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REVIEW

Recommendations of the Italian society for infectious and tropical diseases (SIMIT) for adult vaccinations

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ABSTRACT

Vaccination prevents 2–3 million deaths worldwide every year. Nevertheless, vaccine-preventable diseases (VPDs) still cause a considerable number of deaths especially in subjects belonging to "risk groups." These are represented by older adults, immunocompromised individuals and all subjects with underlying chronic medical conditions (cardiovascular, pulmonary, renal and liver chronic diseases, diabetes, immunodeficiency disorders). They have a weaker immune system and, if infected, are more likely to develop severe complications of their condition or of the preventable-infectious disease. This document summarizes the recommendations for vaccination of the main Global Institutional Organizations and analyses the risks of comorbidities associated with infectious disease and the benefits of vaccination for each specific group. The document provides a clear, practical and authoritative guide to adult vaccination.

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Introduction

According to the latest World Health Organization (WHO) data, vaccination prevents 2–3 million deaths every year;[1] nevertheless, a considerable number of deaths today are still caused by vaccine-preventable diseases (VPDs).[2] Vaccination can benefit persons of all ages but is crucial for those at higher risk of infectious diseases and their complications.[2] Risk groups include people who are more likely than others to develop severe diseases if they are infected. They are represented by older adults (over 65 years old), immunocompromised individuals and all subjects (over six months of age) with chronic medical conditions (cardiovascular, pulmonary, renal and liver chronic diseases, diabetes, immunodeficiency disorders).[3,4] It is essential that subjects belonging to these groups be vaccinated because their immune system is weaker. They are more likely to develop complications of the condition, which may involve long-term illness, hospitalization, and even death from certain vaccine-preventable diseases. For this group of risk patient, prevention is fundamental.[1,3,4]

This document summarizes the recommendations for vaccination of all of the following Global Institutional Organizations: US Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), European Center for Disease Prevention and Control (ECDC), Italian National Health Service (INHS), Standing Committee on Vaccination at the Robert Koch Institute (STIKO), Department of Health of the Australian Government (AUS), UK National Health Service (NHS). In addition, for each specific group, the study analyses: recommended vaccines, risk of comorbidities associated with infectious diseases and the benefits of vaccination.

The aim of this document is to provide a quick, practical and authoritative guide to adult vaccination.

Older adults

Worldwide, populations are aging due to ever-increasing life expectancy and decreasing birth rates.[5] Because of changes in the immune system, older adults (over 65 years old) are more susceptible to infectious diseases and have an altered immune response to vaccinations.[6] Therefore, multiple variables need to be considered when deciding which vaccinations to administer to older adults.[7] The increased susceptibility to infections and reduced immune response to vaccination are due to altered aging-related reactions identified in almost all immune cells. These changes also result in increased inflammatory markers in a variety of tissues in the body.[8] Proper defense from infectious diseases requires a highly coordinated immune response with multiple cell types from both the innate and adaptive branches of the immune system. In older adults, the innate immune system demonstrates delayed migratory ability, impaired phagocytosis, impaired cytotoxicity, reduced cytokine secretion, altered antigen presentation, and altered signaling patterns.[9] The adaptive immune system also becomes dysregulated and loses functionality with increasing age.[10] For these reasons, many countries have established vaccination recommendations specific to older adults. Vaccination against influenza and *Streptococcus pneumoniae* is usually recommended for persons with underlying diseases and elderly, with heterogeneous age limits between ≥ 50 years and ≥ 65 years.[11] The

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Table 1. Recommended vaccines.

Risk population	Recommended vaccines
Adults ≥65 years	**Influenza** -CDC,[19] ECDC,[20] INHS,[21] NHS,[22] NACI,[23] STIKO[24] **Pneumococcal** - CDC,[19] ECDC,[25] INHS,[21] NHS[22] **Tdap** -CDC,[19] ECDC,[26] INHS[21] **Zoster*** -CDC,[15–A,B] CDC,[19–B] ECDC,[27–B] INHS,[21–B] NACI[16–A,B,] NACI,[23–B] STIKO[17–A, B] **COVID-19** -CDC,[28] ECDC,[29] INHS,[30] NHS[31]

*(recombinant, adjuvanted).
A. Zoster vaccine.
B. Recombinant, adjuvanted.
CDC: US Centers for Disease Control and Prevention; ECDC: European Center for Disease Prevention and Control; NHS: UK National Health Service; INHS: Italian National Health Service; NACI: National Advisory Committee on Immunization; STIKO: Standing Committee on Vaccination at the Robert Koch Institute; Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; COVID-19: coronavirus 19 disease.

FDA approved the tetanus-diphtheria acellular pertussis vaccine (Tdap, every 10 years) for use in older adults in 2011.[12] Some countries, including Italy, also recommend vaccination against herpes zoster.[12] The new recombinant zoster vaccine (RZV) is a 2-dose, subunit vaccine containing recombinant glycoprotein E in combination with a novel adjuvant (AS01B).[13] As a result of higher and longer lasting efficacy, RZV is estimated to be more effective in preventing herpes zoster and postherpetic neuralgia compared to zoster vaccine live (ZVL).[14,15] Considering the availability of RZV in Italy in 2021 and according to several Global Institutional Organizations (CDC, STIKO, NACI), RZV is preferred over ZVL for the prevention of herpes zoster and related complications.[15–17] Furthermore, studies have shown that ZVL efficacy wanes substantially over time, leaving recipients with reduced protection against herpes zoster; therefore, RZV is also recommended for immunocompetent adults who previously received ZVL.[15,16]

Regarding the current COVID-19 pandemic, the disease has an overall mortality rate of approximately 2%–3%, but the case fatality rate is higher in older adults. In fact, of the COVID-19 deaths in Italy, 83% were individuals aged 60 or older.[18] For this reason, COVID-19 vaccination is important for this part of the population in order to prevent the infection.

Recommended vaccines for older adults and reasons to get vaccinated are shown in Tables 1 and 2.

Patients with cardiovascular conditions

Cardiovascular disease (CVD) is a leading cause of death globally, with over 17.9 million people dying from a CVD-related event annually.[37] In addition to conventional factors, such as smoking, obesity, hypertension, diabetes and dyslipidemia, influenza and pneumococcal infections represent potential risk

Table 3. Recommended vaccines.

Chronic medical condition	Recommended vaccines
• Coronary artery disease • Heart failure • Hypertensive heart disease • Pulmonary heart disease • Heart valve disorders • Arrhythmias • Congenital heart defects	**Influenza** -CDC,[47] WHO,[48] ECDC,[49] INHS[50] **Pneumococcal** -CDC,[47] STIKO,[24] AUS,[51] NHS,[22] INHS[50] **Tdap** -CDC,[47] INHS[21] **Zoster*** -CDC,[47–A] INHS[50–B] **COVID-19** -CDC,[28] ECDC,[29] NHS,[52] INHS[30]

*(recombinant, adjuvanted).
A. Zoster and recombinant, adjuvanted.
B. Zoster.
CDC: US Centers for Disease Control and Prevention; WHO: World Health Organization; ECDC: European Center for Disease Prevention and Control; NHS: UK National Health Service; INHS: Italian National Health Service; STIKO: Standing Committee on Vaccination at the Robert Koch Institute; AUS: Department of Health of the Australian Government; Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; COVID-19: coronavirus 19 disease.

Table 2. Reasons to get vaccinated.

Risk population	Associated risk	Benefits of vaccination
Adults ≥65 years	Influenza-related complications: -severe infection[7] -pneumonia[7] -hospitalization[7] -risk of death[7] -strokes, congestive heart failure, ischemic heart disease, cancer, and hip fracture, have all been linked to influenza[32] Increased risk of pneumococcal infection[6] Pneumococcal-related complications: -hospitalization[6] -death[7] -higher incidence of CAP, IPD, and related mortality[7] Herpes zoster: -increased risk of varicella virus reactivation (i.e., herpes zoster or shingles) and greater disease severity[11,33] -PHN, whit severe neuropathic pain for months or years[7] -excess risk of stroke amounting to 30% in the year after HZ onset[34] Tetanus: -higher incidence and higher mortality rate if infected[7] Pertussis: -severe symptoms and increased mortality[11,35]	Influenza vaccination: -reduced risk of ischemic stroke and acute myocardial infarction by a third[3,36] Influenza and PPV vaccination:-reduced risk of death and of coronary and intensive care admissions in the year following vaccination[3,36] Zoster vaccine: -reduced incidence of herpes zoster[7,15–17]

PPV: Pneumococcal polysaccharide vaccine; CAP: Community-Acquired Pneumonia; IPD: Invasive Pneumococcal Disease; PHN: postherpetic neuralgia.

Table 4. Reasons to get vaccinated.

Chronic medical condition	Associated risk	Benefits of vaccination
• Coronary artery disease • Heart failure • Hypertensive heart disease • Pulmonary heart disease • Heart valve disorders • Arrhythmias • Congenital heart defects	Influenza-related complications:[53] -hospitalization -pneumonia -risk of death Increased risk of pneumococcal infection:[59] -increased risk for CAPand IPD all year round, especially patients with CHF -increased risk of hospitalization, especially patients with cardiomyopathy and those treated with loop diuretics COVID-19: -A chronic heart disease can impair survival from COVID-19 infection[45]	Influenza vaccination: -significantly reduces the risk of CV death (from 17% to 6% at 1 year)[54] -reduces rate of acute MI[55,56] -reduces risk of death from CV causes, including death from MI or stroke in patients with known CVD[57,58] PPV vaccination: -reduces the risk of ACS[38]

CV: cardiovascular; MI: Myocardial Infarction; CVD: cardiovascular disease; CAP: Community-Acquired Pneumonia; IPD: Invasive Pneumococcal Disease; CHF: congestive heart failure; ACS: acute coronary syndromes; COVID-19: coronavirus 19 disease.

factors.[38] Coronary artery disease is essentially inflammatory, and newer evidence shows that inflammation related to respiratory pathogens such as influenza and *Streptococcus pneumoniae* can trigger this disease.[39,40] CVD is more common in the winter and during influenza epidemics, and this could be partially explained by temperature-induced vascular damage.[41] The mechanisms by which influenza increases the risk of CV events may be related to sympathetic stimulation, pro-inflammatory mediators and coagulation cascade activation, that may trigger rupture of vulnerable atherosclerotic plaques. Contributing factors may include the higher metabolic demand due to adrenergic surge and hyperdynamic CV response and the potential compromise of oxygenation due to pulmonary infection. Moreover, influenza has been shown to cause myocardial dysfunction directly, possibly through increases in proinflammatory cytokines 23.[38] Several epidemiological studies showed that both influenza and pneumococcal infections exacerbate preexisting cardiac diseases and trigger new cases of CVD such as myocardial infarction (MI), congestive heart failure (CHF), arrhythmia, stroke, or transient ischemic attack (TIA).[42,43] Similarly, preexisting cardiovascular disease seems to be linked with worse outcomes and increased risk of death in patients with COVID-19, whereas SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) infections can also induce myocardial injury, arrhythmia, acute coronary syndrome and venous thromboembolism.[44,45] With this in mind, all Global Institutional Organizations recommend COVID-19 vaccination in patients with preexisting cardiac diseases.

Furthermore, cardiovascular patients are at greater risk if infected with herpes zoster (HZ). This because the virus complications can be more severe, including a greater risk of stroke, transient ischemic attacks, and acute cardiac events.[46]

Recommended vaccines for patients with cardiovascular conditions and reasons to get vaccinated are shown in Tables 3 and 4.

Patients with respiratory conditions

Patients with chronic lung diseases, such as chronic obstructive pulmonary disease (COPD), asthma, cystic fibrosis (CF), and interstitial lung diseases (ILD), are susceptible to respiratory lung infections and some of these viral infections can contribute to disease pathogenesis.[60] People with obstructive airways disease are at a higher risk of invasive pneumococcal disease and are also more likely to have complications following influenza infection. Both infections contribute to acute exacerbations in people with asthma and COPD, leading to an increased risk of hospitalization and mortality.[61] Furthermore, seasonal influenza viruses are more common in CF patients than in healthy subjects and play a role in worsening lung function and accelerating disease progression, as suggested by some studies.[62–64] For these reasons, all health authorities recommend influenza vaccination in patients with underlying diseases at increased risk of complications, including those with chronic pulmonary disorders such as CF.[22,47–50] Besides, adults with chronic respiratory diseases should receive particular attention also regarding pertussis infections, as the risk of pertussis and hospitalization is higher in patients with COPD compared to non-COPD patients.[65]

Table 5. Recommended vaccines.

Chronic medical condition	Recommended vaccines
Respiratory conditions • COPD (chronic obstructive pulmonary disease) • Asthma • Cystic fibrosis • Other chronic lung diseases	**Influenza** -CDC,[47] WHO,[48] ECDC,[49] NHS,[22] INHS,[50] STIKO,[24] AUS,[61] GOLD,[67] GINA,[68] **Pneumococcal** -CDC,[47] NHS,[22] INHS,[50] STIKO,[24] AUS,[61] GOLD,[67] **Tdap** -CDC,[4] GOLD,[67] INHS,[21] **Zoster*** -CDC,[4–A] INHS[21,50–B] **MMR, varicella** -CDC,[4] INHS[50] **COVID-19** -CDC,[28] ECDC,[29] NHS,[52] INHS[30]

*(recombinant, adjuvanted).
A. Zoster and recombinant, adjuvanted.
B. Zoster and BPCO patients.
CDC: US Centers for Disease Control and Prevention; WHO: World Health Organization; ECDC: European Center for Disease Prevention and Control; NHS: UK National Health Service; INHS: Italian National Health Service; STIKO: Standing Committee on Vaccination at the Robert Koch Institute; AUS: Department of Health of the Australian Government; GOLD: Global Initiative for Chronic Obstructive Lung Disease; GINA: Global Initiative for Asthma; Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; MMR: measles, mumps and rubella vaccine; COVID-19: coronavirus 19 disease.

Table 6. Reasons to get vaccinated.

Chronic medical condition	Associated risk	Benefits of vaccination
Respiratory conditions • COPD (chronic obstructive pulmonary disease) • Asthma • Cystic fibrosis • Other chronic lung diseases	Influenza-related complications: - lower respiratory tract infection[69] - hospitalization[70,71] - mortality[72] ● hospitalizations for asthma are increased significantly during the influenza season[71]	Influenza vaccination: ● reduces asthma exacerbations, respiratory illness, healthcare utilization, hospitalization and deaths[73–77] ● reduces COPD exacerbations and hospitalizations for ACS in patients with COPD[78,79]
	Pneumonia infection: ● higher risk of CAP and IPD[59] ● risk of CAP varies with the severity of the condition and age[59] ● higher risk of hospitalization and complications[59,65,80]	PPV vaccination In COPD: -more data needed on the role of PPV in protecting patients with COPD from CAP[81–83] -beneficial effect on exacerbation rate, especially when combined with influenza vaccination[81,84] -hypothesized reduction in antibiotic treatment days[85] -early use in the course of COPD could help maintain stable health status[85] In asthma: -decreased pneumonia related hospitalization[86,87]
	Pertussis: -higher incidence in asthma e COPD patients[88–92] - higher risk of hospitalization[93] Pertussis-related complications:[94] -insomnia, apnea, weight loss, urinary incontinence, syncope and rib fracture, pneumonia, otitis media and death -increase in acute exacerbations in patients with asthma or COPD[90]	Tdap vaccination: -reduces disease severity[90] -protective effect against exacerbations of asthma[95]
	COVID-19 -complicates the chronic pulmonary disease[66]	

COPD: chronic obstructive pulmonary disease; ACS: acute coronary syndromes; CAP: Community-Acquired Pneumonia; IPD: Invasive Pneumococcal Disease Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; COVID-19: coronavirus 19 disease.

Finally, according to the CDC, patients with (moderate to severe) asthma are at a higher risk for severe respiratory complications if contracting COVID-19.[28] Moreover, patients with COPD have increased levels of ACE2, the host receptor for SARS-CoV-2, increasing the risk of severe lung disease; in this regard, a meta-analysis showed up to five-fold increased risk of severe COVID-19 disease in patients with COPD.[66] In these patients, prevention through COVID-19 vaccination is fundamental.

Recommended vaccines for patients respiratory conditions and reasons to get vaccinated are shown in Tables 5 and 6.

Patients with diabetes type 1 and 2

Several studies demonstrate that diabetes leads to an increased risk of developing and dying from infectious diseases. Multiple mechanisms can explain such increased risk of infections in patients with diabetes; most of them are related to chronic hyperglycemia, affecting several physiological pathways involved in the immune response against pathogens.[96] Adequate host immune response requires appropriate coordination of barrier defenses (e.g., intact skin and mucosal surfaces), cellular and humoral immunity, production of cytokines and chemokines, and production of reactive oxygen species; many of these factors may be altered in diabetes patients.[97] The peripheral neuropathies seen in diabetes predispose patients to ulcers and altered barrier defenses and impaired glucose control results in hyperglycemia, that can affect cellular immunity. Immune dysfunction can be associated with autoimmunity development in type 1 diabetes and low-grade chronic inflammation in type 2 diabetes.[98] Chronic hyperglycemic states reduce the phagocytic functions of monocytes and inhibit complement effects.[97,99]

It has been shown that certain infectious diseases, such as influenza, not only are more likely to occur in diabetes patients but may generally have a more severe course[100] with a higher incidence of flu-related major adverse outcomes such as all-cause hospitalizations, intensive care unit admissions, and all-cause mortality.[101,102] The increased severity of seasonal flu seen in patients with diabetes is partially determined by the deleterious impact of influenza on the cardiovascular system. For these reasons, diabetes patients who are at high cardiovascular risk have an increased risk of developing AMI following influenza infection.[103]

Regarding COVID-19, diabetes does not seem to increase the risk of infection occurring, but diabetes is more frequent in patients with severe COVID-19. In fact, patients with COVID-19 and diabetes have a worse prognosis because of the concurring effect of multiple factors characteristic of the syndromic nature of diabetes (age, sex, comorbidities such as hypertension and cardiovascular disease, obesity, and pro inflammatory and pro-coagulative state).[104]

Also, people with diabetes are at increased risk for death from pneumonia, bacteremia, meningitis and have higher rates of hepatitis B than the rest of the population.[105]

In such a risk population, vaccines are the safest way to protect health.

Table 7. Recommended vaccines.

Chronic medical condition	Recommended vaccines
Diabetes type 1 and 2	**Influenza** -CDC,[47] ECDC,[49] WHO,[48] NHS,[22] INHS,[50] STIKO,[24] AUS[106] **Pneumococcal** - CDC,[47] NHS,[22] INHS,[50] STIKO,[24] AUS[51] **Hep B** -CDC[47–A] **Tdap** -CDC,[47] INHS[21] **Zoster*** -CDC,[47–C] INHS[21–D,50–D] **Meningococcal** (MenACWY and MenB) -INHS[50–B] **MMR, Varicella** -CDC,47 INHS[50] **COVID-19** -CDC,[28] ECDC,[29] NHS,[52] INHS,[30]

*(recombinant, adjuvanted).
A. for subjects < 60 years old.
B. for diabetes type 1.
C. Zoster and recombinant, adjuvanted.
D. Zoster.
CDC: US Centers for Disease Control and Prevention; WHO: World Health Organization; ECDC: European Center for Disease Prevention and Control; NHS: UK National Health Service; INHS: Italian National Health Service; STIKO: Standing Committee on Vaccination at the Robert Koch Institute; AUS: Department of Health of the Australian Government; Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; MMR: measles, mumps and rubella vaccine; COVID-19: coronavirus 19 disease.

Table 8. Reasons to get vaccinated.

Chronic medical condition	Associated risk	Benefits of vaccination
Diabetes type 1 and 2	• Association between high HbA1c concentrations and a 2-4-fold higher risk of infection.[97] • Different disease courses: increased rates of hospital admissions, length of stay and complications.[97] • *S. pneumoniae* and influenza virus have a more severe course of infection.[97,107] • Increased risk for acute hepatitis B with more severe course.[108,109] • Risk factors for HZ infection sand its severe complication (PHN).[101] - Increased risk of acquiring bacterial meningitis.[110]	Influenza vaccination: -improved outcomes, reduced risk of hospitalization due to stroke, heart failure and flu/pneumonia, respiratory failure all-cause mortality.[101] Pneumococcal vaccination: -improvement in hospitalization, respiratory failure, hospital stay and healthcare costs.[101] -safety profile similar to euglycemic individuals who received the vaccine.[101]

PHN: Postherpetic neuralgia.

Recommended vaccines for patients with diabetes type 1 and 2 and reasons to get vaccinated are shown in Tables 7 and 8.

Patients with liver chronic conditions

Europe has the largest burden of liver disease globally, and the prevalence is increasing due to obesity and high alcohol consumption.[111] It is essential to highlight that the decline in kidney function is associated with a significantly higher risk of serious life-threatening infections, even when moderate. Liver disease progression is associated with immune dysregulation, leading to complications in all common infections.[112] Viral infections such as influenza, pneumococcal, hepatitis A, and hepatitis B result in increased morbidity and/or mortality and, for example, patients with chronic hepatitis B and C co-infection have outcomes that are worse than those with HBV or HCV alone.[113] In addition, it has been shown that the pandemic SARS-CoV-2 virus can damage the liver and that patients with COVID-19 and preexisting chronic liver disease have high mortality rates and increased risk for health complications.[114]

It is important to highlight that immunogenicity of vaccinations varies with the degree of hepatic decompensation. Accordingly, subjects with more severe disease are less likely to seroconvert,[115] for which reason vaccines should be administered prior to planned immunosuppression and before the onset of advanced fibrosis or cirrhosis, if feasible. Household contacts of immunocompromised patients with chronic liver disease should be also vaccinated against influenza (inactivated influenza vaccine is preferred), combined measles, mumps, rubella (MMR) and varicella, in case of patient susceptibility, *Neisseria meningitidis*, hepatitis B and COVID-19.[50,116]

The above underscores the importance of pursuing vaccination strategies early in the course of chronic liver disease, considering that prevention of infection through immunization is an essential part of the management of patients with chronic liver disease.[113]

Recommended vaccines for patients with liver chronic conditions and reasons to get vaccinated are shown in Tables 9 and 10.

Table 9. Recommended vaccines.

Chronic medical condition	Recommended vaccines
Liver chronic disease • Chronic hepatitis • Cirrhosis or liver decompensation • Hepatocellular carcinoma • Liver transplant candidates and recipients	**Influenza** -CDC,[47] ECDC,[49] NHS,[22] STIKO,[24] AUS,[106] IDSA,[116] INHS[50] **Pneumococcal** -CDC,[47] NHS,[22] AUS,[51] IDSA,[116] INHS,[50] **Hepatitis B** -CDC,[47] STIKO,[24] NHS,[22] IDSA,[116] INHS,[50] **Hepatitis A** -CDC,[47] STIKO,[24] NHS,[22] IDSA,[116] INHS,[50] **Tdap, HPV, Zoster*** -CDC,[47] INHS,[50–B] IDSA[116] **MMR, Varicella** -CDC,[47] IDSA,[116] INHS,[50] **Meningococcal** (Men ACWY and Men B)[A] -INHS[50] **Hib** -INHS[50–B] **COVID-19** -CDC,[28] ECDC,[29] NHS,[52] INHS[30]

*(recombinant, adjuvanted).
A. only for severe liver disease B. only for immunocompromised patients or candidates to immunosuppressive treatment /transplant.
CDC: US Centers for Disease Control and Prevention; WHO: World Health Organization; ECDC: European Center for Disease Prevention and Control; NHS: UK National Health Service; INHS: Italian National Health Service; STIKO: Standing Committee on Vaccination at the Robert Koch Institute; AUS: Department of Health of the Australian Government; IDSA: Infectious Diseases Society of America; Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; HPV: HPV: human papillomavirus vaccine; MMR: measles, mumps and rubella vaccine; Hib: Haemophilus influenza type b; COVID-19: coronavirus 19 disease.

Table 10. Reasons to get vaccinated.

Chronic medical condition	Associated risk	Benefits of vaccination
Liver chronic disease • Chronic hepatitis • Cirrhosis or liver decompensation • Hepatocellular carcinoma • Liver transplant candidates and recipients	Pneumococcal: -50 times higher likelihood of hospitalization for pneumococcal pneumonia[117] and higher risk for invasive pneumococcal disease[118] Influenza: ->5-fold increased risk of hospitalization and over 17-fold increased risk of death[119] -increased risk of health complications[113,120] -atypical symptoms[113] Hepatitis A and B: -increased morbidity and mortality[113]	Pneumococcal, HAV, and HBV vaccination: -reduces morbidity, mortality and overall healthcare costs[121] Pneumococcal PCV-13 and PPSV-23: -in cirrhosis patients significant increase of IgA and IgG antibodies at 1 month compared to baseline. A larger decline in IgA and IgM at 6 months was observed compared to controls[113] Influenza: -elicits an effective immune response and reduces the risk of all-cause hospitalization[112]

HAV: hepatitis A virus; HBV: hepatitis B virus, PCV-13: Pneumococcal 13-valent conjugate vaccine; PPSV23: Pneumococcal polysaccharide vaccine.

Patients with renal conditions

Due to impaired immunocompetency and usage of vascular access catheters, long-term peritoneal dialysis catheters, and immunosuppression after transplantation, chronic kidney disease (CKD) patients have an increased risk of incidence and severity of infections. Infections are in second place following cardiovascular diseases among causes of death in dialysis patients.[122] The risk of infection in patients with kidney disease worsens with advancing stages of kidney disease, especially in patients with kidney failure on dialysis.

In patients with chronic kidney disease, various aspects of the host defenses are affected by uremia and its metabolic consequences, including neutrophil function, antigen processing, antibody formation, and cell-mediated immune responses. Neutrophils show decreased chemotaxis, phagocytosis, and intracellular killing. T-cell, B-cell, and monocyte function are impaired, resulting in defective antigen presentation for immune recognition. These alterations in the functional capacity of lymphocytes result in impaired responsiveness to vaccination.[122,123]

Furthermore, adults on dialysis exhibit dialysis-related factors which can affect response to hepatitis B vaccine, including type of dialyzers used[31] and dialysis fluid quality (ultrapure vs the conventional mildly contaminated dialysis fluid).[124] In fact, either double-dose HBV vaccine or adjuvanted vaccine formulation are recommended in these subjects. HBV-antibody titer should be assessed 1 to 2 months after the last dose. If anti-HBsAg is <10 mIU/mL, repetition of the entire vaccine series is recommended. Patients with titers between 10 and 100 IU/L may be at risk of HBV infection and should receive a booster dose. For patients on hemodialysis, the need for booster doses should be guided by annual testing of the anti-HB levels.[125] In addition, high-dose influenza vaccines have shown to be associated with reduced hospitalization rates than standard-dose vaccination in patients receiving dialysis, especially if older than 65.[125, 126, 127] In the COVID-19 era, patients with chronic kidney conditions also have a substantially increased risk of experiencing a severe form of the disease. Given the vulnerability of this group of patients, major nephrology societies and Global Institutional Organizations recommended and prioritized these patients for COVID-19 vaccination.[28–30,52,116]

Concluding, immunization strategies for patients with chronic kidney disease should be formulated before the onset of advanced kidney disease and prior to any planned immunosuppression or transplantation in order to maximize the likelihood of vaccine-induced immunity. Furthermore, to ensure optimal prevention of infections, household members of immunocompromised chronic kidney disease patients should be vaccinated against influenza (inactivated influenza vaccine is preferred), combined measles, mumps, rubella (MMR) and varicella, in case of patient susceptibility, *Neisseria meningitidis*, Hepatitis B and COVID-19.[50,116]

Vaccinating CKD patients against infectious diseases for which a vaccine is available should be a priority given this represents the best method to avoid acute and chronic consequences of infections.

Recommended vaccines for patients with renal conditions and reasons to get vaccinated are shown in Tables 11 and 12.

Immunodeficient population

Immunocompromised patients include those with primary (hereditary or genetic) or secondary immunodeficiency disorders that are generally acquired and occur as a result of a disease or its therapy. This includes human immunodeficiency virus (HIV) infection, cancer, transplantation, asplenia or sickle cell disease and autoimmune inflammatory diseases treated with immunosuppressive medications (corticosteroid therapy, immunomodulatory medications or biological agents).[3,116]

Among the immunocompromised population, the severity of immunosuppression varies depending on the condition and treatment drugs used. These factors influence the infections to which immunocompromised patients are predisposed and the choice of immunization strategy.[44,45,50]

Specialists who care for immunocompromised patients share responsibility with the primary care provider for ensuring that appropriate vaccinations are administered to immunocompromised patients and their household contacts.[116]

There are various barriers to vaccination for immunocompromised individuals. Among these, the concern over the safety of vaccination in this population and possible primary contact with a specialist who does not routinely vaccinate. [135,136] The main

Table 11. Recommended vaccines.

Chronic medical condition	Recommended vaccines
• Chronic kidney disease • Patients on hemodialysis or peritoneal dialysis • Kidney transplant candidates and recipients	**Influenza** – CDC,[47] ECDC,[49] NHS,[22] STIKO,[24] AUS,[106] INHS,[50] **Hepatitis B** – CDC,[47] NHS,[22] AUS,[106] STIKO (for hemodialysis patients),[24] INHS[50] **Pneumococcal** – CDC,[47] NHS,[22] AUS,[51] STIKO,[24] INHS[50] **MMR, varicella** -CDC,[47] INHS[50] **Tdap, HPV, Zoster*** -CDC,[47] INHS[50–A] **Meningococcal** (Men ACWY and Men B) - INHS[50–B] **Hib** - INHS[50–A] **COVID-19** - CDC,[28] ECDC,[29] NHS,[52] INHS,[30] UK renal association[128]

*(recombinant, adjuvanted).
A. only for immunocompromised patients or candidates to immunosuppressive treatment/transplant.
B. only for severe liver disease.
CDC: US Centers for Disease Control and Prevention; WHO: World Health Organization; ECDC: European Center for Disease Prevention and Control; NHS: UK National Health Service; INHS: Italian National Health Service; STIKO: Standing Committee on Vaccination at the Robert Koch Institute; AUS: Department of Health of the Australian Government; IDSA: Infectious Diseases Society of America; Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; HPV: HPV: human papillomavirus vaccine; MMR: measles, mumps and rubella vaccine; Hib: Haemophilus influenza type b; COVID-19: coronavirus 19 disease.

concern about live attenuated vaccines is safety, possibility of reversion to a pathogenic form and the potentially increased risk for adverse reactions through this kind of vaccine.[136] For example, live attenuated vaccines cannot be used in severely immunocompromised patients because of the risk of inducing disease but may be safe in mild or moderately immunocompromised patients. Instead, the primary concern over inactivated vaccines is their effectiveness instead of safety, as these vaccines may indeed be less effective than live attenuated vaccines. All inactivated vaccines can be administered safely to immunocompromised persons.[116]

Inactivated and subunit vaccines are the best alternatives, although in some cases live attenuated vaccines can be administered up to a month before patients are predicted to become immunocompromised.[3,116] Highly immunocompromised patients should also be careful with their household contacts, for example, they should avoid contact with persons who develop skin lesions after varicella or zoster vaccine until lesions clear (IDSA) and refrain from handling diapers of infants who have been vaccinated with rotavirus vaccine for 4 weeks after vaccination.[116] Live attenuated influenza vaccine (LAIV) should not be administered or, if administered, contact between the immunocompromised patient and household member should be avoided for 7 days.[116]

Malignancies

A correct vaccination schedule performed before chemotherapy for cancer guarantees good protection in patients with solid or hematological tumors. Vaccines performed during chemotherapy could not be protective and may require a dose increase. Live attenuated-viral vaccines are contraindicated in patients during radio/chemotherapy but could be safely administered in subjects in remission whose chemotherapy has been discontinued for ≥3 months. As for the COVID-19 vaccine, there is a lack of information as regards the efficacy and duration of vaccine response in patients vaccinated prior to chemo/radiotherapy.[137] However, cancer patients are at an increased risk of developing clinically severe COVID-19, and some scientific societies addressed the advantages and issues of the vaccination to promote vaccination also in this category of patients.[138]

Recipients of Hematopoietic Cell Transplants (HCT)

Patients undergoing HSCT are at increased risk of bacterial and viral infections because of their intricate immune response alteration. In these patients, antibody titers for vaccine-preventable

Table 12. Reasons to get vaccinated.

Chronic medical condition	Associated risk	Benefits of vaccination
• Chronic kidney disease • Patients on hemodialysis or peritoneal dialysis • Kidney transplant candidates and recipients	Pneumonia: -major cause of morbidity and mortality[122] Patients on dialysis: -high incidence of respiratory infections with mortality rates 14- to 16-fold higher than the general population1. -more significant risk for acquiring HBV infection and becoming chronic carriers (potential reservoir)[129] Transplant recipients: -influenza infection is associated with higher morbidity, mortality and graft rejection rates[129] COVID-19 -higher risk of complication or chronic renal diseases[130]	Pneumococcal vaccination: - associated with a significant reduction in all-cause mortality and cardiovascular-related mortality in ESRD patients[131] HBV vaccination -better survival of dialysis patients[124] -elicits seroprotective antibodies in 30–80% of CKD patients. The wide variability is dependent on the type of vaccine used and the vaccination strategy employed[132] Influenza vaccination: -in HD patients, lower probability of pneumonia/influenza, respiratory failure, intensive care unit stay and lower mortality[133] -lower risks of pneumonia/influenza and other morbidities, ICU stay, hospitalization and death, in ESRD patients, particularly in the elderly[133] -reduced all-cause mortality risk by 50%[133] -reduces risk for hospitalizations due to pneumonia/influenza and major cardiac diseases when eGFR ≥ 30 mL/min/1.73 m2[134]

ESRD: end-stage renal disease; HBV: hepatitis B virus; CKD: chronic kidney disease; HD: Hemodialysis; ICU: intensive care unit; COVID-19: coronavirus 19 disease; eGFR: Estimated Glomerular Filtration Rate.

Table 13. Risks associated with immunocompromising conditions and recommended vaccinations.

Immunocompromising conditions	Associated risk	Vaccination
HIV infection	-Increased risk and severity of vaccine-preventable infections[149] -Higher risk of invasive pneumococcal disease[150] -Infection with the hepatitis B virus (HBV) is more likely to progress to cirrhosis and hepatocellular cancer[149]	**YES**, if CD4 ≥ 200/mmc The following vaccines: - **MMR, varicella, inactivated Influenza, Hepatitis B, meningococcal** (Men ACWY and Men B), **PVC/PPV23, Hib, HPV, Rotavirus, HAV** (co-presence of other risk factor), **Tdap** CDC,[47] INHS,[50] SIMIT[151] -**Zoster** (recombinant, adjuvanted) STIKO[17] -All inactivated vaccines can be administered safely to immunocompromised persons[47] -**COVID-19** CDC,[28] ECDC,[29] **NO**, if CD4 < 200/mmc The following live attenuated vaccines: -MMR, varicella, live attenuated influenza vaccine, yellow fever, Ty21a oral typhoid, rotavirus, zoster live attenuated CDC,[47] INHS,[50]
Malignancies	Solid or hematological tumors: • long-lasting altered immune response following radio and/or chemotherapy[116] COVID-19: • increased risk of developing severe clinical disease[152]	**NO** Any live vaccine during chemotherapy and after cancer chemotherapy but some of them are possible respecting a delay after the end of chemotherapy CDC[144] **YES** -**Influenza** inactivated vaccine CDC,[144] INHS,[50] - **Pneumococcal PCV13** followed by a single dose of PPSV23 at least 8 weeks later CDC,[144] INHS,[50] HSE,[146] -**Td or Tdap** booster HSE[146] -**HBV** vaccine titer evaluation and boosting if necessary (co-presence of other risk factor) -**Hib** INHS[50] -**HPV** CDC[144] -**Zoster*** STIKO[17] -**Meningococcal vaccine** (Men ACWY and Men B, for all immunocompromised patients) **and HAV**, if traveling abroad INHS[50] -**COVID-19** CDC,[28,152] NHS,[22] ECDC,[29]

(*Continued*)

Table 13. (Continued).

Immunocompromising conditions	Associated risk	Vaccination
Recipients of hematopoietic cell transplants (HCT)	Altered immune response: -increased risk of bacterial and viral infections[138] COVID-19 -poor prognosis[139]	*3 months after HSCT*: HSE,[146] CDC[144] **PCV** -3 doses 1 month apart followed by a fourth PCV dose in case of GvHD, or one dose of PPSV23 6 months later Hib vaccine, 3 doses at 1 month intervals *6 months after HSCT:* HSE,[146] CDC[144] **Meningococcal** • Men ACWY and Men B vaccine **Diphtheria-tetanus** • 3 doses containing high-doses diphtheria toxoid (DT) at 1–2-month intervals **Pertussis** **Influenza** • the inactivated vaccine should be administered annually **Poliomyelitis** • 3 doses of inactivated vaccine at 1–2-month intervals. **HBV** • before HSCT if anti-HBc positive donor • 6 months after HSCT in HBV-negative and HBc-positive recipients treated with lamivudine *6–12 months after HSCT:* HSE,[146] CDC[144] **HPV** *After 24 months since HSCT:* HSE,[146] CDC[144] **Varicella and MMR** -can be administered in patients who does not have a graft-vs-host disease and are considered immunocompetent **Zoster*** STIKO[17] **COVID-19** CDC,[28] ECDC,[29] NHS,[52] INHS,[30]

(*Continued*)

Table 13. (Continued).

Immunocompromising conditions	Associated risk	Vaccination
Asplenia (absent or dysfunctional spleen)	-Increased risk of severe infections, particularly those caused by encapsulated bacteria (*Pneumococcus, H. influenzae* type b and meningococcus)[140–142,150]	**Pneumococcal, Haemophilus influenzae type b and meningococcal** CDC,[47] HSE,[146] NHS,[22] INHS,[50] -two weeks before elective splenectomy or two weeks post-splenectomy in emergency cases; as soon as possible in case of functional hypo/asplenia. **Pneumococcal** CDC,[153,154] NHS,[155] INHS,[50] HSE,[146] -In naïve subjects, PCV13 (1 dose) followed by PPSV23 (1 dose) at least 8 weeks later. A second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years[155] -In patients who have previously received PPSV23, administer PCV13 > 1 year later. For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23. In patients who have previously received PCV13, repeat 1 dose of PCV13 followed by PPSV23 > 8 weeks later. Repeat one dose of PCV13 if the previous dose was given more than 5 y before, then administer PPSV23 at least after 8 weeks[155] **Meningococcal** CDC,[144] NHS,[22] INHS,[50] HSE,[146] -Naïve subjects: 2 doses of Men ACWY conjugate vaccine given 8–12 weeks apart from each other and revaccinate every 5 years if risk remains - In patients previously vaccinated with a single dose of Men ACWY or Men C, repeat the entire cycle (2 doses 8–12 weeks apart from each other). Subjects who received a single MenACWY dose before developing asplenia should receive another dose as soon as possible (provided that an 8-week minimum interval between doses is maintained) to complete the 2-dose series; restarting the 2-dose series is not required necessary. Revaccinate every 5 years if risk remains. -Men B vaccine: 2-dose primary series MenB-4 C (Bexsero) at least one month apart or 3-dose primary series MenB-FHbp (Trumenba) at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed). 1 dose MenB booster 1 year after primary series and revaccinate every 2–3 years if risk remains **Haemophilus influenzae type b** CDC,[144] NHS,[22] INHS,[50] HSE[146] -Naïve subjects: 1 dose of conjugate Hib vaccine. -In subject previously vaccinated, repeat 1 dose of conjugate Hib vaccine (expert opinion) **Tdap complete vaccination** CDC[47] -naïve subjects, a booster dose in previously vaccinated **Influenza** (annual) CDC,[47] NHS,[22] INHS,[50] **MMR and varicella** CDC,[47] INHS,[50] **HPV** CDC[47] **Zoster*** CDC[47] **COVID-19** Vaccine should be considered

(*Continued*)

Table 13. (Continued).

Immunocompromising conditions	Associated risk	Vaccination
Use of corticosteroids and other immunosuppressive medications • Interleukins • Colony-stimulating factors • Immune modulators (Disease-Modifying Antirheumatic Drugs -DMARs) • Tumor necrosis factor-alpha inhibitors (TNFi) • Anti-B cell antibodies (rituximab RTX)	-Reduced immune response to vaccines -Increased risk of infections	**Influenza inactivated** (annual) NHS,[22] INHS[50] **Pneumococcal** vaccination NHS,[22] CDC[153,154] -PCV13 followed by a single dose of PPSV23 at least 8 weeks later **Td or Tdap** booster **HBV vaccine** (for patients at risk for other causes) titer evaluation and boosting if necessary INHS[50] **Zoster*** STIKO[17] **HPV** CDC[144] **Men ACWY and Men B** INHS[50] **Hib** INHS[50] **COVID- 19** CDC,[28] NHS,[52] ECDC,[29]
Solid organ transplanted patients	-Increased risk of morbidity and mortality[156–160] -Higher incidence rate and higher risks for severity and complications of varicella, measles, influenza and invasive bacterial diseases (IBD)[161] -Higher risks of not having been optimally immunized[156] COVID-19 - Use of anti-rejection medication multiplies the risk of severe COVID-19 disease[162] -Mortality rates between 13 to over 30%, with differences relating to the transplanted organ and rate of immunosuppression[163]	**Influenza inactivated** Annual (standard dose or high dose vaccine, MF59 – adjuvanted) **HBV vaccine** HSE[146] (10, 20 40[A] mg of antigen), protective titers need to be checked **HAV vaccine** (patients at risk for HAV or with liver disease) HSE[146] **Pneumococcal** HSE,[146] CDC[153,154] PCV13 followed by a single dose of PPSV23 at least 8 weeks later. A second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years **Tdap** booster HSE[146] **HPV** (better before transplant) HSE[146,156] **Zoster*** STIKO[17] **Men ACWY and Men B** INHS,[50] HSE[146] **Hib** INHS[50] **COVID-19** CDC,[28] ECDC,[29] INHS,[30] NHS[52]

*(recombinant, adjuvanted).

A. patients with chronic renal failure on dialysis.

CDC: US Centers for Disease Control and Prevention; HSE: health and safety executive; ECDC: European Center for Disease Prevention and Control; NHS: UK National Health Service; INHS: Italian National Health Service; SIMIT: Società Italiana di Malattie Infettive e Tropicali; STIKO: Standing Committee on Vaccination at the Robert Koch Institute; PCV: Pneumococcal conjugate vaccine; PCV13: Pneumococcal 13-valent conjugate vaccine; PPSV23: Pneumococcal polysaccharide vaccine; Td: tetanus toxoid, reduced diphtheria toxoid; Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; HPV: human papillomavirus vaccine; MMR: measles, mumps and rubella vaccine; Hib: Haemophilus influenza type b; Men ACWY: tetravalent conjugate vaccine against meningococcal serotypes A, C, W135 and Y; Men B: monovalent conjugate vaccines against meningococcus serotype B; HAV: hepatitis A virus; HBV: hepatitis B virus; COVID-19: coronavirus 19 disease.

diseases decrease 1–4 years after HSCT, for which reason they are generally considered as never vaccinated subjects that need to receive a complete vaccination program according to age and country recommendations.[138] In HSCT recipients, prognosis of COVID-19 is particularly poor, so scientific societies required prioritization of these patients for Sars-CoV-2 vaccination. According to national guidance, it is recommended that household contacts and family members of HSCT patients receive COVID-19 vaccination as soon as possible.[139]

Asplenia (absent or dysfunctional spleen)

Asplenic patients are at risk of fulminant sepsis syndrome, leading often to death, especially in children. Encapsulated bacteria account for almost 70% of infections in patients with previous splenectomy and Pneumococci are responsible for 50–90% of infections in this population. Other microorganisms are *Neisseria meningitidis* and *Haemophilus influenzae* type b -(Hib).[140,141] In asplenia, invasive bacterial infections occur 10–50 times more often than in the healthy population.[142] Vaccinations have consistently reduced the rate of life-threatening infections in hyposplenic patients. However, there is still a long list of non-vaccine preventable pathogens, which continue to be a threat for this population.[142]

Corticosteroids and other immunosuppressive medications

The administration of glucocorticoids, as well as of monoclonal antibodies, antirheumatic drugs (DMARDs), tumor necrosis factor alpha inhibitors (TNFi) and rituximab (RTX) reduce the humoral response to several vaccines.[143] For this reason, in these patients, it is fundamental to evaluate the most appropriate timing for vaccination in order to obtain the best protective response.

Inactivated vaccines should be administered ≥ 2 weeks prior to immunosuppression, live vaccines should be administered ≥ 4 weeks prior to immunosuppression and avoided within 2 weeks of initiation of immunosuppression.[116] Subjects receiving ≥ 20 mg of prednisone/day or ≥ 2 mg/kg/day for ≥ 14 days should not receive live attenuated vaccines. Live attenuated-virus vaccination should be deferred for at least 1 month after discontinuation of high-dose systemically absorbed corticosteroids given for ≥ 14 days. Aerosolized steroids, like those used for asthma, are no contraindications to vaccination. Live attenuated vaccines should be withheld for 3 months following immunosuppressive therapy. Inactivated and live attenuated vaccines should be withheld for at least 6 months following treatment with RTX.[143,144] Patients on steroid and other immunosuppressive treatments are considered a fragile population that could benefit from COVID-19 vaccination. However, to date there is no data on the efficacy of COVID-19 vaccine in this category of patient.

Solid-organ transplanted patients

Solid-organ recipients are at increased risk of vaccine-preventable infections. Therefore, it is good practice to ensure that patients scheduled to receive solid organ transplant and their family members have completed the vaccination schedule recommended for their age and country.[145] A review of vaccination status and vaccination plan should be an integral part of patient assessment before and after immunosuppressive treatment or transplantation.[146] Live vaccines should be administered ≥ 4 weeks prior to immunosuppression or solid organ transplantation, while inactivated vaccines should be administered ≥ 2 weeks prior to immunosuppression or transplantation for an adequate immune response. If possible, it is important to follow an accelerated dosing schedule in candidates to immunosuppressive treatment or transplantation.[144] In post-transplant patients instead, revaccination is not indicated; vaccination status should be reviewed, and the vaccine doses necessary to complete the pre-transplant vaccination protocol should be administered. Vaccination should be avoided while on treatment for acute rejections.[116] While live vaccines are not recommended after solid organ transplantation, inactivated vaccines are safe. As for the potential decrease in antibody response, it is suggested to postpone vaccinations to at least 3–6 months after transplantation, with the exception of influenza vaccine, which should be administered as early as 1-month post-transplant.[145] COVID-19 has a reported mortality rate of 13 to over 30% in transplant recipients, with differences related to the transplanted organ and rate of immunosuppression.[147] The treatment of COVID-19 in solid organ recipients is often associated with a reduction in immunosuppressive therapy, with potential negative effects on organ rejection prevention. The recent introduction of vaccination against COVID-19 opens up new horizons in terms of potential infection prevention strategies. Despite potentially inadequate antibody response after vaccination, several transplant societies are urging to include transplanted patients in vaccination lists to offer them a possible weapon against disease acquisition.[148]

Risks associated with immunocompromising conditions and recommended vaccinations are shown in Table 13.

Vaccination and pregnancy

Pregnant women and newborn/infants are particularly vulnerable to infections due to an altered maternal immune response and immune system immaturity in newborns. Despite markedly reduced infant mortality in recent decades, infectious diseases are among the most frequent causes of deaths in the early neonatal period. Moreover, infections are still a cause of death in pregnancy.[164,165] Vaccinations are one of the most effective preventive tools in Public Health, as they prevent the development of certain infectious diseases, their complications, and spread. During pregnancy, vaccination aims to protect the mother via induction of active immunity, whereas the passive transfer of specific antibodies through the placenta protects the newborn at birth.[166] Three significant moments have been identified in which mother and child could safely benefit from specific vaccination campaigns and enjoy increased protection against infections: pregnancy planning, pregnancy, and breastfeeding.

Vaccinations against influenza, pertussis and tetanus/diphtheria are indicated during pregnancy and, if not previously administered, during breastfeeding.[21,167,168] Vaccines against measles, mumps, rubella are indicated in women planning pregnancy, instead. Live attenuated vaccines are generally

Table 14. Risks associated with pregnancy and recommended vaccinations.

Pregnancy	Associated risk	Vaccination
Woman planning pregnancy	Rubella, measles chickenpox and Hepatitis B (HBV) can cause embryo/fetal damage and mother complications if acquired during pregnancy[164,171]	**MMR** NIHS,[50] NHS[174]
	It is advisable to obtain the mother's immunization history before pregnancy, and, if history is uncertain or unknown, the assessment of specific antibodies by serological testing may be useful[172,173]	**Varicella** NIHS,[50] NHS[174] -Live attenuated vaccines administration should be completed 4 weeks before pregnancy
Pregnant woman	Seasonal influenza in pregnancy increases the risk of maternal hospitalization, abortion, prematurity, cesarean delivery, fetal distress, and low weight of the newborn.[167]	**Tdap** NIHS,[50] NHS[174]
	Morbidity and mortality of pertussis in newborns/first 3 months of life infants is high, and the infection is often acquired in the family (parents/siblings).[168]	-at 28th week (27–36 weeks) **Influenza**
	In Italy, there has been an increase in diphtheria reports (from 2015 to date), and the incidence of tetanus in adulthood is about ten times higher than in Europe and USA.[175]	NIHS,[50] NHS[174] -inactivated vaccine at any trimester
Breastfeeding woman	Except for smallpox and yellow fever vaccines, other vaccines can be safely administered to lactating women.	**Influenza**[175] -Inactivated vaccine
	Among live vaccines, only rubella vaccine virus has been found in breastmilk, however without causing infection in the newborn.[176]	(if not done in pregnancy) **Tdap**[175] (if not done in pregnancy) **MMR and varicella**, in case of susceptibility[175]

NHS: UK National Health Service; INHS: Italian National Health Service; Tdap: (Tetanus, Diphtheria, Pertussis) vaccine; MMR: measles, mumps and rubella vaccine.

contraindicated during pregnancy, whereas other vaccinations (rabies, poliomyelitis, yellow fever, etc.) can be considered based on exposure.[169]

There is evidence that COVID-19 disease in pregnancy is associated with an increased risk of maternal hospitalization and poor pregnancy and birth outcomes. However, to date, vaccination for COVID-19 in pregnant or breastfeeding women has not officially been included in national vaccination plans yet.[170]

Risks associated with pregnancy and recommended vaccinations are shown in Table 14.

Conclusions

Currently, several diseases may be prevented through vaccination. All adults are recommended to receive vaccinations based on their age, underlying medical conditions, lifestyle and other considerations. For some special groups of population with underlying diseases, being vaccinated against preventable infections is a life-saving act. In fact, their immune system is weaker and they are more likely to develop complications of their condition or from the infectious disease, which may lead to long hospitalizations and even death. For patients with chronic diseases, immunization strategy is particularly important and requires understanding of the underlying disease and of how it could affect the immune system's response to vaccines.

To date, some keys points about vaccination require to be further investigated in these special patients, including optimal timing of administration (especially in transplanted patients), level of protection and development of protective immune response after immunization, and need to revaccinate certain groups of patients if their antibodies decline.

Finally, to ensure that patients with chronic conditions stay up to date on recommended vaccines, some practical advice could be useful:

- assess routinely the patient immunization status through standing orders, patient intake questionnaires, electronic health record prompts or reminders, immunization registries or information systems;
- provide a strong, clear recommendation for patients to receive vaccines as necessary;
- documenting the vaccines administered is the best way to ensure that patients are up to date on their vaccinations.

It is important, for the future, to implement all these strategies targeted to improve the understanding of basic aspects of vaccines among patients. Also, a range of interventions at all levels, including financial incentives and ad hoc training, could be useful to achieve greater awareness among healthcare professionals.

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