

Date November 2, 2011

ATTN: Medical Health Officers and Branch Offices

Public Health Nursing Administrators and Assistant Administrators

Holders of Communicable Disease Control Manuals

Re: Revisions to the Communicable Disease Control Manual –

Chapter II, Immunization Program

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

The significant changes to this section are found on the following pages:

- Pages 4 & 5, Section 3.2 "Backup Power supply"
- Page 5, Section 3.3.1 "Temperature Alarms"

Pages 4 & 5, Section 3.2 "Backup Power Supply":

- New section
- Develop plans to install a backup power supply (generators or battery packs) for all refrigerators to maintain appropriate refrigerator temperatures during power outages.
- Where a backup power supply cannot be installed, establish a written agreement with an alternate storage facility such as a hospital that has a backup power supply.

Recent inventory surveys show that 71% of the health units and hospitals that responded have a back up power supply.

Administrative Circular 2011:17



Page 5, Section 3.3.1 "Temperature Alarms":

- New section
- Develop plans to purchase and install a continuous monitoring alarm in all refrigerators containing biological products by 2014. Substantial losses are incurred when a malfunction occurs outside of regular business hours, including weekends when offices are unattended.
- A fan-out list of health authority/health unit contacts should be provided to the external monitor.
- Written protocols for staff use should be in place when responding to a call, to determine the nature of the malfunction and management of the issue.
- An alarm is not necessary when small quantities of vaccine are in an office only for a clinic day, and vaccines are returned to a central depot when the office is unattended.

Recent inventory surveys show that 69% of the health units and hospitals that responded have a continuous alarm monitoring system.

Other changes to the document include the following:

Page 2, Section 2.0 "General Recommendations":

- Change of wording to the description of the Biological Products Consultant role ("...decision-making regarding continued use of vaccine cold chain incidents, based on known stability data.")
- Addition of auditing inventories to the description of the Biological Products Monitor role.
- Recommendation to designate an individual to review orders quarterly with the BPM; this would be an individual familiar with vaccine schedules, birth cohort in local office area, clinic schedules, school programs and seasonal vaccine programs.

Page 3 & 4, Section 3.1 "Refrigerators":

- Under-the-counter refrigerators that are industrial or pharmacy grade are acceptable for storing biological products.
- Additional information regarding monitoring a new refrigerator for one week to ensure stability of temperature prior to placing vaccines in the unit.
- Reminder to keep all records of refrigerator maintenance and repair for the lifetime of the refrigerator.

Page 7, Section 3.3.5 "Freeze-tags":

- Freeze tags that are product and lot specific will accompany some deliveries to the field. There will be notification on an outer carton that the box contains a Freeze tag.
- A Freeze tag picture will be added to the Resources on the web site.

Pages 9, Section 4.1 "Vaccine Delivery to Health Units":

- Information added regarding the "shake test" that can be used to determine if an aluminum-adjuvanted adsorbed vaccine has been frozen. Links to World Health Organization documents provided.
- Note that BCCDC will not be accepting products from manufacturers when a cold chain incident has occurred, unless there is a significant reason to do so, and the product has been deemed unaffected by the exposure.
- Updated detailed directions (Page 9) for the reading the Temptale4® monitoring device used in shipments from BCCDC vaccine and Pharmacy Services to the field.

Page 11, Section 4.2 "Vaccine Storage":

- When checking inventory on the last working day of the month, check for opened multidose vials that will expire before the end of the next month; note the date of expiry and remove vials on that date.
- Reminder to keep all vaccines in original packaging, unless circumstances warrant providing less the full package amount to a provider, to avoid vaccine wastage.

Page 13, Section 4.5 "Transportation and Management of Vaccines for Clinics":

 Note added that under winter conditions "fewer or no frozen packs" may be needed to maintain the appropriate temperature in a cooler.

Page 17, Section 5.0 "Management of a Cold Chain Incident":

 An example added to clarify the need for a protocol to identify vaccines exposed to multiple exposures.

Pages 20 & 21, "Algorithms 1 & 2":

 Details added: label (dot and date) vaccines exposed to a cold chain incident; notify BPC of incidents; fax copies of completed Cold Chain Incident forms to BCCDC for data entry and analysis (when consulting regarding vaccine use, or when all recommendations for use are made at local level.)

Pages 22 & 23:

- "Forms" are section 7.0,
- "Resources" are section 8.0.
- "Resources" have been updated and renamed for clarity

Please remove and destroy the following pages from the Communicable Disease Control Manual, Chapter 2 – Immunization Program, Section VI: Management of Biologicals:

TOC and Pages 1-21

Dated July 2010

Please insert the following pages in the Communicable Disease Control Manual, Chapter 2 – Immunization Program, Section VI: Management of Biologicals:

TOC and Pages 1-24 Dated November 2011

If you have any questions or concerns, please contact Cheryl McIntyre, Clinical Nurse Specialist, telephone (604) 707-2577, fax (604) 707-2516 or by email at cheryl.mcintyre@bccdc.ca

Sincerely,

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