Indiana Department of Health-Immunization Division

Policy & Procedure Title	Administration of Nonviable or Expired Vaccine	**Issuing Date**	11/19/2014
Policy & Procedure Number	22	**Revision Date**	02/21/2020
Policy & Procedure Approval Authority	Dave McCormick		

Policy Statement

Refrigerators and freezers used to store publicly provided vaccines must be capable of reaching and maintaining the required temperatures established by the vaccine manufactures, the Centers for Disease Control and Prevention (CDC), and the National Institute of Standards and Technology (NIST) standards. If vaccine shipping or storage temperatures are recorded **above** or **below** the required temperature range, do not use the vaccine until the viability (potency) of the vaccine has been established by the vaccine manufacturer.

Vaccines that have been deemed nonviable (to have lost potency) due to temperature excursions or vaccines beyond the expiration date should never be administered. If these vaccines are administered inadvertently, doses are not counted as valid and should be repeated. All patients, not only those who received publicly-funded doses, should be revaccinated. Serologic testing to confirm a vaccine response may be performed for certain vaccinations. This practice is not recommended when the viability is in question due to a temperature excursion.

The Indiana Department of Health (IDOH) Immunization Division will make every effort to work with the enrolled providers to address the administration of the nonviable vaccines while balancing clinic needs, cost to patients, providers and health plans, the risk of illnesses or outbreaks, and overall effect on public health.

In the event that a large number of patients have received doses of nonviable vaccine, providers will be suspended and will be terminated for failure to comply with any corrective action plans that are issued.

Determining the Need for Revaccination

In instances where vaccine potency is lost due to improper storage and handling, the decision to issue a recall notification and/or to revaccinate will be made by the Indiana State Health Commissioner or designee and the Immunization Division Director or designee. All final decisions regarding recall notification and/or revaccination will be sent in writing to the responsible clinician and/or medical director at the facility where the vaccines were administered. Upon receipt of this notification, it will be the responsibility of the provider to determine the names and contact information for all patients in need of revaccination.

In situations where expired doses of vaccine are administered, it will be the responsibility of the clinician and primary vaccine coordinator to notify patients and offer to revaccinate with viable vaccine per the vaccine administration guidelines in this policy.

Vaccine Administration

All patient(s) who receive a nonviable dose of vaccine should be revaccinated. For inactivated vaccines, the patient should be revaccinated as soon as possible. This may be during the same clinic visit if the error is caught during the clinic visit. If the nonviable or expired dose is a live virus vaccine, providers must wait at least 4 weeks, or 28 days, after the previous dose was given to repeat vaccination.

Assistance Provided by IDOH

The Immunization Division will offer assistance to enrolled providers to ensure patients are revaccinated in a timely manner. This includes, but is not limited to:

- Technical assistance using CHIRP for recall purposes.
- On-site assistance to review proper vaccine storage & handling policies and procedures
- Technical assistance with placing additional orders for vaccines
- Technical assistance with developing protocols in conjunction with the clinic, pharmaceutical companies, and Centers for Disease Control & Prevention (CDC)
- Technical assistance with drafting written or verbal patient correspondence

The Immunization Division will document the event in PEAR, including resolution of the issue.

Serology Titers to Validate Immunity

The cost of performing serology testing in lieu of revaccination is the responsibility of the enrolled provider site. The Immunization Division does not offer any technical assistance to conduct post-vaccination serology testing following administration of nonviable or expired vaccine.

The Immunization Division does not recommend serology testing following known temperature excursions. However, an exception could include vaccines for which a series (more than one dose) is indicated and the potency of all doses in the series is questionable. For instance, if an adolescent or adult received three Hepatitis B vaccines during poor storage times, it could be appropriate to give a first potent dose and draw serology tests at the same time. The additional two doses might be waived depending on the test results.

Serology testing exists for some of the vaccines (many are available through clinical labs, but not all). If the provider opts to choose drawing serology titers instead of revaccinating patients, the provider is required to validate the lab is CLIA certified (test is FDA-approved and validated by the lab). Providers also need to consider the following:

1) No level of circulating diphtheria or tetanus antibodies confers absolute protection. Diphtheria has been reported in persons with high antibody levels.
2) An adequate immune response from one component of a combination vaccine is not an indication of the potency of the other vaccine components.
4) Serologic testing is not recommended for poliovirus, pneumococcal, meningococcal, rotavirus, or HPV vaccines.
5) Prevaccination serologic testing for varicella is not recommended for people younger than 13 years. Serologic screening may be considered for people age 13 years and older who do not have a history of chickenpox, a strategy that may be cost effective, depending on the cost of the serologic test. However, it is safe to give varicella to people already immune to the disease, so screening is **not** required under any circumstance.

Provider Responsibility

If a provider declines or is otherwise incapable to recall patients who received questionable doses, the Immunization Division will request a list of affected patients and, in conjunction with the local health department, will conduct its own recall of these patients. In these instances, the provider will be asked to replace the nonviable/expired publicly-purchased vaccine with privately purchased stock. Failure to do so will result in **permanent** termination from all immunization programs with the Indiana Department of Health.

If a clinic declines to provide a list of affected patients, the Immunization Division will issue a community notice alerting patients that they have received potentially nonviable vaccine at this clinic, and encouraging patients to contact the local health department to explore revaccination. The Immunization Division may also send notification to the Indiana Attorney General regarding instances of provider non-compliance to ensure the health and well-being of patients is protected.

References & Resources

Centers for Disease Control and Prevention. (2018) Vaccine Storage and Handling Toolkit, Revised January 2018. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Centers for Disease Control and Prevention. (13th Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

Revision History

11/19/2014, Created
04/01/2017, Revised
01/01/2019, Revised
02/21/2020, Revised