



SARS-CoV-2 (COVID-19) in Acute Leukemia patients

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NOTE: This is not intended to be medical advice and, as every individual case differs, ALAN recommends you consult your hematologist/clinician if you have questions or concerns.

Also, as the situation surrounding COVID-19 and vaccination is evolving rapidly, always refer to your governmental websites.

What is COVID-19?

COVID-19 is the disease associated with severe acute respiratory syndrome coronavirus (SARS-CoV-2). SARS-CoV-2 is a new strain of coronavirus that had not been identified in humans prior to December 2019. There are different types of coronaviruses and, although they mostly circulate among animals, some can also infect humans.

The COVID-19 outbreak that started in late 2019 was declared a pandemic by the World Health Organization on 11 March 2020. This is the first pandemic caused by a coronavirus.

Additional information:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public>

<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response_en

Live Worldwide COVID-19 Situation: <https://gap.ecdc.europa.eu/public/extensions/COVID-19/covid-19.html#global-overview-tab>

Vaccination

What type of approval processes did COVID-19 vaccines undergo?

Due to the existing public health emergency, COVID-19 vaccines went through an accelerated development process but were still subject to the rigorous evaluation methods used by the various health authorities. These vaccines were, and are still, evaluated against the same high standards as any other medicine.

It is important to understand that while the approval for the COVID-19 vaccines was accelerated, vaccines with similar mechanisms of action have been in development for years. The current COVID-19 vaccines were developed using existing research.

Additional information

https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/how-are-vaccines-developed-authorized-and-put-market_en

<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

<https://www.australia.gov.au/covid19vaccines#>

COVID-19 vaccines: development, evaluation, approval and monitoring:
<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-development-evaluation-approval-monitoring>



How do the COVID-19 vaccines work?

Vaccines teach our immune system to recognise and protect us from COVID-19 if/when we get infected with the virus.

The BioNTech/Pfizer and Moderna vaccines are mRNA vaccines. These vaccines use genetic material, called mRNA, which, after injection, enters your cells (note: this genetic material does not enter the innermost part of your cells called the nucleus nor your DNA). The cells then translate the mRNA into proteins that look like the proteins found on the surface of the COVID-19 virus. These proteins then enter your bloodstream, where the body recognises them as foreign and generates an immune response. Therefore, if you contract COVID-19 after receiving the vaccination, your body will recognise the virus and be able to respond quickly to fight the infection.

The AstraZeneca/Oxford and Janssen vaccines use a different approach and use something called viral vectors. These vaccines are made using an inactive adenovirus, which serves as a shell to carry DNA genetic material into your cells (note: this genetic material does not enter the innermost part of your cells called the nucleus nor your DNA). This DNA is then made into mRNA and then into proteins that look like the proteins found on the surface of the COVID-19 virus. These proteins then enter your bloodstream where the body recognises them as foreign and generates an immune response. Therefore, if you contract COVID-19 after receiving the vaccination, your body will recognise the virus and be able to respond quickly to fight the infection.

None of these vaccines contain live viruses and there is no risk of catching COVID-19 (or adenovirus) from the vaccine.

Additional information:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html>

<https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work>

<https://youtu.be/0AssZJON2Ls>

COVID-19 vaccines key facts: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-key-facts>

How effective are these vaccines?

It is important to understand that while each vaccine has different efficacy, they all offer protection against hospitalisation and/or death from COVID-19. Also, given the timing, population, and location of where each vaccine was studied, it is impossible to compare their efficacy and judge any one vaccine to be either inferior or superior to any other.

It is also important to remember that a vaccine with lower effectiveness can still save thousands of lives and prevent millions of cases of COVID-19.

Each of the COVID-19 vaccines was tested in thousands of patients of varying ethnicities and some with medical conditions, for example, lung and heart disease. Acute leukemia patients were not specifically included in these clinical trials nor is there any data on the efficacy of these drugs in the acute leukemia population. It has been suggested that these vaccines may be less effective in immunocompromised patients, but this has yet to be proved and this should not be a reason to forgo immunisation.

ALAN recommends you discuss this matter with doctor/hematologist if you have any questions or concerns.

How safe are these vaccines?

The European Medicines Agency (EMA) and other agencies monitor the safety of COVID-19 vaccines authorized in the world extremely carefully. This enables the detection of any rare side effects that may emerge once many millions of people are vaccinated.



- More than 868 million doses of vaccines have been given to people in the EU and European Economic Area, as of early April 2022.
- The authorized COVID-19 vaccines are safe and effective. They were evaluated in tens of thousands of participants in clinical trials.
- The safety of COVID-19 vaccines is continuously monitored and evaluated.
- The vast majority of known side effects of COVID-19 vaccines are mild and short-lived.
- Serious safety problems are extremely rare.

The health authorities, not only EMA, continue to monitor the safety of the vaccines and their use in real life. The scientific evaluation needs to show that a vaccine's benefits in protecting people against diseases are far greater than any potential risk.

Like any medicine, vaccines have benefits and risks. Although highly effective, no vaccine is one hundred per cent effective in preventing disease or one hundred per cent safe in all vaccinated people.

At the time of approval, the main body of evidence for vaccine safety and efficacy comes from large controlled, randomized clinical trials. Selected volunteers are randomly allocated to receive the vaccine being tested and followed up under controlled conditions in line with strict protocols.

After approval, many people will receive the vaccine. Certain rare or very rare side effects may only emerge when millions of people are vaccinated. EU law requires that the safety of vaccines is monitored while they are in use in routine clinical practice.

Do the COVID-19 vaccines protect against variants?

The COVID-19 vaccines authorized do protect against severe disease and death caused by variants of the SARS-CoV-2 virus. These include Omicron, the variant that is spreading rapidly across the world.

Vaccinated people seem more likely to get infected with Omicron than with other **variants** such as Delta. On the other hand, the Omicron variant appears to cause less severe outcomes - such as hospitalization or death - than other variants.

Vaccines still play a crucial role in **preventing severe COVID-19 disease**: unvaccinated people remain at much higher risk of falling severely ill with COVID-19, compared to people who have not been vaccinated.

While the level of **protection** from COVID-19 vaccines tends to get less over time, people who have had a **booster** dose are less likely to develop severe disease or to die from infection with Omicron than people who have only received their 'primary course'.

What COVID-19 vaccines are approved for use in immunocompromised patients?

Despite several vaccine candidates being in phase II/III clinical trials, no current clinical trial of a COVID-19 vaccine has published data on immunocompromised patients. Thus, the efficacy and safety of a SARS-CoV-2 vaccine has not been established in the different immunocompromised patient populations. There are no data that preferentially support one vaccine over another in this or any population.

Do people with a weak immune system need an additional dose ?

People with weak immune systems may need an additional dose as part of their primary (initial) vaccination to be properly protected against COVID-19.

Studies in organ transplant patients with weak immune systems have shown that an additional dose increases the ability to produce antibodies against SARS-Cov-2. Based on a review, EMA has advised that an additional dose should be given to people with a severely weakened immune system.

Will booster doses of COVID-19 vaccines be needed?

Boosters are useful to prevent a drop in immunity (protection) against infection and disease.



Boosters restore protection against infection and disease as they also provide high levels of antibodies in adults.

Currently, it is not known how long protection after a booster will last.

Recent evidence, including real-world effectiveness data, suggests that people who have had a booster dose appear to be better protected against the Omicron variant of COVID-19 than those who have only received their primary course vaccination.

Experience with vaccines against other diseases than COVID-19 has shown that some require several doses in order to ensure long-term protection (such as vaccines against hepatitis B). Others, like the vaccine against flu, need annual updates. This may become necessary with COVID-19 vaccines.

Can a different vaccine be used for the doses and/ the boosters?

Using a different vaccine for the second dose, or as a booster dose, is safe and effective.

Such a 'mix and match' approach - known as a heterologous vaccination - has been used successfully with other vaccines in the past.

How long does immunity last?

There is evidence that protection against infection and particularly against mild disease decreases around six months after primary vaccination. However, because protection against severe disease lasts longer, in the EU most cases of severe disease occur in unvaccinated people.

At present, it is not known how long immunity (protection) against COVID-19 will last after the booster dose.

The duration of immunity is influenced by several factors. For instance, immunity drops faster in men, older people and those with other health problems.

Also, note that people who have been vaccinated can still catch the SARS-CoV-2 virus. The longer it is since someone was vaccinated, the greater the chance of infection, especially with highly infectious variants such as Omicron. Vaccinated people can also pass on the virus to others. However, the likelihood of this happening compared with unvaccinated people is not yet clear.

Vaccinated people who catch the virus are far less likely to be admitted to hospital or to die than unvaccinated people.

What are the side effects of the COVID-19 vaccines?

Studies investigating the COVID-19 vaccine were done on many patients and showed there is a very low risk of serious side effects from all four vaccines. The most common side effects were chills, headache, pain (generalised body pain or at the injection site), fever, nausea, tiredness and/or redness, and swelling at the injection site. Most of the side effects were considered mild or moderate and resolved within a day or two after the vaccination.

On rare occasions, people developed severe allergic reactions (anaphylaxis) soon after receiving a vaccine. Therefore, COVID-19 vaccines should be given under close medical supervision to monitor potential allergic reactions. Anyone with a history of severe allergic reactions can still receive these vaccines, but they should first consult their doctor to discuss the risks and benefits of the vaccine.

For more information ALAN recommends you discuss this matter with your local health authorities and/or your treating physician.

How does the COVID-19 vaccine affect treatment for acute leukemia?

There is no evidence that the vaccine will have any interactions with the medicines used to treat acute leukemia. However, some drugs used during intensive treatment may weaken the immune system. As a result, patients undergoing intensive therapy may not respond as well to the COVID-19 vaccine. Despite this, it is still recommended to get the vaccine.

For more information ALAN recommends you discuss this matter with doctor/hematologist to determine their options.



Published recommendations by medical societies.

<https://www.hematology.org/covid-19/ash-astct-covid-19-and-vaccines>

<https://ehaweb.org/covid-19/covid-19-recommendations/>

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

<https://bsbmtct.org/wp-content/uploads/2021/01/BSBMTCT-SARS-CoV-2-vaccination-statement-12Jan2021-FINAL.pdf>

<https://www.ebmt.org/sites/default/files/2021-01/COVID%20vaccines%20version%203.04%20with%20table.pdf.pdf>

<https://www.asco.org/covid-resources/patient-care-info>

https://www.univadis.com/viewarticle/covid-19-nccn-issues-guidance-for-vaccinating-cancer-patients-c86a2c13-61f7-39a3-babc-0cbd8960ebbc?fbclid=IwAR0rKaR9ay2tSZG9e2neU3tOOfkEQTTIGQU2STp1iezaMJtUia7N7zzVOcs&utm_medium=email&utm_term=&utm_content=4538691&sso=true&uac=394597DN&ecd=mkm_ret_210211_uniday_MUDGLOBAL_4538691&utm_source=&utm_campaign=medical%2Bupdate%2Bdaily

Treatments

There are potential COVID-19 treatments that are currently approved, under investigation and/or evaluation

<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-treatments>

Why vaccines are needed even if treatments are available?

Vaccines protect from infection and serious disease. They have reduced the impact of the SARS-CoV-2 virus and remain a crucial tool to fight the pandemic.

Some medicines to treat or prevent COVID-19 have been authorized in the EU. These medicines complement vaccines in the fight against COVID-19, but do not replace them.

They provide another way to reduce the burden of disease associated with COVID-19 and prevent hospitalization. They are particularly relevant for vulnerable groups and people who do not respond adequately to vaccination, or who cannot be vaccinated.



APPENDIX

Which COVID-19 vaccines are approved and where?

Coronavirus vaccine tracker: <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html#pfizer>

Live status

COVID-19 vaccination tracker: <https://gap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab>

Tracking COVID-19 vaccination worldwide: <https://edition.cnn.com/interactive/2021/health/global-covid-vaccinations/>

EUROPE

Which COVID-19 vaccines are approved by the European Medicines Agency (EMA)?

There are currently 5 vaccines approved for use by EMA for the prevention of COVID-19 – See Table 1 (Source: EMA, date 20th April 2022)

- Comirnaty - BioNTech/Pfizer COVID-19 vaccine
- Vaxzevria COVID-19 vaccine (previously COVID-19 Vaccine AstraZeneca)
- Spikevax (previously COVID-19 vaccine Moderna)
- Janssen COVID-19 vaccine;
- Nuvaxovid

Comirnaty (developed by BioNTech and Pfizer)	BioNTech Manufacturing GmbH	Conditional marketing authorisation issued: 21/12/2020 Annual renewal issued: 03/11/2021	Latest news Safety updates Clinical data (login required) Paediatric investigation plan
COVID-19 Vaccine Janssen	Janssen-Cilag International NV	Conditional marketing authorisation issued: 11/03/2021 Annual renewal issued: 03/01/2022	Latest news Safety updates Clinical data (login required) Paediatric investigation plan
Nuvaxovid	Novavax CZ, a.s.	Conditional marketing authorisation issued: 20/12/2021	Latest news
Spikevax (previously COVID-19 Vaccine Moderna)	Moderna Biotech Spain S.L.	Conditional marketing authorisation issued: 06/01/2021 Annual renewal issued: 04/10/2021	Latest news Safety updates Clinical data (login required) Paediatric investigation plan
Vaxzevria (previously COVID-19 Vaccine AstraZeneca)	AstraZeneca AB	Conditional marketing authorisation issued: 29/01/2021 Annual renewal issued: 09/11/2021	Latest news Safety updates Clinical data (login required) Paediatric investigation plan

Table 1. Overview of COVID-19 vaccines currently approved by the European Medicines Agency



More information on each vaccine: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorized>

Which additional COVID-19 vaccines are currently being evaluated?

<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-under-evaluation# covid-19-vaccines-under-rolling-review-section>

Which additional COVID-19 vaccines are currently in research and development?

<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-research-development>

Key facts

<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-key-facts>

USA

Which COVID-19 vaccines are approved by the Food and Drug Administration (FDA)?

There are currently three vaccines approved for use by FDA for the prevention of COVID-19 – See Figure 1 (Source: FDA, date 20th April 2022)

Check Fact Sheets for details.

- [BioNTech/Pfizer COVID-19 vaccine](#)
- [Moderna COVID-19 vaccine](#)
- [Janssen COVID-19 vaccine](#)

COVID-19 Vaccines Authorized for Emergency Use or FDA-Approved

**[Comirnaty and Pfizer-BioNTech COVID-19
Vaccine](#)**

[Spikevax and Moderna COVID-19 Vaccine](#)

[Janssen COVID-19 Vaccine](#)

*Fact sheets for health care providers and patients included
Report vaccine side effects toll-free at 1-800-822-7967 or [online](#)*

Figure 1: Overview of COVID-19 vaccines currently approved by the FDA

Additional information:

<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19#new>

COVID Booster <https://www.youtube.com/watch?v=SAB90pFw-g>