


IPI Protocol for Vaccine Storage and Handling Mishaps

(For IPI advisor use only)

- A mishap is temperature(s) out of the recommended range: 35°-46° F (2°-8° C) for the refrigerator and above 5° F (-15° C) in the freezer. Whether or not a vaccine is affected by a mishap depends on the length of time out of range, the temperature(s), and the type of vaccine.
- There are two protocols below: one for handling mishaps in the “Warning Zone” and one for those in the “Danger Zone.”

Type of Mishap/ Temperature Range	Protocol
<p>Warning Zone</p> <p>WARNING</p> <p>If REFRIGERATOR is now or has been at or between:</p> <p style="text-align: center;">33° - 34° F (0° - 1° C) OR 47° - 50° F (8 -10° C)</p> <p>(There is no “warning zone” for frozen vaccines since they are so temperature sensitive.)</p>	<ul style="list-style-type: none"> • If the temperature is currently out of range, instruct clinic staff to adjust the thermostat immediately and recheck the temperature every 30 minutes until it stabilizes within range. Instruct the clinic to document this on the Temperature log or Vaccine Troubleshooting Log. • If the temperature is not back in range within two hours, tell clinic staff to mark the vaccine “Do Not Use,” move it to a different unit, and follow the steps below for handling mishaps in the Danger Zone. • Emphasize the importance of noting the pattern of temperatures over time and aiming at maintaining the refrigerator temperature at 40°F (4°C). • Call the MnVFC program within five working days to report the mishap. • Document the mishap on the IPI Clinic Checklist, and note that the clinic needs to provide a follow-up action plan within 45 days of discovering the mishap. • Right after the MnVFC visit, mail or email the clinic a letter listing action(s) they agreed to take during the visit, including the follow-up action plan, and send a copy of it to your IPI regional coordinator. • Document your observations and the actions taken by you and the clinic on the IPI Clinic Checklist in the Action Plan and Comments column on page 2-3, and complete the Action Plan Follow-up and Summary on page 6.
<p>Danger Zone</p> <p></p> <p>If REFRIGERATOR is now or has been at:</p> <p style="text-align: center;">32°F (0°C) or below OR above 50°F (10°C)</p> <p>.....</p> <p>If FREEZER is now or has been:</p> <p style="text-align: center;">above 5°F (-15°C)</p>	<ul style="list-style-type: none"> • Instruct clinic staff to stop using all vaccine stored in the unit. • Have them clearly mark the affected vaccine “Do Not Use” so no further doses are inadvertently administered and, if possible, move it to a refrigerator/freezer maintaining correct temperature ranges. • For the refrigerator, have them adjust the thermostat and check it every 30 minutes until it is back in range and if it is not back in range within two hours, have it serviced. • For the freezer, have them adjust the thermostat, check it in 30 minutes, and if it’s not back in range move the vaccine and have the unit serviced. • When a unit has been repaired, or a new unit installed, clinic staff should check and record temperatures in it twice a day for one week to ensure it can maintain the correct temperature before using it to store vaccine. • Tell clinic staff to make sure to document their actions on the unit’s Temperature log or Vaccine Troubleshooting Log. • Carefully review clinic temperature logs back three months for any temperatures outside the correct range. Check for frequency and pattern: <ul style="list-style-type: none"> ▪ How often is the temperature outside the correct range? ▪ Is only one “off” temperature documented? ▪ How many out-of-range days are identified? Are they consecutive? ▪ Are they Mondays and/or Fridays, indicating out-of-range temperatures over the weekend? ▪ Are actions in response to “off” temperatures documented? • Emphasize to clinic staff that they can’t tell by looking whether vaccine has lost its potency through improper storage in a refrigerator or freezer. For example, vaccine stored at or below 32°F (0°C) may not appear frozen and precipitate may not be visible. Nonetheless, at that temperature proteins will denature and salts will crystallize, rendering vaccine nonviable. • Determine if vaccine is nonviable. Together with clinic staff, call the vaccine manufacturer(s) of the affected vaccine(s) within 48 hours of discovering the mishap (see phone numbers below). Ideally, have this information available before calling the manufacturer(s):

<p>Danger Zone, continued</p>	<ul style="list-style-type: none"> ▪ Lot numbers of affected vaccine(s); if they are not available, do not wait to call the manufacturer(s). ▪ Expiration dates of affected vaccines. ▪ Current temperature and/or sequence of out-of-range temperatures. ▪ Temperature logs (for the last three months or more) for reference. <ul style="list-style-type: none"> • Ask to speak to the manufacturer’s medical consultant or quality assurance staff and discuss the following with them: <ul style="list-style-type: none"> ▪ Whether vaccine stored at a given out-of-range temperature is viable. ▪ If vaccine is nonviable, does the manufacturer have recommendations about re-administering any doses? They probably will not make a recommendation, but will defer to ACIP recommendations. • If the vaccine is found to be nonviable, instruct the clinic to make sure it is still marked “Do Not Use” and remove it from the refrigerator/freezer immediately to keep staff from inadvertently administering it. • Before they return any nonviable vaccine, instruct the clinic to call the MnVFC program to arrange the pickup. Then they should complete the most current version of the Returning Nonviable MnVFC Vaccine form, following the instructions on the form. • Since privately purchased vaccine may have its own return policy, have the clinic check their contract or ask the manufacturer/distributor directly. • If nonviable vaccine has been administered, refer the clinic to CDC’s General Recommendations on Immunizations; Recommendations of the Advisory Committee on Immunization Practices, MMWR, January 28, 2011 / 60(RR02);1-60, page 18. These recommendations state that a mishandled vaccine dose should not be counted as valid and should be re-administered. • Complete the clinic the Clinician’s Vaccine Mishap Checklist. Consider giving it to the clinic to use as a guide to develop their follow-up action plan. • Document your observations and the actions taken by you and the clinic on the IPI Clinic Checklist in the Action Plan and Comments column on page 2-3, and complete the Action Plan Follow-up and Summary on page 6. • On the IPI Clinic Checklist, in the Action Plan section on page 6, note that the clinic needs to provide a follow-up action plan within 45 days of discovering the mishap. When you receive the clinic’s action plan, send a copy of it and a completed Follow-Up Clinic Visit Form to your IPI regional coordinator. • Right after the MnVFC visit, mail or email the clinic a letter listing action(s) they agreed to take during the visit, including the follow-up action plan, and send a copy of it to your IPI regional coordinator. • Report the mishap to MnVFC within five working days of discovering it. Note any vaccine that has been administered but then determined by the manufacturer to be nonviable. <p>Note: MDH relies on IPI advisors to follow up with clinics to assure compliance with recommendations, including revaccination. If you feel it is more appropriate for MDH to handle a situation, contact your regional IPI coordinator. MDH staff is available at any time for consultation and guidance.</p>
--------------------------------------	--

Vaccine Manufacturers Phone Numbers - Ask for their medical consultant or quality assurance staff:

Novartis	800-244-7668	Merck	877-829-6372
CSL Biotherapies, Inc	888-435-8633	Sanofi Pasteur	800-822-2463
GlaxoSmithKline	888-593-5977	Pfizer (formerly Wyeth)	800-438-1985
MedImmune	877-633-4411		



IPI Program
 P.O. Box 64975
 St. Paul, MN 55164-0975
 651-201-5522 or 1-800-657-3970
www.health.state.mn.us/immunize

