

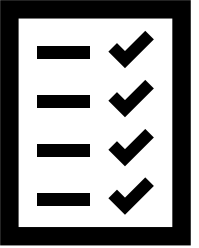
# **Vaccination against COVID-19 - the use of Pfizer BioNTech COVID-19 vaccine**

## **Webinars 4th and 7th December 2020 For Experienced Vaccinators**

*These slides are accurate at time of publication (07.12.20) practitioners should always make sure they refer to the most up to date version.*



# Aim and intended learning outcome



## This resource aims to:

- Equip healthcare practitioners with the knowledge to support safe and effective administration of Pfizer BioNTech COVID-19 vaccine

## On completion of this resource you will be able to:

- Describe the key principles of preparation and administration of COVID-19 Pfizer BioNTech COVID-19 vaccine

*Many thanks to Public Health England for their support in the development of this resource*



# Suggested pre-requisites prior to administration of vaccine

## Before administering COVID-19 vaccine:

- Undertake foundation immunisation training (e.g. online NES/PHS Promoting Effective Immunisation Practice)
- Undertake training in the management of anaphylaxis and Basic Life Support as specified by local area policy
- Undertake any additional statutory and mandatory training as required by your employer e.g. safe sharps and infection prevention and control
- Successfully complete COVID-19 vaccine-specific sessions and assessments
- Receive practical training in COVID-19 vaccine preparation and administration\*
- Complete the COVID-19 vaccinator proficiency tool
- 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
- Access and familiarise with: Green Book COVID-19 chapter and the PHS/NES COVID-19 immunisation programme information for healthcare practitioners and any other guidance
- Ensure that you comply with the clinical and education governance requirements of your employer

# Webinar topics

- COVID-19 vaccination – general aspects
- Pfizer BioNTech COVID-19 vaccine – specific aspects
- Further information

# COVID-19 vaccination – general aspects



# Patient Group Direction (PGD) to give COVID-19 vaccine under regulation 174

- New legislation amending The Human Medicines Regulations 2012 has been passed (Oct 2020)
- The change allows vaccines temporarily authorised for supply in the UK under regulation 174 to be administered in accordance with a PGD
- Registered healthcare professionals may supply and administer COVID-19 temporarily authorised vaccines under Regulation 174 using a PGD
- The workforce that can administer under PGDs has not changed
- PHS have published a sample template PGDs for COVID-19 vaccines

# National Protocol for Administration of COVID-19 Vaccines

- The Human Medicines Regulations amendment brought new regulation (247A)
- Regulation 247A permits the supply or administration of COVID vaccine during a pandemic in accordance with a protocol that is approved by Ministers
- The national protocol may allow specified classes of people, not limited to registered healthcare professionals, to administer COVID-19 vaccine
- Allows flexibility for different delivery models:
  - May be followed wholly from patient assessment through to post-vaccination by a single person
  - Or, multiple persons may undertake stages in the pathway

# Consent

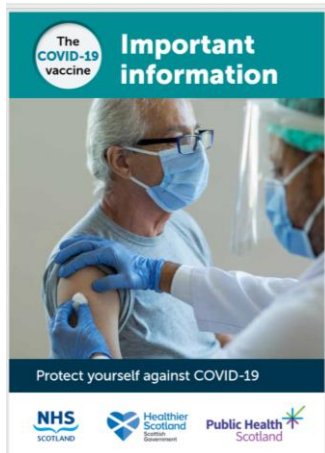
- Before giving COVID-19 vaccine, registered practitioners must ensure they have obtained informed consent
- The vaccinee should receive an explanation of the vaccine and its benefits and risks, either verbally from a clinician, or in the form of a leaflet and letter
- When assessing capacity to consent, the immuniser should be guided by the principles of the Adults with Incapacity (Scotland) Act 2000
- For more information go to the Green Book chapter [consent](#)



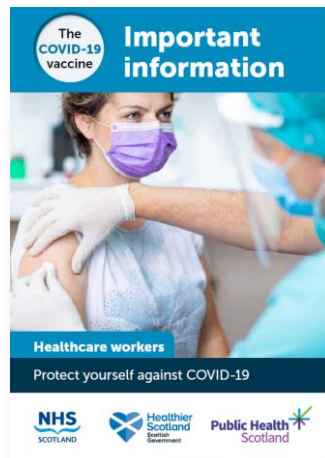
# Leaflets to support informed consent

Available in hard copy or online: [www.nhsinform.scot/covid19vaccine](http://www.nhsinform.scot/covid19vaccine)  
(further information section)

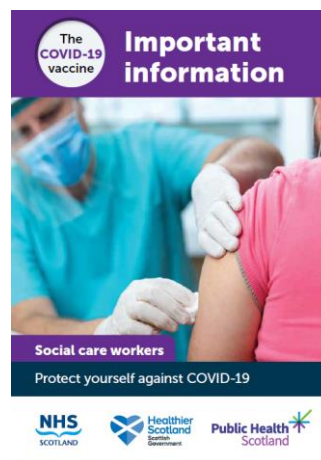
## Adults



## Healthcare



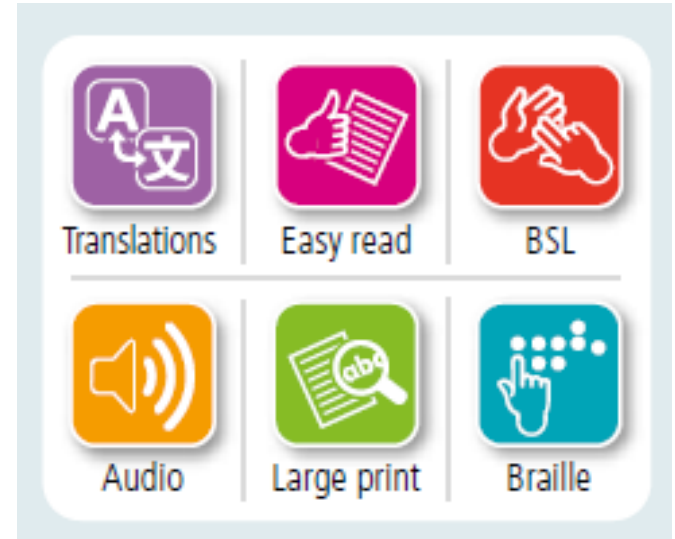
## Social Care



- All those invited to attend for vaccination should have received an information leaflet
- Some may not have read this and so it is important that you are familiar with the contents

## Includes sections on:

- What is COVID-19?
- Why it's important to get your COVID-19 vaccine
- Who is being offered vaccine first
- Is the vaccine safe?
- How does the vaccine work?
- How is the vaccine given?
- How to get the vaccine (if you're ill on the day, had COVID-19, can it be given at same time as other vaccines?)
- Any reasons not to get the vaccine?
- Common side effects (including how to report side effects)
- Reminder of common symptoms of COVID-19
- Further information ([www.nhsinform.scot/covid19vaccine](http://www.nhsinform.scot/covid19vaccine) )



Download at:

[www.nhsinform.scot/covid19vaccine](http://www.nhsinform.scot/covid19vaccine)

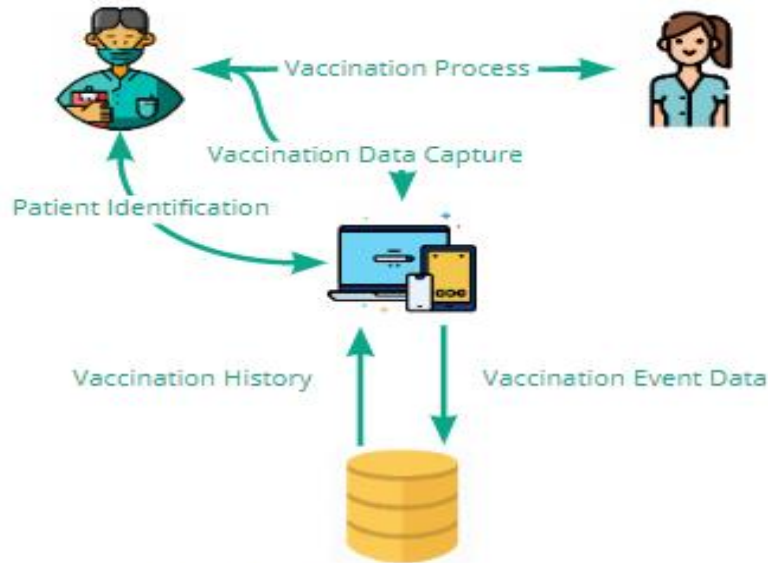
# Documentation and record keeping

- Certain key information is essential for all doses to ensure complete and accurate patient records and to enable correct data extraction for surveillance and vaccine uptake purposes.
- COVID-19 vaccines will be recorded using the vaccine management tool on TURAS.

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

# Recording of data- Turas Vaccination Management Tool



Other data systems e.g. GP IT, National Clinical Data Repository and reporting systems

For the COVID -19 vaccination programme a new vaccine recording tool is in use. The aim of this tool is to manage patient and clinical information, making this available at the point of care. The tool is found on Turas.

# Pfizer BioNTech COVID-19 vaccine - specific aspects

# How does the vaccine work?

- mRNA (messenger ribonucleic acid) vaccine.
- Spike protein genetic sequence found on SARS-CoV-2 virus surface, wrapped in a lipid envelope
- After injection, is taken up by body's cells which translate mRNA to produce spike proteins
- Spike proteins then displayed on cell surface
- Stimulates immune system to produce antibodies and activate T-cells
- Prepares immune system to respond to any future exposure by binding to and disabling SARS-CoV-2 virus
- The vaccine cannot cause disease. mRNA naturally degrades after few days

# How was the vaccine trialled?

- The safety and immunogenicity of the Pfizer BioNTech COVID-19 vaccine has been evaluated in clinical trials in six countries: the USA, Germany, Brazil, Argentina, South Africa and Turkey
- The clinical trials looked at the safety and immunogenicity of the vaccine in two different age groups (18-55 years and 65-85 years) and at different dose levels
- Over 43 500 participants have taken part in the clinical trials of the vaccine, which began in July 2020

# How long does protection last?

- As with any vaccine, not all recipients may be protected and a diminished immune response may be observed in immunocompromised persons or those receiving immunosuppressant therapy
- Protection in different age groups may also differ
- It is not yet known how long protection will last, whether booster doses will be needed and whether the vaccine stops people from catching and spreading the virus or just prevents them from becoming ill
- It is possible that protection will wane over time and people may need booster doses or possibly an annual vaccine as is given for flu



# Is the vaccine safe?

- Clinical trial data are reassuring with no safety concerns reported in vaccine recipients
- Any common serious side-effects should have become apparent in this very large number of trial recipients
- Side-effects seen in clinical trial recipients were mild and self-resolving. Local reactions, such as pain at the injection site, were common.
- Systemic reactions (reactions affecting the whole body) such as fatigue, headache, chills, muscle aches and joint pain were also reported but in small numbers
- Older adults reported fewer adverse events following vaccination
- Ongoing follow-up of those given the vaccine in the clinical trials will continue, both to monitor long-term safety and long-term vaccine effectiveness

# How effective is the vaccine?

- Levels of neutralising antibodies, which bind to the virus and block infection, were the same as, or higher, after two vaccine doses than in patients recovering from COVID-19 disease and a good T-cell response was seen in most vaccine trial recipients
- The phase 3 study demonstrated a vaccine efficacy of 95%, with consistent efficacy across age, gender, and ethnicity
- The observed efficacy in adults over 65 years of age was 94%

# Eligibility

National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time.

Initial groups include:

- Residents in a care home for older adults and their carers
- All those 80 years of age and over
- Frontline health and social care workers (as included in COVID-19 –SARS-Cov-2 chapter of Green Book, JCVI statement and Scottish Government CMO letters)

# Contraindications

- Very few individuals cannot receive Pfizer BioNTech COVID-19 vaccine
- Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local screening and immunisation or health protection team
- Pfizer BioNTech COVID-19 vaccine should not be given to those who:
  - Have had a confirmed anaphylactic reaction to a previous dose of COVID-19 vaccine
  - Have had a confirmed anaphylactic reaction to any components of the vaccine
  - Are pregnant, planning pregnancy or breastfeeding

# Pregnancy and Breastfeeding

- No data yet on safety of COVID-19 vaccines in pregnancy, either human or animal studies
- Specific information on pregnancy, planning pregnancy and breastfeeding.
- Women are being advised that if they are pregnant they should not be vaccinated, but can be vaccinated after the pregnancy is over
- If women think they may be pregnant they should delay vaccination until they are sure they are not
- If planning to get pregnant in the next three months, vaccination should be delayed
- Women should avoid getting pregnant until at least two months after the second dose
- If women are breastfeeding they should wait until they are finished breastfeeding and then have the vaccine.
- Routine questioning about last menstrual period and/or pregnancy testing is not required
- Termination of pregnancy following inadvertent immunisation should not be recommended

# Precautions

- **Acute illness** - immunisation may be postponed fully recovered
- **COVID symptoms** - clinical deterioration can occur up to two weeks after infection, so ideally defer until around four weeks after onset
- **Deterioration of COVID-19 symptoms** - consider deferral of vaccination to avoid incorrect attribution of any change in underlying condition to the vaccine
- **Participation in clinical trial of COVID-19 vaccines** – check with investigators
- **Co-administration with other vaccines** - ideally be an interval of at least 7 days between COVID-19 vaccine and other vaccines

# Administration of Pfizer BioNTech COVID-19 vaccine(BNT 162b2)

# Vaccine presentation

- Pfizer BioNTech COVID-19 vaccine packs contain 195 vials of vaccine (975 doses per pack as each vial contains 5 doses)
- Presented in multidose clear glass vial, with a bung, aluminium seal, flip-off plastic cap
- 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 diluted vaccine will supply 5 doses of 0.3 ml (30 mcg), there will be a small amount of vaccine left in the vial after drawing 5 doses
- This is to ensure that 5 complete doses can be withdrawn, any vaccine remaining in the vial after this should be discarded
- A separate ampoule containing a minimum of 2 ml of normal saline is required for vaccine dilution
- 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



# Storage and use of the vaccine

- The Pfizer BioNTech COVID-19 vaccine has very specific storage, dilution 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 Pfizer BioNTech COVID-19 vaccine must not be given if you are not confident that it has been stored or diluted as recommended by the manufacturer
- If the vaccine is stored incorrectly:
  - Label and isolate affected vaccines in the fridge and do not use until further notice
  - Seek advice in line with local procedures e.g. Vaccine Holding Centre

# Storage and transportation

- The Pfizer BioNTech COVID-19 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 should be unpacked and transferred to a suitable ULT freezer to ensure ongoing storage between  $-60^{\circ}\text{C}$  and  $-80^{\circ}\text{C}$
- The vaccine should be kept upright, in its original packaging and away from prolonged light exposure
- 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

# Delivery to vaccination facilities

- The Pfizer BioNTech COVID-19 vaccine may then be delivered to vaccination facilities thawed but refrigerated between +2 to +8°C.
- Refrigerated vaccine must be transferred immediately to a vaccine fridge on arrival and stored in a carefully monitored temperature range of +2 to +8°C.
- Stability data currently indicates that the Pfizer BioNTech COVID-19 vaccine will remain stable for 5 days (120 hours) when stored in a fridge with a temperature range of +2 to +8°C before dilution and for 6 hours at room temperature after dilution.

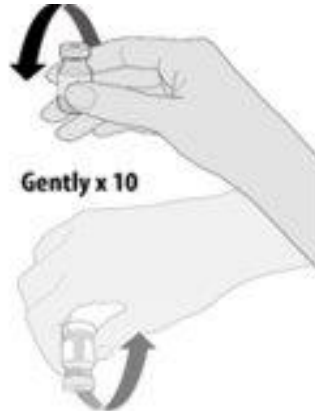
# Dose and schedule

- Pfizer BioNTech COVID-19 vaccine should be administered in 2 doses, a minimum of 21 days apart.
- The Green Book suggests that for operational purposes, scheduling the second dose of COVID-19 vaccine from 28 days may be preferred (although would not preclude scheduling Pfizer BioNTech COVID-19 from 21 days where rapid protection is required).
- Using a consistent interval for all two dose vaccines simplifies the messaging to the public and arrangements within clinic settings where alternative vaccines may be supplied at short notice.
- If an interval longer than the recommended interval is left between doses, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted.

# Vaccine Dilution - equipment

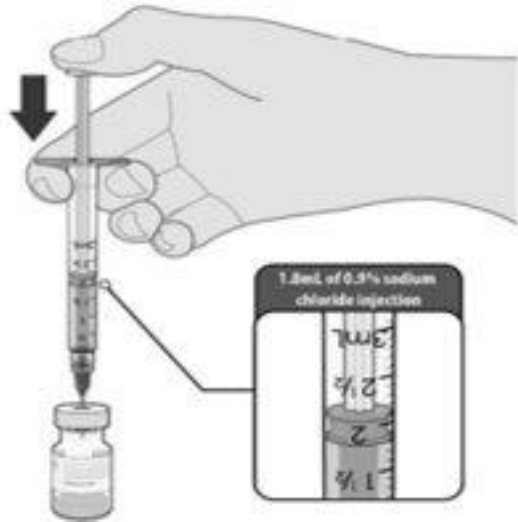
- The following equipment is required for dilution:
  - One Pfizer BioNTech COVID-19 vaccine multidose vial.
  - One plastic ampoule of Sodium Chloride 0.9% Solution for Injection - this will be supplied in multiple presentations (different manufacturers and different sized ampoules) and does not need to be kept in the fridge.
  - A green needle and a 2 ml syringe to reconstitute - needles and syringes will be supplied together in boxes of 100.
- Dilution of Pfizer BioNTech COVID-19 vaccine must be conducted at room temperature as soon as possible, and a maximum of 2 hours, after removal of the vaccine from storage at +2°C to +8°C

# Diluting the vaccine



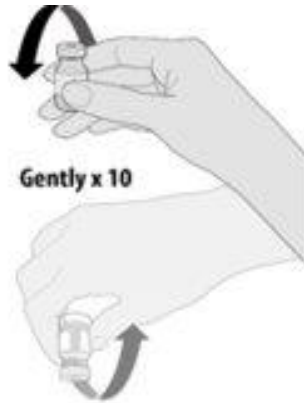
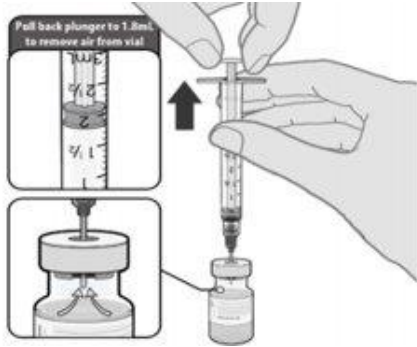
- From cold storage, remove one vial of vaccine and one ampoule of Sodium Chloride 0.9% Solution for Injection
- Check the expiry date and appearance of the vaccine and diluent
- Dilution of Pfizer BioNTech COVID-19 vaccine must be conducted at room temperature as soon as possible, and a maximum of 2 hours, after removal of the vaccine from storage at +2°C to +8°C
- Gently invert 10 times prior to dilution, **do not shake**, prior to dilution the vaccine should present as an off-white solution with no particulates visible
- Discard the vaccine if particulates or discolouration are present

# Diluting the vaccine



- Connect a green needle to a 2 ml syringe
- Clean the vial stopper with a single use alcohol swab and allow to air dry fully
- 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
- Add diluent to the vaccine vial

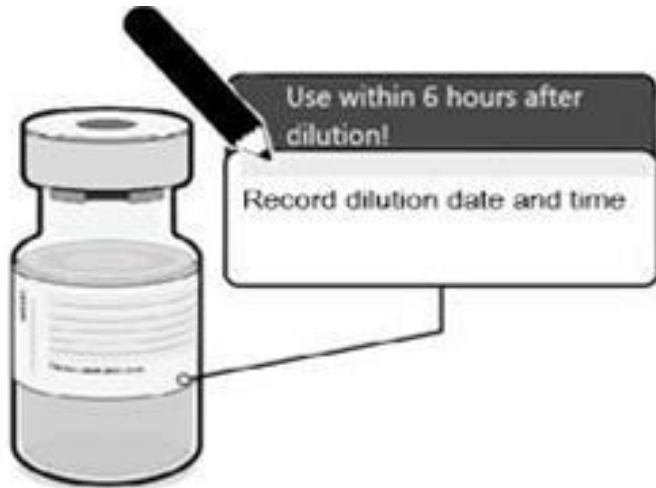
# Diluting the Vaccine



- 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
- Gently invert the diluted solution 10 times
- **This vial should not be shaken**

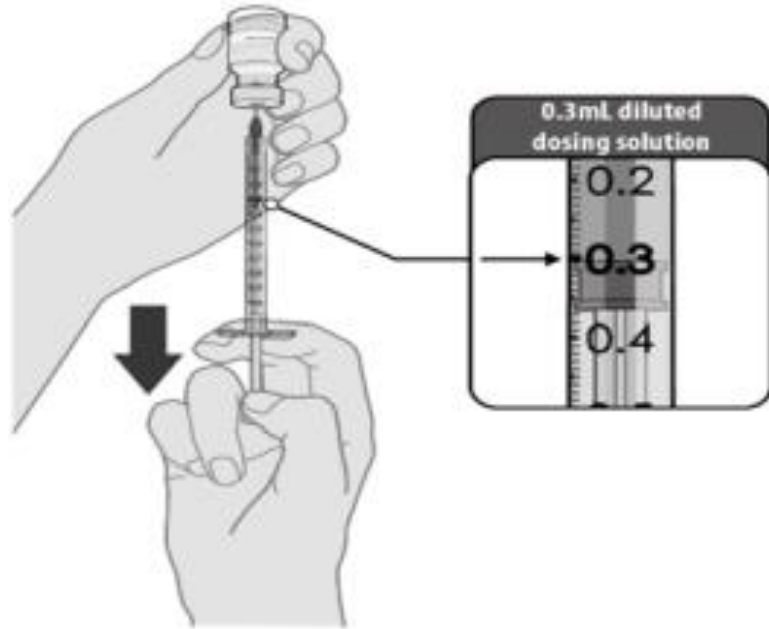


# Diluting the Vaccine



- The diluted vaccine should present as an off-white solution with no particulates visible, discard the diluted vaccine if particulates or discolouration are present
- The diluted vials should be marked with the dilution date and time and stored between 2 °C to 25 °C
- Diluted vaccine can be stored between +2°C to +25°C but **must be used within 6 hours following dilution**

# Vaccine Dose Preparation



- Place a 23 g/25 mm blue hub needle onto a 1 ml combined needle and syringe provided (recommended needle length depends on body mass of patient)
- If the vaccine has previously been diluted, check that the time of dilution was within the last 6 hours
- Clean top of vial with a single-use alcohol swab and allow to air dry fully
- Withdraw a dose of 0.3 ml of diluted product for each vaccination. Any air bubbles should be removed before removing the needle from the vial in order to avoid losing any of the vaccine dose
- There is no requirement to change the needle between the vial and the patient unless the needle is contaminated or damaged

# Infection Prevention and Control: Disposal of consumables

- Health care practitioners should follow the recommendations for personal protective equipment (PPE) that are current at the time of vaccination.
- Practitioners should refer to Public Health Scotland and ensure that they are accessing the most recent guidance.
- Needle, syringes, used vials and ampoules should be disposed of immediately after use in a yellow, blue lidded puncture-resistant sharps bin.

# Post vaccination observation

- Recipients of COVID-19 vaccine should be observed for any immediate reactions during the period they are receiving any post-immunisation information and subsequent appointment if required.
- There is no evidence that longer observation is necessary.
- As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

# Post Vaccination Information

- Following vaccination, vaccine recipients should be given information about possible reactions to the vaccine, how to treat these, and when and from whom to seek further advice if required
- Vaccinees should be advised that they can also report any adverse reactions to the MHRA using the online [Coronavirus Yellow Card reporting scheme](#)



Public Health  
Scotland

NHS  
Education  
for  
Scotland

# Post Vaccination Information (Cont'd)

- Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever which usually resolves within 48 hours, this is a common, expected reaction and isolation is not required unless COVID-19 is suspected
- Feeling generally unwell, shivery, achy and tired were also symptoms reported by vaccine recipients in the clinical trials
- If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol-containing products) may be used

# Reporting adverse reactions

- Vaccines are carefully monitored to ensure they are safe, not causing untoward side effects and are suitable for the immunisation programme.
- Suspected adverse reactions following administration of COVID-19 vaccine should be reported to the MHRA using the Yellow Card scheme [coronavirus-yellow card](#).
- Adverse events should also be reported in the usual way for NHS Board or care setting.
- Surveillance of inadvertent administration in pregnancy is being conducted for the whole UK, including Scotland by the PHE Immunisation Department, to whom such cases should be reported (Tel: 020 8200 4400).



# Reporting and escalating adverse events relating to the COVID-19 immunisation programme

**Clinic level - If the vaccinators, clinic manager, other staff at the vaccine clinics or health protection staff become aware of any adverse event that occurred during the vaccination clinic, even if transpiring some time following the clinic, they have a responsibility to:**

↓

Manage and report this incident in the usual way for the NHS Board or care setting e.g. Datix, yellow card  
**If the event is significant** – the clinic lead should contact their Board Immunisation Coordinator as soon as the event becomes apparent

Please be aware of the framework for monitoring adverse events reporting for the COVID-19 vaccination programme in Scotland, further information is available in the core COVID-19 vaccination resources





# Further information

- COVID-19 Vaccines TURAS Learn  
<https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines>
- Green Book Chapter 14 <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>
- Joint Committee on Vaccination and Immunisation (JCVI) statement 2<sup>nd</sup> Dec  
<https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-2-december-2020>
- Chief Medical Officer letter <https://www.sehd.scot.nhs.uk/>
- National Infection Prevention and Control Manual  
<http://www.nipcm.scot.nhs.uk/scottish-covid-19-infection-prevention-and-control-addendum-for-acute-settings/>
- Nursing and Midwifery Council (NMC) Vaccine Information and advice  
<https://www.nmc.org.uk/news/coronavirus/vaccines/>

This resource may be made available, in full or summary form, in alternative formats and community languages.  
Please contact us on **0131 656 3200** or email **altformats@nes.scot.nhs.uk** to discuss how  
we can best meet your requirements.

**NHS Education for Scotland**  
**Westport 102**  
**West Port**  
**Edinburgh**  
**EH3 9DN**

**[www.nes.scot.nhs.uk](http://www.nes.scot.nhs.uk)**

© NHS Education for Scotland 2017. You can copy or reproduce the information in this resource for use within NHSScotland and for non-commercial educational purposes. Use of this document for commercial purposes is permitted only with the written permission of NES.