

Frequently Asked Questions

about the **National Adult and Influenza Immunization Summit** “Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations” and Pledge for Implementing the Checklist

■ The questions in this document relate to the checklist and pledge found here:

CHECKLIST: www.izsummitpartners.org/off-site-vaccination-clinic-checklist

PLEDGE: www.izsummitpartners.org/pledge-for-organizations-conducting-off-site-vaccination-clinics

Questions about the purpose of the checklist and pledge

1 What is the purpose of the checklist? It seems long and complicated.

Recently, reports have been published of major errors occurring at vaccination clinics held at satellite, temporary, or off-site locations related to the safe transport, storage, and administration of vaccines. These reports are likely the tip of the iceberg. To prevent future errors at clinics in these settings, we developed this checklist as a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness.

2 What is the pledge, who is it for, and why should we sign up to be a pledging organization?

This pledge is for any organization that conducts satellite, temporary, or off-site vaccination clinics to sign annually affirming that they will adhere to best practices by using the “Checklist of Best Practices” at every vaccination clinic they hold in these settings. Organizations that sign the pledge will be recognized on the Summit website for their commitment to provide safe and effective vaccine clinics. This can be a great way to promote your organization as one that conducts vaccination clinics using the highest standards. Additionally, companies seeking to hire an organization to conduct a vaccination clinic can check to see if that organization has signed the pledge and is recognized on the Summit website.

Questions related to the intended users of the checklist

1 All of our staff have many years of experience and we do hundreds of vaccination clinics a year. Do we still need to use the checklist?

Yes! For organizations like yours where running vaccination clinics is central to your mission, it is important to use the checklist because it allows you to DOCUMENT that you are using best practices. Your organization likely already has protocols in place that cover the topics in the checklist. Thus, checking off the boxes should take a few extra minutes since you are likely already doing all of the items in the rows anyway. Also, if your organization takes the pledge stating that it



intends to have its clinic coordinators implement the vaccine checklist at each vaccination clinic, it can be recognized as a leader in the field and one that consistently follows best practices. It's a win-win.

2 We have many new staff all over the country. The checklist seems too cumbersome to use in our situation. Do we need to use it?

Yes! It is precisely in these situations that the checklist should be utilized so that you can ensure consistency and best practices from clinic to clinic. Part of the reason that the checklist is so long is because it is comprehensive. The checklist covers best practices during each stage of the vaccination clinic.

Questions about how to use the checklist

1 If nurses in the field hit a stop sign, it would be a real burden/inconvenience to stop the clinic. For efficiency, do we still need to use the checklist in these situations?

Yes! Even though it might be very inconvenient to stop the clinic when you encounter a "No" at a stop sign, clinics should never continue when the quality of the vaccine has been compromised, or when unsafe administration practices have been identified. Using the checklist is very important at every clinic, to ensure that the vaccine is being delivered safely.

2 Is every staff member at the clinic supposed to fill out the checklist?

No, only the clinic supervisor/coordinator needs to fill out the checklist. However, we encourage the clinic coordinator to print out the checklist and give copies to all personnel who are vaccinating at the clinic to ensure that all staff members are aware of best practices.

3 What if our vaccination clinic does not have a clinic coordinator/supervisor?

We ask that prior to the start of the clinic, you designate one of the team members to be the clinic coordinator/supervisor so that one person is responsible for filling out the checklist and returning it to an appropriate storage place upon completion of the clinic.

4 Is it okay if we concentrate on one section of the checklist and only fill out that section at each clinic?

Ideally, the best approach is to complete the entire checklist at every vaccination clinic. If you do not think your organization can follow each row of the checklist (for instance, if you have already purchased your supplies for the flu season, and you did not purchase appropriate qualified containers and pack-outs, but have confirmed correct temperatures were maintained throughout the clinic), we encourage you to try completing as much as you can on the checklist during your clinics this year, and make sure that you include resources to purchase appropriate materials for next flu season.

Technical questions

1 The checklist states that CDC prefers direct shipment of vaccine, rather than transporting vaccine. However, when direct shipments are made to healthcare providers who participate in the "Vaccines for Children" program, there is a list of administrative requirements that they must check

off to ensure proper storage and handling of vaccines when they receive the direct shipment. Why is there nothing comparable for clinics in satellite, temporary, or off-site locations that will be receiving direct shipments?

Immunization programs may have additional requirements that are state-specific. Nonetheless, it is important for organizations that receive vaccines as direct shipments for satellite, temporary, or off-site vaccination clinics to follow guidelines outlined on p. 32 of the Vaccine Storage and Handling Toolkit (“Vaccine Deliveries”): www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. For more detailed, state-specific requirements, please consult with your state immunization program.

- 2 We use a thermometer that is not digital during transport, but there is a stop sign in that row of the checklist, implying that the thermometer must be digital. However, our thermometers are tested for accuracy and we trust their readings. How should we answer this section (especially since there is a stop sign)?**

The safest option for the vaccine is to use the digital data logger during transport. Although there might be situations where your non-digital thermometers are accurate, we have several concerns about utilizing these for maintaining the cold chain. The nature of one-time use indicators prevent device validation. Additionally, the interpretation of the “trip points” for these indicators only provide a range of potential exposure and not specific data. Due to these concerns, we feel the requirement for a digital data logger with a buffered probe is warranted and the clinic should not proceed. For specific storage and handling-related questions, please refer to CDC’s Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

- 2 Is every staff member at the clinic supposed to fill out the checklist?**

No, only the clinic supervisor/coordinator needs to fill out the checklist. However, we encourage the clinic coordinator to print out the checklist and give copies to all personnel who are vaccinating at the clinic to ensure that all staff members are aware of best practices.

- 3 Manufacturers that ship directly to our site do not use digital data loggers. Yet, the checklist requires that we use digital data loggers when transporting. Why is this discrepancy allowed?**

Manufacturers have their product’s specific stability data that they use in calculating their shipping processes. This makes it hard to compare what the manufacturer does during vaccine shipment to what we recommend for the public during vaccine transport.

- 4 We obtain different temperature readings during transport based on where the probe is placed in the pack-out. It is all within the acceptable range, but it varies widely. Is there guidance on how to do this correctly for consistent temperature readings?**

As stated above, we recommend using a digital data logger for more accurate and consistent temperature readings. It is not uncommon to have different temperature readings within a transport unit or a vaccine storage unit. Passive transport containers might have more variability due to the design of the container. However, if they are qualified to maintain temperature between 2-8C and are maintaining temperature, there should not be an issue with the temperature variability. The probe should continue to be placed in the area of the pack-out with the vaccines to best monitor the temperature.

5 What is meant by qualified container and pack-out?

Qualified containers and pack-outs are types of containers and supplies specifically designed for use when packing vaccines for transport. They are “qualified” through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time. We cannot endorse a specific brand, but if you type “qualified container and pack-out” into your internet search bar, you will find many acceptable options.

6 Are we allowed to use coolers purchased at big box stores/retail stores for transporting vaccine?

No. This is not an acceptable practice. Vaccine should be transported in qualified containers and pack-outs (see above).

7 In some of our off-site vaccination clinics, we give over 1,000 doses of vaccine per day. Our clinic wants to use qualified containers and pack-outs, but in order to hold this many doses, the qualified containers and pack-outs available are too heavy for our staff to lift.

There are several companies that make qualified containers and pack-outs that are lightweight (16–21 lbs, depending on the model). Some of these lighter weight options hold up to 100 pre-filled syringes. You could purchase several of these qualified containers and then make multiple trips to refill, as needed. Many State health departments follow the guide from the Oregon “Vaccines for Children” program that outlines the CDC requirements and recommendations for appropriate vaccine storage units: www.oregon.gov/oha/ph/PreventionWellness/Vaccines/Immunization/ImmunizationProviderResources/vfc/Documents/VFCfridgefreezerguide.pdf.

8 In the “Vaccine Preparation” subsection of the checklist, it states that vaccines must be prepared in a clean, designated medication area. However, a few rows down, it states that vaccines should be prepared at the time of administration. What is the proper protocol?

Multi-dose vials (MDVs) that will be used for >1 patient should not be kept or accessed in the immediate patient treatment area. Thus, if the vaccine is coming from an MDV that will be used as a source of vaccine for multiple patients, doses should not be drawn up in the same space where the injections are being administered. This link provides guidance on MDVs that explains the logic: www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html. If the injection is being prepared from a single-dose vial (SDV), which should be used for only 1 patient, we wouldn’t have the same concerns but would want to make sure that the vial is being handled aseptically in a clean area (e.g., any waste from the previous patient has been discarded).

9 In the “During the Clinic” section of the checklist, there is a row under the “Vaccine Documentation” subsection for patients to receive documentation of the vaccination for their personal records and to share with their medical providers. However, many of our clients decline this documentation and state, “I’ll just lose it” or “you have it in your system”. Do we have to offer documentation to all of our clients since it does not seem to be a priority for most of the people we serve?

Yes, it’s a best practice to provide clients with their vaccination information that includes the vaccine given, the lot number, the date, and the signature of the person who gave the vaccination. Once the parent/client has been given the information, they can then decide if they want to keep the information. The provider can also offer the parent/client an opportunity to take a cell phone picture of the signed form. Then they own the information.

10 If my state has an Immunization Information System (IIS, or registry) do I still need to give the patient a vaccine record card?

Yes. Patient-held cards are an extremely important part of a person's medical history. The person may move to an area without a registry, and the personal record may be the only vaccination record available. In addition, even within a state, all healthcare providers may not participate in the registry, and the personal record card would be needed.

Do you have additional questions? Send us an email as shown below.

Questions about the Checklist: checklist@izsummitpartners.org

Questions about the Pledge: vaxclinicpledge@izsummitpartners.org