Recommendations of the National Comprehensive Cancer Network® (NCCN®) COVID-19 Vaccination Advisory Committee *

- Updates from Version 7.0 include:
  - Removal of monoclonal antibodies used as prophylaxis or therapy for COVID-19
  - Update to Figure 1 and related text
  - Recognition that vaccine supply (in context of infection risk) is no longer limited, and sections for prioritization of use in the general population removed
- The committee endorses vaccination for all eligible persons, including both cancer patients undergoing treatment and cancer survivors 6 months of age and older, based on FDA-approved indications or emergency use authorization (EUA).
- The committee endorses vaccination for household contacts and other close contacts of people with cancer, as per standard vaccination recommendations (see pages 9-10).
- The committee prefers the use of mRNA vaccines for the primary series and boosters.
- mRNA vaccines are the only vaccines indicated for use in persons 6 months to 11 years of age. mRNA-1273 (Moderna) vaccination is the preferred primary series vaccine for immunosuppressed pediatric patients.
- Currently (as of 2/27/2023), additional dose and booster recommendations under available EUAs vary by vaccine (see Figure 1) in the different age groups.
- Most patients with cancer should receive a primary COVID-19 vaccination series (including approved boosting) as soon as possible, regardless of their cancer treatment, with the exceptions to consider in Table 1. Vaccine delays in patients with cancer should also include those recommended by the CDC for the general public (eg, recent exposure to COVID-19).
- COVID-19 vaccinations can be given without regard to timing of other vaccines (except those receiving an Orthopoxvirus vaccine [eg, Jynneos or ACAM2000 vaccines]). Administer each injection in a different injection site.
- Revaccination (of the 3-dose primary series and booster) is recommended 3 months following HCT or CAR T-Cell Therapy, if a patient was vaccinated before such therapy.
- COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies.

Table 1. Unique COVID-19 Vaccination Timing Considerations for Selected Patients with Cancer

All patients should otherwise receive their vaccination as soon as possible

Patients Treatment/Cancer Type	Timing to Start Series
Hematopoietic Cell Transplantation (HCT)/Cellular Therapy	
Allogeneic/autologous transplantation Cellular therapy (eg, CAR T cell)	At least 3 months post-HCT/cellular therapy[a]
Hematologic Malignancies	
Receiving intensive cytotoxic chemotherapy (eg, cytarabine/anthracycline-based induction regimens for acute myeloid leukemia)	Delay until absolute neutrophil count (ANC) recovery[b] or for those not expected to recover, as soon as possible
Solid Tumor Malignancies	
Major surgery	Separate date of surgery from vaccination by at least a few days[c]

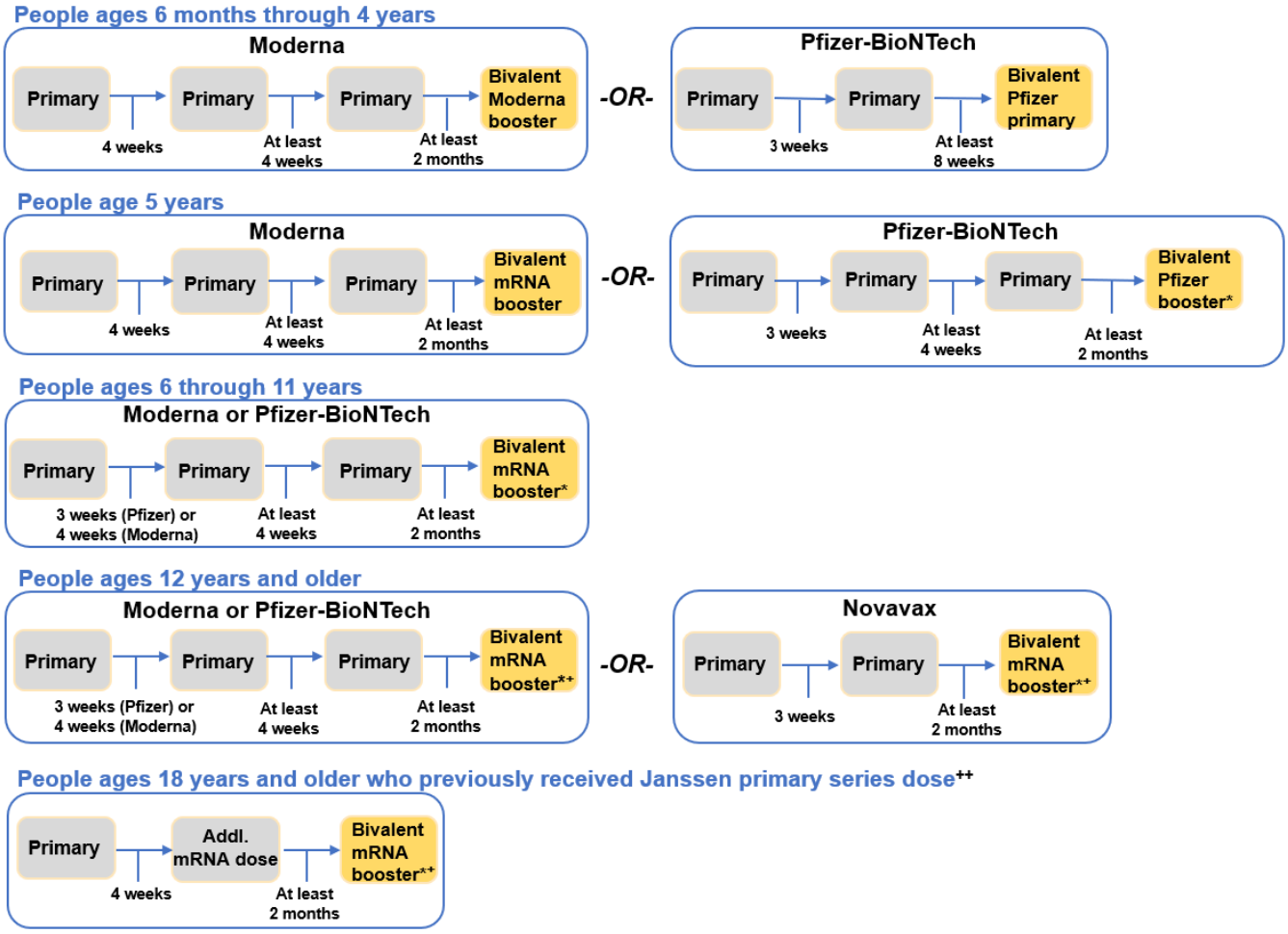
a) Graft-versus-host disease (GVHD) and immunosuppressive regimens to treat GVHD (eg, systemic corticosteroids and targeted agents) are expected to blunt immune responses to vaccination. Delay of vaccination until immunosuppressive therapy is reduced and/or based on immunophenotyping of T-cell and B-cell immunity can be considered.

b) The committee recognized that granulocytopenia does not, in itself, significantly affect immunologic response to vaccination. It is used in the setting of profound immunosuppression for patients with hematologic malignancies as a surrogate marker for recovery of adequate immunocompetence to respond to vaccines.

c) The primary reason for avoiding vaccine in the perioperative period is so that symptoms (eg, fever) can be correctly attributed to surgery versus vaccination. For more complex surgeries (eg, splenectomy or which may lead to an immunosuppressive state), surgeons may recommend a wider window (+/- 2 weeks) from the time of surgery.

Figure 1. COVID-19 Vaccination Schedule Infographic for People who are Moderately or Severely Immunocompromised

Source: Centers for Disease Control and Prevention (CDC). Accessed on February 27, 2023.
For the most updated information and vaccine schedules, see the CDC website.



* For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

[+]A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered **at least 6 months** after completion of a primary series.

[++]Janssen COVID-19 Vaccine should only be used in certain limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

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ADDITIONAL PRIMARY SERIES VACCINE DOSE:

The FDA issued an update to the EUA for the BNT162b2 (Pfizer/BioNTech) mRNA vaccine (Comirnaty®) and the mRNA-1273 (Moderna) mRNA vaccine to include an additional dose after an initial 2-dose series for moderately to severely immunocompromised patients. The amendment applies to mRNA COVID-19 vaccines and was based on a growing body of literature showing that immunocompromised patients can have impaired immune responses to vaccination. Data in immunosuppressed patients show a substantial effect of an additional dose in augmenting antibody responses to vaccination after completion of a 2-dose series.[1] The additional primary dose of an mRNA COVID-19 vaccine is intended to improve immunocompromised people's response to their primary vaccine series.

The CDC recommends a third dose of the mRNA vaccines for the primary series in moderately to severely immunocompromised people, defined as:

- Those who have been receiving active cancer treatment for tumors or cancers of the blood
- Those who have received an organ transplant and are taking medicine to suppress the immune system
- Those who have received an HCT within the last 2 years or are taking medicine to suppress the immune system
- Those with moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Those with advanced or untreated HIV infection
- Those on active treatment with high-dose corticosteroids or other drugs that may suppress immune response

The NCCN Committee fully supports an additional dose in the primary series for immunocompromised patients as indicated by age group and vaccine product under currently available EUAs. Below, we provide consensus recommendations on patients with cancer who should be prioritized for an additional dose.

a) **Solid tumor malignancies:** We recommend an additional dose for patients who received cancer therapy within 1 year of the initial vaccine administration. Realizing that specific therapies have different effects on the immune system, this recommendation applies to all cancer therapies, including but not limited to chemotherapy, targeted therapy, immunotherapy, hormonal therapy, surgery, radiation, and investigational agents. In addition, patients with newly diagnosed cancer or recurrent cancer who will receive cancer therapy are included among patients prioritized for a third dose. These criteria do not apply to non-melanoma skin cancers or superficial mucosal lesions treated solely with local therapy.

b) **Hematologic malignancies:** We recommend that all patients with active hematologic malignancies receive an additional dose regardless of whether they are receiving cancer therapy. The reason for this recommendation is that patients with hematologic malignancies are at high risk for poor serologic responses to vaccination both as a result of immunodeficiency due to the malignancy and their associated cancer therapies (eg, B-cell–depleting agents such as anti-CD 19, -CD20, and -CD 22 antibodies and Bruton tyrosine kinase inhibitors).[2-10] As examples, patients with Hodgkin and non-Hodgkin lymphoma, chronic lymphocytic leukemia, multiple myeloma, myelodysplastic syndrome, or chronic myeloproliferative neoplasms should be prioritized for an additional dose even if not on active therapy for these malignancies.

c) **Hematopoietic cell transplant and cellular therapy:** We recommend an additional dose in HCT recipients and those who received engineered cellular therapy (eg, CAR T cells), prioritizing those who are ≤2 years post-procedure. An additional dose is recommended for all allogeneic HCT recipients who are actively receiving immunosuppressive therapy or with a history of GVHD regardless of the time post-transplant.

d) **Cancer and other immunosuppressive conditions that do not meet other criteria:** We recommend an additional dose for patients with cancer who have other concurrent immunocompromising conditions, such as HIV infection or autoimmune diseases. In addition, patients with cancer treated with systemic corticosteroids and other immunosuppressive agents separate from cancer therapy should be prioritized for a third dose.

Timing of Administration of Third Primary Series Dose:
The CDC recommends the additional dose of an mRNA COVID-19 vaccine (for immunocompromised individuals) be administered 4 weeks after a standard vaccine series of the BNT162b2 (Pfizer/BioNTech) or mRNA-1273 (Moderna) vaccine. The only group who is not eligible for additional doses are patients ≥6 months to <5 years of age who receive the Pfizer vaccine series, which is at baseline a three-dose series. A detailed timing schedule can be found on the CDC website (or see Figure 1)[63]. For people who received the BNT162b2 (Pfizer/BioNTech) or mRNA-1273 (Moderna) COVID-19 vaccine series, an additional dose of the same mRNA vaccine should be used if possible. If the same mRNA vaccine isn't available for the additional dose administration or if the prior vaccine is unknown, either mRNA COVID-19 vaccine may be used.

a) We do not recommend (outside of a research study) the use of antibody titers to determine if patients should receive additional doses of vaccine.
b) Patients who have a history of COVID-19 following their initial vaccine series should also receive an additional dose (delayed >4 weeks post completed vaccine series and until recovery from the acute illness [if symptoms were present] and criteria to discontinue isolation have been met).

VACCINE BOOSTERS:
A booster is administered when a person has completed their vaccine primary series to augment immune responses that may have decreased over time. The CDC's recommendation on an additional primary series vaccine administration for immunocompromised patients was soon followed by a recommendation for booster vaccines for the general public. The rationale for boosters is to address the reduction of vaccine effectiveness over time that is likely due to waning immunity and the greater infectiousness recent variants. In the case of the mRNA-1273 (Moderna) COVID-19 vaccine booster dose, the booster is half the dose of that given for the primary series. Boosting with the BNT162b2 (Pfizer/BioNTech) vaccine reduced COVID-19 incidence and severe illness, including mortality.[48-50] Among patients with a history of cancer, those who do not meet the criteria of moderate to severely compromised should be offered a booster similar to the general population.

The CDC previously recommended a second booster with an mRNA COVID-19 vaccine for all adults 50 years and older. This recommendation was for a second booster (fourth vaccine dose) based on recent waves of the Omicron variants and data from Israel showing a reduction in rates of SARS-CoV-2 and severe COVID-19 after the second booster was administered to persons 60 years and older.[58-59] An mRNA COVID-19 vaccine was preferred as the first booster, while the second was an mRNA vaccine. The NCCN Committee supported the recommendation for a second booster in the general public based on age.

Specific guidance for immunocompromised patients is included in CDC guidelines, as boosting varies by age and vaccine product (see Figure 1). For patients with cancer and other immunocompromised persons, the first booster (fourth vaccine dose) may be administered as soon as 2 months after the primary series. Most recently, with the EUA approval of the mRNA bivalent boosters, which include both the Wuhan Hu-1 strain and a BA.4/5 strain, recommendations have shifted to target these as boosters. The FDA has eliminated the EUA allowing for booster doses using only the monovalent (primary series) vaccines. Importantly, although the overall dose is similar in the new boosters, the dose is split between the Wuhan Hu-1 ancestral strain and the Omicron BA.4/5 strain. In normal hosts, data have shown that immune responses are enhanced to Omicron strains with the new bivalent booster, and boosting was non-inferior to ancestral strain; however, data on efficacy in immunosuppressed hosts is not known.[66] The committee supports this recommendation but awaits additional data to determine if additional booster doses are needed.

Additionally, CDC guidelines previously state that immunocompromised persons who may be younger than 50 (but ≥ 12 years old for Pfizer, and ≥18 years of age for Moderna) could receive a second booster (fifth dose) of an mRNA vaccine at least 4 months after the first booster. With updates to the new bivalent booster, current recommendations from the CDC/FDA have shifted to a single bivalent booster for those who have completed their primary series (i.e., three doses), including those undergoing re-vaccination post-HCT, CAR-T cell therapy or post-anti-CD-20 antibody therapy. However, due to the waves of more contagious subvariants and excess morbidity and mortality of COVID-19 among patients with cancer, the NCCN Committee favors the previous CDC guidelines for a second booster for patients with cancer. The same advice applied to patients who received stem cell transplantation or engineered cellular therapy within the past 2 years or who are receiving immunosuppressive agents. Although patients with solid tumors are more likely to mount immune responses to vaccination, we recommended a second booster for patients who received cancer therapy within 1 year of the initial vaccine administration. For patients receiving immune checkpoint inhibitors (ICI), the data show that mRNA COVID-19 vaccines are safe.[60] Further, the committee considered the risk of severe COVID-19 (including cardiac complications) to be greater than the potential risk of a fifth vaccine dose, and therefore recommended the second booster for all these identified immunocompromised patients.

Furthermore, patients who have previously been boosted, even those who have received two monovalent boosters after their primary series with the monovalent vaccine, are eligible to receive an updated booster with the bivalent booster (equivalent to a sixth dose for those fully boosted); bivalent boosters can be given as early as 2 months following the last monovalent booster. Bivalent boosters are available for children ≥5 years of age (Pfizer), or ≥6 months of age (Moderna) (see Figure 1). The need for additional bivalent boosters to improve immune responses in immunosuppressed patients remains an outstanding question, and we hope that additional studies help to address this question.

Janssen/Johnson & Johnson Vaccine as initial single-dose primary vaccination

In most situations, the mRNA vaccines (Pfizer-BioNTech or Moderna) are preferred over the JNJ-78436735 (Janssen/Johnson & Johnson) vaccine due in part to reports of thrombosis with thrombocytopenia syndrome among JNJ-78436735 vaccine recipients.[57] Those who are not moderately or severely immunocompromised and are ages 18 years or older should receive 1 **bivalent** booster dose of a COVID-19 vaccine, at least 2 months after the primary JNJ-78436735 (Janssen/Johnson & Johnson) vaccine. For people who previously received a monovalent booster dose, the bivalent booster dose should be administered at least 2 months after the last monovalent booster dose.

All moderate to severely immunocompromised patients ages 18 years and older should receive a second (additional) dose using a monovalent mRNA COVID-19 vaccine, at least 4 weeks after the primary JNJ-78436735 (Janssen/Johnson & Johnson) vaccine and 1 bivalent mRNA booster dose at least 2 months later (see Figure 1).

NVX-CoV2373 (Novavax) Vaccine as initial primary vaccination series

There are limited data on the efficacy of the protein subunit vaccine, NVX-CoV2373 (Novavax), in cancer patients and, therefore, the committee does not recommend it for routine use. NVX-CoV2373 (Novavax) vaccine can be considered as an option for patients who are unable to be vaccinated with available mRNA vaccines (eg, due to allergic response to vaccination or known allergy to vaccine component). NVX-CoV2373 (Novavax) vaccine may also provide an alternate option for patients who previously have been unwilling to be vaccinated with either mRNA or AdV-vector based vaccines. Currently NVX-CoV2373 (Novavax) is only licensed for a two-dose regimen, with a three-week interval between doses. Additional and booster NVX-CoV2373 (Novavax) doses are currently not approved by the FDA or ACIP even for immunosuppressed patients, but these patients, per CDC recommendations, can be offered an age-appropriate mRNA bivalent booster at 2 months post completion of their primary series.

Mix and Match Dosing

Heterologous prime–boost strategies, in which the booster is a different formulation than the vaccine used in the primary series, have the potential to extend immune protection and could simplify the logistics of vaccine administration if the selection of the booster formulation is not restricted to the vaccine used in the primary series (homologous booster). Initial data from the phase 1–2 study showed that heterologous boosters were safe and immunogenic in adults who had completed a primary Covid-19 vaccine regimen at least 12 weeks earlier.[47] A heterologous booster resulted in similar or higher antibody responses than a homologous booster. Based on initial data from this study, the FDA has authorized the use of heterologous boosters for currently available COVID-19 vaccines. The NCCN Committee considers both homologous and heterologous boosters to be appropriate options.

Moderately or severely immunocompromised people who received COVID-19 vaccines not available in the United States but accepted for use outside the US should either complete or restart the recommended COVID-19 vaccine series, including boosters, in the United States. The CDC provides detailed guidelines on specific scenarios for persons who received a COVID-19 vaccine listed for emergency use by the WHO, but not approved or authorized by the FDA.[62]

Revaccination Following HCT, CAR T-Cell Therapy or B-cell Depleting Therapies:

In patients who received COVID-19 vaccination prior to HCT or engineered cellular therapy, there is major concern for loss of immunity. Loss of vaccine-induced immunity following these therapies is observed in several childhood vaccines (eg, measles, mumps, and rubella vaccine), necessitating re-vaccination post-therapy. The same depletion of immunity is expected for COVID-19 vaccines. These patients are expected to have attenuated responses to COVID-19 vaccination post-transplant, particularly in the setting of GVHD. In addition, lymphodepletion prior to CAR T-cell and other cellular therapy regimens is expected to attenuate post-therapy immune responses to vaccination.[51] Recognizing these limitations, the CDC, American Society for Transplantation and Cellular Therapy (ASTCT), and American Society of Hematology (ASH) recommend that patients completing these therapies should receive a repeat vaccination series (3 dose primary series and booster) starting at 3 months post-treatment. We support these recommendations. Additionally, the CDC recommends that revaccination may also be considered for patients who received 1 or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies (eg, rituximab, ocrelizumab) that were administered over a limited period (eg, as part of a treatment regimen for certain malignancies). The suggested interval to start revaccination is about 6 months after completion of the B-cell-depleting therapy. As we learn more about vaccine-induced immunity in these settings, these recommendations on revaccination may be modified.

OVERVIEW:

Large cohort studies have demonstrated that patients with cancer are at high risk for COVID-19–associated complications.[11-14] Based on an analysis of the CDC's National Vital Statistics System, the percentage of cancer deaths with COVID-19 as the underlying cause increased during peaks in COVID-19 incidence and among the following patients with cancer: age ≥65 years, males, American Indian or Alaska Native, Hispanic, Black, and persons with hematologic cancers, including leukemia, lymphoma and myeloma.[70] As an at-risk population, there is a clear need for vaccinating these patients to avoid excess morbidity and mortality during the SARS-CoV-2 pandemic. In addition, since immunosuppressed patients may be sources of prolonged viral shedding and development of variants,[15,16] prioritizing vaccinations to these vulnerable patients may provide an additional societal benefit. Individuals with active cancer or with active, recent (<6 months), or planned cancer treatment should be considered highest priority to receive one of the currently available COVID- 19 vaccines.[17-19] This document, while focusing on approved vaccines in the United States, can also be used to support vaccination and prevention approaches in patients with cancer in other parts of the world.

The NCCN Committee recommends that COVID-19 vaccines should be given to all patients with cancer, as well as household contacts and caregivers; the committee believes that mRNA vaccines should be offered as the

preferred vaccine(s). Data from vaccine trials have demonstrated that vaccines decrease the incidence of COVID-19 disease and complications, and data suggest that these vaccines may additionally prevent SARS-CoV-2 infection and subsequent risk of transmission.

Due to emerging data relating to vaccine effectiveness in patients with active malignancy, recommendations are based on available data and on the expert opinion of the committee; *as additional data continue to accumulate, our approach will be modified accordingly.* Decisions about when to offer COVID-19 vaccines should also take into account the National Academies of Sciences, Engineering, and Medicine (NASEM) Framework for Equitable Allocation of COVID-19 Vaccine that includes: risk of infection, severe morbidity and mortality, excess burden of COVID-19 on specific communities, and transmission to others.[20]

VACCINE SAFETY AND EFFICACY IN PATIENTS WITH CANCER:

Patients with cancer should be counseled that although these vaccines have been shown to be safe and effective in the general population, data on their effectiveness in immunosuppressed patients are emerging. The data on COVID-19 vaccine immunogenicity are mostly limited to measurement of post- vaccine antibody titers to the viral spike protein. Still, early data have demonstrated blunted antibody responses in patients with solid tumors and hematologic malignancies, particularly patients on active treatment;[34-38] data among other immunosuppressed populations also indicate more limited antibody responses.[39] Antibody responses are particularly poor among patients with hematologic malignancies, including those receiving monoclonal antibodies targeting CD19, CD20, CD22, and CD38 (eg, blinatumomab, rituximab, inotuzumab, daratumumab, isatuximab). Antibody responses should be interpreted with caution, as they are only a surrogate marker for vaccine protection. Some studies have demonstrated additional T-cell responses to vaccination,[40] although the strength and duration of neutralizing antibody responses or cellular immunity are not known at this point. With the widespread emergence of SARS-CoV-2 variant strains, the protective benefit of vaccination in reducing COVID-19 incidence in the general population has waned when compared to the initial mRNA vaccine trials. However, the major benefit of vaccination is avoidance of severe COVID-19, including hospitalization and death. Among patients with cancer, the magnitude of vaccine-derived protection from severe COVID-19 is expected to vary based on age, co-morbidities, and immune compromise, but remains the most effective tool we have to reduce COVID-19 severity.

There are no safety signals that suggest adverse events specifically among patients with cancer receiving currently available COVID-19 vaccines, although rare case reports have been reported in cancer populations.[41] Current SARS-CoV-2 mRNA vaccines (eg, Pfizer/BioNTech, Moderna) and the protein subunit vaccine (Novavax) do not contain live virus and do not pose an immediate safety risk for immunosuppressed patients. The available single-dose SARS-CoV-2 viral vector (Adenovirus-type 26 [AdV-type 26]) vaccine (Janssen/Johnson & Johnson) is safe for use in immunosuppressed hosts, as the adenovirus vector has been modified to make it replication incompetent.[21] NVX-CoV2373 (Novavax) (protein subunit vaccine) is safe for use with immunosuppressed patients. Although other vaccines are currently available in other parts of the world (eg, Astra-Zeneca COVID-19 vaccine, Sputnik [AdV-type 26, AdV-type 5 vaccine], Covaxin [killed whole virus vaccine with adjuvant], Sinovac [killed whole virus vaccine]), they are not currently available for use in the United States. The side effect profile of mRNA vaccines in infants and children tend to be similar to youth and adults.

All four available vaccines (in the United States) have been shown to be safe in the general population, although post-vaccination arm soreness, fatigue, fever, and headache, among other side effects are not uncommon.[17-19] Short-term safety of the BNT162b2 (Pfizer/BioNTech) mRNA COVID-19 vaccine in patients with cancer treated with immune checkpoint inhibitors has been reported.[33] Anaphylaxis has been reported with both mRNA vaccines, although incidence is very low, ranging from 2.5 to 4.9 cases per million doses

administered;[22] severe allergic responses have also been reported with the AdV-type 26 vector vaccine and the NVX-CoV2373 (Novavax), protein subunit vaccine.

COVID-19 vaccination in patients with cancer, including those receiving immunotherapy, targeted regimens, and investigational therapies, have to date consistently shown an acceptable safety profile of COVID-19 vaccination.

Pediatric Cancer Patients: In immunocompromised (including those with cancer) infants and children 6 months to 11 years of age, only the mRNA vaccines are authorized for use. The number of vaccine doses and the antigen content per dose differs depending on which mRNA vaccine is administered. In clinical trials of infants and children <5 years of age, data suggests more rapid initial attainment of prespecified FDA immunogenicity endpoints using the mRNA-1273 (Moderna) vaccination schedule as compared to the BNT162b2 (Pfizer/BioNTech) vaccination schedule, which might be taken into consideration in the immunocompromised pediatric population. The committee prefers the mRNA-1273 (Moderna) vaccine for pediatric immunosuppressed patients. The mRNA-1273 (Moderna) vaccine is also approved for a booster dose after the primary vaccine series in ages 6 months to 4 years in immunosuppressed populations; the Pfizer vaccine is approved for three doses regardless of immunosuppression level and has as of yet not been approved for a booster dose in the 6 months to 4 years age group. All children 5 years and older should be given a BNT162b2 (Pfizer/BioNTech) or mRNA-1273 (Moderna) bivalent COVID-19 booster at least 2 months after the completion of the primary vaccine series or after last non-bivalent booster. The NVX-CoV2373 (Novavax) vaccine may be used in adolescents 12 -17 years of age who have a contraindication to receiving an mRNA vaccine. This vaccine is given as a 2-dose series with the 2nd dose given 3 to 8 weeks after the 1st dose. Currently NVX-CoV2373 (Novavax) is not recommended for use as a booster.

***Post-vaccine thrombosis*:** The available single-dose SARS-CoV-2 viral vector (AdV-type 26) vaccine (Janssen/Johnson & Johnson) has been associated with an exceedingly rare risk of thrombosis with low platelets after vaccination (Thrombosis with Thrombocytopenia syndrome [TTS]); similar findings have been linked to the Astra-Zeneca (AdV-type 26) vaccine.[42] The mechanism that causes TTS is not fully understood. To date there have been no associations between TTS and patients with cancer, but patients who have a history of heparin-induced thrombocytopenia and/or thrombosis should be counseled to receive a different vaccine.

Guillain-Barre Syndrome: The FDA has added a warning for Guillain Barré Syndrome (GBS) for the JNJ-78436735 (Janssen/Johnson & Johnson) COVID-19 Vaccine. In those who developed GBS, symptoms began within 42 days following receipt of the JNJ-78436735 (Janssen/Johnson & Johnson) COVID-19 Vaccine.[65] GBS has rarely been reported following mRNA vaccination but is not currently listed as warning in package inserts; GBS and Novavax has not been reported.

Myocarditis: Beginning in April 2021, increased cases of myocarditis and pericarditis were reported in the United States after receipt of mRNA COVID-19 vaccination (BNT162b2 (Pfizer/BioNTech) and mRNA-1273 (Moderna). Multiple studies show a very rare risk for myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines. These rare cases have occurred most frequently in adolescent and young adult males, ages 16 years and older, within 7 days after receiving the second dose of an mRNA COVID-19 vaccine (BNT162b2 (Pfizer/BioNTech) and mRNA-1273 (Moderna)). There has not been a similar reporting pattern observed after receipt of the JNJ-78436735 (Janssen/Johnson & Johnson) COVID-19 Vaccine. Preliminary CDC data from surveys assessing long term outcomes of myocarditis after mRNA COVID-19 vaccination conducted at least 90 days after the myocarditis diagnosis showed most patients were fully recovered from their myocarditis.

IMPORTANCE OF COVID-19 VACCINATION AMONG PATIENTS WITH CANCER, THEIR HOUSEHOLD MEMBERS, AND THE GENERAL POPULATION:

Patients with cancer face two major obstacles regarding vaccination: lack of effective immune responses due to their underlying disease and/or therapy; and vaccine hesitancy in the general population that impedes the development of herd (community) immunity. Emerging data demonstrate that certain patients with cancer (eg, those receiving B-cell–depleting agents) may not have protective antibody titers following vaccination. Although we strongly continue to recommend that these patients be immunized because the vaccine may confer some protection against COVID-19, the most effective protection for specific immunocompromised patients with cancer is likely to be through a reduction of community spread of SARS-CoV-2 by widespread vaccination. **We also note the particular importance for eligible household members and other close contacts of patients with cancer to be immunized. This is of significant importance in the pediatric population, given the age and weight limitations (≥12 years of age and ≥40 kg) in the use of monoclonal antibodies and other treatment regimens.**

Additionally, the committee strongly supports vaccination mandates for health care workers (see statement).

Vaccination of patients with cancer enrolled/planning to enroll in clinical trials: Patients currently being treated on clinical trials, or considering enrollment on a clinical trial should not defer COVID-19 vaccination or be ineligible for enrollment or continuation on a clinical trial because of COVID-19 vaccination, unless there is a specific scientific contraindication. The same should apply to COVID-19 antibody treatment. Clinical trials currently ongoing or nearing initiation should allow for COVID-19– related interventions without excluding candidacy or ongoing participation. The COVID-19 and Cancer Clinical Trials Working Group also recommended that patients with cancer enrolled in clinical trials be prioritized for COVID-19 immunization, which should not affect clinical trial eligibility.[44]

SOCIETAL CONSIDERATIONS:

It is imperative that all patients have equitable access to the vaccines. The NASEM guidelines have recommended the incorporation of social vulnerability indices to mitigate health inequities that have clearly arisen during the COVID-19 pandemic.[20] Notably, similar to the general non-cancer population, Black/African American, Hispanic/Latino, and Native American patients with cancer have been observed to have increased risk of developing COVID-19.[30] Consequently, we encourage health systems to incorporate social vulnerability markers tailored to their populations to address the myriad of health inequities that have arisen during this pandemic.[31] In addition, patients who may not have access to electronic health record platforms or email should be considered when vaccine invitation and scheduling are being operationalized. Special efforts should also be made to engage and incorporate patients and family members with limited English proficiency. Finally, health systems are encouraged to collect—to the extent possible—both race-ethnic and socioeconomic data for patients who receive the vaccine, so that these data can be periodically reviewed, and if inequities develop, aggressively addressed.

POST-VACCINE PREVENTION:

The committee strongly recommends continued vigilance for patients with cancer after completion of COVID-19 vaccination. As patients with cancer are at increased risk for COVID-19 complications and may have less protection from available vaccines, patients should continue to wear masks, maintain social distancing, avoid crowds, and follow guidelines and other recommendations for COVID-19 prevention. Efforts to protect patients should also expand to families, caregivers, and household contacts, where targeted vaccination approaches can help assure patients are less likely to acquire SARS-CoV-2 from those closest to them.[45]

Supplementary Tables for Reference:

- Summary Document for Interim Clinical Considerations (CDC)[68]
- Pediatric COVID-19 Vaccine Dosing Quick Reference Guide (American Academy of Pediatrics)[69]

*The current vaccine recommendations and prioritization guidelines will be updated regularly based on availability of new data. There are important gaps in knowledge on vaccine immunogenicity in specific patients with cancer and therapies. We will learn more about specific therapies that limit vaccine efficacy and would warrant vaccine delay. The durability of vaccine protection is being investigated in the general population and is shown to be attenuated in immunocompromised patients with cancer.

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