

IPCRG practice driven answers on COVID-19 and respiratory questions



What are the safety concerns and what are the serious side effects reported with existing SARS-CoV-2 vaccines?

What the research says

Clinical trial results support the safety of currently available SARS-CoV-2 vaccines (Yuan et al 2021). The most commonly reported side effects in clinical trials were injection site pain, fatigue, headache, fever and chills. Serious adverse events were rare and the number and nature of such events was similar between vaccine and placebo groups.

Extensive real-world data safety surveillance is underway. Rare cases of Vaccine Induced Thrombocytopenic Thrombosis (VITT; also described as thrombosis with thrombocytopenia syndrome [TTS]) have been reported following administration of the Oxford-AstraZeneca (EMA 2021) and the Johnson & Johnson/Janssen viral vector vaccines (CDC July 13, 2021). VITT are thrombotic events in the context of thrombocytopenia (including clots in the vessels draining blood from the brain [CVST] and disseminated intravascular coagulation [DIC]) (Greinacher et al 2021). For the Oxford-AstraZeneca SARS-CoV-2 vaccine VITT have been reported at a rate of around 25 events per 20 million vaccinations (EMA 2021).

For both vaccines, the majority of such events have been reported among women <50 years of age. Severe cases of anaphylaxis have been reported following administration of the Pfizer RNA-based SARS-CoV-2 vaccine at a rate of ~5 cases per 1 million vaccinations as of February 2021 (Remmel 2021). Severe cases of anaphylaxis have also been reported following administration of the Moderna RNA-based SARS-CoV-2 vaccine. In the USA 10 cases per ~4 million vaccinations had been reported as of January 10 2021 (CDC January 29, 2021). Such events usually occur within ~15 minutes of vaccine administration. These safety concerns appear to arise mainly following the first dose of vaccine.

Rare cases of myocarditis have been reported following administration of the Pfizer and Moderna RNA-based SARS-CoV-2 vaccines, notably among male adolescents and young adults, more often after the second dose and typically emerging within a few days of vaccination (CDC June 23, 2021).

Risk-benefit analysis remains in favour of vaccination: World Health Organization (WHO) statement "At this time, WHO considers that the benefits of the AstraZeneca vaccine outweigh its risks and recommends that vaccinations continue". The WHO provide a reporting route for any adverse events (WHO Team 2021).

What this means for your clinical practice

- Continue to vaccinate using available, approved vaccines according to National guidance.
- The WHO recommend monitoring patients for 15 mins after vaccination and for 30 mins for those with previous reaction to vaccination (WHO Team 2021).
- Monitor for and report any adverse events in the usual way (WHO Team 2021).

Useful links and supporting references

CDC. COVID-19: J&J/Janssen update, July 13, 2021. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html>. Accessed August 2021.

CDC. Allergic reactions including anaphylaxis after receipt of the first dose of Moderna COVID-19 vaccine – United States, December 21, 2020 – January 10, 2021. Available at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm>. Accessed August 2021.

CDC. Myocarditis and pericarditis following mRNA COVID-19 vaccination. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>. Accessed August 2021.

EMA. COVID-19 vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low platelets. Available at: <https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots>. Accessed April 2021.

Greinacher A, et al. Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 vaccination. NEJM 2021;doi:10.1056/NEJMoa2104840. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa2104840>. Accessed August 2021.

Rommel A. COVID vaccines and safety: What the research says. Nature 2021;590:538-40. . Available at: <https://www.nature.com/articles/d41586-021-00290-x>. Accessed August 2021.

WHO Team. How to monitor and report COVID-19 vaccine side effects. 15 March 2021. Available at: <https://www.who.int/publications/m/item/how-to-monitor-and-report-covid-19-vaccine-side-effects>. Accessed April 2021.

Yuan P, et al. Safety, tolerability, and immunogenicity of COVID-19 vaccines: A systematic review and meta-analysis. Lancet 2021. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3746259. Accessed March 2021

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