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ATAGI targeted review 2025: Immunisation considerations for immunocompromised people in Australia

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Contents

Review article

Abstract

Vaccination plays a pivotal role in protecting people who are immunocompromised, and who may therefore be at increased risk of infectious diseases, including vaccine preventable diseases (VPDs). However, there are special challenges in clinical practice and the development of immunisation policies to accurately address the vaccination needs of this heterogeneous population. This review aims to highlight the immunisation needs and challenges of immunocompromised populations, and to summarise the rationale behind the immunisation recommendations for these populations in Australia.

The chapter *Vaccination for people who are immunocompromised*, in the Australian Immunisation Handbook, was recently updated by the Australian Technical Advisory Group on Immunisation (ATAGI). The updated chapter introduces new categorisation and risk classification for various types of immunocompromise, alongside the principles of immunisation. When planning immunisation for immunocompromised people, it is crucial to consider their underlying diagnoses, exposure to immunosuppressive therapies, susceptibility to VPDs, and their immune response to vaccination. Strategies to improve protection for immunocompromised persons include booster doses or altered schedules of routine vaccines; additional vaccines to prevent specific VPDs; and complete revaccination following immune reconstitution. Several national and jurisdictional vaccination programs have been implemented for immunocompromised populations (alongside other priority populations); however, monitoring vaccine coverage in these groups is challenging, and strategies to improve coverage are needed.

There are significant evidence gaps in vaccine research for immunocompromised people, particularly regarding the optimal timing and scheduling of vaccinations to ensure maximum efficacy and safety. Future research should prioritise the inclusion of immunocompromised people in clinical trials and should integrate evidence from post-licensure use through data linkage. Emerging vaccine technologies may enable the development of more immunogenic vaccines or may offer more effective vaccination strategies for better protection against VPDs in immunocompromised people.

Keywords: immunocompromise; vaccine-preventable diseases; immunisation programs; inborn errors of immunity; immunosuppressive medication; Australian Technical Advisory Group on Immunisation (ATAGI)

Introduction

Immunisation plays a pivotal role in preventing infectious diseases and safeguarding public health. People who are immunocompromised often require tailored vaccination strategies, due to their increased susceptibility to vaccine-preventable diseases (VPDs), the potential for reduced immune responses to vaccination, and safety concerns from live vaccines. The coronavirus disease 2019 (COVID-19) pandemic, caused by the SARS-CoV-2 virus, highlighted the importance of modifying standard vaccination protocols to address the needs of individuals with various immunocompromising conditions.[1]

Assessing the vaccination needs of immunocompromised people requires specific considerations. Firstly, there is a diverse range of conditions that can cause immunocompromise, including inborn errors of immunity (IEI, sometimes referred to as 'primary immunodeficiencies') and acquired immunocompromise secondary to immunosuppressive medications or medical conditions (e.g. cancer, organ transplant or stem cell transplant). Secondly, determining the level of immunocompromise and susceptibility to specific VPDs is challenging, as these risks vary based on the underlying diagnoses, comorbidities, and exposure to immunosuppressive therapies, which may have cumulative immunosuppressive effects. Thirdly, live attenuated vaccines may pose safety risks to severely immunocompromised individuals, due to their potential to cause serious adverse events such as disseminated infection by the vaccine virus/bacterium. Finally, although non-live vaccines are safe to administer to immunocompromised people, the vaccine-induced immune response may be diminished; and in some cases, additional doses may be recommended to achieve or maintain immunity.

The Australian Technical Advisory Group on Immunisation (ATAGI) is committed to the ongoing development of immunisation guidance for healthcare providers caring for people with immunocompromise. In recent years, ATAGI has provided specific recommendations on the use of various vaccines for populations with diverse immunocompromising conditions, such as for vaccines against COVID-19, herpes zoster and respiratory syncytial virus (RSV) disease. In 2025, the Australian Immunisation Handbook chapter, *Vaccination for people who are immunocompromised*, was updated to provide improved clarity and additional guidance on the safe and effective use of vaccines in immunocompromised people.[2]

The chapter consolidates guidance on categorisation and risk classifications among various immunocompromising conditions and principles of vaccine recommendations for immunocompromised people. The updated chapter also includes new immunisation guidance on IEI and novel biological immunosuppressive therapies. These recommendations are informed by the best available evidence that has been systematically identified, alongside expert clinical consensus where evidence remains limited.

The aim of this targeted review is to highlight the needs and challenges of immunising immunocompromised people in Australia. It summarises the rationale that underpins the ATAGI recommendations for these populations and outlines research gaps and future directions.

Vaccine-preventable diseases among immunocompromised people in Australia

Epidemiology of immunocompromising conditions

Immunocompromise can arise from a broad range of diseases and therapies, some of which are frequently under-detected (e.g. IEI). Immunocompromise may occur as a temporary or permanent state, and its severity (from clinically insignificant to severe) is influenced by many factors that may co-exist, such as age, comorbidities, and exposure to multiple immunocompromising medications. Accurately estimating the national prevalence of immunocompromise is therefore challenging, as this heterogeneous group is not easily categorised and measured at a population level. For example, the Australian Burden of Disease study (ABDS)[3] captures data on various conditions separately (e.g. cancer, autoimmune/inflammatory disorders, rheumatic diseases), and these data have not been aggregated in the context of immunocompromise.

Common immunocompromising conditions include inflammatory conditions (such as autoimmune or rheumatic diseases) and malignancies. For both groups, an upward trend in their population prevalence has been recorded over recent years.[4,5] The estimated incidence of cancer in Australia is around 500 per 100,000 persons per year,[5] whilst the use of conventional and biological disease-modifying anti-rheumatic drugs (DMARDs) in Australia increased by 74% from 2004 to 2014.[6]

Data on rare disorders (including many IEI disorders) are limited, as they are more difficult to define and detect. The prevalence estimates of IEI in the literature vary widely depending on the setting and definition being used, ranging from 1 in 100,000 to 1 in 100 persons.[7,8] Earlier data from Australian patient registry cross-sectional surveys reported rates of IEI of 2.1 per 100,000 persons in 1997 and 5.6 per 100,000 persons in 2007.[9,10]

Risk of vaccine-preventable disease in immunocompromised people

There is a higher incidence of many VPDs, including influenza, COVID-19, pneumococcal disease, human papillomavirus (HPV) disease and herpes zoster, among immunocompromised individuals compared with those without immunocompromise.[11–14] In addition, these VPDs tend to cause more severe outcomes and complications in immunocompromised people.[11]

In Australia, specific data are lacking on the burden of VPDs and vaccine coverage among people who are immunocompromised. While there are limited additional data on immunocompromising conditions within routine administrative records or standard health surveys, interpreting and utilising these data could be challenging without sufficient clinical details. Examples such as the Australian Immunisation Register (AIR) and National Notifiable Diseases Surveillance System (NNDSS) do not adequately collect and track information on specific underlying medical conditions that are sufficient to define immunocompromise. Those important details include the severity and duration of underlying disease or medication exposure, as well as specifics around any prescribed (or co-prescribed) immunosuppressive therapies.

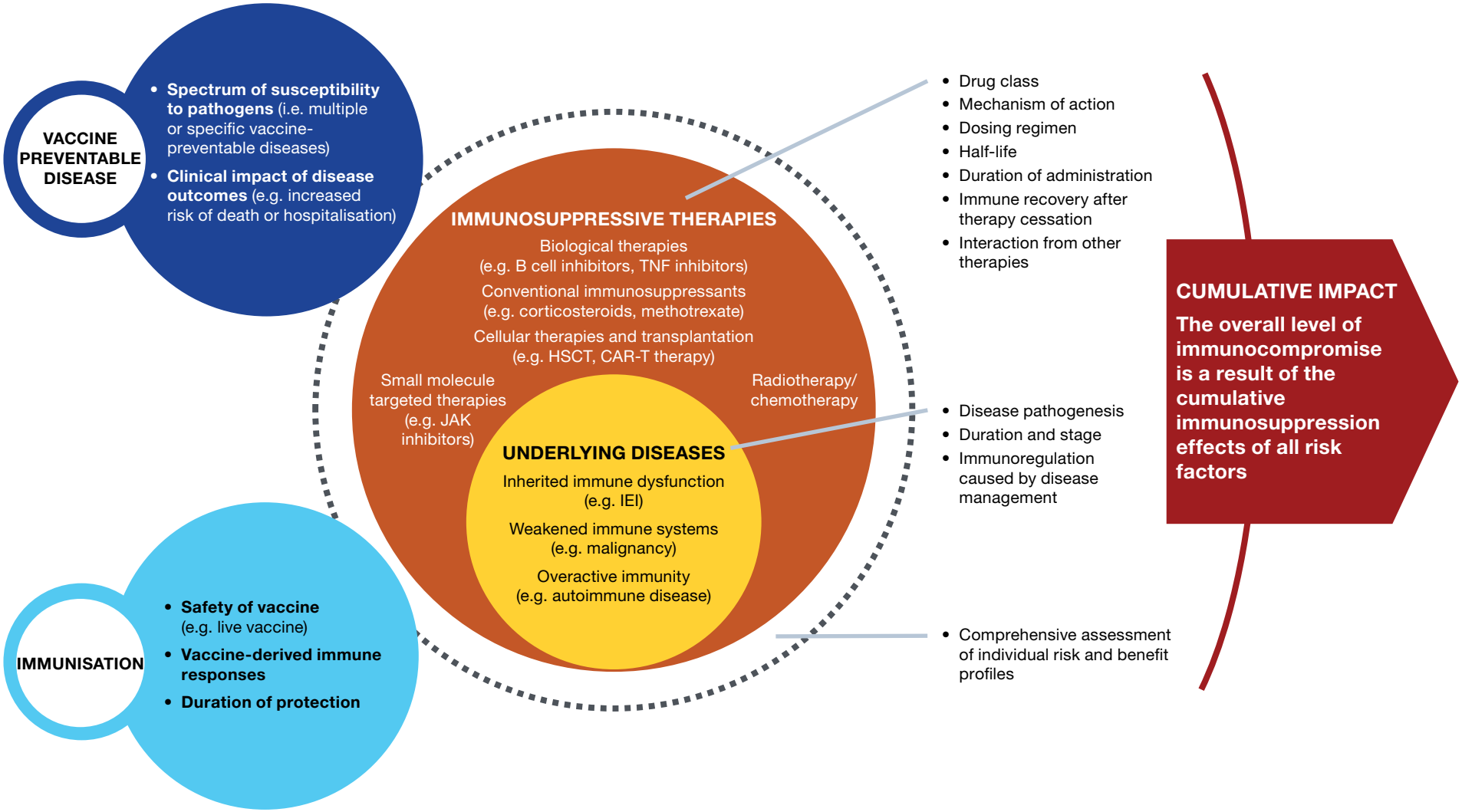
Timely integration of existing population datasets, such as linking the Australian Immunisation Register with other health datasets (e.g. the Person Level Integrated Data Asset and the National Health Data Hub), may inform future vaccine policy development and immunisation program evaluation. Importantly, the integrated dataset should be a live, easily accessible resource that allows real-time monitoring and analysis, enabling providers to make informed decisions for immunocompromised patients. Although data linkage initiatives can help address the current surveillance gaps, there are challenges in implementing them. These may include issues related to data governance, privacy and consent; variability in data quality and completeness across sources; delays in data availability; and the technical and resource requirements needed to establish and maintain timely analyses.

Immunocompromise risk categorisation

Challenges in estimating level of immunocompromise

There is evidence to suggest that generally, the more severe the immunosuppression, the higher the infectious disease risk, and the lower the vaccine-induced immunity following immunisation in immunocompromised people.[15] Of note, these levels of risk are not uniformly distributed, but instead can vary across a wide spectrum, since various diseases and therapies influence different components of the immune system. Clinicians frequently need to consider the cumulative effect of multiple concomitant immunosuppressive conditions or therapies for an individual patient at a certain timepoint.[16] It is crucial to highlight the heterogeneity that exists even within the same immunocompromising condition, based on the stage and severity of the disease; on the use of immunosuppressive therapies; and on any comorbidities. For example, an autoimmune disease may be subclinical and may not require any immunosuppressive therapy (leaving a person unlikely to be particularly immunosuppressed). Conversely, it may cause significant disease that requires multiple concurrent immunosuppressive medications to control, resulting in significant immunocompromise, which could be driven both by immune dysregulation from the underlying disease and by the impact of concurrent therapies. The levels of immunocompromise risk, therefore, vary from person to person, resulting in various levels of risk of VPDs, influenced by the characteristics of the pathogen, the individual risk of exposure to VPDs, and other environmental factors (Figure 1). The diversity within immunocompromised populations complicates the generalisation of findings from one group to another, making it challenging to draw appropriate comparisons for levels of risk.

Figure 1: The overarching factors and considerations when assessing the level of immunocompromise during immunisation decision-making[a]



a HSCT: haematopoietic stem cell transplant; IEI: inborn errors of immunity; JAK: Janus kinase inhibitor; TNF: tumour necrosis factor; CAR-T: chimeric antigen receptor T cell.

ATAGI risk categorisation of immunocompromising conditions

To date, there is no universally accepted risk categorisation or well-documented rationale to guide immunisation providers in determining the level of immunocompromise among diverse populations. However, some general principles can be applied, as summarised in Figure 1. The key considerations are the likelihood that each condition and/or therapy may increase a person's susceptibility to a VPD or may diminish the vaccine-induced immune response.[17]

Based on the best available evidence and utility of guidance for clinical practice, ATAGI has classified various primary and secondary immunodeficiencies into three categories: mild, moderate and severely immunocompromised. The types of immunocompromise are considered as severe if they have a broad and extensive suppression of the immune systems, exhibiting a high risk of infections across a wide range of VPDs. Live vaccines are contraindicated in people who are severely immunocompromised because of the potential safety concerns. Mild to moderate immunocompromise are those conditions or medications which cause partial or specific reduction in immune function or which lead to a small to moderate risk of infections. The full list of conditions and therapies categorised by their immunocompromising potential are included in the Australian Immunisation Handbook chapter, *Vaccination for people who are immunocompromised* and its associated resources.[2]

Immunisation for people who are immunocompromised

Vaccine safety considerations

Generally, non-live vaccines are safe to be given to immunocompromised people, since the ingredients in the vaccine do not pose a risk of disseminated infection (as evidenced by clinical reviews and long-standing post-licensure safety data).[18] For many severely immunocompromising conditions, live vaccines are contraindicated because rare but serious adverse events, including disseminated infections from uncontrolled vaccine virus or bacteria replication, have been reported in case series and pharmacovigilance data.[19–21]

However, increasing evidence from observational and post-marketing safety studies shows that most live vaccines, such as those for varicella-zoster and yellow fever, are well tolerated in people with mild-to-moderate immunocompromising conditions.[22–27]

Immunisation strategies for different scenarios

People with mild or moderate immunocompromise may have adequate initial responses to vaccination, but their immunity may wane more quickly, necessitating additional vaccine doses (either as one-off 'booster' doses, or regularly) to extend the duration of protection.[28,29] In some situations, such as for HPV vaccine, immunocompromised individuals are recommended in the Australian Immunisation Handbook to receive a primary schedule that contains additional doses to establish immunity.[2] Individuals with specific immunocompromising conditions are also sometimes more susceptible to certain pathogens, and may require targeted additional vaccinations. For instance, those with functional or anatomical asplenia are predisposed to infections with encapsulated bacteria[30] and are recommended to receive additional pneumococcal, meningococcal and *Haemophilus influenzae* vaccines.[2]

People who have undergone haematopoietic stem cell transplant (HSCT) or other cellular therapies, such as chimeric antigen receptor T-cell (CAR T) therapy, may lose immunity to diseases that they were previously vaccinated against.[31,32] Additionally, any chemotherapy and/or radiation therapy which they have undergone can destroy the memory B cells responsible for long-term immunity.[33] These individuals are recommended to be completely re-vaccinated following immune constitution (i.e. repeat primary vaccine courses) to re-establish immunity to VPDs (Table 1).

Table 1: Key immunisation strategies used for different immunocompromising conditions in the Australian Immunisation Handbook[a,b] (as of December 2025)

Immunisation strategy	Recommended vaccine and dosing schedule[c]	Population/condition and public funding if applicable[d]	Rationale
Additional (booster) dose(s) of routine vaccine	Influenza: annual dose	All immunocompromising conditions – *NIP*	Increased risk of respiratory infections and pneumococcal disease.
	Pneumococcal: 1 additional dose of PCV and 2 doses of PPV (for adults only)	All immunocompromising conditions – *NIP, only funded for selected conditions*	
	Meningococcal: ongoing booster of MenACWY every 5 years; 1 booster dose of MenB.	Asplenia (or hyposplenia) – *NIP*; Complement deficiency (or receiving complement inhibitors) – *NIP*; HIV	Increased risk of bacterial infections, particularly due to encapsulated bacteria.
	Hib: 1 additional dose	Asplenia (or hyposplenia) – *NIP*; Complement deficiency (or receiving complement inhibitors)	Increased risk of encapsulated bacteria.
Altered schedule or interval	COVID-19: 3-dose primary schedule and additional doses every 6–12 months based on individual risk assessment	All severe immunocompromising conditions, such as inborn errors of immunity, immunosuppressive therapy, malignancy, organ transplant[e]	Increased risk of severe disease or complications from COVID-19.
	HPV: 3-dose primary schedule	≥ 9 years old with immunocompromising conditions – *NIP*	Increased risk of persistent HPV infection and related diseases.
	Herpes zoster: 2-dose primary schedule	≥ 18 years old with immunocompromising conditions – *NIP*	Increased risk of herpes zoster and associated complications, such as post-herpetic neuralgia.
	MenACWY: one extra primary dose MenB: one extra primary dose for < 12 months	Asplenia (or hyposplenia) – *NIP*; Complement deficiency (or receiving complement inhibitors) – *NIP*; HIV	Increased risk of bacterial infections, particularly due to encapsulated bacteria.
Additional vaccine (not routinely recommended for healthy people)	RSV: 1 single dose	≥ 60 years old with immunocompromising conditions – *NIP*	Increased risk of severe RSV disease and complications.
	Hepatitis A: 2-dose schedule	Liver transplant	Increased risk of hepatitis infection
	Mpox: 2-dose schedule (give the second dose as close as possible to 28 days after the first dose, but not earlier)	HIV and at risk of mpox exposure[c]	Increased risk of severe mpox disease.

Immunisation strategy	Recommended vaccine and dosing schedule[c]	Population/condition and public funding if applicable[d]	Rationale
Complete revaccination (routine vaccine and additional doses)	All routine and additional doses	HSCT; CAR-T cell therapy	Increased risk to various pathogens due to loss of immunity and receipt of immunosuppressive therapies.

a Current as of December 2025.

b CAR: chimeric antigen receptor; COVID-19: coronavirus disease 2019; Hib: *Haemophilus influenzae* type B; HIV: human immunodeficiency virus; HPV: human papillomavirus; HSCT: haematopoietic stem cell transplant; MenACWY: meningococcal ACWY vaccine; MenB: meningococcal B vaccine; NIP: national immunisation program; PCV: pneumococcal conjugate vaccine; PPV: pneumococcal polysaccharide vaccine; RSV: respiratory syncytial virus.

c The listed dosing schedules are additional doses on the basis that the age-appropriate routine immunisation schedule was completed.

d Vaccination recommendations listed in the table are only for people with immunocompromised conditions, not including other medical conditions or at-risk groups. For a full list of conditions and funding status, please refer to the relevant disease chapter in the Australian Immunisation Handbook, and to Immunisation recommendations for people with certain medical risk conditions

e Funded under emergency measures.

Timing of vaccination

The timing of vaccination for immunocompromised people requires consideration of the dosing regimen/duration of immunosuppressive treatments, and the expected timeline for immune reconstitution. Additionally, it should account for potential breaks from immunosuppressive therapy and for the infection risk associated with deferring vaccination. In principle, immunisations should be administered before any planned period of significant immunosuppression, or should be deferred if immunocompromise is expected to be time limited. However, there are significant evidence gaps regarding the ideal intervals between completion of therapy and re-initiation of vaccination for each type of immunosuppressive therapy and immunisation. Much of the historical evidence in this area comprises expert reviews or small clinical studies, indicating reduced vaccine responses in the early post-HSCT or solid organ transplant (SOT) period, and better immunogenicity when vaccination is deferred until 3–12 months after immune reconstitution.[34] However, these considerations need to be balanced against the improved protection provided by more prompt re-vaccination in these populations. Although data remain limited in scope and population, a few recent prospective observational studies and clinical trials of COVID-19 and influenza vaccines suggest that earlier vaccination can achieve immunogenicity similar to later vaccination among HSCT recipients.[35,36]

Overview of Australian programs

In addition to recommending vaccines for immunocompromised people, the Australian National Immunisation Program (NIP) funds several additional vaccines and/or doses for people with specific medical risk conditions. For example, annual influenza and additional COVID-19 vaccines are recommended and funded for people with immunocompromising conditions. Extra doses of pneumococcal, *Haemophilus influenzae* type b (Hib), herpes zoster, and meningococcal vaccines are also funded for various types of immunocompromise. In addition to the NIP, state and territory governments also offer jurisdictional programs for at-risk immunocompromised people against specific VPDs, such as mpox and hepatitis A/B for people living with HIV.[37–40]

Enhancing immunisation programs for immunocompromise

Challenges in formulating immunisation policy and recommendations

Immunisation guidelines that provide clear, consistent and concise advice are imperative, but must be developed with consideration of the limited published evidence for this population. Consider the example of the immunosuppression induced by biological agents. In view of their different mechanisms of action, therapeutic indications and dosages, it is not feasible to provide universally applicable guidance for each class of biological or biosimilar agents, particularly in the absence of suitable evidence that pertains to the specific clinical scenario which agents are prescribed to treat. Therefore, published guidance may adopt a more conservative precautionary approach by withholding live vaccines, even where the use of such medications might not pose theoretical risk of adverse effects arising from their immunomodulating properties. This approach is primarily due to the lack of published data around immunisation in these populations. In addition, due to the paucity of robust evidence, recommendations in most existing guidelines are mostly based on expert opinions, resulting in large discrepancies between regional and international recommendations.[31,41,42] For example, the optimal spacing between the administration of live vaccines and immunosuppressive agents (e.g. tumour necrosis factor-alpha inhibitors or Janus kinase inhibitors) ranges from 4 weeks to 12 months across several published national immunisation guidelines.[43–45] While these guidelines provide valuable frameworks for clinical practice, the final decisions need to be adapted to the unique circumstances of each individual, with consideration given to their underlying disease, comorbidities, and risk of exposure to VPDs.

Vaccine uptake and program implementation

Poor vaccine coverage is frequently identified in immunocompromised populations.[46,47] Many patients with severe chronic conditions are likely to miss opportunities for necessary immunisation, due to ongoing exposure to immunocompromising therapies and to uncertainty about which care team is responsible for providing vaccines.[48] It is important to ensure these populations have improved vaccine coverage and are provided, in complex cases, with personalised immunisation guidance. Implementing integrated immunisation teams and establishing dedicated specialist immunisation services, or equivalent local public health authorities, can help to address these needs.[49] To meet the growing demand, access to such specialised services should be enhanced and expanded, including across rural and regional areas.

Inadequate knowledge of best practice immunisation recommendations for immunocompromised people has been identified as a common barrier acknowledged by healthcare professionals at all levels.[50–52] The expanding number of biological therapies, and the intricate nature of their immunocompromising potential, makes it difficult for clinicians to be abreast of the latest evidence. This challenge is further intensified by the swift evolution of licensed vaccines in recent years. It is crucial to provide ample educational resources and to ensure training is accessible and manageable. Intuitive immunisation decision aids can assist providers to more rapidly identify which vaccines are recommended for individuals with immunocompromise (or other risk factors for VPDs). An example is the National Immunisation Catch-up Calculator (NICC), which has been developed to provide guidance on catch-up immunisation for people up to 20 years of age, and which incorporates tailored advice for specific immunocompromising conditions.[53]

Future research directions for immunocompromised populations

There are significant evidence gaps in vaccine research for immunocompromised populations that warrant further investigation to better define the clinical effectiveness, efficacy and safety of various vaccines in this population. As outlined in the previous sections, these research gaps are compounded by limited population-level data on disease burden, vaccine uptake, and clinical characteristics of immunocompromised individuals, reflecting current shortcomings in information available only through routine surveillance and administrative datasets. Notably, data are needed to ascertain the optimal timing of administration and appropriate dosing schedules for many VPDs. Most published studies focus on only a single VPD, such as influenza or COVID-19, in a single immunocompromised population.[54,55] Limited data are available for other VPDs and are often derived from retrospective observational studies yielding a low-quality evidence base for immunisation providers.[56] Long-term studies on the persistence of vaccine-induced immunity and booster effects in immunocompromised populations are also scarce.

Immunocompromised individuals are frequently excluded from clinical trials due to safety concerns, variable immune responses and ethical and logistical constraints. Addressing these challenges requires the development of robust clinical trial infrastructure and creative study designs. Lessons learned from the COVID-19 pandemic highlighted the lack of regulatory mandates to conduct and fund trials in immunocompromised populations, which should be a key focus for future vaccine studies.[57] Innovative study designs, such as adaptive trials, emulated trials or linked longitudinal studies using post-licensure evidence in various populations, can significantly bridge the gaps left by traditional trials. Further research is also required to explore whether vaccines based on newer platforms (e.g. viral vector, mRNA vaccine) for the same VPD in one individual (a strategy known as heterologous boosting) can improve the immune response.[58] Another emerging field of study that provides potential to improve our understanding of immunisation in this population is the identification of biomarkers for stratifying risk and predicting vaccine efficacy in immunocompromised individuals (such as focusing on cellular immunity or innate cells, as opposed to conventional neutralising antibody responses).[59]

New approaches in analytical methodologies and computational modelling may help to identify immune responses that correlate and/or predict vaccine efficacy in immunocompromised individuals, to improve our understanding of the definition of clinical protection.[60,61]

The shift in vaccine development (from traditional whole-cell or whole-virus vaccines to subunit vaccines) has revealed that isolated antigens often lack sufficient immunogenicity, requiring the addition of adjuvants to generate adequate immune protection, particularly for immunocompromised individuals.[62] Emerging non-viral vaccine technologies, such as virus-like particle and nanoparticle vaccines, may offer innovative approaches to address existing challenges.[63] Newer vaccine technologies should also be developed to enable enhanced immunogenicity and safety in vaccine delivery for those individuals. High-dose or adjuvanted influenza vaccines (e.g. Fluad) have been widely used in immunocompromised populations, offering enhanced protection over standard vaccines. Novel pipeline adjuvants and delivery systems, such as toll-like receptor agonists, liposome formulations and saponin complexes, also show significant potential,[64,65] but require further research to stratify their safety profile and immunogenicity in immunocompromised individuals.

Conclusion

Vaccination for immunocompromised individuals requires an individualised and nuanced approach that considers the type of underlying immunodeficiency; the exposure to immunosuppressive therapies; the likelihood of infections; and the vaccine-induced immune response. However, significant evidence gaps remain that prevent the optimisation of immunisation coverage and clinical protection against VPDs in immunocompromised people. Improved data collection that facilitates the assessment of disease burden, vaccine coverage, optimal schedules and vaccine efficacy/effectiveness is needed. Future efforts must focus on innovative clinical trials, advanced analyses using linked data, and the development of novel vaccine technologies that evaluate immune responses in these high-risk groups.

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