Saskatchewan Immunization Manual Amendments March 2023

Instructions: Please remove and discard the corresponding pages in each chapter section as applicable and insert the amended pages as noted below in each corresponding chapter section.

Chapter 7 Immunization of Special Populations

- Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women
  - First bullet under **NO** now states: Recommend and offer her one Tdap dose, ideally between 27 to 32 weeks gestation.
- Appendix 7.8: Publicly Funded Immigrant and Refugee Immunization and Serology Recommendations
  - Specific HB serology tests recommended; and
  - New footnote #2: HB vaccination can occur prior to specified serology being completed. There should be a minimum of 1 month between a HB vaccine and HBsAg test to avoid false positive result. Complete the HB immunization series if serology results are received during the series unless the HBsAg or Anti HBc total come back positive. Once the HB vaccine series is completed, HBsAb can be drawn 1 month after the last dose.

Chapter 10 Biological Products

- TOC page 1 revised:
  - New! MODERNA Spikevax® 18+ 0/O Original/Omicron BA.4/5 **Bivalent** formulation (Royal blue cap/grey label)
- COVID-19 Booster Dose Parameters and Recommendations
  - Previous bullets referring to fall program deleted.
  - Last bullet addressing monovalent vaccine error deleted as covered in COVED-19 Vaccine Q & A for Immunizaers.
  - New vaccine option added: Moderna Spikevax™ BA.4/5 Bivalent (50 mcg (0.5 mL) ≥ 18 years and 12-17 years **&** 25 mcg (0.25 mL) 6-11 years
- COVID-19 Vaccine Q &A for Immunizers
  - Minimum 3 month interval pertaining to booster doses removed throughout document.
  - #2 – during a primary series added to question.
  - #4 – reference to immunocompromised adults changed to individuals. a
  - #6 –permitted off-label Moderna BA.4/5 bivalent for 6-17 years added.
  - #7 – last response sentence amended to A 6 months interval (min. interval 3 months) is recommended before administering a bivalent dose, however consult a Medical Health Officer if a shorter interval is requested.
  - #11 – Question now reads: If a client 12+ chooses bivalent vaccine off-label for or to complete their primary series, are they eligible to receive a booster in 6 months?
  - #12: *Primary series* added to questions and responses.
    - 6 months to 4 years bullet now reads as For those 6 months to 4 years of age who are moderately to severely immunocompromised, a primary series of Moderna vaccine (25 mcg) is preferred because it only requires 3 doses. However, 4 doses of the Pfizer (3mcg) vaccine may be offered if Moderna is not readily available.
- Janssen (Johnson & Johnson) 18+ JCOVDEN™ Monovalent
  - Product monograph date updated to Feb. 16, 2023
  - Pregnancy
    - First bullet revised: There is limited experience with the use of JCOVDEN in pregnant women. Animal studies with JCOVDEN did not indicate harmful effects with respect to reproductive toxicity.
    - Added to second bullet: Administration of JCOVDEN in pregnancy should only be considered when the potential benefits outweigh any potential risks to the mother and fetus.

- Lactation
  - Vaccine name added within second bullet: It is not known whether the components of JCOVDEN or antibodies induced by JCOVDEN are excreted in human milk. Human data are not available to assess the impact of JCOVDEN on milk production or its effects on the breastfed child.

- Moderna Spikevax® 0/O Bivalent Original/Omicron BA.1 (Blue cap/green label) 6+ years
  - 6 month interval recommended between COVID-19 infection and bivalent immunization.
  - Product monograph date updated.
  - Possible reactions now includes systemic reactions.
- New! MODERNA Spikevax® 0/O Original/Omicron BA.4/5 **Bivalent** formulation (Blue cap/grey label) for 18+ years
  - NOTE: As this vaccine is currently licensed for age 18+, and will replace the Modern BA.1 bivalent vaccine that is licensed for 6+ years, the Ministry of Health permits the **off-label** use of Moderna's BA.4/5 bivalent vaccine as a booster dose for 6-17 years.
- Pfizer Comirnaty Bivalent Original & Omicron BA.4/5 vaccines for 5-11 years and 12+ years
  - 6 month interval recommended between COVID-19 infection and bivalent immunization.
- GARDASIL HPV-t
  - Product monograph date and link updated
  - Indication for males clarified:
    - Males born since January 1, 2006, who are either currently in Grade 6 or who did not receive or complete a series when in Grade 6, up to and including 26 years old.
    - Buller re males born in 2005 removed as ineligible for publicly funded HPV-9 vaccine.
  - Pregnancy no longer noted under Contraindications as per product monograph. Footnote 1 deleted.
  - Vaccine components: Latex, antibiotic and preservative free.
  - Expected reactions:
    - Local: Mild to moderate pain, swelling, erythema and pruritus at injection site.
    - **Reported post-market**: vomiting, swollen glands (neck, armpit, or groin), Guillain-Barré syndrome, joint pain, aching muscles, unusual tiredness, weakness, or confusion, chills, stomach ache, muscle weakness, leg pain, shortness of breath, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection.
  - Effectiveness: Please refer to the product monograph for data for females and males in specific age categories.
  - Other Considerations:
    - Immunization with HPV vaccine does not remove the need for screening for cervical, vulvar, vaginal, anal, and certain head and neck cancers, such as throat and back of mouth cancers as recommended by a health care professional; women should still get routine cervical cancer screening.
    - It is not known whether GARDASIL®9 is excreted in human milk.
    - There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, pregnancy should be avoided during the vaccination regimen for GARDASIL®9. Women who become pregnant before completion of the vaccine series should complete their vaccination schedule after childbirth. Pregnant women exposed to GARDASIL® are encouraged to report their exposure or suspected adverse reactions by contacting Merck Canada Inc., at 1-800-567-2594.