



May 28, 2009

BC Centre for Disease Control
AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY

ATTN: Medical Health Officers and Branch Offices
Public Health Nursing Administrators and Assistant Administrators
Holders of Communicable Disease Control Manuals

**Re: Revisions to Communicable Disease Control Manual:
Chapter II – Immunization Program**

Please note the following changes to the Communicable Disease Control Manual, Chapter II – Immunization Program, Section VI – Management of Biologicals:

This section has been updated and changes from the previous document are outlined below.

Page 1, Section 1.0 “The Cold Chain”:

- New information added regarding refrigerator temperatures 0°C to +2°C. This range can be considered “refrigerator conditions”, with due regard to the accuracy of the temperature reading device; no product needs to be discarded following exposure in this range, nor does exposure in this range require reporting as a “cold chain incident.” The refrigerator temperature must be adjusted and returned to the +2°C to +8°C range immediately.
- New information added regarding freezing of biological products and temperatures below 0°C.
- 2009 Addendum to Vaccine Stability Chart: additional stability information from the vaccine product monographs. This Addendum will be distributed to Biological Product Consultants to guide product use when biologicals are exposed to temperatures outside the acceptable range.

Page 2, Section 2.0 “General Recommendations”:

- Two designations, Biological Product Consultant and Biological Product Monitor, replace the previous “Biological Product Coordinator.”
- The Biological Product Consultant, at the HSDA level, is responsible for decision-making regarding vaccine use following cold chain incidents, ensuring that staff are trained in biological management procedures, and confirming that conditions have been met for return of vaccines to BCCDC for redistribution.

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- The Biological Product Monitor, at the Health Unit Office level, is responsible for ordering biological products, refrigerator monitoring and maintenance, and documentation of storage conditions to support return of products for redistribution.

Page 3, Subsection 3.1, “Refrigerators”:

- This section has links to the National Vaccine and Storage Guidelines for Immunization Providers for detailed information on refrigerators and refrigerator maintenance.
- When laboratory specimens must be stored in a vaccine refrigerator, specimens should be stored in a clearly marked, separate container.

Page 4, Subsection 3.2, “Temperature Monitoring”:

- Fluid- filled liquid thermometers are no longer recommended; they indicate the temperature at the time of reading only, and out-of-range temperatures may not be detected.
- This sectional has a link to national guidelines for additional information on temperature monitoring devices.
- Thermometers should be calibrated to an accuracy of +/- 1° or better.
- Check temperature monitoring devices annually, or according to manufacturer’s specifications, to ensure devices are functioning properly.
- Record refrigerator temperatures at the start and end of each workday, even when there is a continuous recording wheel in use, or when the refrigerator is connected to an alarmed temperature monitoring system.
- Retain completed Temperature Logs and recording graphs for a minimum of three years. These records are needed to confirm storage conditions for vaccines being returned for redistribution, and to assess whether vaccines can be used after exposure to out-of-range temperatures.

Page 6, Subsection 3.5, “Insulating Materials”:

- The list of insulating materials for vaccine transport include flexible insulating blankets and gel packs at refrigerator temperature, crumpled packing paper, bubble wrap and Styrofoam peanuts. A layer of paper toweling is not sufficient as a barrier to protect vaccines from contact with frozen material.

Page 7, Subsection 4.1, “Vaccine Delivery to Health Units:”

- This section has been revised to include information about using a TempTale® device.
- Biological products should not be left unrefrigerated when the Monitor or designate is unavailable to unpack a delivery.



An individual who receives a vaccine shipment and is unfamiliar with the TempTale[®] device should refrigerate the vaccines **and** the TempTale[®] **immediately**, and notify the Biological Product Monitor or designate that a shipment was received.

Page 7, Subsection 4.2, “Vaccine Storage”:

- This section emphasizes practices to decrease vaccine wastage:
 - Use vaccines with the shortest expiry date first;
 - Check for expired vaccines on the last working day of the month, and remove vaccines that will not be used by the end of that day in clinics;
 - Check for multidose vials that have not been used within the specified time period and remove these from the refrigerator;
 - Within the HA, redistribute vaccines that will expire within three months if use is unlikely in the local office; under certain conditions, these vaccines may be returned to BCCDC (see Section 4.7, below);
 - Move vaccines that have experienced a cold chain incident, but are good to use, to the front of the refrigerator, and use these at first opportunity.
- Store adrenalin at room temperature (15° to 30°C) and protect from light, heat and moisture.

Page 9, Subsection 4.3, “Vaccine Orders”:

- Order vaccines using the schedule for vaccine ordering/delivery established by BCCDC Vaccine and Pharmacy Services.
- Establish base orders for all vaccines, considering size of age cohort, doses in a routine program, and seasonal and program demands, and review base order quantities quarterly. Base orders should include only a small “buffer” amount to meet an unexpected increased demand.
- For school-based programs, order only the doses needed for the first dose in a series, and order subsequent doses at a later date as needed. This is important in terms of refrigerator space, and avoiding loss of costly vaccines because of cold chain incidents.

Page 10, Subsection 4.5, “Transportation and Management of Vaccines for Clinics”:

- The recommended packing configuration for vaccines being transported to a clinic includes the placement of frozen ice packs or frozen gel packs at the **top** of the cooler, separated from the biological products with insulating material
- Monitor the temperature in the cooler when vaccines will be in the cooler for more than 4 hours

Page 11, Subsection 4.6, “Mass Immunization Clinics”:

- This new section refers to the BC Mass Immunization Cold Chain Project (2005-2006). The full report is available on the BCCDC web site.

Page 11, Subsection 4.7, “Returning Biological Products”:

- Encourage the return of damaged/wasted vaccines from other providers to public health.
- Return all BCCDC-supplied biological products on a monthly basis if possible.
- When vaccines require return under cold chain conditions, contact the Biologicals Desk in Vaccine and Pharmacy Services to arrange for a TempTale[®] for monitoring during transport. BCCDC will also advise on a packing configuration for the shipment.
- Products may be returned to BCCDC **for redistribution** when they have been received directly from BCCDC, and remained on site, under the recommended storage conditions, and in the original packaging, sealed and unopened. The storage site must be secure (locked refrigerator or locked room), and refrigerator temperatures must have been recorded twice daily. Products being returned for redistribution must have 3 months dating before reaching expiry.

Page 13, Section 5.0, Management of a Cold Chain Incident

This section contains the new information and direction for temperatures 0°C to +2°C, and temperatures below 0°C.

Page 18, 7.0 Resources:

- Form names have been simplified: Biologicals Requisition Form (previously, Biological Products Replenishment Requisition); Field Return Form (previously Field Return Report); Redistribution Form (new); Cold Chain Incident Form (previously Incident Report: Cold Chain Failure); Temperature Form (previously Vaccine Temperature Log for Public Health Use.)
- Cold Chain Resources for Physician has been renamed to “Cold Chain Resources for Community Vaccine Providers.”



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Please remove and destroy the following pages from the Communicable Disease Control Manual, Chapter II – Immunization Program, Section VI – Management of Biologicals:

Table of Contents
Pages 1 – 16

Dated May 2005

Please insert the following replacement pages in the Communicable Disease Control Manual, Chapter II – Immunization Program, Section VI – Management of Biologicals:

Table of Contents
Pages 1 – 19

Dated May 2009

If you have any questions or concerns, please contact Cheryl McIntyre, Associate Nurse Epidemiologist, or Karen Pielak, Nurse Epidemiologist at telephone (604)660-6061, fax (604)660-0197, or by email at cheryl.mcintyre@bccdc.ca or karen.pielak@bccdc.ca

Sincerely,

Dr. Monika Naus, Director
Medical Director, Immunization Program and
Associate Director, Epidemiology Services
B C Centre for Disease Control



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