COVID-19 vaccination and MSK

08/01/2021 by Garreth

Principles for COVID-19 Vaccination in Musculoskeletal and Rheumatology for Clinicians

(Version 2, 27th January 2021)

Amendment 27th Jan 2021: *Document updated to reflect updated Green Book recommendation about timings of vaccine for people due to start immunosuppression, in whom it is safe to delay by a few weeks. Please see updated sections 6, 9, 10 and 17. We are in discussions to explore how this change can be delivered and will update the document accordingly.*

All patients should be encouraged to receive one of the COVID-19 vaccines. This is regardless of their treatment regimen or underlying diagnosis. The benefits of the COVID-19 vaccination outweigh the risks and by having the vaccine, this will reduce the risk of developing severe complications due to COVID-19. Vaccinations will be offered in line with the prioritisation criteria from the Joint Committee for Vaccination and Immunisation (JCVI) (please see the prioritisation section below).

We are receiving a large volume of calls from patients to our departmental advice and patient charity advice lines about the suitability and timing of the COVID-19 vaccines. It is important that we try to provide the same advice where possible.

This is a working document and it will be updated as new information/data becomes available.

The following principles may help us to achieve this:

AVAILABLE VACCINATIONS

1.There are a number of different COVID-19 vaccines under development, and as of 11th January 2021 three have been approved for use by the MHRA. Table 1 lists these vaccines. The table will be updated as needed.

2. None of the current UK approved COVID-19 vaccines are considered to be 'live' vaccines. The COVID-19 vaccines are considered safe for use in immunosuppressed patients. Whether any new future COVID-19 vaccine is categorised as 'live' or not will need to be reviewed for each vaccine as it is authorised by the MHRA by looking in the summary product characteristics (SPC) document for the product. The Oxford/AstraZeneca vaccine contains a live adenovirus vector but is non-replicating so cannot cause infection and is therefore safe for people who are immunosuppressed.

3. The Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2 has been approved for use in individuals 16 years of age and older by the MHRA and is being rolled out. The Oxford/Astra Zeneca (ChAdOx1 nCoV-2019 vaccine) was approved by the MHRA for use on 30th December 2020 and roll out started on 4th January 2021. The Moderna vaccine was authorised for use on 8th January 2021 and will be rolled out in the coming months.

Table 1

[This table has five columns – scroll right]

Vaccine name	Live or not live (MHRA classification?)	Date approved by MHRA	Approved for	Dose administration
Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2	Not live	03/12/2020	16 years and older	2 doses up to 12 weeks apart
Oxford/Astra Zeneca (ChAdOx1 nCoV-2019) vaccine	Not live*	30/12/2020	18 years and older	2 doses up to 12 weeks apart
Moderna	Not live	08/01/2021	18 years and older	2 doses

*This vaccine contains a live adenovirus vector but it is non-replicating so cannot cause infection and is therefore safe for people who are immunosuppressed.

4. The environment used for the administration of the vaccine should be as safe as possible for patients and staff and should adhere to the principles of social distancing

and use of appropriate levels of PPE

SAFETY

5. Cautions are the same for patients as for the general population:

- A very small number of individuals have experienced anaphylaxis when vaccinated with the Pfizer BioNTech vaccine. Following close surveillance of the initial roll out, the MHRA has advised that individuals with a history of anaphylaxis to any vaccine, medicine or food, can receive any COVID-19 vaccine as long as they are not allergic to any component (excipient) of the vaccine. The Pfizer/BioNTech COVID-19 vaccine contains polyethylene glycol (PEG), which is from a group of known allergens commonly found in medicines and also household goods and cosmetics. Known allergy to PEG is extremely rare but would contraindicate receipt of this vaccine. Of note certolizumab pegol contains PEG so patients who have had an allergic reaction to certolizumab pegol should not receive the Pfizer/BioNTech vaccine. PEG is also an excipient in the Moderna mRNA COVID-19 vaccine; individuals who have a systemic allergic reaction to the Pfizer-BioNTech vaccine should not be given a dose of the Moderna vaccine and vice versa. The British Society for Allergy and Clinical Immunology has advised that individuals with a history of immediate onset anaphylaxis to multiple classes of drugs or unexplained anaphylaxis should not be vaccinated with the Pfizer BioNtech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated).
- The vaccines should not be administered to individuals suffering from an acute severe febrile illness.
- Patients should continue to perform social distancing/shield after their vaccination.

6. The Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2 and Oxford/Astra Zeneca (ChAdOx1 nCoV-2019 vaccine) vaccines are considered safe for immunocompromised persons, as they are not live vaccines. Frequently, the immune response of immunocompromised persons to these vaccine antigens is not as good as that of immunocompetent persons. Immunocompromised persons include individuals receiving immunosuppressant therapy, including corticosteroids. Detailed information and data about the efficacy of COVID-19 vaccination in the immunosuppressed are not yet available but national studies are already underway to answer this. The Green Book Chapter 14a was updated on 21st January 2021 (see point 9 below for full information).

VACCINATION OF THE CLINICALLY EXTREMELY VULNERABLE POPULATION

7. Clinically extremely vulnerable people are expected to receive a vaccination against COVID-19 before the general population. The local NHS will ensure that they receive the vaccine as safely as possible, as well as any care and support needed. Patients who have had both doses of the vaccine should continue to follow the shielding advice until further notice as we continue to assess the impact of vaccination among all groups. The people they live with should continue to follow the public health rules and guidance as long as they are in place, including if the CEV person has received the vaccine and also if they have received the vaccine.

INTERACTION WITH ONGOING TREATMENT

8. Patients should not stop their immunosuppression.

9. It is known that some drugs e.g. rituximab reduce the response to some vaccines such as the seasonal flu vaccine. It is anticipated that patients receiving rituximab may potentially have a reduced response to the COVID-19 vaccines. It may not be possible to time the administration of the vaccine with the course/start of immunosuppression treatment. The benefits versus the risks need to be considered and discussed with the patient and a shared decision made. Patients are still advised to receive the COVID-19 vaccine. The Green Book Chapter 14a was updated on 21st January 2021. The following paragraph is now included in the Green Book: 'As there is no evidence on response (to the COVID-19 vaccines) in immunosuppressed individuals, there is also no evidence upon which to base advice on the optimal timing of delivery. Specialists may advise their patients based on their knowledge and understanding of their immune status and likely immune response to vaccination, but should also consider the risk from COVID-19 and the patient's likelihood of exposure. **The small number of patients who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression.** Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID19 and from their underlying condition. Although the immune correlates of protection are currently unknown, post-vaccination testing may be considered.'

10. Considerations regarding the use of Rituximab:

Please read point 9 before reading this point. As above, the Green Book Chapter 14a was updated on 21st January 2021. Although Roche, the manufacturer of the rituximab originator drug, has advised that a pulse of rituximab should be given 'at least 4 weeks after a dose of the COVID-19 vaccine', the update to the Green Book Chapter 14a on 21st January 2021 advises 'ideally at least 2 weeks', and the exact interval should be decided by clinician discretion. Depending on the urgency of treatment it would be preferable for the 2-dose schedule to be completed prior to commencing rituximab by offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) instead of waiting up to 12 weeks. Local discussions will have to take place to explore possible logistical options to organise this e.g. the vaccinations could be done in existing hubs/centres or perhaps by a rheumatology department whichever works best for that geographical area.

The following should be considered:

i. Rituximab should not be delayed in patients with acute severe organ-threatening multi-system disease who need urgent treatment to control their disease. In this scenario, treatment with rituximab and the concurrent administration of the

vaccination should go ahead regardless of timings i.e. as soon as they are available.

ii. If a patient needs to start a new DMARD/biologic but has not been vaccinated, it may be appropriate to consider selecting an alternative DMARD / biologic medication to rituximab, if available and appropriate, e.g. in patients with rheumatoid arthritis.

i. For patients receiving non-urgent/maintenance rituximab, consider deferring a rituximab course until 2 weeks after completing a course of the COVID-19 vaccine. Please see table 2.

Table 2 summarises the steps/schedule to be used in patients who are due to start a course of non-urgent/maintenance IV rituximab

COVID-19 Vaccine Brand	**Pfizer/BioNTech**	**Oxford/AstraZeneca**
Vaccine Dose 1	Give on day 0	Give on day 0
Vaccine Dose 2	Give on day 21	Give on day 28
Rituximab 1g IV	Give on day 35	Give on day 42

The following summarises the advice for the likely scenarios:

- If a patient has been offered a date for vaccination, then vaccinate and delay rituximab as per schedule in table 2.
- If vaccine is available now for the patient but patient is still B-cell depleted on rituximab, then do not delay vaccination until B-cells recover but vaccinate now. There is no evidence to suggest how long after a pulse of rituximab a patient should delay vaccination with the COVID-19 vaccine but consensus suggests this should ideally be 4-8 weeks after rituximab if it is ok to defer the COVID-19 vaccine. This decision may depend upon the prevalence of COVID-19. A shared decision should be made with the patient.
- If vaccine is not available now for the patient, and it's not safe to delay rituximab for four weeks e.g. because of organ threatening disease, then give rituximab without delay and vaccinate whenever vaccine is available
- If vaccine is not available now, and it is safe to delay rituximab or to switch to an alternative treatment, then consider these options. A shared decision should be made with the patient.

11. Corticosteroids: oral, intra-articular, intra-muscular or IV and timing of the COVID-19 vaccination

There are some general principles but in each case the benefits and risks should be discussed with the patient to arrive at a shared decision:
• It is safe to have the COVID-19 vaccine alongside steroid exposure, but the patient may not mount such a good immune response.
• Do not delay vaccination for someone who is taking, has received or is soon to receive steroids in any form.

• If additional steroids are required to control inflammatory disease, that may take priority, as a flare can also worsen the risk from COVID-19
• It may be appropriate to delay a non-essential steroid injection, as part of a shared decision, so that the response to the vaccine is more effective. For a patient who is on an elective waiting list for a steroid injection of up to 80mg methylprednisolone or 80mg triamcinolone, the administration of the COVID-19 vaccine is the priority if the vaccine has been offered to the patient and the prevalence of COVID-19 is high. In this scenario, the steroid injection should be deferred by 2 weeks after the vaccine, to enable the patient to mount the best response to the COVID-19 vaccine.

PRECAUTIONS AND CONTRAINDICATIONS

12. Pregnancy: The available data for the Pfizer-BioNTech and AstraZeneca COVID-19 vaccines do not show any safety concerns or harm to the mother or baby during pregnancy. However, there is insufficient evidence to recommend routine use of the vaccines during pregnancy. Routine pregnancy testing before administration of the vaccine is not required. However, vaccination during pregnancy should be considered if there is a high risk of exposure to SARS-CoV2 infection or if the pregnant woman has underlying conditions that put them at very high risk of serious compilations if they develop COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnancy. Termination of pregnancy following inadvertent immunisation should not be recommended.

13. Breastfeeding: There is no known risk associated with giving non-live vaccines whilst breastfeeding. The JCVI advises that breastfeeding women may be offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines, following a discussion about the developmental and health benefits of breastfeeding along with the mother's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.

14. Elective surgery: It is recommended that people undergoing elective surgery have 7 days between the vaccination and surgery (both before and after surgery). This applies to both doses of the vaccine. The rationale for separating the date of surgery from vaccination is so that any symptoms such as fever post vaccination might be correctly attributed to the consequences of either vaccination or the operation itself. People underdoing elective surgery who have been vaccinated are still asked to self-isolate prior to surgery and take a COVID test before surgery.

15. Urgent/emergency surgery: For those requiring urgent/emergency surgery, surgical intervention should proceed.

PRIORITISATION

Table 3 outlines the priority groups for vaccination as advised by the JCVI:

Priority group	
1	Residents in a care home for older adults Staff working in care homes for older adults

2	All those 80 years of age and over Frontline Health and social care workers
3	All those 75 years of age and over
4	All those 70 years of age and over Clinically extremely vulnerable individuals (not including pregnant women and those under 16 years of age)
5	All those 65 years of age and over
6	Adults aged 16 to 65 years in an at-risk group
7	All those 60 years of age and over
8	All those 55 years of age and over
9	All those 50 years of age and over

16. All clinicians should continue to identify patients who are at the highest risk from COVID-19 (the Clinically Extremely Vulnerable (CEV)), and submit their details to NHS Digital, so that they can be added to the shielded patients list (SPL). All NHS Trusts have a mechanism to do this. Decision-support tools to help identify these patients are available on the British Society for Rheumatology's (BSR) website. This is guidance, and ultimately the decision to submit patient details to NHS Digital/add a person to the SPL list will be made on a case by case basis.

17. In this early phase of vaccine roll out, it may not be possible to deliver the vaccine to all patients with urgent clinical need e.g. patients who are due to commence a course of rituximab in the next couple of months. However, this may be something that is possible in the near future as logistics become easier, particularly in light of the Green Book Chapter 14a amendment on 21st January 2021, as fully reported in point 9 above. Clinicians may be able to recommend that a patient should receive a vaccination at a specific time to optimise response according to the treatment schedule by contacting their local vaccination hub e.g. for a small number of patients receiving non-urgent/maintenance rituximab as outlined in point 9. We will continue to have discussions about the logistics of trying to deliver this pragmatic approach with NHS England and will update this document accordingly.

FURTHER QUESTIONS

The data and evidence regarding the safety and effectiveness of the COVID-19 vaccines continues to emerge. Many unanswered questions remain but data are being collected to try to answer these questions.

These questions include:

- *'How long does the vaccine last/ what is the duration of immunity?'*
- *'Should methotrexate be suspended temporarily around the time of the COVID-19 vaccine?'*

This document will be updated as new evidence emerges to answer these and other current pertinent questions.

REFERENCES

JCVI website:
https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation

Green book chapter 14a COVID-19- SARS-CoV-2:
https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment

BSR website: https://www.rheumatology.org.uk/covid-19/

Versus Arthritis website: https://www.versusarthritis.org/news/2020/april/coronavirus-covid-19-and-arthritis-where-to-go-for-information/

Decision Support Tool: https://www.versusarthritis.org/media/23183/msk-rheumatology-decision-support-tool-covid-19-vaccines-final-15012021.pdf

Royal College of Obstetricians and gynaecologists: https://www.rcog.org.uk/en/news/covid-19-vaccination-and-pregnancy/

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: *Arthritis News, Resources, Treatments & Therapies*
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