

Vaccinations for patients (>18 years) with autoimmune inflammatory rheumatic diseases (AIIRD) in Australia General Practitioner and Allied Health Professional information

Key Points

- Vaccination and immunity status should be reviewed and addressed prior to commencement and escalation of immunosuppressive therapy and reviewed annually.
- Live vaccines are generally contraindicated in significantly immunosuppressed patients due to possible vaccine-induced infection.
- All patients presenting for a live vaccine should be checked for coexistent immunosuppressive therapy.
- Inactivated vaccines are safe, but vaccine effectiveness may be reduced by immunosuppression and active disease.
- Despite lower post-vaccination antibody titres in the setting of immunosuppression, these are usually adequate for clinical protection, and so the risk-benefit ratio of vaccination in this context is usually favourable.

Available live vaccinations

Varicella Zoster

- Please see below for information on the inactivated varicella zoster vaccine, Shingrix
 which is now available on the National Immunisation Program (NIP) and the preferred
 vaccine for people on immunosuppressive therapy as it can be administered regardless
 of current immunosuppressant medicines.
- The live varicella zoster vaccinations are Varivax and Varilrix which are low-dose formulations approved for vaccination against varicella (chicken pox) in the paediatric and adult population.
- It is advisable to assess varicella zoster status in immunosuppressed patients prior to vaccination. If serological evidence of previous varicella zoster infection is absent, vaccination with the lower dose live varicella vaccine (Varivax and Varilrix) to prevent chickenpox may be considered after assessment of level of immunosuppression please see below (two doses, > 4-8 weeks apart for Varivax and > 6 weeks apart for Varilrix in those aged ≥13 years).
- Varicella Zoster vaccination (Varivax and Varilrix) is recommended to be given at least one month before treatment starts with b/tsDMARDs.
- Zoster vaccination is NOT contraindicated if the patient is taking any ONE of the following: low dose glucocorticoids (equivalent to prednisolone ≤20mg/day) or the following conventional synthetic DMARDs (csDMARDs): hydroxychloroquine, sulfasalazine, methotrexate (≤0.4mg/kg/week) and azathioprine (≤3mg/kg/day). These medicines do not need to be stopped/withheld if a zoster vaccine is administered. If the patient is taking a combination of any of the above medicines, seek rheumatologist advice. There is no consistent advice on whether Varicella Zoster vaccine is safe for people taking leflunomide.
- While data is lacking, b/tsDMARDs should be stopped prior to administration of a live vaccine. Seek rheumatologist advice regarding the number of doses to be missed and when to recommence b/tsDMARD. Regardless, patients should be advised to seek prompt

- medical attention for possible anti-viral therapy should they develop symptoms of a viral illness following a live vaccine.
- If immunosuppressed patients who are not immune to varicella-zoster virus are exposed to it, post-exposure prophylaxis should be considered. This may require discussion with an infectious diseases physician.

Measles, mumps and rubella (MMR)

- MMR-containing vaccines are contraindicated in people receiving high-dose systemic <u>immunosuppressive therapy</u>, including b/tsDMARDs and high dose oral glucocorticoids (equivalent to prednisolone >20mg/day).
- Those only mildly immunosuppressed (including those receiving selected csDMARDs in low doses, either on their own or in combination with low-dose glucocorticoids, as per doses listed above) may be able to receive the MMR vaccine on advice from an infectious diseases specialist or rheumatologist after a thorough risk-assessment on a case-by-case basis.
- Post-exposure prophylaxis for non-immune exposed immunosuppressed adults should be considered.

Bacillus Calmette Guerin (BCG)

• As this vaccine is a live formulation, it is not recommended in the setting of immunosuppression.

Available inactivated vaccinations

For information on COVID-19 vaccination for AIIRD patients see here.

Influenza vaccines

- Immunosuppressed patients should receive the influenza vaccine annually.
- Immunosuppressed patients with AIIRD who receive the influenza vaccine for the first time may benefit from receiving two doses ≥4 weeks apart, and one dose annually thereafter.
- If a new influenza virus is detected (e.g., during a pandemic), people who are immunosuppressed should receive 2 doses of influenza vaccine, ≥4 weeks apart, regardless of previous influenza vaccine.

Pneumococcal vaccines

- Immunosuppressed patients should receive 13vPCV (Prevenar 13), followed by the PPV23 (Pneumovax) >2 months later. An additional PPV23 dose should be given ≥5 years later.
- If immunosuppressed patients have previously received PPV23, 13PCV should be given ≥12 months later. This "prime and boost" strategy uses both pneumococcal vaccines, thus providing broader protection.

Varicella Zoster vaccine - Shingrix

- Shingrix is an inactivated varicella zoster vaccine available in Australia.
- Shingrix is the preferred vaccine for people on immunosuppressive therapy as it can be administered regardless of current immunosuppressant medicines.
- From 1 Sept 2024, it is covered on the NIP for the prevention of shingles and postherpetic neuralgia for the following groups:
 - o People aged ≥ 65 years
 - o First Nations people aged > 50 years
 - o Immunocompromised people aged ≥18 years and older who are at increased risk of herpes zoster which includes who are currently taking or have taken within the last 6 months:
 - Conventional immunosuppressive agents e.g. high-dose methotrexate <u>></u>20 mg per week (oral and subcutaneous), azathioprine <u>></u>3mg/kg/day
 - Biologic therapies e.g. tumour necrosis factor inhibitors (TNFi), t-cell costimulation modulators e.g. abatacept, interleukin inhibitors
 - Oral small molecule targeted therapies e.g. JAK inhibitors.
 For the full list of medications, please see: <u>NIP Shingrix Vaccination</u>
 Factsheet.
- For immunocompromised people aged ≥18 years and older, a 2-dose vaccination schedule administered 1-2 months apart is recommended.
- For people aged ≥ 65 years and First Nations people aged ≥ 50 years, a dosing schedule
 2-6 months apart in immunocompetent people is recommended.
- The need for booster doses has not been established.

Diphtheria, tetanus and pertussis

- No previous history of dT vaccination: 3 doses of dT vaccine, at least 4 weeks between doses. 1st dose preferably dTpa. Booster doses at 10 and 20 years after primary course.
- Adults >50 years without a booster dose of diphtheria and tetanus toxoid in the preceding 10 years should receive the dTpa (diphtheria-tetanus-pertussis acellular) preparation.

Hepatitis B (HBV)

- All patients with AIIRD should be screened for HBV (anti-HBs AND anti-HBc) before immunosuppression.
- Vaccination should be considered in immunosuppressed patients with inadequate immunity (anti-HBs <10mIU/mL).
- Vaccination should be administered at months 0,1 and 6, with measurement of blood HBsAb 4-8 weeks after the last dose.
- Booster doses of hepatitis B vaccine are recommended for the immunosuppressed. Monitor the person's levels of antibody to hepatitis B surface antigen every 6–12 months and give a booster dose when needed.

Human papilloma virus

- A 3-dose schedule of 9vHPV vaccine is recommended for people who are immunosuppressed, regardless of their age when they started vaccination. This is because their immune response is likely to be lower than healthy people. They are also more likely to develop a persistent HPV infection and HPV-related disease.
- The decision to vaccinate those with AIIRD should consider the likelihood of previous exposure to HPV, the future risk of HPV exposure, the extent/duration of immunosuppression and cost, as this indication is not currently funded under the PBS.

Travel vaccination

This is a complex area and often requires specialist input to determine the risk/benefit based on travel itinerary, rheumatological diagnosis and immunosuppression.

Cholera

The Dukoral vaccine is inactivated and should be considered in the immunosuppressed as they have a higher risk of diarrhoeal disease.

Hepatitis A

Pre-travel vaccination (2 doses, 6 months apart) should be considered in all immunosuppressed patients.

Meningococcal B

Pre-travel vaccination with the inactivated meningococcal B vaccination (Bexsero or Trumenba) should be considered in highly immunosuppressed patients and travellers. The live vaccine is contraindicated in the immunosuppressed.

Polio

One booster vaccination with inactivated polio vaccine (Ipol) is advised in adulthood, if travelling to an at-risk destination and not already received.

Sabin is a live attenuated vaccine and contraindicated in the immunosuppressed.

Typhoid

The parenteral inactivated polysaccharide vaccine should be considered prior to travel to endemic areas.

The oral live vaccine is contraindicated in the immunosuppressed.

Yellow Fever

This is a live vaccine and contraindicated in immunosuppressed patients. Seek specialist advice if patients are planning travel to a high-risk area. Some countries require evidence of Yellow Fever vaccination prior to entry.

Vaccinations in infants born to mothers who received b/tsDMARDs in pregnancy

- All b/tsDMARDs except certolizumab are likely to be transmitted to the infant in utero.
- The safety of live vaccines in infants exposed to b/tsDMARDs or thiopurines in utero or through breast milk is unclear. Inactivated vaccines should be given according to the National Immunisation Program (NIP).
- The rotavirus vaccine is the only live vaccine routinely administered to infants <12 months old. Recent updates confirm rotavirus vaccine can be given to babies of mothers taking TNFi's* during pregnancy and/or in the first 6 months of life.
- The likelihood of rotavirus infection is less in infants > 6 months old, so "catch-up" dosing is probably not required if the vaccine was not given in the first 6 months of life.

*TNFi's include adalimumab, certolizumab, etanercept, golimumab and infliximab.

Household contacts of immunosuppressed patients

Immunocompetent household members of patients with AIIRD should be encouraged to receive vaccines according to national guidelines. Immunosuppressed patients should avoid handling nappies of infants vaccinated against rotavirus for 4 weeks following administration of this vaccine.

Useful references:

https://www.health.gov.au/initiatives-and-programs/national-immunisation-program

https://www.health.gov.au/health-topics/immunisation

https://immunisationhandbook.health.gov.au

Wong PKK, Young L, Johnson DF. **Vaccination of patients with autoimmune inflammatory rheumatic disease.** Medicine Today 2019; 20(7): 50-53.

Wong PKK and Johnson DF. Live vaccinations and immunocompromised patients. How can GPs ensure this cohort is safely protected against disease? Medical Observer, 14th August 2019.

Furer et al. **2019 update of EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases.** Ann Rheum Dis 2020;79:39-52.

Glossary

AIH	Australian Immunisation Handbook 2022
AIIRD	autoimmune inflammatory rheumatic disease
bDMARDs	biologic disease modifying antirheumatic drugs
"Catch-up"	The process of planning and scheduling vaccines for people who have missed 1
vaccination	or more doses of scheduled vaccines
csDMARDs	conventional synthetic disease modifying antirheumatic drugs
Immunocompetent	Having a normal immune response
Immunocompromised	Having an immune system that is weakened and unable to protect the body
	from disease. It can be caused by disease or some medicines
Immunosuppressed	A state in which the immune system is suppressed by medicines or radiation, in
	order to prevent the rejection of grafts or transplants or to control autoimmune
	diseases.
Immunosuppressive	Medicines used to treat certain conditions, but that also weaken the immune
therapy	system, e.g. oral corticosteroids
Live vaccine	A vaccine containing live virus or bacteria that are weakened (attenuated) to
	produce an immune response in the recipient without causing the serious
	effects of the disease
Post-exposure	Providing immunoglobulin (or sometimes vaccine) to a person exposed to an
prophylaxis	infectious agent, to prevent them developing the disease
Significantly	Includes patients on b/tsDMARDs and patients on glucocorticoids equivalent to
immunosuppressed	prednisolone >20mg/day, methotrexate >0.4 mg/kg/week and azathioprine
patients	>3mg/kg/day.
TNFis	Tumour necrosis factor inhibitors (adalimumab, certolizumab, etanercept,
	golimumab and infliximab)
tsDMARDs	targeted synthetic disease modifying antirheumatic drugs

Reference: https://immunisationhandbook.health.gov.au/technical-terms

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