

Manitoba's School Immunization Program

Questions & Answers for Health Care Providers

The following is a set of commonly asked questions and answers to help guide health care providers in the implementation of Manitoba's publicly-funded (i.e. free-of-charge) School Immunization Program.

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1. What is Manitoba's School Immunization Program?

Manitoba's School Immunization Program is based on Manitoba's Recommended Routine Immunizations Schedule for Infants, Children and Adults (www.manitoba.ca/health/publichealth/cdc/div/schedules.html).

Every year, public health nurses within each Regional Health Authority go into every school in the province to offer students the human papillomavirus (HPV) vaccine hepatitis B vaccine and meningococcal conjugate quadrivalent (Men-C-ACYW-135) vaccine in grade 6, as well as the tetanus, diphtheria and acellular pertussis (Tdap) vaccine in grade 8/9 (varies by region). Immunizing students in schools is safe, effective and cost-effective and ensures high vaccine uptake.

2. When did Manitoba's School Immunization Program start?

All of the vaccine programs offered in Manitoba's School Immunization Program started at different times and have gone through several changes throughout the years.

Manitoba's Hepatitis B Immunization Program: Introduced September 1998 for girls and boys in grade 4, born during or after 1989. The vaccine was a 3-dose program (0.25mL/dose) until September 2017 when it transitioned to a 2-dose (1.0mL/dose), grade 6 program. (While the Program was transitioning, no hepatitis B vaccine was provided in schools in 2015 or 2016 however, no child missed the opportunity to be immunized).

Manitoba's HPV Immunization Program: Launched September 2008 for girls in grade 6, born during or after 1997. In September 2015, it transitioned from a 3-dose program to a 2-dose program. A year later, September 2016, boys born during or after 2005 were added to the grade 6 program, and a 3-year catch-up program was launched for boys in grade 8 or 9, born between January 1st 2002 and December 31st 2004. In 2018/19, Gardasil®9 replaced Gardasil®4.

Meningococcal Immunization Program: Started in 2004 and offered in grade 4. The vaccine was not offered in 2017 and 2018 while it transitioned from grade 4 to grade 6. Starting September 2019, meningococcal conjugate quadrivalent (Men-C-ACYW-135) vaccine will be offered in grade 6 for those born during or after 2008. No child will have missed the opportunity to be immunized against meningococcal disease.

Tetanus and Pertussis Immunization Program: Since 2003, MHSAL has offered the vaccine against tetanus, pertussis and diphtheria (Tdap) to students in grade 8 or 9. The grade in which it is offered varies by region because the school structure and logistics in each region varies.

3. What is the immunization schedule offered in Schools?

Manitoba's routine schedule for its School Immunization Program is as follows:

Vaccine	Grade of Child	
	<u>Grade</u>	<u>Grade</u>
	<u>6</u>	<u>8 or 9</u>

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Meningococcal Conjugate Quadrivalent (Men-C-ACYW-135)	◆	
Hepatitis B (HB)	◆◆	
Human Papillomavirus (HPV)	◆◆	
Tetanus, Diphtheria, Pertussis (Tdap)		◆

◆ = A single vaccine dose given.

- **HB:** Children in grade 6 or between 11 and less than 16 years of age should be given two adult (1.0mL/dose) hepatitis B vaccine doses;
 - Children under 11 years of age who want to be immunized prior to the school program should receive three pediatric hepatitis B vaccine doses (0.5mL/dose);
 - Monovalent hepatitis B vaccines may be used interchangeably, according to the recommended dosage and schedule;
 - Children 11 to less than 16 years of age who have had one or more pediatric doses (0.5mL/dose) can finish the 3 dose series with 1.0mL adult dose(s), if necessary. However, it is recommended that if available, a child finishes their pediatric hepatitis B vaccine schedule with the pediatric hepatitis B vaccine (0.5mL/dose).
- **HPV:** Children in grade 6 should be given 2 doses of HPV vaccine. However, the National Advisory Committee on Immunization (NACI) identifies differing HPV vaccine schedules depending on the individual's age at first dose as well as if any immunocompromising conditions exist (www.phac-aspc.gc.ca/naci-ccni/acs-dcc/2015/hpv-vph_0215-eng.php):
 - **Healthy females and males (9 - 14 years of age):** either a 2-dose or 3-dose schedule of Gardasil®9 is recommended for immunocompetent, non-HIV infected persons 9 - 14 years of age. For a 2-dose schedule, at least 6 months between the first and second dose is recommended. If the interval between doses is shorter than 6 months, a third dose should be given at least 6 months after the first dose.
 - **Healthy females and males (≥ 15 years of age):** a 3-dose schedule of Gardasil®9 (0, 2 and 6 months) is recommended for persons 15 years of age and older, unless the first dose of HPV vaccine was administered before the age of 15 years. If the first dose was administered between 9 - 14 years of age, a 2-dose schedule is sufficient for persons ≥ 15 years of age, with the second dose administered at least 6 months after the first dose.
 - **Immunocompromised individuals and immunocompetent HIV-infected individuals (see question 8 for a list of immunocompromising conditions):** a 3-dose schedule of Gardasil®9 (0, 2 and 6 months) is recommended for individuals who are immunocompromised and immunocompetent HIV-infected individuals. There is insufficient evidence to recommend a 2-dose schedule in these populations; therefore, a 3-dose schedule continues to be recommended for individuals who are immunocompromised and for immunocompetent HIV-infected individuals.
- **Men-C-ACYW-135:** Starting September 2019, one dose of the meningococcal conjugate quadrivalent (Men-C-ACYW-135) vaccine will be offered in grade 6 to those born during or after 2008. Those born in 2008 are the first cohort who were eligible for the meningococcal conjugate type c (Men-C-C) vaccine at 12 months of age.

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- If they do not have a Men-C-C dose on their immunization record when they are in grade 6, the Men-C-ACYW-135 vaccine will bring them up-to-date and no further immunization with Men-c-c is required.
- Tdap: For example: Tdap-IPV vaccine can be offered in grade 8/9 in lieu of Tdap vaccine for those individuals who missed one or more doses of polio (IPV) vaccine in childhood.

Every effort should be made to catch children up on any missed childhood vaccines in grade 6 as well as grade 8/9 based on regional operating practices.

4. What is MHSAL's eligibility criteria for the vaccines provided as part of Manitoba's School Immunization Program?

All Manitoba children in grades 6 and 8/9 are eligible for the vaccines that are offered as part of Manitoba's School Immunization Program.

In addition to being offered as part of Manitoba's Recommended Routine Immunization Schedule, there is additional eligibility criteria that is outlined for the vaccines offered to Manitobans. If the criteria is met, the vaccine is available free-of-charge as part of the publicly funded immunization program. Please see www.gov.mb.ca/health/publichealth/cdc/vaccineeligibility.html in order to find the most current criteria.

5. What if an individual misses one or more doses of a vaccine offered as part of the School Immunization Program; will he/she still be eligible?

Yes. Based on Manitoba's Once Eligible, Always Eligible policy, if a child misses one or more doses of any of the School Immunization Program vaccines, the vaccine(s) can still be provided free-of-charge at a doctor's office, public health office, nursing station/health centre or ACCESS Centre.

Additionally, for any missed HPV vaccine and/or Tdap vaccine doses, a pharmacist can also immunize people 7 years of age and older (please note: as per *The Pharmaceutical Act* and accompanying *Regulation*, pharmacists are not authorized to provide publicly-funded hepatitis B or meningococcal vaccines).

6. Is consent required to administer the school immunizations?

Yes. Prior to the school immunization program, each regional health authority creates information packages that are sent home to the families of the children. These packages typically include a letter to the parents, a consent form for the parent to review, sign, and return to the school, and factsheets on the immunizations that are being offered.

It is preferred that parents provide the consent for their children. However, children 16 years of age and older can consent to be immunized outside of parental consent (Mature Minor) as per 4(2) of the *Health Care Directives Act*.

Provincial Informed Consent Guidelines for Immunization can be located at: www.manitoba.ca/health/publichealth/cdc/protocol/consentguidelines.pdf

7. How are decisions made to fund vaccines in Manitoba?

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Manitoba Health, Seniors and Active Living (MHSAL) gathers evidence-based information from a variety of sources, including current research and data (e.g. epidemiology, vaccine safety and effectiveness data, cost-effectiveness data, etc.), programs in other provinces and territories, and recommendations from national and provincial public health expert panels, such as Manitoba's Provincial Vaccine Advisory Committee and the National Advisory Committee on Immunization (NACI). All of these sources of evidence are taken into account to develop recommendations for new vaccine programs and expansions, and are weighed by the Province against other competing department initiatives and resources.

8. Are the vaccines that are part of the School Immunization Program safe?

Yes, all of the vaccines provided as part of Manitoba's School Immunization Program are considered safe and all are approved by Health Canada. As with all drugs, including vaccines, adverse events may occur. Information about possible side effects of the vaccines offered as part of the School Immunization Program can be found online, in the individual vaccine factsheets, located at: www.manitoba.ca/health/publichealth/cdc/div/vaccines.html.

Once a vaccine is approved, Health Canada and the Public Health Agency of Canada (PHAC) monitors its use and safety. PHAC coordinates and supports the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), which collects reports on adverse events following immunization (AEFI) either directly from health care providers or through each different jurisdiction's passive surveillance system. Canada also has an active surveillance system that is based out of 12 pediatric hospitals across Canada, called IMPACT (Immunization Monitoring Program ACTIVE) that also collects information about AEFIs. In addition, Manitoba has an expert committee that assesses reports based on various criteria, including seriousness, and determines whether the vaccine was likely to have caused the identified reaction. For more information about vaccine safety and AEFI, please go to: www.gov.mb.ca/health/publichealth/cdc/div/aefi.html.

9. How do I report an adverse event following immunization (AEFI)?

In accordance with *The Public Health Act*, health care providers are required to report a reportable Adverse Event Following Immunization (AEFI) within seven days of becoming aware of the AEFI (as per section 59 of the Act). Health care providers are required to report a serious AEFI (see below) within one business day.

A reportable AEFI is an event that:

- a. Is temporally associated with a vaccine;
- b. Has no other clear cause at the time of reporting; and
- c. Is either serious, of special importance, or is unexpected.

An AEFI is "serious" if **any one** of the following criteria is met:

- Results in death;
- Is life-threatening, that is, where the patient was at real, rather than hypothetical, risk of death at the time of the event/reaction;
- Requires in-patient hospitalization, defined as any of the following:
 - Hospital stay lasting \geq 24 hours based on known date/time of admission and discharge; or,

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- Hospital stay involving all or part of two consecutive days (i.e. admission and discharge date are at least one day apart but specific time of admission is not specified)
- Results in prolongation of existing hospitalization;
- Results in persistent or significant disability/incapacity (if known at the time of reporting); or,
- Is a congenital anomaly/birth defect.

An AEFI is of “special importance” if it is **any one** of the following:

- Anaphylaxis
- Encephalitis (including SSPE)
- Acute disseminated encephalomyelitis
- Myelitis
- Aseptic meningitis/other meningitis (physician diagnosis)
- Guillain-Barré Syndrome (GBS)
- Acute cerebellar ataxi
- Intussusception
- Thrombocytopenia (Brighton Collaboration diagnostic certainty level 1: platelet count < 150 AND clinical signs/symptoms of spontaneous bleeding)
- Emerging signal event

An AEFI is “unexpected” if it is:

- Not listed in the most current Health Canada-approved product monograph for the vaccine marketed in Canada; or,
- Listed in the product monograph but is of a different nature, severity, frequency, specificity or outcome.

The most current Health Canada-approved product monographs can be found online through the Drug Product Database Online Query at <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>.

Regional public health is to report AEFIs using the Public Health Information Management System (PHIMS). The PHIMS reports are to be completed with as much information as possible.

All other health care providers must submit completed AEFI reports to the regional Medical Officers of Health (MOH) listed in Appendix A of the *Reporting Form for Adverse Events Following Immunization*, at www.gov.mb.ca/health/publichealth/cdc/docs/aefi_form.pdf.

All recommendations made by an MOH with respect to an AEFI should be recorded in the client's personal health record.

For more information, please visit: www.gov.mb.ca/health/publichealth/cdc/div/aefi.html.

10. What do I do if a vaccine schedule is interrupted?

As per the Canadian Immunization Guide, if either the HPV or hepatitis B vaccine schedule is interrupted, either vaccine series does NOT need to be restarted.

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For the hepatitis B vaccine, administer the second dose as soon as possible (but no sooner than the minimum interval – see question 13).

In individuals 15 years of age and older who received the first HPV vaccine dose between 9 to less than 15 years of age, a 2-dose schedule can be used to complete the series, with the second dose administered at least 6 months after the first dose.

For the meningococcal conjugate quadrivalent (Men-C-ACYW-135) vaccine, there is only one dose. If an individual misses the school immunization program, they can see their health care provider to obtain the immunization.

11. Are additional doses (boosters) required?

Hepatitis B: Routine re-immunization with hepatitis B vaccine is not required.

- People who develop an anti-hepatitis B titre of at least 10 IU/L (adequate anti-hepatitis B titres) following the completion of a recommended schedule are considered protected for life.
- Routine booster doses of hepatitis B vaccine are not recommended for immunocompetent persons.
- Individuals at high risk of hepatitis B infection or complications who do not develop anti-hepatitis B titre of at least 10 IU/L after the initial hepatitis B vaccine series should receive a second hepatitis B vaccine series. (**NOTE:** *additional doses of a vaccine that are given outside of MHSAL's publicly funded, recommended immunization series are provided free-of-charge to individuals with certain high-risk medical conditions, as well as to individuals with an inadequate immune response post-immunization (up to one additional series), as determined by a health care provider.*)
- Additional vaccine doses (up to 3) received in a second immunization series will produce a protective antibody response in 50% to 70% of healthy adults and children who did not initially respond to the vaccine. Individuals who fail to respond to 3 additional doses of vaccine are unlikely to benefit from further immunization and should be counselled on alternative risk reduction measures.
- Immunocompromised persons and persons with chronic renal disease who have responded initially to hepatitis B vaccine may require booster doses periodically if anti-hepatitis B titres fall below 10 IU/L. If a higher strength vaccine dose was indicated for the initial vaccine series, a higher strength hepatitis B vaccine dose should be used for all subsequent immunizations.

HPV: Re-immunization with HPV vaccine is not indicated at this time, as protection lasts at least 10 years.

- There is insufficient evidence at this time to recommend, at a population level, re-immunization with HPV9 (Gardasil®9) vaccine in individuals who have completed an immunization series with HPV4 (Gardasil®4) vaccine.
- However, re-immunization with Gardasil®9 following the Gardasil®4 vaccine (series) is safe and may provide additional protection against cervical/non-cervical cancers and their precursors.
- Patients should be informed that additional dose(s) above the initial HPV vaccine series is a non-insured service that requires a prescription to be filled/paid for at a pharmacy (with potential third party reimbursement).

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Men-C-ACYW-135: As only one dose is required, re-immunization with meningococcal conjugate quadrivalent (Men-C-ACYW-135) vaccine is not required.

- Those with certain high-risk medical conditions may require additional doses depending on the age of first dose and the high-risk medical condition. Those high-risk medical conditions include:
 - Functional or anatomic asplenia
 - Complement, properdin, factor D or primary antibody deficiency
 - Persons with acquired complement deficiency due to receipt of the terminal complement inhibitor eculizumab (Soliris™)
 - Certain genetic risk factors (e.g. polymorphisms in the genes for mannose-binding lectin and tumor necrosis factor)
 - Immunocompetent HIV-infected
 - Hematopoietic stem cell transplantation ([as per CancerCare Manitoba Blood and Marrow Transplant \(BMT\) Immunization Schedule](#))
 - Solid organ transplantation
 - Patients currently under the care of a haematologist or oncologist from CancerCare Manitoba (CCMB) who have the following conditions and have been provided a CCMB directed Immunization Schedule:
 1. Malignant neoplasms (solid tissue and haematological) including leukemia and lymphoma, or clonal blood disorder, and who will receive or have completed immunosuppressive therapy including chemo therapy or radiation therapy, or
 2. Hypo- or asplenic (Sickle Cell Disease, etc.)

For the recommended dosing schedule, see the Canadian Immunization Guide at: <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-13-meningococcal-vaccine.html>

Tdap: At this time, MHSAL recommends and publicly funds the Tdap vaccine for the following individuals 18 years of age and older:

- Adults who due for a Td booster and have not previously received a pertussis-containing vaccine in adulthood;
- Pregnant women in every pregnancy. Optimal timing is between 27 and 32 weeks gestation, although Tdap vaccine can be given at any time during pregnancy.
- All individuals ≥ 7 years of age are recommended and eligible to receive a Td vaccine every 10 years.

12. What are the minimum intervals between HPV vaccine doses?

Every effort should be made to administer HPV vaccines at the recommended intervals. When an abbreviated schedule is required, vaccine doses should not be administered earlier than the minimum intervals. For a 2-dose or 3-dose schedule, the minimum interval between the first and last doses is 24 weeks (6 months). In a 3-dose schedule, the minimum interval between the first and second doses of vaccine is 4 weeks (1 month), the minimum interval between the second and third doses of vaccine is 12 weeks (3 months).

13. What are the minimum intervals between hepatitis B vaccine doses?

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Efforts should be made to administer hepatitis B vaccine at the recommended intervals. Depending on the product being used, the grade 6, 2-dose hepatitis B vaccine schedule is as follows:

- Engerix®-B (1.0 mL/dose) at 0 and 6 months; or
- Recombivax HB® (1.0 mL/dose) at 0 and 4 - 6 months

For those that require a 3 dose hepatitis B immunization series, the recommended interval are 0, 1 and 6 months.

Month 0 is the date of the first dose is given. The timing of subsequent doses is based on the date the first dose was given.

14. What is the minimum interval between the Td and Tdap vaccine?

There is no minimum interval between the Td and Tdap vaccine.

15. How do I report vaccine doses administered?

Immunization doses administered to Manitobans are captured in the Manitoba Immunization Registry in one of three ways:

1. Electronically uploaded from the Drug Program Information Network (DPIN) when immunizations are administered by pharmacists.
2. Electronically uploaded from Claims Processing System (Physician Billing) when publicly funded immunizations are administered by fee-for-service physicians and other health care providers that shadow bill (e.g. regional nurse practitioners).
3. Direct entry into the Public Health Information Management System (PHIMS) : health care providers that have access to PHIMS can enter immunization data directly into Manitoba's Immunization Registry (assuming their permissions allow for data entry).

Health care providers who fall into at least one of the following categories must complete and submit *The Immunization Inputting Form for Health Care Providers* (www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf) for manual entry into PHIMS by regional public health staff:

- a. Those who do not have access to PHIMS and do not bill the Province for reimbursement via the DPIN system or Physician Billing.
- b. Those who are reporting doses administered to patients without a valid (or unknown) MHSAL personal health identification number (PHIN) (i.e. visitors, newcomers, etc.). Regional procedures for entry into PHIMS varies.
- c. Non-publicly funded vaccines provided by fee-for-service physicians or other health care providers that shadow bill (e.g. regional nurse practitioners).

All vaccine doses administered to Manitobans are to be recorded in Manitoba's Immunization Registry.

16. How do I order vaccines?

Publicly funded vaccines are to be ordered through the Provincial Distribution Warehouse (PDW) only by a health care provider (or designate) who is registered with MHSAL. Health care providers order vaccines by completing *The Vaccines and Biologics Order Form* (www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf).

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The vaccines provided as part of MHSAL's School Immunization Program are provided to health care providers for the sole purpose of administering Manitoba's School Immunization Program based on Manitoba's Recommended Routine Immunization Schedule.

Vaccines ordered through the PDW are not to be used for clients who do not meet Manitoba's eligibility criteria for publicly funded vaccines (www.gov.mb.ca/health/publichealth/cdc/vaccineeligibility.html). If a client does not meet the criteria for a publicly funded vaccine, they can obtain a prescription from a licensed health care provider, purchase the vaccine(s) at a pharmacy, and then make an appointment with a health care provider that provides immunization services (e.g. doctor, pharmacist, nurse practitioner, etc.) to administer the vaccine. A client would be responsible for all costs associated with the vaccine and its administration. Typically, public health nurses do NOT administer non-publicly funded vaccines.

17. What are the storage and handling requirements?

All vaccines and biologics should be stored as per the product monograph. Health care providers are to refer to the online *Cold Chain Protocol – Immunizing Agents and Biologics* and corresponding resources for all storage and handling requirements including on transporting and storing vaccine off site. (www.gov.mb.ca/health/publichealth/cdc/coldchain.html).

In the event of an exposure outside of the storage requirements, please review and complete the *Manitoba Health Adverse Storage Condition (ASC) Form and Procedure* available at: <https://www.gov.mb.ca/health/publichealth/cdc/docs/ccf.pdf>

18. Does immunizing against HPV mean that screening is no longer needed?

No. All females and males regardless of immunization history should continue to seek appropriate HPV-related screening and care. The HPV vaccine has been shown to be highly effective against nine types of HPV that can cause cancer and their precursors, as well as non-cancerous genital lesions, including:

- 90% of cervical cancers
- 90% of anal cancers
- 90% of (benign) genital warts
- 65% of vaginal cancers
- 60% of penile cancers
- 15% of vulvar cancers
- An unknown percentage of head and neck cancers

Those vaccinated can still be susceptible to infection from other high-risk HPV types not covered in the vaccine.

All women should continue to participate in the currently recommended provincial cervical cancer screening programs. For more information, visit CervixCheck, CancerCare Manitoba at: www.getcheckedmanitoba.ca/cervixcheck.html.

19. Where can I find more information about the HPV, Hepatitis B, Meningococcal Conjugate Quadrivalent, and Tdap vaccines?

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MHSAL has information available about HPV, hepatitis B, meningococcal conjugate quadrivalent (Men-C-ACYW-135), and Tdap vaccines, including factsheets, on its website at: www.gov.mb.ca/health/publichealth/cdc/div/vaccines.html. **Only** regional public health offices can order vaccine factsheets for Manitoba's School Immunization Program free-of-charge by completing the online order form available at: www.gov.mb.ca/health/jmc/index.html.

NACI statements are available online at: www.phac-aspc.gc.ca/naci-ccni/. As well, the Canadian Immunization Guide also includes vaccine information on HPV, hepatitis B, meningococcal, and Tdap vaccines at: www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines.html.

Vaccine-specific information, including contraindications, adverse reactions, ingredients, storage and dosage, can be accessed through the vaccine-specific product monograph by searching the appropriate tradename at: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>. For a listing of the most current vaccines that MHSAL carries (i.e. tradename), please access MHSAL's *Vaccines and Biologics Order Form* (www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf).