Guidance for the New York State COVID-19 Vaccination Program:
Vaccination of Children Ages 5-11

May 21, 2022

Note: This document applies specifically to health care providers offering COVID-19 vaccinations to children ages 5 to 11. Guidance for the New York State COVID-19 Vaccination Program pertaining to individuals ages 12 and older can be found on the New York State COVID-19 Vaccine Information for Providers page.

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Summary of Recent Changes

- In view of the fact that recommendations and eligibility for COVID-19 vaccination are expected to be updated repeatedly in coming months and potentially years, and that New York State (NYS) clinical guidance is aligned with the Centers for Disease Control and Prevention (CDC) clinical guidance, the format of this document has been updated to refer providers to CDC’s *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States* for clinical guidance. NYS clinicians are encouraged to read and become thoroughly familiar with that document, which is the best source for both general guidance and guidance for special situations. This NYS guidance document retains a list of recent changes, key points, sections with NYS-specific information, sections for certain special situations, and sections or links with important information that is not included in CDC’s Clinical Considerations document (e.g., storage and handling.)
- The CDC recommends a single Pfizer-BioNTech COVID-19 vaccine booster dose for person ages 5-11 years, who are NOT moderately to severely immunocompromised, at least 5 months after the primary series under the FDA’s EUA.
- The CDC recommends a single Pfizer-BioNTech COVID-19 vaccine booster dose for person ages 5-11 years, who ARE moderately to severely immunocompromised, at least 3 months after the primary series under the FDA’s EUA.
- The CDC clinical considerations were amended to provide considerations for people who recently had SARS-CoV-2 infection to delay their primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic). For more information, please see the CDC clinical considerations.
- Storage and handling requirements, including temperature monitoring and temperature excursion reporting requirements, for COVID-19 Vaccination Providers have been outlined.
- The Food & Drug Administration has approved an amendment to the EUA for Pfizer Pediatric Vaccine (orange cap for ages 5 through 11, with diluent) thereby extending the shelf-life of the Pfizer product formulation from 9 to 12 months.
- Regarding considerations for COVID-19 revaccination, the CDC previously provided recommendations for those who received one or more COVID-19 vaccines prior to or during treatment with HCT or CAR-T-cell therapy. They have now updated considerations for COVID-19 re-vaccination for patients who received one or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies (e.g. rituximab, ocrelizumab) that were administered over a limited period of time. More information regarding COVID-19 revaccination considerations can be found here.
- New clarifying updates were made regarding the considerations to initiate COVID-19 vaccination in children with a history of multisystem inflammatory syndrome in children (MIS-C). These updates can be found here.
- There are updates to information about individuals who were vaccinated outside the U.S. and individuals who were vaccinated as part of a clinical trial. See appendices A (*People who received COVID-19 vaccine outside the United States*) and B (*People who received COVID-19 Vaccine as part of a clinical trial*) for recommendations for these populations.
- Link to NYS Wastage Guidance has been updated to reflect updated guidance.
- Link to Redistribution Guidance has been updated to reflect updated guidance.
Key points about COVID-19 Vaccine for Children Ages 5-11

- All children ages 5 to 11 are eligible to receive a two-dose primary series of the pediatric formulation Pfizer-BioNTech COVID-19 vaccine (i.e., Pfizer Pediatric (orange cap) vaccine).
- Additionally, children 5 to 11 with certain immunocompromising conditions are eligible for a third primary dose. Further information on this 3rd primary dose for immunocompromised children aged 5 to 11 can be found in CDC’s Interim Clinical Considerations document, section entitled Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised. In summary:
  - Immunocompromised children ages 5 to 11 who received 2 doses of Pfizer-BioNTech COVID-19 vaccine at least 28 days prior should receive a 3rd primary dose of the Pfizer-BioNTech vaccine.
  - Immunocompromised children ages 5 to 11 who received a primary series of a non-FDA authorized or approved COVID-19 vaccine at least 28 days prior should receive an additional dose of the Pfizer-BioNTech vaccine. More information can be found within the CDC Clinical Considerations.
- As of May 19, 2022, children ages 5-11 are eligible for a Pfizer-BioNTech booster dose:
  - Pfizer-BioNTech: 10 ug in a volume of 0.2 mL (same dose as the primary series).
  - Persons aged 5 to 11 who received the Pfizer-BioNTech primary vaccination and are NOT moderately or severely immunocompromised should receive a COVID-19 vaccine booster dose at least 5 months after their 2nd primary series dose.
  - Children ages 5 to 11 who received a three-dose primary series of an mRNA COVID-19 vaccine and ARE moderately to severely immunocompromised should get a booster dose at least 3 months after their 3rd primary series dose.
  - People who recently had SARS-CoV-2 infection may consider delaying a booster dose (as well as primary series doses) by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a booster dose after infection. For more information, please see the CDC Clinical Considerations.
- There is no minimum interval between COVID-19 vaccine and other vaccines. CDC states that “COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.” For more information, see CDC’s Interim Clinical Considerations section entitled Coadministration of COVID-19 vaccines with other vaccines.

Scheduling the Second COVID-19 Vaccine Dose

All providers should schedule the second dose appointment for recipients at the time the first dose is administered. If scheduling a second dose appointment is not possible, providers must supply information on how/where to obtain a second dose of vaccine.

Circumstances may arise where a child may need to receive their second dose at a different location than their first. Providers who have determined that the child cannot return to the location where they received their first dose should schedule a second dose for these individuals or must supply information on how/where to obtain a second dose of vaccine. Vaccine availability can be located using the CDC’s VaccineFinder. Please ensure all individuals are informed on how to locate second dose appointments.
Special Considerations for Individuals Receiving Their Primary Series Doses Outside New York State

Children who received their primary series of COVID-19 vaccine (one or both doses) outside of New York State will not have a record of this dose(s) in NYSIIS or CIR. Providers should either enter the dose(s) in NYSIIS/CIR as part of the historical record using data listed on the child’s COVID-19 Vaccination Record Card OR advise the parent that they ask their primary care provider to enter their primary series doses into NYSIIS/CIR so the state has a full record of both doses of COVID-19 vaccine.

Special Considerations for Individuals Receiving COVID-19 Vaccine Outside the United States

The CDC guidance for fully vaccinated people states that “this [CDC] guidance can also be applied to COVID-19 vaccines that have been authorized for emergency use by the World Health Organization (WHO) (e.g., AstraZeneca/Oxford).”

Children ages 5 to 11 who received only the first dose of a two-dose mRNA COVID-19 vaccine are not considered fully vaccinated in the United States. They should be offered an age-appropriate second dose of an mRNA vaccine (i.e., Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5-11).

For COVID-19 vaccines not authorized by the FDA but listed for emergency use by the WHO:
- Please visit the CDC’s guidance on vaccines listed for emergency use by the WHO but not approved/authorized by the FDA.
- Children who have received all recommended doses of a COVID-19 vaccine that is listed for emergency use by the WHO do not need any additional doses with an FDA-authorized COVID-19 vaccine.

For COVID-19 vaccines neither authorized by FDA nor listed for emergency use by the WHO:
- For children who received all or some of the recommended doses of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by the WHO, the CDC does NOT consider these persons to be fully vaccinated. They should be offered a two-dose series of the age-appropriate COVID-19 vaccine (i.e., Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5 to 11). For more information, please visit the CDC’s guidance on these vaccines.

COVID-19 Vaccines Listed for Emergency Use by the WHO

As of May 1, 2022, the WHO has listed a number of COVID-19 vaccines for emergency use. There are several vaccines on this list that are also authorized by the FDA for Emergency Use in the United States. These include:
- Pfizer-BioNTech COVID-19 vaccines (e.g., COMIRNATY, Tozinameran)*
- Janssen (Johnson & Johnson) COVID-19 vaccine*
- Moderna COVID-19 vaccine (Spikevax)*

For more information regarding other vaccines listed for emergency use by the WHO, please visit the WHO website.

Please note that the minimum interval between receipt of the non-FDA-approved/authorized vaccine and initiation of the FDA-approved/authorized COVID-19 vaccine primary series is at least 28 days.

Vaccine Safety

Post-vaccination monitoring is an essential part of the COVID-19 vaccination program. The CDC is promoting and encouraging all those being vaccinated to participate in V-Safe, a smart-phone based application that will allow those vaccinated to enter their symptoms in the days after vaccination using text messaging. V-Safe also
provides reminders for the second dose and telephone follow up for anyone who reports medically significant adverse events. V-Safe materials can be found at [http://www.cdc.gov/vsafe](http://www.cdc.gov/vsafe), including a V-Safe information sheet. Please print out the information sheet and hand to each person vaccinated.

You must report any adverse events that occur after vaccination to the Vaccine Adverse Events Reporting System (VAERS) at info@VAERS.org or by calling 1-800-822-7967. For a list of administration errors and deviations and what action to take after an error or deviation has occurred, please refer to this CDC resource: Appendix C. Vaccine Administration Errors and Deviations.

Information on COVID19 vaccine safety signals that have been assessed by one or more of these mechanisms can be found in CDC’s [Selected Adverse Events Reported after COVID-19 Vaccination](https://www.cdc.gov/vaccines/safety/reports/selected-events.html). Additional information can be found in CDC’s Interim Clinical Considerations:

- Section entitled Safety considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna (including considerations surrounding myocarditis and pericarditis), and
- Section entitled COVID-19 vaccination and SARS-CoV-2 infection including MIS-C and MIS-A (including considerations for vaccination after MIS-C).

Regarding vaccine demand and hesitancy—serious safety problems associated with COVID-19 vaccines are rare. Still, patient perception of COVID19 vaccine safety, often fueled by false reports on social media, can impact public trust in vaccination. Information on common myths about COVID-19 vaccine safety (including impact on fertility and DNA) can be found at the [CDC’s Facts webpage](https://www.cdc.gov/vaccines/safety/facts-for-public.html) and New York State’s webpage [Combatting Misinformation about the COVID-19 Vaccines](https://www.ny.gov/topic/coronavirus-vaccines).

**Consent for Vaccination of Minors**

The following guidance is used by NYS operated mass vaccination sites. Other entities operating vaccination sites may use it as a model for securing consent for vaccination of minors, in consultation with counsel as needed. It is important to verify the age of any individual who appears to be a minor to ensure consent is obtained, confirm eligibility, and ensure the administration of the proper COVID-19 vaccine.

Proof of age should be requested but is not required where the parent or guardian is available to attest to the minor’s age. Documentary proof may include (but is not limited to):

- Driver’s license or non-driver ID
- Birth certificate issued by a state or local government
- Consulate ID
- Current US passport or valid foreign passport
- Permanent resident card
- Certificate of Naturalization or Citizenship
- Life insurance policy with birthdate
- Parent/guardian attestation

For all minors, a parent or legal guardian must provide consent for vaccination.

**16 and 17-year-olds:**

For minors 16 or 17 years of age, consent should be provided either in person or by phone, at the time of vaccine appointment. Providers may elect to accept a written statement of consent from the parent or guardian, where the parent or guardian is not available by phone to provide consent to vaccinate an unaccompanied minor. They may be considered for this purpose.
5 through 15-year-olds:
For minors who are 5 through 15 years of age, additionally, an adult caregiver should accompany the minor. If the adult caregiver is not the parent/guardian, the adult caregiver should be designated by the parent/guardian. The parent/guardian must still provide consent to the vaccination.

Pfizer-BioNTech COVID-19 Vaccine Pediatric Formulation
The Pfizer-BioNTech vaccine for ages 5 to 11 has a different pediatric formulation (10 µg per dose), packaging, preparation, and national drug code (NDC) from the Pfizer-BioNTech COVID-19 vaccine for ages 12 years and older. The Pfizer vaccine formulations for adults and adolescents (purple cap and gray cap; 30 µg per dose) CANNOT be used in children ages 5 to 11 years old. Children ages 5 to 11 years old should receive the age-appropriate vaccine formulation regardless of their size or weight. The vaccine dosage should be based on the child’s age on the day of vaccination. For more information regarding the dosing and pediatric formulation please visit the CDC’s clinical considerations.

For information on the packaging of the Pfizer Pediatric vaccine see section 19 “How Supplied/Storage and Handling” of the EUA Prescribing Information. The product is delivered in a single-use product shipper at -80°C (on dry ice). For information on Pfizer shipment notifications, the cold chain monitor, and how to unbox your Pfizer shipment, please visit the Controlant on-site monitoring website.

COVID-19 Pfizer pediatric (orange cap) vaccine requires dilution. Reconstitution of the product for use on ages 5 to 11 requires 1.3 mL of diluent, which is a different volume than the adolescent/adult Pfizer 12+ purple cap formulation. The diluent provided with ancillary supplies are 10 mL vials of sterile 0.9% Sodium Chloride. One vial of diluent is provided for each vial of vaccine ordered. While these vials appear to contain sufficient diluent for multiple vials, they must only be used once due to the risk of bacterial infection. Diluent vials are a one-time-use item and should be discarded with the remaining content after each use.

Ordering Instructions
Please see the NYSDOH COVID-19 Vaccine Information for Providers page for more information on ordering pediatric Pfizer-BioNTech COVID-19 vaccine in NYSIIS. Providers in New York City should follow instructions from NYC DOHMH and CIR.

All facilities or practices are required to track vaccine uptake among their staff and must furnish uptake data to the NYSDOH via HERDS survey upon request, or as directed by your agency or organization.

Storage and Handling Requirements
Vaccines must be stored and handled properly from the time they are manufactured until they are administered to maintain the cold chain, thus protecting the potency and effectiveness of the vaccine and ensuring vaccine recipients are fully and safely protected from vaccine-preventable diseases. Detailed information regarding COVID-19 vaccine storage and handling requirements is available at CDC Vaccine Storage and Handling Toolkit. A storage and handling summary for the Pediatric Pfizer vaccine is available here.

As part of the COVID-19 Vaccination Provider Agreement, providers are required to:
- Store and handle vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in the Vaccine Storage and Handling Toolkit.
• Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the toolkit. Every storage unit that holds COVID-19 vaccines must have a digital data logger (DDL). Staff must check and record temperatures each workday and regularly check the DDL temperature data.
• If the temperature of the storage unit goes outside of the recommended temperature range, the temperature excursion must be reported immediately. Providers located outside NYC must complete the COVID-19 Vaccination Program Temperature Excursion Report.
• Monitor and comply with COVID-19 vaccine expiration and beyond use dates.
• Preserve all records related to COVID-19 vaccine management, including temperature records, for a minimum of three years.
• Comply with CDC instructions and timelines for disposing of COVID-19 vaccine and diluent, including used doses.

Updates to Pfizer-BioNTech Pediatric COVID-19 Vaccine Expiration

On April 13, 2022, the FDA approved a shelf-life extension for the Pfizer Pediatric vaccine (Orange cap, ages 5 to 11, diluent required). The approval and updated EUA Fact Sheet takes effect immediately. This extension applies to frozen (ULT) inventories only.

The date printed on the Pfizer Pediatric (orange cap) vaccine vials indicate the manufacture date and NOT the expiration date. Originally, the expiration date was 6 months from the manufacture date, when stored in ultracold freezer temperatures (-90 to -60° C). The expiration date for Pfizer orange cap vaccine has now been extended to 12 months (while held at ULT frozen). Vials may also be stored up to 10 weeks in the refrigerator (2-8° C); however, vials stored in refrigerated vials (2-8° C) are NOT eligible for extension, regardless of the expiration date. No standard freezer storage is approved for the pediatric formulation. Once thawed, vials CANNOT be refrozen.

The Fact Sheet for the pediatric orange cap vials provided by the FDA now reads “regardless of storage conditions, vaccines should not be used after 12 months from the date of manufacture printed on the vial and cartons.” Therefore, vaccine must be used by the expiration date, or the 10-week beyond use date for refrigerator storage, whichever comes first. The updated expiry dates for the orange cap vials based on 12 months from the date of manufacture are provided below.

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<tr>
<th>Printed Manufacturing Date</th>
<th>12-Month Expiry Date*</th>
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<tr>
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*Date of expiration always falls on the last day of the month
Responsible wastage policies remain in effect. Providers should plan to minimize waste to the best of their ability but should not miss the opportunity to vaccinate a willing individual, even if it results in other wasted doses.

**Beyond Use Dates (BUDs)**

All vaccines have expiration dates, and some routinely recommended vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first punctured and the storage information in the package insert. Whenever a vial of COVID-19 vaccine is moved to storage conditions that affect BUD or a multidose vial is punctured, label the vial(s) with the beyond use date/time. **The BUD must never exceed the labeled expiration date.** Once the vaccine has reached its expiration or beyond use date/time, unused doses must be disposed of as medical waste and reported as wastage in NYSIIS or CIR. A summary of COVID-19 vaccine beyond use dates and resources are listed below.

- **Pfizer Pediatric Tris (Orange Cap):** [Beyond-Use Date (BUD) Tracking Labels for Vaccine During Refrigerator Storage](#)
  - Refrigerator (2° C to 8° C): 10 weeks
  - **NOTE: NO standard freezer (-25° C to -15° C) storage allowed**
  - Room temperature (8 ° C to 25° C): 12 hours prior to first puncture
  - After Puncture: 2° C to 25° C for up to 12 hours. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.

Each provider that receives vaccine:

- Must make best efforts to use all vaccine doses before expiration or reaching beyond use dates based on temperature storage requirements by assessing the COVID-19 vaccination status of each patient and offering the vaccine to all eligible individuals. Pediatric vaccine vials do not have expiration dates printed on the label. Instead, the date of manufacture is printed on the label, along with the lot number. Vials must be used before the expiration date, which is **twelve (12)** months after manufacture date if stored ultra-cold, or the beyond use date of 10 weeks once placed in the refrigerator, whichever comes first.
- Providers should continue to report all doses administered to NYSIIS and CIR, including third vaccine doses and booster doses as appropriate based on ACIP recommendations. It is critical that providers follow the appropriate intervals and product combinations in order for these doses to be considered valid. Providers should fully utilize both NYSIIS and CIR to confirm patients’ previous dose dates and vaccine type. Full contact information for the parent/guardian of the child receiving the vaccination, including phone number, email and zip code, should be entered as well.

In addition, to ensure all New Yorkers can find vaccination locations close to them, **vaccine providers are strongly encouraged to have their facility/facilities opt-in to the CDC’s online VaccineFinder tool** ([Vaccines.gov](https://www.vaccines.gov)). To do so, providers should set the display field in the COVID-19 Locating Health Portal to “display” if the facility is currently providing vaccinations to the general public. This will allow patients in the local area to see in real-time whether the facility has doses of each brand available, enabling vaccination access for a broader population.

- NYSDOH reports inventory to the CDC every Monday through Friday for each organization. Therefore, organizations do not need to report inventory to VaccineFinder (despite having access). Providers must maintain accurate inventory in NYSIIS or CIR. Additional information on the VaccineFinder tool can be found [here](#).
Vaccine Redistribution

As the ordering quantities and the storage conditions have become more practical, providers are encouraged to place direct orders in NYSIIS and avoid redistribution whenever possible, even if all doses cannot be used. Vaccine may be redistributed to another facility, provider, practice, or local health department that is enrolled in the COVID-19 vaccination program, with proper notice to the NYSDOH. Prior to redistributing vaccine, facilities must submit a completed redistribution form to COVIDVaccineRedistribution@health.ny.gov and can proceed with the redistribution once submitted. Redistributions must follow the New York State COVID-19 Vaccine Program Guidance for Vaccine Transport, including use of a digital data logger to monitor temperatures during transport. Direct orders are the preferred and safest way to receive vaccine.

A provider may transport vaccine to another location for the purpose of holding a limited duration vaccination clinic without notifying the NYSDOH. If the provider is administering the doses and reporting doses administered against their own inventory in NYSIIS, all unused vaccine must be transported back to the original location at the conclusion of the clinic that day. The provider must retain possession and control of the vaccine for the duration of the transport and administration.

Responsible Wastage

The CDC released guidance on May 11, 2021, regarding wastage along with a critical message to “take every opportunity to vaccinate every eligible person.” As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase. While enrolled providers must continue to follow clinical best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

As the ordering quantities and the storage conditions have become more practical, we are encouraging providers to place direct orders whenever possible, even if you cannot use all doses. This is the safest way for providers to receive vaccine and reduces the risk of temperature excursions and the burden of continued redistribution.

- Currently available COVID-19 vaccine products are all multidose vials. Vaccine vials must often be punctured without using the full number of doses printed on the label. Do not turn anyone away because you do not have additional people to vaccinate with remaining doses in a vial. Discarding the remaining doses is acceptable wastage (and needs to be reported as wastage in NYSIIS). Doses not administered within the limits below post-puncture must be wasted:
  - 12 hours: Pfizer ages 5-11 orange cap/pediatric

Please note: Any vial of vaccine that exceeds the shelf life indicated by the manufacturer (expiration date OR beyond use date) must be disposed of as regulated medical waste and reported as wastage in consultation with the manufacturer.

Equity and Access

Efforts must be made to conduct outreach to families in all communities and settings. Children and families in areas that have a high social vulnerability index are particularly vulnerable to COVID-19 and should be notified about how they can receive vaccine. Every effort should be made to increase their access to vaccination opportunities.
Communicating the Plan

Please be sure to clearly communicate this critical guidance to all staff involved in the vaccination program.

This guidance is in effect from the date of issuance until it is updated, or additional guidance is issued by NYSDOH. For questions, please contact the New York State Department of Health, Bureau of Immunization at COVID19vaccine@health.ny.gov.

Resources

- Pfizer-BioNTech COVID-19 Vaccine FDA EUA for 5-11 Years of Age for Caregivers & Recepients
- Pfizer-BioNTech COVID-19 Vaccine FDA EUA for 5-11 Years of Age for Vaccination Providers
- Vaccine Administration Resource Library for Healthcare Professionals (CDC)
- Epidemiology and Prevention of Vaccine-Preventable Diseases: Vaccine Administration (CDC)
- COVID-19 Vaccine Webinar Series (CDC)
- COVID-19 Vaccination Clinical and Professional Resources (CDC)
- How to Administer Intramuscular and Subcutaneous Vaccine Injections (Immunization Action Coalition)
- Medical Management of Vaccine Reactions in Children and Teens in a Community Setting (Immunization Action Coalition)
- Protective Measures for Vaccinating During the COVID-19 Pandemic (Immunization Action Coalition)
- Skills Checklist for Vaccine Administration (Immunization Action Coalition)
- Supplies You May Need at an Immunization Clinic (Immunization Action Coalition)
- Ask the Experts: COVID-19 Specific Information (Immunization Action Coalition)
- Ask the Experts: Administering Vaccines (Immunization Action Coalition)
- Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host.