Summary Crib Sheet

National Protocols for COVID-19 mRNA BNT162b2 (Pfizer/BioNTech)

<https://www.gov.uk/government/publications/national-protocol-for-covid-19-mrna-vaccine-bnt162b2-pfizerbiontech>

***Clinicians of LSMP using this quick reference guide must ensure that they have also read and signed a copy of the full National Protocol Document .***

**Exclusions:**

* No consent
* <16 (**under 18 requires a PSD**)
* previous systemic allergic reactions (including immediate onset anaphylaxis) to a previous dose of COVID-19 mRNA Vaccine BNT162b2 or to any component of the vaccine or residues from the manufacturing process
* history of immediate-onset anaphylaxis to multiple classes of drugs or unexplained anaphylaxis
* Pregnancy – however JCVI has advised that vaccination in pregnancy **should** be considered where the risk of exposure to SARS-CoV2 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. **Vaccination of pregnant women is not covered by this protocol so a prescriber or PSD would be required.**
* are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination)
* are participating in a clinical trial of COVID-19 vaccines
* have received a dose of COVID-19 vaccine in the preceding 21 days
* have completed a course of COVID-19 vaccination

**Cautions:**

* 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 any component (excipient) of the vaccine.
* 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 (such as a hospital)
* individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting
* Individuals with a bleeding disorder may develop a haematoma at the injection site.
* Individuals with bleeding disorders may be vaccinated if clinically assessed as safe to receive - A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used followed by firm pressure applied to the site **(without rubbing)** for at least 2 minutes.
* Vaccination should be deferred in those with confirmed COVID infection. Ideally vaccination should be deferred to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic.
* Prolonged COVID-19 symptoms are not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person’s underlying condition to the vaccine.
* Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators.
* Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine but it is still important that they are immunised.
* If a woman finds out she is pregnant after she has started a course of vaccine, routine advice is to complete her pregnancy before finishing the recommended schedule. Women should be offered vaccine as soon as possible after pregnancy.
* 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 COVID-19 mRNA vaccine BNT162b2.
* It should not be routine to offer appointments to give this vaccine at the same time as other vaccines. Scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential side effects. However, where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination **should** still be considered and may be provided under the protocol, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring two vaccines.

**Common After effects:**

* pain at the injection site
* fatigue
* headache
* myalgia
* chills
* arthralgia
* Mild pyrexia
* Redness at the injection site and injection site swelling,
* nausea
* Lymphadenopathy is very rare

**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.**

**Vaccine Info:**

* Multi-dose vial - 1 vial (0.45ml) contains at least 5 doses of 30micrograms of BNT162b2 RNA (embedded in lipid nanoparticles).
* Vials may alternatively be labelled: BNT162b2 (SARS-COV-2-mRNA vaccine), or Pfizer-BioNTech COVID-19 vaccine
* Undiluted vaccine can be stored for up to 5 days (120 hours) at 2-8°C, or up to 2 hours at temperatures up to 25°C, prior to use.
* During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.
* Once thawed the vaccine cannot be re-frozen.
* After aseptic dilution, vials should be marked with the dilution date and time, stored at 2°C to 25°C and used as soon as practically possible and within 6 hours from the time of dilution. The vaccine does not contain preservative.
* Once the dose is drawn up from the vial it should be administered immediately.
* Using aseptic technique, thawed COVID-19 mRNA Vaccine BNT162b2 requires dilution in its original vial with 1.8ml of unpreserved sodium chloride 0.9% solution for injection, prior to withdrawing a 0.3ml dose for administration.
* Gently invert the diluted solution 10 times. Do not shake the vaccine.
* The vaccine dose should be drawn up from the diluted vial immediately prior to administration.
* Inspect visually prior to administration - it should be an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present.
* Each vial contains at least 5 doses. It is normal for a small amount of liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial after 5 doses have been extracted may be sufficient for an additional (sixth) dose. Care should be taken to ensure a full 0.3ml will be administered. Where a full 0.3ml dose cannot be extracted the contents should be discarded. Any unused vaccine should be discarded 6 hours after dilution.
* A two-dose course should be administered consisting of 30micrograms in 0.3ml followed by a second dose of 30micrograms in 0.3ml after an interval of at least 21 days. For operational purposes the second dose may be given between 3 to 12 weeks following the first dose or in accordance with official guidance at the time.
* The course does not need to be restarted if the second dose is outside of this time frame
* COVID-19 mRNA Vaccine BNT162b2 30micrograms in 0.3ml, is for administration by intramuscular injection only, preferably into deltoid region of the upper arm – alternative IM site e.g thigh if deltoid not usable.
* **Do not shake the vaccine.**
* Check product name, batch number and expiry prior to administration.
* Where the individual has been identified by the assessing registered professional as being at increased risk of bleeding, a fine needle (equal to 23 gauge or finer calibre such as 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/carer should be informed about the risk of haematoma from the injection.
* Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment

**Documentation:**

* valid informed consent was given or a decision to vaccinate made in the individual’s best interests in accordance with the Mental Capacity Act 2005
* name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP and that appropriate advice has been given)
* name of immuniser and, where different from the immuniser, ensure the professional assessing the individual, person preparing the vaccine, and person completing the vaccine record are identified
* name and brand of vaccine
* date of administration
* dose, form and route of administration of vaccine
* quantity administered
* batch number and expiry date
* anatomical site of vaccination
* advice given, including advice given if excluded or declines immunisation
* details of any adverse drug reactions and actions taken
* supplied via national protocol
* Records should be signed and dated (or password-controlled immuniser’s record on e-records).

**Clinical risk groups 16 years of age and over who should receive COVID-19 immunisation**

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| Chronic respiratory disease | Individuals with a severe lung condition, including those with asthma that requires continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission, and chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). |
| Chronic heart disease and vascular disease | Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease. This includes individuals with atrial fibrillation, peripheral vascular disease or a history of venous thromboembolism. |
| Chronic kidney disease | Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation. |
| Chronic liver disease | Cirrhosis, biliary atresia, chronic hepatitis. |
| Chronic neurological disease | Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). This includes individuals with cerebral palsy, severe or profound learning disabilities, Down’s Syndrome, multiple sclerosis, epilepsy, dementia, Parkinson’s disease, motor neurone disease and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability. |
| Diabetes mellitus | Any diabetes, including diet-controlled diabetes. |
| Immunosuppression | Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, patients undergoing radical radiotherapy, solid organ transplant recipients, bone marrow or stem cell transplant recipients, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement disorder, SCID).Individuals who are receiving immunosuppressive or immunomodulating biological therapy including, but not limited to, anti-TNF, alemtuzumab, ofatumumab, rituximab, patients receiving protein kinase inhibitors or PARP inhibitors, and individuals treated with steroid sparing agents such as cyclophosphamide and mycophenolate mofetil.Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day.Anyone with a history of haematological malignancy, including leukaemia, lymphoma, and myeloma and those with systemic lupus erythematosus and rheumatoid arthritis, and psoriasis who may require long term immunosuppressive treatments.Some immunosuppressed patients may have a suboptimal immunological response to the vaccine. |
| Asplenia or dysfunction of the spleen | This also includes conditions that may lead to splenic dysfunction, such as homozygous sickle cell disease, thalassemia major and coeliac syndrome. |
| Morbid obesity | Adults with a Body Mass Index ≥40 kg/m². |
| Severe mental illness | Individuals with schizophrenia or bipolar disorder, or any mental illness that causes severe functional impairment |
| Adult carers | Those who are in receipt of a carer’s allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill. |

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| Younger adults in long-stay nursing and residential care settings | Many younger adults in residential care settings will be eligible for vaccination because they fall into one of the clinical risk groups above.Given the likely high risk of exposure in these settings, where a high proportion of the population would be considered eligible, vaccination of the whole resident population is recommended.Younger residents in care homes for the elderly will be at high risk of exposure, and although they may be at lower risk of mortality than older residents should not be excluded from vaccination programmes (see [priority 1](#Priority) above).For consideration of children under 16 see [Action to be taken if the patient is excluded](#ActionIfExcluded).  |