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# Vaccination of immunosuppressed patients

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## CLINICAL REVIEW

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**Chronically ill patients with a weak immune system are at increased risk of severe infections, often as a result of immunomodulatory therapy rather than the underlying disease. Many patients in this group exhibit reduced vaccine responses and require tailored vaccination regimens. Following the launch of the national Adult Immunisation Programme, all doctors must stay abreast of current guidance on vaccination in immunosuppressed patients. This clinical review article summarises interdisciplinary knowledge on patients with a reduced vaccine response.**

The launch of the Adult Immunisation Programme in Norway represents a shift towards lifelong immunisation and requires general practitioners (GPs) and hospital specialists to have greater expertise in vaccinating immunosuppressed patients [\(1, 2\)](#). A functional adaptive immune system is needed for vaccination. The risk of infection increases with age, organ dysfunction and comorbidity, and is further amplified by immunosuppression due to reduced humoral and cellular immunity, impaired vaccine response and an increased risk of severe disease and death [\(3\)](#).

An increasing proportion of patients with a chronic disease or cancer, or who have undergone organ transplantation, are treated with immunomodulatory therapies that improve disease control and quality of life. However, these

medications also lead to immunosuppression, requiring additional vaccine doses or revaccination and increasing the risk of prolonged and severe infections, including influenza and pneumococcal disease (4).

This article provides a practical overview of vaccination in immunosuppressed patients, based on selected literature, national recommendations and the authors' clinical experience. Patients with primary immunodeficiency are not discussed in this article.

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## Factors that lead to variations in vaccine responses

Immunomodulatory therapy is used to treat a range of diseases and conditions, such as organ transplantation, multiple sclerosis, inflammatory bowel disease, malignant diseases, dermatological conditions and rheumatic disorders. These medications affect the immune system in different ways and can impair both the humoral (B-cell-mediated) and cellular (T-cell-mediated) immune responses. In the article, we discuss a selection of medications that are particularly relevant in clinical practice in Norway (Table 1) (5–26), but there are numerous other immunosuppressive medications that are not covered here.

Prolonged treatment with *systemic corticosteroids* ( $\geq 20$  mg prednisolone daily for  $> 2$  weeks) leads to broad immunosuppression with reduced T-cell function, antibody production and inflammatory responses. This increases the risk of opportunistic infections and impairs vaccine responses, particularly during ongoing treatment. The effect is dependent on dose and duration and is gradually reduced after discontinuation (5, 6).

*Antibodies against B cells and plasma cells* cause profound and prolonged immunosuppression. CD20 antibodies (rituximab, ocrelizumab, ofatumumab, etc.) are used in, for example, multiple sclerosis, lymphoma, transplantation and rheumatoid arthritis, and result in effective B-cell depletion with reduced or absent vaccine responses, particularly to novel antigens, although T-cell function is largely preserved (7–10). The risk of severe bacterial (pneumococci, meningococci) and viral infections is significantly increased. Toxin-conjugated antibodies targeting B-cell markers (CD79b, CD22) also reduce antibody production. Plasma cell-targeted agents (CD38 antibodies) cause similar immunodeficiency in multiple myeloma, while CD52 antibodies (alemtuzumab) affect both T and B cells (11, 12). New bispecific antibodies and T-cell-engaging antibodies against B-cell maturation antigens (BCMA), GPRC5D, CD19 and CD20 are expected to become increasingly important and may cause combined B- and T-cell failure (13, 14).

*TNF inhibitors* (e.g. infliximab and adalimumab) are used for chronic inflammatory conditions such as arthritis, spondyloarthritis, inflammatory bowel disease and psoriasis. TNF blockade suppresses T-cell and macrophage activation, granuloma formation and control of intracellular pathogens, particularly *Mycobacterium tuberculosis*. Vaccine responses are generally preserved but can be reduced when combined with other immunosuppressive

agents. The risk of infection is moderately increased, particularly for severe bacterial infections and reactivation of latent tuberculosis, while the risk of severe viral infection is lower than with B-cell-targeted therapies (15–18).

*Calcineurin inhibitors* (tacrolimus and ciclosporin) are primarily used to prevent transplant rejection and in certain autoimmune diseases. They inhibit calcium- and calcineurin-dependent T-cell activation and reduce the cellular immune response. This impairs vaccine responses and increases the risk of viral and opportunistic infections (19, 20).

*JAK inhibitors* (e.g. baricitinib and tofacitinib) are used for autoimmune diseases, myeloproliferative disorders and graft-versus-host disease following allogeneic stem cell transplantation. By blocking Janus kinase signalling pathways, they suppress cytokine-driven T- and B-cell activity, reducing vaccine responses and increasing the risk of infection, particularly herpes zoster and other severe viral infections (21).

*Complement inhibitors* that target complement protein C5 (e.g. eculizumab and ravulizumab) are used for complement-mediated diseases such as atypical haemolytic uraemic syndrome, paroxysmal nocturnal haemoglobinuria and certain autoimmune neuromuscular disorders. Treatment causes pronounced and persistent functional hyposplenism with markedly reduced bacterial clearance and is associated with a 1000–2000-fold increased risk of invasive meningococcal disease (22). Vaccination against meningococcal disease (ACWY and B vaccines) is therefore required prior to treatment, despite the significant reduction in vaccine efficacy and the risk remaining high. Patients should also be vaccinated against *Haemophilus influenzae* type b and pneumococci. Clinical vigilance for severe infection is essential during ongoing therapy.

*CAR-T cell therapy* (chimeric antigen receptor T-cell therapy) involves the genetic modification of the patient's T cells to recognise tumour antigens, typically CD19 in B-cell malignancies and BCMA protein (B-cell maturation antigen) in multiple myeloma, but it is also used in certain autoimmune diseases. The treatment can lead to long-term remission but often results in persistent B-cell aplasia, reduced antibody responses and an increased risk of severe infection, including COVID-19 (23, 24).

*Haematopoietic stem cell transplantation*, either autologous or allogeneic, is used for haematological malignancies, bone marrow failure, immunodeficiency, metabolic disorders and certain autoimmune diseases such as multiple sclerosis, systemic sclerosis and lupus. The procedure causes profound, transient immunosuppression with markedly reduced vaccine responses and high infection risk, particularly following allogeneic transplantation (25, 26).

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## Risk stratification and possible measures

The composition and intensity of immunosuppression affect both the risk of infection and vaccine efficacy. With combination therapy, high cumulative doses or recent initiation of treatment, vaccine responses are often reduced, which can require additional doses or use of adjuvanted vaccines (9, 27–31). In

some situations, such as after transplantation of solid organs or blood stem cells, postponing vaccination is recommended until the risk of rejection has decreased and the daily dose of immunosuppressive medication is lower, which can take 3–6 months.

After haematopoietic stem cell transplantation, it is also important to achieve a degree of humoral and cellular immune reconstitution. Clinical experience and established guidelines indicate that some patients can achieve adequate protection with additional doses, but this must be assessed on an individual basis (32, 33). The goal is to ensure optimal vaccine protection while maintaining patient safety (Table 2) (2, 11, 18, 32, 34–36). A multidisciplinary approach involving infectious disease specialists, rheumatologists, neurologists, haematologists and other relevant specialists is important to ensure optimal timing and follow-up of vaccination.

The need for vaccination must be balanced against the need for prompt initiation of treatment. Whenever possible, vaccination should be completed before starting immunosuppressive therapy, ideally at least 2–4 weeks beforehand to enable an optimal immune response. When deciding whether to vaccinate a patient prior to starting treatment, the need for immunomodulatory therapy must be weighed against the risk of infection. Live attenuated vaccines are generally contraindicated during and immediately after immunosuppressive therapy due to the risk of vaccine-associated infection (34).

Revaccination or booster doses of previous vaccines may be necessary during and after treatment with, for example, B-cell- or plasma cell-targeted antibodies, or following stem cell transplantation, due to reduced or lost vaccine efficacy (12, 32, 33, 35). Vaccination of close contacts is recommended in selected groups to provide indirect protection to the patient, particularly against infections with a high transmission risk, such as influenza and COVID-19 (36).

Post-vaccination antibody testing (e.g. hepatitis B, COVID-19 and varicella) can be carried out to assess the need for additional doses. However, it is important to note that vaccine efficacy should not be evaluated solely on the basis of humoral responses, since cellular (T-cell) immunity may be preserved even when antibody levels are reduced (7, 37, 38).

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## Other vaccines of importance

In addition to the vaccines included in the Adult Immunisation Programme, there are several other vaccines that may be relevant for immunocompromised patients (2, 11, 12, 18, 32, 34–36) (Table 3). For example, booster doses of the primary vaccine against diphtheria, tetanus, pertussis and polio (DTP-IPV vaccine) are recommended every 10 years. Patients receiving immunosuppressive therapy in particular should be considered for boosters, as even moderate impairment of the immune system can increase the risk of a severe disease.

The measles, mumps and rubella (MMR) vaccine should be offered to adults born after 1960 who are not fully vaccinated, especially those planning pregnancy, working in health care or travelling to high-incidence areas (36). In immunosuppressed patients, live vaccines (e.g. varicella vaccine and MMR vaccine) are contraindicated, but assessing vaccination status and, where appropriate, vaccinating close contacts is important for indirect protection. Herpes zoster occurs more frequently and with greater severity in older adults and people with a weakened immune system (39). New, non-live recombinant vaccines provide an opportunity for safe and effective prevention for many in this patient group. International guidelines recommend systematic assessment of vaccination in older and immunosuppressed people (40).

Other vaccines may be relevant in selected risk groups (2). The hepatitis B vaccine is recommended for patients receiving blood products or with an increased risk of exposure (41). The meningococcal vaccine is relevant for patients with anatomical or functional hyposplenism, complement deficiencies or when using complement C5 inhibitors such as eculizumab (42). The varicella vaccine can be considered in adults without prior infection before initiation of – or after completion of – immunosuppressive therapy (43). Vaccination against human papillomavirus (HPV) should be considered following haematopoietic stem cell transplantation, particularly in women under the age of 45 (44).

Overall, we believe that the assessment of vaccination status in immunosuppressed patients should be broad and systematic and not limited to the vaccines included in the Adult Immunisation Programme (Table 4) (2, 11, 18, 32, 34–36). A systematic approach to additional vaccines can prevent severe infections, reduce complications and improve patient safety for this vulnerable group.

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## Division of responsibilities and coordination

Following the launch of the Adult Immunisation Programme, vaccination is now an established part of the health service's core remit and requires structured coordination between primary care and the specialist health service. Primary care has overall responsibility for the administration of vaccines, while the specialist health service, in selected cases, performs risk assessments and provides treatment-related vaccine advice for patients at increased risk of infection. Coordination between primary care and the specialist health service is crucial for ensuring appropriate prioritisation and vaccination practices.

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