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein.

It also contains:

- L-Histidine
- L-Histidine hydrochloride monohydrate
- Magnesium chloride hexahydrate
- Polysorbate 80
- Ethanol
- Sucrose
- Sodium chloride
- Disodium edetate dihydrate
- Water for injections

The vaccine does not contain preservative and it does not contain any components of animal origin.

Presentation

- COVID-19 Vaccine AstraZeneca is presented in a multidose vial containing a solution which should be colourless to slightly brown, clear to slightly opaque and free of particles
- the vial has a halobutyl rubber stopper and is sealed with an aluminium overseal. There is no latex in the vial stopper (bung)
- AstraZeneca vaccine will be delivered in packs that contain 10 vials
- two different presentations of the AstraZeneca vaccine are expected to be provided:
    - 80 dose packs (ten 4 ml vials with at least 8 doses per vial)
    - 100 dose packs (ten 5 ml vials with at least 10 doses per vial)
- the majority of the vaccine will be supplied as the 8 doses per vial presentation but the 10 dose vial may be provided initially. Only one product presentation will be available to order at one time
- **Vaccinators must check how many doses the vial they are using contains so that vaccine is not wasted**

Additional doses from vaccine vial

- each vial contains at least the number of doses stated
- after withdrawing 8 or 10 full 0.5ml doses from the vial (depending on vial size), it may be possible to withdraw an additional full dose if the dose-sparing needles and syringes being provided with the vaccine are being used
- care should be taken to ensure a full 0.5 mL dose will be administered to the patient from the same vial
- where a full 0.5 ml dose cannot be extracted, the remaining contents should be discarded

Ordering

- COVID-19 Vaccine AstraZeneca should be ordered via PHE's ImmForm platform
- combined 1 ml fixed-needle (23g or 25g, 25mm length) dose-sparing syringes for administration will be available to order separately on ImmForm
- syringes and longer-length (38mm) needles for administration can be ordered for those who are morbidly obese
- each carton of vaccine vials will include one Healthcare Professional Information sheet and one pad of the corresponding number of Patient Information Leaflets
- patient vaccination record cards will also be supplied with vaccine ordered
- vaccinators are advised to read the latest administration instructions electronically www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

Storage

- upon delivery, AstraZeneca vaccine should be transferred to a fridge immediately and stored between +2ºC and +8ºC
- vials should be kept upright in their box and away from direct sunlight to prevent prolonged light exposure
- once the vial bung is punctured, the vaccine must be used as soon as possible and within 6 hours of first puncture (during which time it can be stored between +2°C to +25°C)
- as the vaccine does not contain preservative, any unused vaccine must be discarded if not used within this 6 hour time period

Store the vials upright

The vaccine vials must be stored upright (mulberry colour panel is the bottom)

Dose and schedule

- a single dose is 0.5ml
- two doses of AstraZeneca vaccine are required with a minimum 28-day interval between doses
- operationally, it is recommended that the second dose of COVID-19 vaccine should be routinely scheduled between four and 12 weeks after the first dose
- this will allow more people to benefit from the protection provided from the first dose during the roll out phase and will have a greater impact in reducing mortality, severe disease and hospitalisation
- high levels of protection are evident after the first dose of vaccine
- longer term protection will then be provided by the second dose

Vaccine dose preparation (1)

- **COVID-19 Vaccine AstraZeneca does not require reconstitution**
- before drawing up a dose of vaccine from the multidose vial, clean hands with alcohol-based gel or soap and water
- each multi-dose vial should be clearly labelled with the date and time it was first punctured
- do not use the vaccine if the time of first puncture was more than 6 hours previously
- check the appearance of the vaccine. It should be colourless to slightly brown, clear to slightly opaque and free of any particles. Discard the vaccine if particulates or discolouration are present.
- do not shake the vaccine vial
- the vial bung should be wiped with an alcohol swab and allowed to air-dry fully

Vaccine dose preparation (2)

- a 1 ml dose-sparing syringe with a 23g or 25g, 25mm fixed-needle should be used to draw up and administer the AstraZeneca vaccine
- separate 38mm length needles and syringes should be used for morbidly obese patients to ensure the vaccine can be injected into the muscle
- withdraw a dose of 0.5 ml for each vaccination. **Take particular care to ensure the correct dose is drawn up as a partial dose may not provide protection**
- any air bubbles should be removed before removing the needle from the vial in order to avoid losing any of the vaccine dose

Disposal

Needles should not be re-sheathed under any circumstances following vaccine administration

- COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs)
- sharps waste and empty vials should be placed into yellow lidded puncture-resistant sharps bins and sent for incineration; there is no need for specific designation as GMO waste
- any blood-stained gauze or cotton wool should be placed in a bin for clinical waste
- vaccine cardboard packaging should be placed in a yellow clinical waste bag for incineration
- local policy should be followed for disposal of PPE. Potentially contaminated gloves and aprons can be disposed of in yellow/black striped offensive waste bags
- an appropriate viricidal disinfectant should be available for managing spills in all settings where vaccination is administered