|  |  |
| --- | --- |
| **Senior Medical Officer (Cancer)**  Dr Azmat Sadozye |  |
|  |  |

\_\_\_

**Our ref: Covid-19 vaccination in patients with cancer and on anti-cancer treatment**

The following guidance is issued to assist in addressing patient enquiries. The overriding recommendation is to advise all eligible patients to be vaccinated as soon as they are offered it. Reducing the risk of serious illness as a result of COVID-19 (CV-19) infection far outweighs any possible risk from the vaccine itself.

Below is a summary of current advice and frequently asked questions regarding vaccination with the Pfizer BioNTech COVID-19 vaccine and the Astra Zeneca COVID-19 vaccine in patients with cancer or receiving systemic anti-cancer therapy (SACT). This is a rapidly evolving area and the most up to date information regarding all CV-19 vaccines and the national vaccination prioritisation schedule can be found in the [“Green Book”, Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) and can be accessed at: <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>.

**Summary Guidance**

**It is recommended that all patients with cancer, including all those receiving systemic anti-cancer therapy (which includes cytotoxics, immunotherapy and targeted therapies), radiotherapy or steroids, should be considered for CV-19 vaccination.** Whilst CV-19 vaccines have not been specifically studied in this group of patients, the leading authorities in the UK (including the Joint Committee for Vaccination and Immunisation, which is independent of government) consider both the Pfizer BioNTech CV-19 vaccine and the Astra Zeneca CV-19 vaccine to be safe in patients with suppressed immune systems. Immunosuppression may however reduce the efficacy of vaccines so patients should not presume they are immune after receiving the vaccine, but should continue with strict adherence to measures to reduce exposure to the virus.

Patients receiving systemic anti-cancer therapy, radical radiotherapy or whose immune system is suppressed eg by steroids or disease, and all patients who are, or have been, on the shielding list since the start of the pandemic, fall into the ‘clinically extremely vulnerable’ (CEV) category. The current recommendation is that this group is ‘priority group 4’ in the UK national vaccination schedule, along with all those aged 70-74 years. Whilst cancer itself is felt to somewhat increase the risk of severe CV-19 infection it is not currently listed as a CEV category. Patients with cancer who are not on the shielding list, whose immune system is not suppressed, and who do not have other CEV risk factors (eg diabetes, morbid obesity, chronic respiratory, heart, kidney, liver or neurological disease) should be vaccinated according to standard age group prioritisation.

There are very few individuals who cannot receive the CV-19 vaccines. The only specific contraindication to vaccination is those who have had a previous systemic allergic reaction to a previous dose of the same CV-19 vaccine or any component of the CV-19 vaccine. Both vaccines are given by the intramuscular route but specific blood testing is not usually required before vaccination. Anti-cancer treatment should not be deferred or delayed due to CV-19 vaccination.

A letter for GPs on CV-19 vaccines in cancer patients has been produced and below are answers to some frequently asked questions.

**Frequently asked questions (FAQs)**

* **FAQ 1**: Is either of the vaccines preferable for patients with suppressed immune systems?

The Pfizer BioNTech CV-19 vaccine is a nucleoside-modified messenger RNA vaccine. It is not a live vaccine. The Astra Zeneca CV-19 vaccine uses a **replication deficient chimpanzee adenovirus as a vector** to deliver the spike protein genetic sequence into the host cell. Although this vaccine contains a live adenovirus vector, it is impossible for the vaccine to replicate or cause disease in humans, and it is **considered safe** in immunosuppressed individuals.

**Recommendation:** Both vaccines are felt to be safe for immunosuppressed patients.

* **FAQ 2:** What counts as immunosuppressive SACT?

The Green Book does not define this.

**Recommendation:**  Any SACT with potential to cause immunosuppression, especially regimens causing immune cell depletion, containing a cytotoxic agent or including steroids. Tyrosine kinase inhibitors (TKIs) and many monoclonal antibody treatments do not cause significant immune suppression but patients may have suppressed immune systems for other reasons.

* **FAQ 3:** Should patients receiving immunotherapy receive the vaccine?

There is a small risk that immunotherapy toxicity could be exacerbated by CV-19 vaccination, particularly for those patients receiving anti-CTLA4 therapy. However, the evidence is weak and not felt clinically relevant.

**Recommendation**: Patients receiving immune checkpoint inhibitors can safely receive the CV-19 vaccine at any point during the treatment cycle.

* **FAQ 4:** Should patients on SACT clinical trial receive the vaccine?

**Recommendation**: Unless vaccination is contra-indicated (or excluded) in a clinical trial of SACT, patients in trials should be considered for CV-19 vaccination.

* **FAQ 5:** Is there an optimal time to administer the CV-19 vaccine relative to the SACT cycle?

There is no evidence on which to base advice about optimal timing of vaccination relative to SACT. Decisions should take into account risk of CV-19 exposure and infection as well as risk of attenuated response to vaccine after immunosuppressive therapy.

**Recommendation:** Whenever possible, the administration of the vaccine should be performed before initiation of chemotherapy. Often this will not be possible and SACT should not usually be delayed to enable vaccination. Empirical advice for other vaccines is to have the vaccine when the full blood count is at the highest ie towards the end of the cycle/ just before the next cycle of treatment, and preferably not on the same day as intravenous cytotoxics.

* **FAQ 6:** Can SACT patients with bleeding disorders or on anti-coagulation be vaccinated?

The CV-19 vaccines are given by small volume intramuscular injections via a 23g/25g x 25mm needle. This can be administered safely to most patients, including those on antiplatelet therapy, with low platelets or on anticoagulation, including warfarin, as long as their most recent INR was within their recommended range.

**Recommendation:** Routine blood checks or INR checks are not required prior to vaccination but if there are concerns about bleeding risk for an individual, firm pressure should be applied to vaccination site after injection. Specialist advice should be sought prior to vaccination if there are specific clinical concerns.

* **FAQ 7:** Should CV-19 vaccine be administered if patient is neutropenic?

**Recommendation:** Ideally injection should be avoided in a patient who is unwell with neutropenia until neutrophil counts have recovered to >1 x 109/L and the patient is well. In patients with chronic neutropenia vaccine can be administered at any time.

* **FAQ 8:** Can CV-19 vaccine be administered alongside other vaccines eg seasonal flu vaccine?

There is little data on this but overall it is felt that interference is unlikely. It is possible that it could result in a slightly reduced immune response to one of the vaccines. Additionally co-administration of vaccines makes attribution of causality of adverse events more difficult.

**Recommendations:** It is recommended that vaccines are given at least 7 days apart.

* **FAQ 9**: Is there advice for patients who have recently undergone stem cell transplant or CAR-T therapy?

Data is currently lacking concerning the efficacy and immunogenicity of the vaccine in this group, or optimal timings of vaccination. The European Society for Blood and Marrow Transplantation (EBMT) has produced [guidelines for CV-19 vaccination](https://www.ebmt.org/sites/default/files/2020-12/COVID%20vaccines%20version%202.03%20with%20table.pdf) in this group, stating vaccination 3-6 months after transplant depending on local transmission rates.

**Recommendation:** International, national and local guidelines should be reviewed and adhered to when available.

* **FAQ 10:** Is CV-19 vaccination effective in patients receiving SACT?

Patients receiving immunosuppressive SACT may not mount as robust an immune response as others.

**Recommendation:** Protective measures including washing hands, wearing masks, social distancing and isolation of contacts should continue after vaccination, to reduce risk of infection.

* **FAQ 11:** Is there a risk of interaction of CV-19 vaccines with SACT?

There is currently no data on this.

**Recommendation:** No obvious safety concerns have been raised. If an interaction is suspected then this should be reported to the MHRA using the [Coronavirus Yellow Card reporting scheme](https://coronavirus-yellowcard.mhra.gov.uk/) (coronavirus-yellowcard.mhra.gov.uk or phone 08007316789).

* **FAQ 12:** Can patients be moved up the priority list if they are about to start SACT?

Recommendation:

No. Current advice is that patients must be vaccinated according to the nationally agreed vaccination prioritisation schedule, other than in rare exceptional cases.

Websites for further information and the most up to date information about CV-19 vaccines:

The Green Book Chapter 14a: <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

ASCO guidance: <https://www.asco.org/asco-coronavirus-resources/covid-19-patient-care-information/covid-19-vaccine-patients-cancer>

ESMO guidance: <https://www.esmo.org/covid-19-and-cancer/covid-19-vaccination>

EBMT guidance: <https://www.ebmt.org/sites/default/files/2020-12/COVID%20vaccines%20version%202.03%20with%20table.pdf>

ACP (UK) guidance: <https://www.ukchemotherapyboard.org/publications>