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Immunizations in solid organ and hematopoeitic stem cell transplant patients: A comprehensive review

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The Solid Organ Transplantation (SOT) and Haematopoietic Stem Cell Transplantation (HSCT) population is continuously increasing as a result of broader indications for transplant and improved survival. Infectious diseases, including vaccine-preventable diseases, are a significant threat for this population, primarily after but also prior to transplantation. As a consequence, clinicians must ensure that patients are optimally immunized before transplantation, to provide the best protection during the early post-transplantation period, when immunosuppression is the strongest and vaccine responses are poor. After 3–6 months, inactivated vaccines immunization can be resumed. By contrast, live-attenuated vaccines are lifelong contraindicated in SOT patients, but can be considered in HSCT patients at least 2 years after transplantation, if there is no immunosuppression or graft-versus-host-disease. However, because of the advantages of live-attenuated over inactivated vaccines - and also sometimes the absence of an inactivated alternative - an increasing number of prospective studies on live vaccine immunization after transplantation are performed and give new insights about safety and immunogenicity in this population.

Introduction

The number of Solid Organ Transplant (SOT) and Haematopoietic Stem Cell Transplant (HSCT) recipients are continuously increasing, with life expectancy and lifestyle being closer to non-transplanted persons.[1] For example, in the United States, over 600,000 SOTs have been performed since 1988 and approximately 29,000 SOTs are performed annually.[2] In addition, worldwide there are over 19,000 HSCTs performed annually.[3] Patients are also exposed to vaccine-preventable diseases in the community both pre- and post-transplantation,. Except in rare cases such as fulminant hepatitis or other emergent causes for transplantation, most SOT and HSCT candidates have chronic diseases, some of which require or produce immunosuppression before transplantation, such as in leukemia. After transplantation, the infectious risk may be greater: SOT recipients receive immunosuppression to avoid organ rejection, whereas conditioning regimens for HSCT weaken the immune system to ensure engraftment. Moreover, baseline immunosuppression may be augmented in case of SOT graft rejection or HSCT graft vs. host disease (GvHD). For these reasons, clinicians must understand the optimal vaccination schedule and the immunogenicity of vaccines to ensure the best immunization of their patients and their household members (HM), as well as health-care workers (HCW) in contact with these patients, before and after transplantation. We review here the principles, major studies and vaccine recommendations for SOT and HSCT patients, pre- and post-transplantation (**Table 1**).

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Solid Organ Transplantation

General principles

SOT patients require lifelong immunosuppression to prevent graft rejection which results in diminished B and/or T-cell immunity. Prior to SOT, the majority of patients still have adequate immune responses, but a subgroup have lower immune responses due to the effect of chronic end organ diseases or their therapies; nevertheless, every effort should be made to complete pre-transplantation immunization for all candidates. More attention should be paid to patients with chronic diseases who are already at increased risk for infectious diseases in the pre-transplant setting: despite suboptimal immune response, their vaccine responses may still be better than in the post-transplantation period.

During the pre-transplant assessment, immunization status should be documented. This is an opportunity to determine vaccine antibody titers and administer catch-up immunization depending on vaccine status and serologies.[4,5] However, vaccine-specific antibody waning after SOT is well described.[6-17] As pre-transplantation titers have been shown to be predictive of post-transplantation titers, the importance of the best possible immunization before SOT should be emphasized.[13] Regarding inactivated vaccines, experts generally recommend to follow

Table 1. Summary of vaccines recommended for transplant recipients

Vaccine	SOT*	HSCT**	Comments
Inactivated Vaccines			
Pneumococcal	1 dose PCV-1 dose PPV23	3 doses PCV-1 dose PPV23	For HSCT, can start at 3 months post-transplant
Influenza (inactivated)	Annually	Annually	Poor immunogenicity < 3 months post-transplant
Hepatitis B	3 doses	3 doses	Post-transplant, use high dose vaccine, check anti-HBs regularly
H. influenzae type b	1 dose	3 doses	Can use combination vaccines
Tetanus-diphtheria	1 dose	3 doses	
IPV	1 dose	3 doses	
Meningococcal (MCV4)	2 doses – 8 weeks apart for all children and adults with risks	2 doses – 8 weeks apart	Risks: Travel to endemic area, hyposplenism, eculizumab use
Hepatitis A	2 doses	2 doses	
HPV	3 doses	3 doses	Routine schedule
Live Vaccines			
Varicella	Pre-transplant: -children >9mo: 2 doses –adults: 1 dose Post-transplant: consider in long term transplant patients on minimal immunosuppression	Pre-transplant: -children >9mo: 2 doses –adults: 1 dose Post-transplant: 2 doses starting 2 years post-transplant if no immunosuppression or GvHD	If VZV IgG positive, no need for vaccination
Herpes Zoster	1 dose pre-transplant	1 dose pre-transplant. No data post-transplant; if VZV IgG negative, give Varicella vaccine	
MMR	2 doses pre-transplant or documentation of immunity	2 doses starting 2 years post-transplant if no immunosuppression or GvHD	If IgG positive, no need for vaccination
LAIV	Annually for children 2-17 years	Contraindicated	
Rotavirus	Contraindicated	Contraindicated	

SOT: Solid organ transplantation. HSCT: Haematopoietic stem cell transplantation; PCV: Pneumococcal conjugate vaccine; PPV: Pneumococcal polysaccharidic vaccine; IPV: Inactivated polio vaccine; MCV: Meningococcal conjugate vaccine; HPV: Human papilloma virus; MMR: Measles-mumps-rubella; GvHD: Graft versus host disease; VZV: Varicella Zoster virus.

*For SOT, vaccines should be administered pre-transplant if possible. Otherwise, start vaccination at 6 months post-transplant. For influenza, vaccination can be started at 3 months.

**For HSCT, start vaccines at 6 months post-transplant. For influenza and pneumococcal, start at 3 months post-transplant.

Pneumococcal conjugate vaccine may be available as 10-valent (PCV10) or 13-valent (PCV13).

routine national immunization schedules to ensure adequate protection before SOT, and to start reimmunization 3–6 months later, when the risk of graft dysfunction and immunosuppression is lowered.[4,5,18] However, as immune response depends on type and dosage of immunosuppressants, general recommendations concerning adequate timing are difficult to make. Live attenuated vaccines (LAV) have several advantages compared to inactivated vaccines. They induce an immune response which more closely mimics a wild-type infection with greater cell-mediated immunity (CMI), greater humoral immunity, and more rapid onset immunity without the need for an adjuvant. Moreover, they do not usually require a booster dose. However, LAV are generally contraindicated in the post-transplant setting because of the possible risk of vaccine-induced disease. For this reason, experts recommend to ensure LAV immunization before SOT.[4,5] However, there is greater interest in studying the possibility of LAV administration after SOT and this will be discussed in each specific vaccine section.

Specific vaccines

Influenza

Annual immunization is the one of the most effective methods of protecting against seasonal influenza,[19] which is estimated to cause up to 50 million cases per year in the USA.[20] Two types of influenza vaccines are available: an inactivated influenza vaccine (IIV), and a live attenuated influenza vaccine (LAIV). IIV is the most commonly used and the trivalent form contains two A and one B strains based on yearly WHO recommendations.[21] Quadrivalent IIV (containing two A and two B strains) will likely be available in subsequent influenza seasons. Because of an increased risk for severity of influenza disease and its potential impact on

the allograft,[22-24] yearly immunization of SOT patients with IIV is recommended, but LAIV is contraindicated.[4,25,26] Seroconversion rates after IIV in the SOT population are highly variable, ranging from 15 to 93%.[25] This can be explained by varying transplant types, immunosuppressive regimens and vaccination timing as well as different study endpoints. The optimal timing for IIV administration after SOT is debated: the American Society of Transplantation (AST) recommends immunization from 3–6 months after SOT,[4] whereas the Infectious Diseases Society of America (IDSA) recommends immunization from 2–6 months after SOT, except in an outbreak in which IIV can be administered as early as one month after SOT.[5] Similarly, the Kidney Disease – Improving Global Outcomes (KDIGO) group recommends IIV administration as early as 1 month post-transplantation.[27] Administration of IIV in the first 6 months after SOT has been shown to be less immunogenic although no safety issues have been reported.[28,29] Receipt of a lung transplant and the use of mycophenolate mofetil for immunosuppression are significant factors that contribute to decreased immunogenicity.[28,30] Multiple strategies have been attempted to improve the immunogenicity of IIV in SOT patients. These include intradermal administration or increasing the number of doses.[31,32] No significant improvements in immunogenicity are reported using these methods. A recent randomized study comparing adjuvanted IIV to unadjuvanted IIV shows potential benefit for the 18–65 year age group in favor of adjuvanted IIV although this should be confirmed in larger studies.[33] In addition, high dose IIV showed promise in a small pediatric cohort and is under further study in the transplant population.[34] With regards to safety of the vaccine, several studies have reported no increase in humoral alloimmune responses after seasonal IIV immunization. [28,35,36] However, several groups have described increased anti-HLA antibody production after immunization with the H1N1(pdm09) adjuvanted vaccine, even if its clinical significance remains unclear.[37,38] Therefore, despite variable and reduced antibody response rates compared to healthy controls, data support yearly IIV administration in this population.

LAIV is authorized for children 2–17 years of age and has been shown to be more effective than IIV in children, but not in adults.[39] Although LAIV is not indicated after transplant, it has several advantages over IIV: its intranasal administration route avoids painful injection and allows replication in the nasal mucosa, inducing a mucosal immunity closer to natural immunity.[40,41] For this reason, it may induce longer protection as well as a cross-protection against serotypes not included in the vaccine.[42-44] Last, LAIV is safe and immunogenic in moderately immunosuppressed children with cancer or HIV.[45-47] To our knowledge, no similar studies exist in SOT patients. For HM and HCW, yearly immunization is recommended and IIV is preferred over LAIV when available.[26]

Streptococcus pneumoniae (Pneumococcus)

S. pneumoniae can cause severe invasive pneumococcal diseases (IPD) including bacteremia, meningitis and pneumonia. SOT candidates should be immunized against *S. pneumoniae* as they have in the post-transplant period a 12.8 times increased risk for IPD compared to the general population.[48] Two vaccine types are available: a 23-valent pneumococcal polysaccharide vaccine (PPV23) and a 13-valent pneumococcal conjugate vaccine (PCV13) which has replaced the previously available 7-valent conjugate (PCV7). In some areas, a 10-valent conjugate formulation may also be available.[49] PCV7/10/13 but not PPV23 induces a T-cell dependent immune response that subsequently induces memory B-cell stimulation and confers long-term protection.[50] In children, the inclusion of conjugate pneumococcal vaccines in immunization schedules has correlated with a dramatic decrease in IPD.[51,52] Among immunosuppressed patients, PCV7 demonstrated greater immunogenicity compared to PPV23, despite being transient in some studies.[53,54] Similarly, PCV7 but not PPV23 was associated with a reduction in IPD in HIV-infected patients.[55,56] In the last years, based on immunogenicity studies, recommendations have favored the use of PCV over PPV23.[5,57,58] To provide additional serotype protection, a booster with PPV23 at least 8 weeks after primo-vaccination with PCV is often recommended.

Hepatitis A and B virus vaccines

Hepatitis A vaccine is an inactivated vaccine that can be administered to SOT recipients who are traveling to endemic areas;[57] it is also recommended for transplant candidates and recipients if risks for severe infection are present such as underlying chronic liver disease. However, decreased post-transplantation immunogenicity and accelerated antibody titers waning after Hepatitis A virus (HAV) immunization requires serological monitoring and booster doses when needed.[12,59,60] For example, 2 doses of hepatitis A vaccine were shown to induce seroconversion in only 27% of seronegative kidney transplant recipients and 26% of liver transplant recipients.[60,61] The immunogenicity of more than 2-doses of Hepatitis A vaccine in transplant recipients is an area for study.

Hepatitis B virus (HBV) immunization is an effective way to prevent HBV infection. Similar to the general population, HBV vaccine is recommended for SOT candidates and incomplete vaccination should be completed after SOT.[4,5] Immunization is important for all transplant candidates as it will likely reduce the risk of HBV transmission from anti-HBc positive donors if these organs are used.[62] Seroconversion rates among SOT candidates after a high dose immunization schedule ranged from 20 to 37%,[14,15,63] slightly more after booster doses. Among patients immunized after SOT, seroconversion rates varied between 40 and 70%.[7,64] Antibody waning after SOT was frequent.[7,14-16] High-dose vaccine should be used pre-transplant in dialysis patients and after SOT.[5] In general, anti-HBs titers should be monitored post-transplant and booster doses (1–3 boosters) should be administered if titers fall below protective levels (<10 IU/mL). In persons that are primary non-responders, a repeat vaccine series using high-dose vaccine can be administered. If seroconversion is not achieved, counselling regarding post-exposure prophylaxis and avoidance of high-risk behavior can be provided.

Varicella-Zoster virus

Varicella-zoster virus (VZV) infection in SOT patients is associated with increased morbidity and mortality because of disseminated disease but also because of graft rejection.[65,66] VZV vaccine is a LAV developed using the Oka strain,[67] that was authorized for use in the 1990's.[68] Because of the potential for vaccine-related disease, VZV vaccine is contraindicated in SOT recipients but recommended for non-immune transplant candidates, up to 4 weeks before transplantation,[4,5] with a single dose schedule for adults and a 2 doses schedule for children >9 months. Seroconversion rates reach up to 95% before SOT.[6,9] A positive vaccine history or VZV antibody titers before SOT protect against VZV disease after SOT.[9,69] In non-immune transplant recipients, exposure to VZV usually requires Varicella Zoster immunoglobulin (VZIG) treatment within 10 days (with or without antiviral prophylaxis) whereas VZV disease requires IV acyclovir treatment.[70] Since 1994, several groups have prospectively administered VZV vaccine in carefully selected SOT children with resulting seroconversion rates ranging from 65–87% and few side-effects.[6,8,71-74] More recently, Posfay-Barbe et al reached a 100% seroconversion rate, as well as a significant increase in CMI, in a cohort of 36 liver transplanted children.[75] Similarly, Weinberg et al described increased CMI in 86% of liver and intestine transplant patients after immunization.[74] This is interesting as epidemiological studies have shown that CMI is a better predictor of protection against VZV disease than humoral immunity.[76] However, it has also been shown that despite being an interesting predictor, CMI in SOT patients is lower compared to healthy patients.[77] Most of these patients were immunized at least 6 months after SOT, with no allograft rejection or high immunosuppression. Follow-up showed moderately waning antibody titers.[6,8,71,75] Larger studies, as well as studies in the adult population, are needed to confirm safety and immunogenicity of VZV vaccine in the post-transplant setting.

Reactivation of VZV (Herpes Zoster) is a frequent complication in SOT patients, with incidence estimated from 27 to 55 cases per 1000 person-years.[78,79] Since 2006, the FDA authorized the licensing of an Oka vaccine against herpes zoster (HZ, shingles) for previously immune adults >50 years, containing 14 times more plaque-forming units (PFUs) than the VZV vaccine.[80] This vaccine is currently contraindicated in SOT patients but can be given to those waiting for transplant up to 4 weeks before transplantation.[4,5] To date, there are no data regarding HZ vaccine in SOT patients but studies are currently ongoing to evaluate immunogenicity of HZ vaccine in transplant candidates. VZV immunization continues to be recommended in HM or HCW in contact with SOT patients as the risk of transmission is minimal.[4] Inactivated vaccines for herpes zoster are under development and will need to be evaluated in the pre- and post-transplant setting.

Measles-mumps-rubella

Measles is an epidemic, severe, mostly pediatric disease with around 20 million estimated cases yearly.[81] The extensive morbidity and mortality in immunocompetent and immunosuppressed patients, including SOT recipients, is due to pneumonia, acute encephalitis and the rare late-onset subacute sclerosing panencephalitis. There is no specific antiviral therapy against measles and only intravenous immunoglobulin (IVIG) can be offered in case of exposure. Therefore, immunization is the only effective measure to eliminate the disease by conferring lifelong protection. The measles vaccine (Edmonston B strain) was licensed in Europe and US in the 1960's and is now available as a combined vaccine that also includes live attenuated strains of Mumps and Rubella formulated as the Measles-Mumps-Rubella (MMR) vaccine. Because it is a LAV, current recommendations contraindicate its use in SOT recipients. However, as with other live vaccines, it can be given up to 4 weeks before SOT in case of negative vaccine history or unprotective titers. Children > 6 months and adults waiting for transplant can receive 2 doses at least 4 weeks apart if there is no prior history of immunization or immunity. Pre-transplantation immunization against measles has been shown to be safe, with seroconversion rates ranging from 80% to 98%.[82-84] The fact that measles pre-transplantation titers are predictive of post-transplantation titers confirms the importance to ensure adequate immunization before SOT.[13] With respect to post-transplant immunization, only 4 prospective studies have evaluated carefully selected children immunization after SOT. Side-effects were mild and seroconversion rates were highly variable, ranging from 40 to 100%.[6,8,72,85] Data concerning antibody waning were controversial.[6,8] Unfortunately, CMI was not assessed in these studies. There are currently no data concerning measles immunization in adult SOT recipients. Data concerning immunogenicity for mumps are rubella are scarce, with very variable seroconversion rates after SOT (82-100% for mumps and 100% for rubella).[6,8] HM and HCW can be immunized with the MMR vaccine.[4]

Human papilloma virus (HPV)

There are 2 HPV vaccines, a bivalent vaccine protecting against HPV16 and HPV18, the major strains responsible of cervical cancer, and a quadrivalent vaccine conferring additional protection against HPV6 and HPV11, responsible of 90% of genital warts. Very recently a 9-valent HPV vaccine has been licensed in the USA and will likely replace the quadrivalent formulation. A 3-dose HPV immunization schedule should be offered to male and female SOT candidates and patients aged 11–26 years.[4,5] As HPV-related warts are responsible for a significant morbidity in SOT patients,[86] the quadrivalent vaccine is preferred. To date, few studies have evaluated HPV vaccine immunogenicity in SOT patients, with variable results.[87,88] Higher doses of immunosuppression, early immunization after SOT and receipt of a lung transplantation were risk factor for low immunogenicity. Despite immunization, young female patients should continue their yearly gynecological screening.

Diphtheria-tetanus-pertussis (DTaP or TdaP)

Diphtheria-Tetanus-acellular Pertussis vaccine is available as a combination vaccine. For diphtheria immunization, the primary immunization series in children uses a higher dose of diphtheria antigen than the adult booster. SOT candidates should receive 1 dose of DTaP or TdaP vaccine before transplantation depending on age. Specifically, tetanus serology, which is the best correlate for vaccine-induced protection after DTaP immunization, can be checked during pre-transplant assessment when available, irrespective of patient vaccine history, to ensure catch-up before SOT if needed. After SOT, tetanus vaccine should be updated every 10 years; where available, serologic monitoring can be used to guide the need for booster immunization.[4]

Rotavirus vaccine

Rotavirus is a live attenuated oral vaccine that can be given to immunocompetent infants. The vaccine series can be started as early as 6 weeks of age and 2 or 3 doses are required depending on the type of vaccine (RotaTeq™ or Rotarix™).[89] The vaccine should not be given to those who have already received transplants. In theory the vaccine could in theory be administered to infants awaiting transplants who meet the age criteria. However, it is important to note that viral antigen is well known to shed in stool at least up to 28 days post-first vaccination;[90] one study has shown viral shedding can occur for prolonged periods (up to 8 months in nonimmunocompromised infants).[91] Therefore, it may not be practical to administer this vaccine to infants awaiting transplant – since the urgency of the transplant and potential for prolonged shedding will likely preclude vaccine administration.

Specific vaccines for splenectomy

SOT patients with functional or anatomic asplenia are at increased risk of infection, especially with encapsulated bacteria such as *S. pneumoniae*, *N. meningitidis*, and *H. influenzae*. All patients with asplenia should receive PCV13 followed by PPV23, one dose of *H. influenza*e vaccine, and quadrivalent meningococcal conjugate vaccine (MCV4, active against serogroups A, C, Y, W135). MCV4 is recommended before and after SOT in all patients without asplenia aged 11–18 years.[4] With SOT patients with asplenia, recommendations extend to any age as early as 9 months. These extended recommendations also apply to other categories at increased risk, such as patients living in groups (military, campus), traveling to high risk areas, or with specific immunodeficiencies (properdin and complement deficiency, eculizumab treatment). For *N. meningitidis* serogroup B, the general recommendations for the country in which the patient resides should be followed.

Haematopoietic Stem Cell Transplantation

General principles

HSCT aim is to replace the lymphohematopoietic system of one patient. There are 2 processes to do so. First, an autologous HSCT, where the patient's own cells are sampled and then reinfused after HSCT conditioning with indications such as neoplastic diseases. Second, an allogeneic HSCT, where the patient receives cells from another individual, related or not and with broader indications than for autologous HSCT: besides neoplastic diseases, allogeneic HSCT is indicated for hemoglobinopathies, congenital immunodeficiencies as well as enzymatic diseases, myeloproliferative and bone marrow failure syndromes. The risk of infection after allogeneic HSCT is considerably higher than autologous HSCT, especially because of the risk of graft rejection and GvHD. Trying to reinforce the effect of the newly infused immune system against tumoral cells (so-called the graft-versus-leukemia effect), without having a GvHD is a delicate equilibrium.

However, despite considerable improvement, infection is still one of the leading causes of mortality in the HSCT population, especially in case of allogeneic HSCT. GvHD is the main factor predisposing for infection and its severity is considered as a good correlate for infectious risk. Other predisposing factors are HLA incompatibility, time from infusion to engraftment and type of conditioning.[92] The new reduced-intensity conditioning regimens have lower infectious risks than classic myeloablative conditioning, especially during the early post-HSCT period, probably because of a shorter pancytopenia and lower mucosal toxicity.

The restoration of the immune system after HSCT is a long and progressive process. It requires environmental, as well as vaccine antigen reexposure, to replete the pool of memory B cells. The immune system is sufficiently restored to respond to vaccines at least 6 months after HSCT, explaining why recommendations advise to reimmunize with inactivated vaccines from 6–12 months after HSCT.[92] Immunity then continues to increase until 24 months after HSCT. At this time, and if the patient has no active GvHD or iatrogenic immunosuppression, the patient can be considered as immunocompetent. Consequently, criteria for LAV immunization are being at least 2 years after HSCT and free of immunosuppressant medication or GvHD.[92,93] Patients that undergo autologous HSCT likely have a faster restoration of immunity. However, given the heterogeneity in this population, the vaccine recommendations are similar to those receiving allogeneic HSCT.

Donor Vaccination

As for SOT, HSCT donors should be up to date with their routine immunization according to national immunization guidelines but should avoid LAV administration in the 4 weeks preceding stem cell collection.[5] Unlike SOT however, there is a transfer of antigen-specific immunity between the donor and the recipient during HSCT. The post-transplantation immunity was increased among patients whose donors were immunized during the 6 months preceding HSCT.[94,95] Moreover, immunizing the donor before HSCT has been shown to increase antibody titers after HSCT, whether booster doses were administered or not.[96-98] To date, a potential benefit has only been demonstrated for tetanus, *H. influenzae* type b, *S. pneumoniae*, and possibly diphtheria.[92] However, vaccination of the donor specifically to benefit the recipient is generally not performed and raises ethical

issues.[5,92] Logistical issues are also a factor since in cases of unrelated transplant, the donor is also no readily available.

Specific vaccines

Influenza

The combined guidelines of the European Bone and Marrow Transplant (EMBT) group, the American Society of Blood and Marrow Transplantation (ASBMT) and IDSA recommend yearly IIV immunization as early as 4–6 months after HSCT, but contraindicate LAIV.[92,93] As immunogenicity is related to time since HSCT, they recommend considering a second dose if the first vaccination happens between 4 to 6 months post HSCT. The more recent IDSA guidelines recommend starting influenza immunization 6 months after HSCT, except in case of a community outbreak, where immunization can start 4 months after HSCT.[5] For HM and HCW, yearly immunization is recommended with IIV but LAIV is contraindicated.[92,93] Any person immunized with LAIV should avoid contact with an HSCT patient during the 7 days following immunization.[19]

Streptococcus pneumoniae

As for SOT, HSCT patients are at increased risk for IPD in the post-transplant period, compared to the general population (Odds Ratio: 30), especially after allogeneic HSCT.[99] A prospective study showed greater immunogenicity with PCV7 vaccine compared to PPV23.[100] PCV7 immunization in children after HSCT showed >80% seroconversion rates.[101] Cordonnier et al. performed a study of 3 doses of PCV7 followed by PPV23. Patients were randomized to start early (3 months post-transplant) vs. late vaccination (9 months post-transplant). Although both groups had a vaccine response, those that started later had a more sustained response.[102] Therefore, experts currently recommend to administer 3 doses of PCV13 starting 3 months after HSCT, with a booster dose with PPV23 at least 6 months after the last PCV13 dose.[5,92]

Hepatitis A & B virus vaccines

Hepatitis A vaccine is recommended for HSCT recipients[92] especially in those who will be traveling to endemic areas or have underlying chronic liver disease. However, the immunogenicity of this vaccine in HSCT recipients is not well studied although is expected to be low as in organ transplant recipients (see above). HBV is a blood-borne virus and there is a small but potential risk of HBV transmission during blood product infusion. As a consequence, all HSCT candidates should be immunized against HBV, even in patients undergoing chemotherapy who are at increased risk for hyporesponse.[5,92] Moreover, HBV negative patients should not receive HSCT from donor with positive HBsAg or HBV DNA, if another donor is available.[92] Jaffe et al studied immunogenicity of post-transplant HBV vaccination in a cohort of 292 HSCT patients: seroconversion rate reached 73% of children and 59% of adults. GvHD was a risk factor for hyporesponse, but not conditioning regimen or the infusion of a T-cell depleted graft.[103] Other groups demonstrated seroconversion rates of 100% in smaller cohorts immunized after HSCT.[104,105] In all cases, antibody waning was frequent.[103-105] Therefore, anti-HBs should be checked at regular intervals and booster doses given if this falls below the protective level.

Varicella-zoster virus

VZV infection is frequent and a major cause of morbidity in HSCT patients.[106] Immunization is recommended in seronegative HSCT candidates but optimal timing before conditioning is unclear.[93] After HSCT, VZV immunity may be lost and immunization should be considered. VZV vaccine can be given to HSCT recipients if they are at least 2 years post-transplant and have not had therapy for GVHD for at least 3 months. Recent immunoglobulin administration will also interfere with the immunogenicity of vaccine and at least 8 months should elapse after the last IVIG administration.[5,93] Seroconversion rates are approximately 65% with mild side-effects.[47,107] Interestingly, one study showed similar seroconversion rates between recipients of a T-cell depleted or repleted graft, as well as between recipients of a matched related or unrelated graft.[107] Studies where patients are immunized with VZV vaccine <6 months after HSCT have shown variable immunogenicity but no major safety issues.[108,109]. In susceptible patients, VZV exposure requires prophylaxis with varicella zoster immune globulin within 10 days of exposure and/or antiviral prophylaxis.[92]

Herpes Zoster immunization is also recommended in HSCT candidates >4 weeks before transplantation but contraindicated after HSCT because of lack of data regarding safety of this vaccine since it contains greater amount of plaque forming units than the VZV vaccine.[5,93] Recently, 2 studies reported no major safety issue after HZ immunization in HSCT patients but unfortunately, no data concerning immunogenicity was provided.[110,111] Two non-live vaccines against HZ are currently under evaluation and could become interesting alternatives for this population. First, an adjuvanted subunit vaccine has demonstrated safety and immunogenicity as early as 2–4 months after HSCT in Phase 1/2 studies.[112] Second, a heat-inactivated vaccine induced CMI but no humoral immunity in patients immunized <6 months after HSCT.[113,114] Another study showed that pre- and post-HSCT immunization with this vaccine induced CMI and reduced incidence of HZ.[115] No major safety issues were reported. Naive HM or HCW can be immunized with either VZV or HZ vaccines.[92,93]

Measles-mumps-rubella

Measles outbreaks continue to occur worldwide. MMR immunization is recommended up to 4 weeks before HSCT but contraindicated during the first 24 months after HSCT, in case of GvHD or immunosuppression.[5,92,93] As antibody waning is common, there is a frequent need to reimmunize after HSCT.[116,117] Immunization has been shown to be safe with satisfactory seroconversion rates (77%, 64%, and 75% for measles, mumps, and rubella, respectively) when performed under criteria for LAV administration.[117] Another group showed 100% seroconversion rate when patients without GvHD and free from immunosuppression for more than 12 months were immunized

at least 18 months after HSCT.[101] Therefore, experts advise to start reimmunization at least 2 years after HSCT, and only if there is no GvHD and no immunosuppression.[5,92,93] When patients were immunized earlier, such as in an outbreak setting, seroconversion rates for measles ranged from 33 to 100% but no safety issues were described.[116,118,119] Therefore, immunization could be considered in case of outbreak earlier than 2 years after HSCT only if there is no GvHD or iatrogenic immunosuppression.[120] As there is no evidence that vaccine viruses are transmitted between persons, MMR immunization of HM and HCW is recommended.[92,93]

N. meningitidis

Meningococcal vaccine is recommended for patients after HSCT due to functional asplenia. Despite the absence of comparative studies, it is considered that conjugate vaccine (MCV) is more immunogenic in the HSCT population than the polysaccharide vaccine, similar to that for *S. pneumoniae*. As a consequence, immunization with MCV4 is recommended 6–12 months after HSCT to patients aged 11–18 years.[5] These recommendations should probably be extended to all age groups >9 months old in case of eculizumab treatment. 100% of children immunized after HSCT (>12 months for autologous, >18 months for allogeneic) mounted protective titers against *N. meningitidis* type C.[101] There are no data concerning routine immunization with *N. meningitidis* serogroup B vaccine. However, it is recommended to use this vaccine in outbreak situations.[121]

Human Papilloma Virus

Simliar to SOT, a 3-dose schedule with the HPV vaccine is recommended in male and female HSCT patients according to national age recommendations.[5] The effectiveness of this strategy post-HSCT has not been studied.

Diphtheria-tetanus-pertussis

HSCT candidates and patients should be immunized according to national schedules, with regular serologic monitoring when available and booster when needed,[92] as antibody waning is frequent.[17]

Serologic Monitoring

Serological monitoring is a cornerstone of vaccinology in the transplant setting for several reasons. First, standard immunization schedules are inappropriate because of the high inter-patient variability in terms of transplanted organ, degree of immunosuppression and comorbidities. Second, these patients often have suboptimal immune responses and accelerated antibody waning due to immunosuppression. Irrespective of their vaccine history, all transplant candidates should have their serologies checked during pre-transplantation assessment for HAV, HBV, VZV and Measles, as well as tetanus and *S. pneumoniae* where available.[4,92,93] When unprotective titers are detected, immediate catch-up immunization should be performed followed by repeat serologies 4–6 weeks later, and reimmunization if needed. As accelerated schedules have been shown to be non-inferior compared to classic schedules,[16] clinicians must keep in mind that it is never too late to immunize, except for LAV that are contraindicated <4 weeks before transplantation. This ensures optimal protection before transplantation, but also in the early post-transplant period, as pre-transplantation antibody titers have been shown to be predictive of post-transplantation titers.[13,15] After transplantation, yearly serologic monitoring should be performed, as antibody waning is frequent.[6-17] The efficacy of serology-based tailor-made recommendations to increase protection against vaccine-preventable diseases has been demonstrated in liver transplanted children.[13,122]

Travel Vaccines

After the acute post-transplantation period, as patients return to normal activity, they also desire to travel abroad.[1] As a consequence, clinicians must ensure travel immunizations are up to date and based on the location and duration of travel.

Poliovirus is a neurotropic enterovirus responsible for neurological entities such as acute flaccid paralysis. Despite the risk of vaccine-induced poliomyelitis (VIP), most developing countries still use the Sabin LAV (oral polio vaccine, OPV), especially because of the prolonged fecal shedding conferring herd immunity.[123] In developed countries, experts recommend the Salk vaccine (inactivated polio vaccine, IPV) since VIP cases secondary to mass OPV immunization outnumbered wild polio cases.[123,124] Because of the risk of VIP, OPV is contraindicated in SOT and HSCT patients, their HM, and HCW, but IPV can be administered.[5,57,92,93] There are currently no studies concerning OPV immunization in SOT and HSCT patients as there is an efficient inactivated vaccine.

Certain areas of the world including areas of Africa and South America are endemic for Yellow Fever (YF). Only a LAV is available for this disease and this is contraindicated in SOT recipients;[4,57,125] therefore, patients living in endemic countries or planning to travel after transplantation should have YF vaccine administered before transplantation. Patients that have received the vaccine pre-transplant have been shown to have antibody persistence after SOT.[126] In a report from Brazil, 19 SOT patients were inadvertently immunized against YF without serious adverse events;[127] however, more studies are needed to evaluate safety and immunogenicity in this population before a post-transplant recommendation can be made. For HSCT patients, YF immunization can be considered if LAV criteria are met, especially for patients living in endemic countries but risks and benefits must be clearly weighed and individually discussed with the patient.[5,92,93]

Two typhoid vaccines are available: one inactivated injectable vaccine which can be administered to SOT patients and one oral LAV which is contraindicated.[4,57] Concerning HSCT patients, there are no data concerning both vaccines recommendations.[92,93] HM and HCW in contact with SOT and HSCT patients can be immunized with YF and oral typhoid vaccine.[5]

There are 4 vaccines against Japanese encephalitis (JE): one mouse brain-derived vaccine which is now discontinued, one cell culture-derived inactivated vaccine, as well as one cell culture-derived (known as SA14-14-2) and one genetically engineered chimeric LAV.[128] Only the inactivated vaccine can be given to SOT and HSCT patients but the optimal timing after transplantation is unknown.[4,57,92,93] In one study, SA14-14-2 was administered at least 2 years after HSCT, with moderate seroconversion rates and frequent waning of antibody. No safety issue was reported but data are insufficient to recommend routine use of SA14-14-2 in HSCT patients.[129]

Rabies vaccine is an inactivated vaccine that can be given to SOT and HSCT recipients that anticipate ongoing frequent animal contact.[4,93]

Two oral inactivated cholera vaccines are available in some areas of the world. Dukoral™ protects against both cholera and travelers' diarrhea from enterotoxigenic *E. coli*.[130] Shanchol™ is a bivalent whole-cell vaccine safe and immunogenic as young as 1 year of age.[131] Both vaccines provide short term protection and can be given to immunocompromised patients. However, the immunogenicity of these vaccines in the transplant setting is unknown.

BCG vaccine is one of the most frequently administered vaccines worldwide. It is contraindicated in SOT and HSCT patients and candidates because of the risk of dissemination.[4,5,57,92]

Smallpox, a severe disease caused by variola virus, has been eradicated in the late 1970's due to mass immunization with a LAV. However, the risk of disease may theoretically still exist in the bioterrorism setting. Despite the inherent risk of severe disease, SOT experts recommend prompt immunization in case of close contact with a confirmed case;[4] there are no recommendations for HSCT patients.

MCV4 immunization is recommended for SOT and HSCT patients older than 9 months traveling to endemic areas.[4]

Vaccines in the Pipeline

For the past 4 decades, efforts have been made to develop a vaccine against CMV, mainly to prevent congenital infection and post-transplant CMV-related complications. Currently, several vaccines types are under evaluation but 2 seem more promising. First, a recombinant vaccine targeting the envelope glycoprotein showed satisfactory immunogenicity and reduced incidence of infection among healthy patients,[132,133] whereas duration of viremia and antiviral use was reduced in a cohort of SOT candidates.[134] The second is a DNA plasmid vaccine (known as ASP0113) who showed no safety issue among healthy patients in Phase 1 study.[135] Among HSCT patients, ASP0113 reduced the frequency and duration of viremia episodes compared to placebo in Phase II study.[136] A Phase II trial is currently ongoing for SOT patients.[137] There is also a LAV who demonstrated low immunogenicity but no safety issues in kidney transplant candidates.[138] CMV vaccines and trials are reviewed here.[137] Other pipeline vaccines include vaccines for pathogens important in transplant recipients such as RSV, EBV, norovirus, *Clostridium difficile*, and *Staphylococcus aureus*. However, these are currently in early stages of development.

Conclusion

Despite considerable progress in immunization in the transplant setting during the last decades, more studies are needed to determine the optimal timing for (re)immunization, but also to confirm safety and immunogenicity of LAV in the transplant population. Since multiple immunizations are required for transplant recipients, it is reasonable to use combination vaccines where available. However, it is important to note that the amount of antigen may vary in combination vs. individual vaccines; therefore, when using a combination vaccine, the practitioner should ensure the antigen is sufficient. It should also be noted that data with combination vaccines in the transplant setting are limited. Moreover, efforts should be made to individually evaluate each patient in terms of humoral and cell-mediated immunity and therefore ensure the best protection against vaccine-preventable diseases.

Disclosure of Potential Conflicts of Interest

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