

## *Canadian Immunization Guide, 2006, 7<sup>th</sup> Edition*

### **Errata/Clarifications, March 2008**

#### **Part 1 – General Guidelines**

##### **Chapter entitled: *General Considerations***

###### **Page 7**

In Table 1, Type and Contents of Vaccines Currently Approved for Use in Canada, the abbreviation for Boostrix<sup>®</sup>, appearing in the Immunogen+ column should read “T, d, ap”.

#### **Part 2 – Vaccine Safety and Adverse Events Following Immunization**

##### **Chapter entitled: *General Contraindications and Precautions***

###### **Page 76**

In Table 6, Conditions that are NOT Contraindications to Immunization, the heading of the sixth row of the table (third row on page 76) should read:

“Minor acute illness (with or without fever).”

This change has been made to avoid confusion; it refers to fever in general.

##### **Chapter entitled: *Anaphylaxis: Initial Management in Non-Hospital Settings***

###### **Page 81**

In the paragraph at the bottom of page 81, the reference to diphenhydramine hydrochloride has been removed and the text should read as follows:

“Swelling and urticarial rash (i.e. hives) at the injection site can occur but are not always caused by an allergic reaction. The swelling or hives should be observed for at least 30 minutes in order to ensure that the reaction remains localized, and if so, the patient may be discharged after this observation period. Ice can be put on the injection site for comfort. If the hives or swelling disappear, or there is no evidence of any progression to other parts of the body or any other symptoms within the 30-minute observation period, no further observation is necessary. However, if any other symptoms arise, even if considered mild (e.g., sneezing, nasal congestion,

tearing, coughing, facial flushing), or if there is evidence of any progression of the hives or swelling to other parts of the body during the observation period, epinephrine should be given (see below). There is little risk to the unnecessary use of epinephrine, whereas delay in its administration when required may result in difficulty to treat anaphylaxis. A mild local reaction resolving by itself within a few minutes does not require special observation.”

### **Part 3 – Recommended Immunization**

#### **Chapter entitled: *Immunization of Adults***

##### **Page 102**

In Table 6, Adult Immunization Schedule – Specific Risk Situations, the indication for Poliomyelitis (eighth row) should read as follows, for comprehensiveness:

“Travel to endemic area(s) *or any areas where the virus is known or suspected to be circulating, or other risk group*”

#### **Chapter entitled: *Immunization of Immunocompromised Persons***

##### **Page 123**

Under the sub-section “Immunosuppressive therapy,” modifications were made to the first paragraph at the top of page 123 in order to clarify the timeframe for all types of vaccines:

“There is no contraindication to the use of any inactivated vaccine in these people, and particular attention should be paid to the completion of childhood immunizations, annual influenza immunization and pneumococcal immunization (with a booster after 3-5 years). Ideally, all appropriate *inactivated vaccines* should be administered to these individuals at least 14 days before the initiation of therapy. *If indicated, MMR should be administered at least 14 days before the initiation of therapy and varicella vaccine should be administered at least 6 weeks before the initiation of therapy.* If this cannot be done safely, a period of at least 3 months should elapse after immunosuppressive drugs have been stopped before administration of both inactivated and component vaccines (to establish immunogenicity, although inactivated vaccines can be administered if required for post-exposure or outbreak management) and live vaccines (to reduce the risk of dissemination). However, the interval may vary with the intensity of the immunosuppressive therapy, underlying disease and other factors. If immunosuppressive therapy cannot be stopped, inactivated or component vaccines should be given when the therapy is at the lowest possible level. Live vaccines are generally contraindicated, although the risk-to-benefit ratio for several of these vaccines can favour immunization if only low doses of immunosuppressive drugs are required and there is significant risk of wild-type infections (e.g. varicella vaccine in seronegative individuals).”

With regard to the sub-section “Solid organ transplantation,” the fifth bullet from the top of page 126 has been updated as follows:

- ♦ “Varicella vaccine: recommended before transplantation for non-immune (as determined by serology) children and adults. Until further data are available, the same age appropriate dosage schedule as for healthy children may be followed. Susceptible persons awaiting solid organ transplants may be immunized with one to two doses of varicella vaccine (depending on their age), the last dose being given at least 6 weeks prior to transplantation. The suggested wait period makes vaccination practical mainly in the context of elective transplantation. The person should not be receiving immunosuppressive treatment at the time of vaccination.”

“Varicella vaccine is not recommended after solid-organ transplantation. Some experts have vaccinated children with varicella vaccine at least 6 months post-transplantation, when there was no evidence of organ rejection and the patient was deemed to be on minimal immunosuppressive agent(s). No serious adverse effects were noted, but the number of patients vaccinated was too small to make any conclusions about the safety of varicella vaccine in this immunocompromised population. More research is needed.”

Please note that Table 8, Vaccination of Individuals with Immunodeficiency, should not include Oral cholera vaccine (last row) since it is not marketed in Canada.

**Chapter entitled: *Immunization of Persons with Neurologic Disorders***

Under the section "Neurologic events following immunization," the word “or” has been changed to “and” in the last sentence of the second paragraph:

“People with encephalopathy or encephalitis that develops within 7 days after immunization should be investigated. Those who have an alternative etiology for the encephalopathy (e.g., viral infection) or who recover fully by the next scheduled vaccination may be immunized without deferral. People with encephalopathy that persists *and* who have no alternative etiology should be referred to a specialist for further consultation and may be immunized if their condition is stable and found not to relate to immunization.”

## **Chapter entitled: *Immunization of Travellers***

### **Page 139**

Please note that the International Certificate of Vaccination, as mentioned in the first and second paragraphs under the sub-section “Yellow fever,” has been renamed, and it is now called “the International Certificate of Vaccination or Prophylaxis,” according to the revised International Health Regulations 2005.

### **Page 142**

As mentioned on page 8 in Table 1, Type and Contents of Vaccines Currently Approved for Use in Canada, the tickborne encephalitis (TBE) vaccine is marketed in Canada under the brand name FSME - IMMUN. This vaccine would belong under the section “Recommended Immunizations,” before the sub-section on Typhoid at the top of page 142. To identify travellers who are at risk of contracting the TBE virus, the Committee to Advise on Tropical Medicine and Travel (CATMAT) recommends that travel medicine professionals should consider the season of travel, travel itinerary, and the activities of the traveller. For additional information, please visit PHAC’s website for the CATMAT Statement on TBE (April 2006) at <<http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/06pdf/acs-32-03.pdf>>.

## **Part 4 – Active Immunizing Agents**

### **Chapter entitled: *Hepatitis A Vaccine***

### **Page 185**

In Table 3, Doses and Schedules for Monovalent Hepatitis A Vaccines, the last cell of the bottom row with heading “Vaqta<sup>®</sup> Pediatric/Adolescent” should read: 1 to 17 years.

### **Chapter entitled: *Hepatitis B Vaccine***

### **Page 194**

Under the sub-section “Pre-exposure prophylaxis—Others at increased risk,” the fifth bullet from the top of page 194 should read:

- ◆ *pre-dialysis chronic renal failure and hemodialysis patients (40 µg of vaccine antigen per dose should be used);*

Modifications were brought to Table 4, Doses and Schedules for Monovalent Hepatitis B Vaccines, as shown below (see changes/additions in italics):

**Table 4. Doses and Schedules for Monovalent Hepatitis B Vaccines**

Recipients	Recombivax HB®			Engerix® -B		
	µg	mL	Schedule (months)	µg	mL	Schedule (months)
Infants of HBV-negative mothers or children < 11 <i>years*</i>	2.5	0.25	0, 1, 6 **	10	0.5	0, 1, 6 or 0, 1, 2, 12
Infants of HBV-positive mothers*	5.0	0.5	0, 1, 6 **	10	0.5	0, 1, 6 or 0, 1, 2, 12
11 to 15 years ( <i>inclusive</i> )	10.0	1.0	0, 4-6	20	<i>1.0</i>	0, 6
11 to 19 years ( <i>inclusive</i> )	5.0	0.5	0, 1, 6 **	10 †	0.5	0, 1, 6 or 0, 1, 2, 12
<i>20 years and older</i>	10.0	1.0	0, 1, 6 **	20	1.0	0, 1, 6, or 0, 1, 2, 12 or 0, 7, 21 and 365 days
<i>16 to 19 years (inclusive), for pre-dialysis chronic renal failure patients and hemodialysis patients</i>	<i>n/a</i>	<i>n/a</i>	<i>n/a</i>	<i>40</i>	<i>2.0</i>	<i>0, 1, 2, 6</i>
<i>20 years and older, for pre-dialysis chronic renal failure patients and hemodialysis patients</i>	40.0	1.0 ‡ or 4.0 ‡	0, 1, 6	40	2.0	0, 1, 2, 6

Individuals under 19 years of age who may be hyporesponsive: double the microgram dose for healthy individuals of the same age and use the three or four dose schedule only.

- \* The thimerosal preservative-free preparation is recommended. For the post-exposure schedule for children of HBV-infected mothers, please refer to the Figure and the text section on post-exposure prophylaxis.
- \*\* Although a schedule of 0, 1 and > 2 months is approved, the preferred schedule is 0, 1 and 6. Refer to text.
- † The manufacturer recommends the standard adult dosage (20 µg, 1.0 mL) if it is unlikely that there will be compliance with this schedule.
- ‡ 1.0 mL of the dialysis formulation, 4.0 mL of the standard formulation.

**Chapter entitled: Rabies Vaccine**

With regard to the section “Post-exposure management,” the third paragraph on page 290 has been modified. The phrase “as well as stray or unwanted dogs or cats and other biting animals” was removed to avoid confusion with respect to domestic animals (e.g. dogs, cats, ferrets, etc.), and a new sentence was added at the end of the paragraph to deal with stray or ownerless

animals. The word “only” in the expression “only readily demonstrable” was removed to reflect the fact that the virus will be demonstrable in animals when they are symptomatic. The third paragraph should read as follows:

“Signs of rabies cannot be reliably interpreted in wild animals. These animals should immediately be humanely killed in a way that does as little damage as possible to the head, which should be submitted for laboratory examination. For advice regarding appropriate killing of animals please call your local public health office. A domestic dog, cat or ferret that is evaluated by a veterinarian and determined to be normal should be kept under secure observation for 10 days even if it has a history of vaccination. If the animal is still clinically well after that time, it can be concluded that it was not shedding rabies virus at the time of the exposure and was therefore non-infectious. If illness suggestive of rabies develops during the holding period, the animal should be humanely killed *in a way that does little damage to the brain* and the head submitted for examination. Rabies virus *is readily demonstrable* in brains of animals that have neurologic symptoms. *Stray or ownerless dogs or cats that seem healthy should be observed for evidence of rabies for 10 days if feasible, but if isolation and observation are not feasible, the animal should be euthanized and tested for rabies.*”

#### **Page 291**

A clarification has been brought to Table 12, Post-exposure Prophylaxis for Persons Not Previously Immunized Against Rabies. Not all bites to the head or neck require post-exposure prophylaxis to begin immediately. Point 2, as shown in the third column, of the first row, should read as follows:

“2. At first sign of rabies in animal, give RabIg (local and intramuscular) and start HDCV or PCECV, unless bite wound to the head or neck (*generally begin immediately, see text on page 292 for other considerations*)”

#### **Page 292**

Under the sub-section “Post-exposure prophylaxis of previously unimmunized individuals,” information has been added to the second paragraph and it now reads as follows:

“... However, if the bite wound is to the head and neck region, prophylaxis should *generally* begin immediately and not be delayed. *Considerations that may support delaying initiation of prophylaxis and instead observing the animal for a 10-day period include:*

- *if the animal is a domestic pet;*
- *if the animal is fully vaccinated;*
- *if the bite was provoked; and*
- *if there is very low prevalence of rabies in the area.*

When notification of an exposure is delayed, prophylaxis may be started as late as 6 or more months after exposure.”

Furthermore, for increased clarity, the fourth sentence of the fourth paragraph should read as follows:

“If not anatomically feasible, any remaining volume of *RabIg* should be injected, *using a separate needle and syringe*, intramuscularly at a site distant from vaccine administration.”

**Page 293**

Under sub-section “Post-exposure prophylaxis of previously immunized individuals,” the first bullet in point 1 should read:

- ♦ “completion of an approved course of pre- or post-exposure prophylaxis with HDCV or PCECV.”

Under the same subsection, the term “in A above” in point 2 should be replaced by the term “in point 1 above”.

In addition, the second sentence in point 2 should read:

“A serum sample may be collected before vaccine is given, and *if an acceptable* antibody level ( $\geq 0.5$  IU/mL) is demonstrated, the course may be discontinued, provided at least two doses of vaccine have been given.”

The symbol “ $\geq$ ” has been used instead of the symbol “ $>$ ” since 0.5 IU/mL may also be considered an acceptable antibody level.

**Page 293**

Under the section “Route of administration,” the first sentence has been modified to be consistent with the statement on the previous page, which mentions the administration of *RabIg* *into* the wound (4<sup>th</sup> paragraph), and should read as follows:

“*RabIg* is always given intramuscularly. If possible, the full dose of *RabIg* should be thoroughly infiltrated into the wound and surrounding area. If this is not anatomically feasible, any remaining volume of *RabIg* should be injected, using a separate needle and syringe, intramuscularly at a site distant from vaccine administration.”

**Chapter entitled: *Varicella Vaccine***

**Page 332**

Under the sub-section “Susceptible immunocompromised people—Groups for whom varicella vaccination may be considered, if the pre-requisite conditions allow,” modifications have been brought to the second and third bullets from the top of page 332. These bullets should read as follows:

- ◆ Before solid organ transplantation – recommended before transplantation for non-immune (as determined by serology) children and adults. Until further data are available, the same age appropriate dosage schedule as for healthy children may be followed. Susceptible persons awaiting solid organ transplants may be immunized with one to two doses of varicella vaccine (depending on their age), the last dose being given at least 6 weeks prior to transplantation. The suggested wait period makes vaccination practical mainly in the context of elective transplantation. The person should not be receiving immunosuppressive treatment at the time of vaccination.
- ◆ After solid organ transplantation – varicella vaccine is not recommended. Some experts have vaccinated children with varicella vaccine at least 6 months post-transplantation, when there was no evidence of organ rejection and the patient was deemed to be on minimal immunosuppressive agent(s). No serious adverse effects were noted, but the number of patients vaccinated was too small to make any conclusions about the safety of varicella vaccine in this immunocompromised population. More research is needed.

### **Chapter entitled: *Yellow Fever Vaccine***

#### **Page 343**

The following is an update that replaces the second paragraph on page 343:

“Under the revised International Health Regulations (IHR) of 2005, there is no longer any obligation per se to report yellow fever (or cholera or plague) to the World Health Organization (WHO), but there is an obligation to assess whether the occurrence of these and other diseases constitute a potential public health emergency of international concern, given their demonstrated ability to seriously affect public health and to spread internationally. Furthermore, countries are obliged under the IHR (2005) to report to WHO imported cases of disease that are a public health risk and that may cause international disease spread. Yellow fever is also a nationally notifiable disease. Therefore urgent reporting of yellow fever is required within Canada through provincial or territorial public health authorities. The contact number to reach the PHAC duty officer is: 1-800-545-7661.”

#### **Page 346**

The section “Recommended usage” has been updated with the revised name of the International Certificate of Vaccination; it is now called “the International Certificate of Vaccination or Prophylaxis” according to the revised IHR.

**Page 347**

The section “Storage requirements” has been updated to reflect the granting of a “Notice of Compliance” to Sanofi Pasteur, the manufacturer of the YF-VAX<sup>®</sup> vaccine, in October 2007 stating that the vaccine should now be stored under refrigeration upon delivery as shown below:

“YF-VAX<sup>®</sup> vaccine and the corresponding diluent for reconstitution (sodium chloride injection, which contains no preservative) should be stored in the refrigerator at +2° to +8° C. The vaccine and diluent should not be allowed to freeze. Any unused reconstituted vaccine must be discarded 1 hour after reconstitution.”

Given that older lots of the YF-VAX<sup>®</sup> vaccine, which were authorized to be stored at freezing temperatures, may still be in use, the Public Health Agency of Canada recommends that all designated yellow fever vaccination centres follow the manufacturer's storage instructions as indicated in the product monograph.

**Page 348**

Under the section “Adverse reactions,” an error appears in the second paragraph from the top of page 348. The term “neurotropic” should be changed to “viscerotropic” in the first sentence only. The statistics have also been updated as follows:

“In 2001, a syndrome of fever and multiple organ failure was first described in recipients of YF vaccine and is now referred to as yellow fever vaccine associated *viscerotropic disease* (YFV-AVD). All affected persons have required care in an intensive care unit, and the associated mortality rate is estimated to be between 70% and 80%. Among US civilians aged  $\geq$  60 years immunized with yellow fever vaccine, the estimated risk of YFV-AVD is 1.8 per 100,000 doses.

Yellow fever vaccine associated neurotropic disease (YFV-AND) has previously been described as an adverse event in young infants following yellow fever immunization, with an estimated incidence of 0.5 to 4 per 1,000 doses. YFV-AND has now also been reported in adults, and the risk of YFV-AND in adults increases with older age. The rate is estimated to be 1.4 per 100,000 doses in persons  $\geq$  60 years.”