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10 December 2021

9(2)(a)
[redacted]

RE Official Information Act request CDHB 10772

I refer to your email dated 2 December 2021 requesting the following information under the Official Information Act from Canterbury DHB regarding Pfizer Comirnaty Vaccine information. Specifically:

1. **The important risks, missing information and additional pharmacovigilance activities and information with regards to the Pfizer Comirnaty Vaccine data for use in autoimmune or inflammatory disorders such as Rheumatoid Arthritis.**
2. **The important potential risk for Vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VEARD) in persons with an autoimmune or inflammatory disorder such as Rheumatoid Arthritis.**

We believe the best place to address your questions for vaccine safety data in people with autoimmune conditions is direct to Pfizer NZ. You can submit your questions to them via their website https://www.pfizermedicalinformation.co.nz/en-nz/patient/contact-us or phone them on 0800 736 363.

COVID vaccines have been found to be safe in auto-immune disease and are recommended by international bodies for rheumatological conditions. People with autoimmune diseases tend to do worse with COVID and are often prioritised for vaccination. The concerns over VAED have not eventuated. We are attaching as **Appendix 1 and 2** the American and Australian guidelines.

I trust that this satisfies your interest in this matter.

Please note that this response, or an edited version of this response, may be published on the Canterbury DHB website after your receipt of this response.

Yours sincerely

Tracey Maisey
Executive Director
Planning, Funding & Decision Support

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COVID-19 Vaccine Clinical Guidance Summary for Patients with Rheumatic and Musculoskeletal Diseases

Version 4

Revised October 27, 2021

Developed by the ACR COVID-19 Vaccine Clinical Guidance Task Force

*This summary was initially approved by the ACR Board of Directors on February 8, 2021 and updated on March 4, 2021. A full paper (Version 1), was published in Arthritis & Rheumatology on May 24, 2021.**

*New recommendations regarding mycophenolate, methotrexate, acetaminophen, and NSAID timing considerations[+] were added to this summary on April 28, 2021 and were added to the full paper (Version 2), which was published in Arthritis & Rheumatology on June 15, 2021.***

*Updated recommendations regarding age restrictions, preferences between specific vaccines, and need for continued preventive measures were added to this summary on June 19, 2021 and were added to the full paper (Version 3), which was published in Arthritis & Rheumatology on August 4, 2021.****

Updated recommendations regarding preference for use of mRNA vaccines, use of a supplemental vaccine dose (i.e., 'booster') and associated temporary interruption of immunomodulatory medications, and the FDA EUA for post-exposure prophylaxis with monoclonal antibody treatment for vaccinated AIIRD patients were added to this summary on August 19, 2021. These recommendations were added to the full paper (Version 4), which will be submitted to Arthritis & Rheumatology for publication.

Updated recommendations for supplemental (booster) dosing and revised information for holding immunomodulatory medications were added to the version 4 summary on October 27, 2021. These recommendations were added to the full paper (Version 4), which will be submitted to Arthritis & Rheumatology for publication.

Purpose

The purpose of this document is to provide guidance to rheumatology providers on the use of the COVID-19 vaccine and the associated management of rheumatic and musculoskeletal disease patients around the time of vaccination against SARS-CoV-2. These statements were based upon a dearth of high-quality data and are not intended to replace clinical judgment. Modifications made to treatment plans, particularly in complex rheumatic disease patients, are highly disease-, patient-, geography-, and time-specific and, therefore, must be individualized as part of a shared decision-making process. This guidance is provided as part of a 'living document,' recognizing rapidly evolving evidence and the anticipated need for frequent updates as such evidence becomes available.

Methods

The North American Task Force panel, consisting of 9 rheumatologists, 2 infectious disease specialists, and 2 public health experts with current or past employment at the Centers for Disease Control (CDC), convened multiple times in December 2020 and January 2021. The Task Force proposed a variety of clinical questions related to COVID-19 vaccination in patients with rheumatic and musculoskeletal diseases (RMD), divided itself into subgroups (i.e., teams), and assigned the clinical questions to the various teams by topic (e.g., vaccine effectiveness, safety). Each team was charged to generate an evidence review covering that topic; the evidence reviews were combined into an evidence summary document that was collated and disseminated to the entire Task Force. The Task Force reviewed the clinical questions and associated proposed vaccine guidance statements that were evaluated using a well-established method of consensus building (modified Delphi process). This process included two rounds of asynchronous anonymous rating by email and two live webinars including the entire Task Force. Panel members rated their agreement with draft statements using a numeric scoring system, and consensus was determined to be either "moderate" (M) or "high" (H), based on the dispersion in the rating results. To be approved as guidance, median ratings were required to correlate to pre-defined levels of agreement (with median values interpreted as "agreement," "uncertainty" or "disagreement") with either moderate or high levels of consensus based on the statements as they were originally voted upon, unless they were subsequently reconsidered. For

this summary document, several rating statements that were initially separate were combined to facilitate clarity and conciseness.

Results and Conclusion

General considerations related to COVID-19 vaccination in rheumatic and musculoskeletal disease patients are shown in Table 1. Statements more specific to patient groups, as well as general disease- and timing-related considerations, are presented in Table 2. No evidence was found to support a concern regarding the use or timing of immunomodulatory therapies in relation to vaccine safety. Therefore, guidance regarding immunomodulatory medication and vaccination timing (Table 3) was given considering the intent to optimize vaccine response. An important set of guiding principles, foundational assumptions and limitations are mentioned in the Supplemental Table. The ACR is committed to updating this guidance as a 'living document' as new evidence emerges. Statements in **bold** are those that have been revised or added in the most current version of the document. These changes are also summarized in the Appendix Table.

Recommendations

Table 1: General Considerations Related to COVID-19 Vaccination in Rheumatic and Musculoskeletal Disease Patients

	Guidance Statement	Level of Task Force consensus
	The rheumatology healthcare provider is responsible for engaging the RMD patient in a discussion to assess COVID-19 vaccination status and engage in a shared decision-making process to discuss receiving the COVID-19 vaccine.	Strong-Moderate
	Acknowledging heterogeneity due to disease- and treatment-related factors, and after considering the influence of age and sex, AIIRD patients are at higher risk for hospitalized COVID-19 and worse outcomes compared to the general population.	Moderate
	Based on their risk for COVID-19, AIIRD patients should be prioritized for vaccination before the non-prioritized general population of similar age and sex.	Moderate
	Beyond known allergies to vaccine components, there are no known additional contraindications to COVID-19 vaccination for AIIRD patients.	Moderate
	The expected response to COVID-19 vaccination for many AIIRD patients on systemic immunomodulatory therapies is blunted in its magnitude and duration compared to the general population.	Moderate
	A theoretical risk exists for AIIRD flare or disease worsening following COVID-19 vaccination. However, the benefit of COVID-19 vaccination for RMD patients outweighs the potential risk for new onset autoimmunity.	Moderate

RMD = rheumatic and musculoskeletal disease; AIIRD=autoimmune and inflammatory rheumatic disease

Table 2: Recommendations for Primary and Supplemental Dosing of the COVID-19 Vaccine in RMD Patients*

Guidance Statement	Level of Task Force consensus
RMD and AIIRD patients should receive COVID-19 vaccination, consistent with the age restriction of the EUA and/or FDA approval.†	Moderate
RMD patients without an AIIRD who are on immunomodulatory therapy should be vaccinated in a similar fashion as described in this guidance for AIIRD patients receiving those same treatments.	Moderate
For AIIRD patients not yet vaccinated, either of the mRNA vaccines is recommended over the single dose J&J vaccine. There is no recommendation for one mRNA vaccine over another.	Moderate
For a multi-dose vaccine **(e.g. the Pfizer or Moderna mRNA vaccine series),** AIIRD patients should receive the second dose of the same vaccine, even if there are non-serious adverse events associated with receipt of the first dose, consistent with timing described in CDC guidelines.	Strong
For patients who previously completed the 2-dose mRNA series or received the 1-dose J&J COVID-19 vaccine, a supplemental (booster) COVID vaccine dose is recommended at least 28 days after the completion of the vaccine series for AIIRD patients receiving any immunosuppressive or immunomodulatory therapy other than hydroxychloroquine monotherapy.	Moderate
For patients who previously completed the mRNA COVID-19 vaccine series or 1-dose J&J COVID-19 vaccine, and who are receiving a supplemental (booster) dose, an mRNA vaccine supplemental dose of either type (Pfizer or Moderna) is preferred.	Moderate
Healthcare providers should not routinely order any lab testing (e.g., antibody tests for IgM and/or IgG to spike or nucleocapsid proteins) to assess immunity to COVID-19 post-vaccination, nor to assess the need for vaccination in a yet-unvaccinated person.‡	Strong
Following COVID-19 vaccination, RMD patients should continue to follow all public health guidelines regarding physical distancing and other preventive measures.§	Strong
AIIRD patients at high risk for poor outcomes related to COVID should receive monoclonal antibody therapy with REGEN-COV if available, either as prevention (i.e. post-exposure prophylaxis for asymptomatic, recently-exposed patients) or as treatment for newly symptomatic patients.	Moderate
Household members and other frequent, close contacts of AIIRD patients should undergo COVID-19 vaccination when available to them to facilitate a 'cocooning effect' that may help protect the AIIRD patient. No priority for early vaccination is recommended for household members.	Moderate
While vaccination would ideally occur in the setting of well-controlled AIIRD, except for those patients with life-threatening illness (e.g., in the ICU for any reason), COVID vaccination should occur as soon as possible for those for whom it is being recommended, irrespective of disease activity and severity.	Strong-Moderate

* RMD = rheumatic and musculoskeletal disease; AIIRD=autoimmune and inflammatory rheumatic disease; EUA = Emergency Use Authorization; FDA = US Food and Drug Administration; mRNA = messenger RNA; CDC = Centers for Disease Control and Prevention; ICU = intensive care unit

† Age ≥12 as of June 7, 2021

‡ Given uncertainties in the interpretation of lab testing following vaccination as it would impact clinical decision-making, the panel reaffirmed this statement in Version 4 of this guidance document.

§ The Task Force discussed the possibility of recommending additional and more sustained public health measures in AIIRD patients. After deliberation, they did not elect to exceed current public health authority guidance given uncertainties about the clinical effectiveness of vaccination in such patients. The appropriateness for continued preventive measures (e.g., masking, physical distancing) should be discussed with patients as their rheumatology providers deem appropriate.

Table 3: Guidance Related to the Use and Timing of Vaccine Dosing and Immunomodulatory Therapy in Relation to COVID-19 Vaccination in RMD Patients

Medication	Timing Considerations for Immunomodulatory Therapy and Vaccination (applies to both primary vaccination and supplemental [booster] dosing)	Level of Task Force Consensus
Abatacept IV	**Time vaccination so that it occurs one week prior to the next dose of IV abatacept**	**Moderate**
Abatacept SQ	**Hold for one to two weeks (as disease activity allows) after each COVID vaccine dose**	**Moderate**
Acetaminophen, NSAIDs	Assuming that disease is stable, hold for 24 hours prior to vaccination. No restrictions on use post vaccination to treat symptoms.	Moderate
Belimumab SQ	**Hold for one to two weeks (as disease activity allows) after each COVID vaccine dose**	**Moderate**
TNFi, IL-6R, IL-1R, IL-17, IL12/23, IL-23, and other cytokine inhibitors†	**The Task Force failed to reach consensus on whether or not to temporarily interrupt these following each COVID vaccine dose, including both primary vaccination and supplemental (booster) dosing**	**Moderate**
Cyclophosphamide IV	**Time CYC administration so that it will occur approximately 1 week after each vaccine dose, when feasible**	**Moderate**
Hydroxychloroquine	**No modifications to either immunomodulatory therapy or vaccination timing**	**Strong**
Rituximab or other anti-CD20 B-cell depleting agents	**Discuss the optimal timing of dosing and vaccination with the rheumatology provider before proceeding‡**	**Moderate**
All other conventional and targeted immunomodulatory or immunosuppressive medications except those listed above§	**Hold for one to two weeks (as disease activity allows) after each COVID vaccine dose**	**Moderate**

Note: individual medications that were specifically voted on by the task force are listed on separate rows and were not collapsed, even if the resulting recommendation was similar to others.

***** RMD = rheumatic and musculoskeletal disease; IVIG = intravenous immunoglobulin; TNFi = tumor necrosis factor inhibitor; IL = interleukin; JAKi = janus kinase inhibitor; CYC = cyclophosphamide; RTX = rituximab; IV = intravenous; SQ = subcutaneous; NSAID = non-steroidal anti-inflammatory drugs

† Examples of specific cytokine inhibitors are as follows: IL-6R = sarilumab; tocilizumab; IL-1R = anakinra, canakinumab; IL-17 = ixekizumab, secukinumab; IL-12/23 = ustekinumab; IL-23 = guselkumab, rizankizumab; JAKi = baricitinib, tofacitinib, upadacitinib

***‡** Some practitioners measure CD19 B cells as a tool with which to time the booster and subsequent rituximab dosing. For those who elect to dose without such information, or for whom such measurement is not available or feasible, provide the booster 2-4 weeks before next anticipated rituximab dose (e.g., at month 5.0 or 5.5 for patients on an every 6 month rituximab dosing schedule)*

§ Includes apremilast; azathioprine; calcineurin inhibitors; cyclophosphamide (oral); IVIG; leflunomide; methotrexate, janus kinase inhibitors [JAKi] (baricitinib, tofacitinib, upadacitinib), mycophenolate; sulfasalazine

Supplemental Table: Foundational Principles, Assumptions, and Considerations for the Guidance Statements

ACR guidance statements are not intended to supersede the judgement of rheumatology care providers nor override the values and perspectives of their patients. Guidance was based on weak and/or indirect evidence and required substantial extrapolation by an expert task force. All statements, therefore, should be considered conditional or provisional. The ACR is committed to updating this guidance document as new evidence emerges.
The rheumatology community lacks important knowledge on how to best maximize vaccine-related benefits. RMD patients exhibit high variability with respect to their underlying health condition, disease severity, treatments, degree of multimorbidity, and relationship with their specialist provider. These considerations must be considered when individualizing care.
Based on evidence published to date, the expected benefits of the COVID-19 vaccine outweigh the potential for vaccine harm in most RMD patients.
The future COVID landscape is uncertain with respect to vaccine effectiveness and safety, uptake, durability, mitigating societal behavior, and emerging viral strain variants. Clinicians nevertheless must act with their best judgement despite this highly uncertain and rapidly changing landscape.
The risk of deferring vaccination and thus failing to mitigate COVID-19 risk should be weighed against a possible blunted response to the vaccine if given under suboptimal circumstances. As a practical matter, this tension must be resolved in the context of imperfect prediction as to whether those circumstances may be transient, and a paucity of scientific evidence.
Both individual and societal considerations related to a limited vaccine supply should be considered in issuing vaccine guidance and making policy decisions. Given that context, simplicity should be the touchstone: to avoid confusion, improve implementation, and maintain scientific credibility.

RMD = rheumatic and musculoskeletal disease; mRNA = messenger RNA

[+] **Appendix Table 1: History of Major Changes to ACR COVID Vaccine Guidance Statements in the Summary Tables (i.e., this online document) and Locations in the Published Manuscript Tables and Prose Where Guidance Was Revised**		
Provided guidance to hold acetaminophen and NSAIDs for 24 hours prior to vaccination, assuming disease is stable	Table 5 (Summary Table 3)	Version 2
Modified guidance for mycophenolate to hold for 1 week after each vaccine dose	Table 5 (Summary Table 3)	Version 2
Modified guidance for methotrexate to hold for 1 week after each of the 2 mRNA vaccine doses, and for 2 weeks after single-dose COVID vaccine	Table 5 (Summary Table 3)	Version 2
Citations added describing the attenuation of SARS-CoV-2 vaccine response observed in patients receiving mycophenolate, methotrexate, janus kinase inhibitors, and other immunomodulatory therapies	Prose accompanying Table 5	Version 2
Age restriction lowered to age 12	Footnote to Table 3 (Summary Table 2)	Version 3
Preference for mRNA vs. non-mRNA vaccines	Footnote to Table 3 (Summary Table 2)	Version 3
Need for continued preventive measures	Footnote to Table 3 (Summary Table 2)	Version 3
Preference for two-dose mRNA vaccine over single-dose vaccine in AIIRD patients	(Summary Table 2)	Version 4
Recommendation for booster vaccination in AIIRD patients	(Summary Table 2)	Version 4
Recognition of the FDA Emergency Use Authorization for use of post-exposure prophylaxis with casirivimab and imdevimab (REGEN-COV) for prevention of COVID-19 in AIIRD patients	(Summary Table 2)	Version 4
Recommended temporary interruption of oral calcineurin inhibitors at time of vaccination	(Summary Table 3)	Version 4
Recommendations for temporary treatment interruption of various immunomodulatory therapies at the time of receipt of a vaccine booster dose.	(Summary Table 3)	Version 4
Recommendation for supplemental (booster) dosing for mRNA and J&J vaccine recipients	**(Summary Table 2)**	**Version 4 Revised**
Preference for the same type of mRNA supplemental (booster) dose in patients previously completing either the Pfizer or Moderna mRNA vaccine series	**(Summary Table 2)**	**Version 4 Revised**
Recommendation for monoclonal antibody therapy with REGEN-COVID as either prevention (i.e., post-exposure prophylaxis) or as treatment for high-risk patients	**(Summary Table 2)**	**Version 4 Revised**
Complete revision of immunomodulatory medication recommendations regarding timing in relation to COVID-19 vaccine series and supplemental (booster) dosing.	**(Summary Table 3)**	**Version 4 Revised**

Recommendations updated April 28, 2021
Link to Version 1 manuscript added May 24, 2021
Link to Version 2 manuscript added June 15, 2021
Recommendations updated June 19, 2021
Link to Version 3 manuscript added August 4, 2021
Recommendations updated August 19, 2021
Recommendations updated October 27, 2021
Link to version 4 manuscript pending

***** How to cite this article:**
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Australian Rheumatology Association

Patient Information on the COVID-19 vaccination in autoimmune inflammatory rheumatic diseases (AIRD) 2 November 2021

Why is it important for me to have the vaccine?

Some diseases (including rheumatoid arthritis) are caused by the body's immune system, which usually protects us from infection. When the immune system is affected by arthritis or drugs to treat the condition, the risk from COVID-19 may be increased.

If you get vaccinated, you will be less likely to get COVID-19. Even if you are infected, it is more likely to be a milder illness.

People who catch COVID-19 can become very unwell. Many people will need hospital treatment even if they do not have a health condition.

What vaccines are available?

Three COVID-19 vaccines are currently available in Australia – AstraZeneca (Vaxzevria/Oxford) vaccine, Pfizer (Comirnaty) and Moderna (Spikevax) vaccine**. All of these are suitable for rheumatology patients whose immune system may not be strong.** The AstraZeneca vaccine is a viral vector vaccine. The Pfizer and Moderna vaccines use messenger RNA (mRNA).

The COVID-19 vaccines available in Australia are safe for people with arthritis and people taking drugs that suppress the immune system, even if the condition is active. This is because none of these is a "live" vaccine.

Which vaccine should I have?

The Australian Technical Advisory Group on Immunisation (ATAGI) currently recommends the use of the Pfizer or Moderna vaccine over the AstraZeneca vaccine in people aged 12-60 years.

The AstraZeneca vaccine can be used in adults aged 18-60 years where the benefits are likely to outweigh the risks for that individual and the person has made an informed decision based on an understanding of the risks and benefits.

People over the age of 60 can receive any of the COVID-19 vaccines (provided that they don't have the conditions listed below) as the benefits of the AstraZeneca vaccine continue to outweigh the risk of adverse effects in this age group.

The Pfizer or Moderna vaccines are the preferred vaccine in patients with: a history of cerebral venous sinus thrombosis (CVST), a past history of heparin-induced thrombocytopenia (HIT), a past history of idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis and antiphospholipid syndrome with thrombosis.

People who have had their first dose of the COVID-19 AstraZeneca vaccine without any serious adverse events or allergic reactions can safely be given their second dose. This includes adults under the age of 60.

The Pfizer and Moderna vaccines should not be given if you have had a serious adverse event (including myocarditis and/or pericarditis) or an allergic reaction to a previous dose. In some people with rare inflammatory heart disorders (e.g., recent or current myocarditis, endocarditis,

pericarditis or rheumatic fever) or severe heart failure, the mRNA vaccines (Moderna and Pfizer) may not be suitable. Discuss with your specialist if you have concerns. Note that the mRNA vaccines are safe to use in people with most common forms of heart disease (including angina or a history of heart attacks).

When will people with rheumatology conditions receive the vaccine?

In Australia anyone aged ≥12 years can now receive the vaccine.

Protection from COVID-19

All the vaccines are very good at stopping severe symptoms and hospitalisation caused by COVID-19 after 2 doses.

All the vaccines require a second dose:

- AstraZeneca usually 4-12 weeks after the first dose.
- Pfizer vaccine usually 21 days after the first dose.
- Moderna vaccine usually 28 days after the first dose.

The first dose does provide some protection. The second dose gives more long-term protection from COVID-19.

What is a third primary dose and how is it different to a booster dose?

A third primary dose is usually given 2-6 months (28 days can be considered in exceptional circumstances) after the second dose in people who may not have had a strong immune response to the 2 initial doses due to their medical conditions and/or medications. This third primary dose "completes the primary course" for these people. Some people with AIRD on immunosuppressant therapy will fall into this category.

A third primary dose is different to a booster dose. A booster dose refers to an additional vaccine dose after the primary vaccine course is complete which for most people is 2 doses. This is usually given 6 months after the second dose.

At this stage there are no recommendations for booster doses for people who receive a third primary dose as part of their primary vaccine course, however this may change with time as more information is available.

Do I need a third primary dose?

Not all people with rheumatological diseases will need a third dose, however ATAGI are recommending a third dose for people who might not have had a complete response to the first two doses due to the use of the following immunosuppressive therapies:

- High dose corticosteroid treatment equivalent to >20mg/day of prednisone for ≥14 days in a month, or pulse corticosteroid therapy
- Multiple immunosuppressants where the combination is considered to be severely immunosuppressive
- At least one of the following conventional synthetic DMARDs:
    - methotrexate (≥10mg/week)
    - leflunomide
    - mycophenolate
    - azathioprine (≥1mg/kg/day)
    - cyclosporine
    - cyclophosphamide
    - tacrolimus
- At least one of the following biological or targeted synthetic DMARDs:
    - janus kinase (JAK) inhibitor (for e.g., baricitinib, tofacitinib, upadacitinib)

- abatacept
- rituximab

Some other treatments or combinations of treatments and/or conditions might also qualify for a third vaccine dose - ask your specialist if you are uncertain.

- Pfizer or Moderna are preferred for the third dose however you can receive AstraZeneca for your third dose if you have already been vaccinated with AstraZeneca or if you have had a significant adverse reaction after a previous Pfizer or Moderna dose.
- The third dose is usually given 2-6 months after the second dose of vaccine (28 days can be considered in exceptional circumstances).
- Talk to your rheumatologist about the timing of your medicines around your third primary dose as you did with the previous doses.

The ATAGI recommendations can be found here; https://www.health.gov.au/news/atagi-statement-on-the-use-of-a-3rd-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised

Will the drugs that I take for my condition affect the way the vaccine works?
Some people who are taking drugs that suppress the immune system may be given advice to continue avoiding exposure to COVID-19 after they have had the vaccine. This is because their medications could mean their immune system does not respond as strongly to the vaccine as people who don't take these drugs. **This does not mean you should stop your treatment, because this can result in a flare of your condition which puts you at greater risk from COVID-19.** Everyone in Australia will need to follow Government advice on reducing the spread of COVID-19, even after they have had the vaccine.

Can I have other vaccines (e.g. influenza vaccine) at the same time as the COVID-19 vaccine?
The administration of any other vaccine on the same day as the COVID-19 vaccine is generally not recommended. The preferred minimal interval between the COVID-19 vaccine and the influenza vaccine is 7 days (previously 14 days). In some situations a shorter interval is acceptable (including co-administration) You do not need to delay your influenza vaccine until you complete the course of two COVID-19 vaccines.

Should I delay my rituximab treatment so that I can have the COVID-19 vaccine?
To ensure the best response to the COVID-19 vaccine, it is recommended that vaccination is performed towards the end of a rituximab dosing cycle or before initiation of rituximab therapy. Please discuss the timing with your rheumatologist.

Should I continue to take methotrexate when I have the COVID-19 vaccine?
There is some evidence that responses to the COVID-19 vaccine are reduced in people treated with methotrexate. Therefore, interruption of methotrexate therapy during COVID-19 vaccination may be considered, but only in patients with stable rheumatic disease at low risk of flare, or those for whom protection from COVID-19 is of particular importance. **This decision to hold methotrexate for one or two doses following each vaccination should be individualised and discussed with your treating rheumatologist.**

More information on the use of other immunomodulatory medicines with the COVID-19 vaccine is available here: https://drive.google.com/file/d/16uiV5Ug51NiuPi5m1ToIsXMfrhxbqgFX/view

Can I have denosumab (Prolia) at the same time as the COVID-19 vaccine?
There is currently no evidence to support separating the doses of denosumab and the COVID-19 vaccine. If they are to be given on the same day, it would be advised to use different injection sites for to minimise the possibility of an injection site reaction.

Can I have surgery after having the COVID-19 vaccine?

Surgery guidelines recommend people do not have major surgery and vaccines within one week of each other. This is because both surgery and the vaccine can cause a fever.

Can I have the COVID-19 vaccine if I am pregnant or breastfeeding?

The Australian Government recommends the use of either the Pfizer or Moderna vaccine in pregnant women at any stage of their pregnancy. This is because the risk of severe outcomes from COVID-19 is significantly higher for pregnant women and their unborn baby. Women who are trying to become pregnant do not need to delay vaccination or avoid becoming pregnant after vaccination. More information can be found here;
https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021

All 3 vaccines can be given to women who are breastfeeding. **Breastfeeding women do not need to stop breastfeeding to receive the vaccine.** More information can be found here; https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/News/RANZCOG-ABA-NZBA-COVID-19-vaccination-and-breastfeeding-infographic-final.pdf You can talk to your midwife and/or rheumatology healthcare team if you are not sure what to do.

Can children have the COVID-19 vaccine?

All children ≥ 12 years are eligible to receive the COVID-19 vaccine. Only the Pfizer and Moderna vaccines are approved for use in children ≥12 years. More information can be found here: ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia | Australian Government Department of Health

Are there any side effects?

Some people will get mild side effects. These can include pain where the injection goes in, tiredness, headache and aching of muscles. Serious reactions like allergic reactions are extremely rare. People with a history of severe allergic reactions can be vaccinated but should be monitored for 30 minutes after receiving the vaccine. If you have any concerns about the vaccine, ask your doctor, nurse or pharmacist.
You should seek medical advice as soon as possible if:

- You have any of the following symptoms, particularly around 4 to 42 days after vaccination with AstraZeneca: headache that persists beyond 48 hours after vaccination or appears later than 48 hours after vaccination. Simple painkillers may alleviate headache initially, but it persists, blurred vision, weakness of face or limbs, confusion or seizure, shortness of breath, chest pain, persistent abdominal pain, leg swelling or a pin-prick rash or bruising not at the injection site that cannot be explained.
- You experience chest pain, pressure or discomfort, irregular heartbeat, skipped beats or 'fluttering', fainting, shortness of breath or pain when breathing after the Pfizer or Moderna vaccine.

If I didn't have a side effect does this mean that the vaccine didn't work?

Not everybody will have side effects from the COVID-19 vaccine. If you don't get any side effects this does not mean that the vaccine did not work.

What about reports of blood clots (thrombosis) with the AstraZeneca vaccine?

ATAGI and the Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ) released a statement on the 23 May 21 regarding thrombosis with thrombocytopenia syndrome (TTS) with the AstraZeneca vaccine. This statement outlines that there is unlikely to be an increased risk of TTS in people with the following conditions, and people in these groups can receive the AstraZeneca vaccine:

- History of blood clots in typical sites
- Increased clotting tendency that is not immune mediated

- Family history of blood clots
- History of ischaemic heart disease or stroke
- Current or past thrombocytopenia (low platelet count)
- Those receiving anticoagulation therapy (for e.g. apixaban, dabigatran, rivaroxaban, warfarin)

However, if you have a history of; CVST, HITT, idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis and antiphospholipid syndrome with thrombosis, the Pfizer or Moderna vaccine is recommended.

TTS can now be treated very effectively. Due to better awareness, early diagnosis and appropriate treatment, the outcome and prognosis of the majority of those who have experienced this syndrome is good. More information can be found here; https://www.health.gov.au/news/joint-statement-from-atagi-and-thanz-on-thrombosis-with-thrombocytopenia-syndrome-tts-and-the-use-of-covid-19-vaccine-astrazeneca

Should I take aspirin before having my COVID-19 vaccine to reduce my risk of getting blood clots?
There is no evidence that taking low-dose aspirin before having a COVID-19 vaccine will reduce your risk of blood clots.

What should I do if I take "blood thinners"?
Continue to take your medicines as prescribed by your doctor. There is no reason to stop or change your dose of blood thinners before the COVID-19 vaccine.

Do you still need to have the vaccine if you have had COVID-19?
It is possible for people who have already had COVID-19 to have the vaccine for it. It is not known yet how long the antibodies made by your body in response to COVID-19 last, so a vaccine could offer more protection or boost any antibodies your body has already made.

Please encourage your household members and other close contacts to have the COVID-19 vaccine once they are eligible as this may offer you further protection from getting COVID-19. This is known as the "ring" vaccination concept.

An Australian Government COVID vaccine fact checker is available at;
https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true

More information for your treating doctors can be found here.
https://drive.google.com/file/d/16uiV5Ug51NiuPi5m1ToIsXMfrhxbqgFX/view
https://app.magicapp.org/#/guideline/LqRV3n/rec/EZ6z8E/practical
https://www.health.gov.au/news/atagi-statement-on-the-use-of-a-3rd-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised

The ARA will update this advice as new information becomes available.