THIS CHAPTER MEETS THE FOLLOWING IMMUNIZATION COMPETENCIES FOR HEALTH PROFESSIONAL (PHAC, 2008): http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

 # 3: Vaccine Development and Evaluation

- Competency: Integrates into practice knowledge about the main steps in vaccine development and evaluation.

 # 5: Population Health

- Competency: Applies relevant principles of population health for improving immunization coverage rates.

#12: The Canadian Immunization System

- Competency: Demonstrates an understanding of the immunization system in Canada and its impact on his/her own practice.

1.0 INTRODUCTION and DISCLAIMER for PUBLIC HEALTH NURSES

The Saskatchewan Immunization Manual (SIM) prescribes publicly funded immunization program parameters, evidence-based practice standards and immunization recommendation as approved and authorized by the presiding Chief Medical Health Officer or designated Deputy Chief Medical Health Officer. The Medical Directive below **authorizes Public Health Nurses** (PHNs) to assess a client's immunization status and administer recommended publicly funded vaccines and services according to prescribed protocols approved by the Ministry of Health and contained in the SIM and its future revisions. This allows PHNs to assess and immunize clients with publicly funded vaccines or initiate anaphylaxis management in clients without the need for a clinician examination or real-time client-specific medical directive from a Medical Health Officer at the time of the PHN-client interaction. **This disclaimer is not applicable to any other healthcare providers.**

Medical Directive: As Registered Nurses, Public Health Nurses shall practice and deliver publicly funded immunization services as prescribed in the Saskatchewan Immunization Manual and its future revisions; and as prescribed in current and future publicly funded immunization programs notifications and amendments issued by the Ministry of Health.

Approved by: _____	2016-09-15	2020-09-30
Chief Medical Health Officer	Date Approved	Date for review

The SIM is intended to assist public health personnel in the promotion, delivery and management of publicly funded immunization programs for the purpose of preventing vaccine-preventable diseases. As the key provincial immunization resource, the SIM supports quality immunization practices and services.

General immunization principles and procedures are applied throughout the provincial health regions. Situations may exist where regional/jurisdictional policies govern the fulfillment of the provincial public health immunization mandate. PHNs must seek advice from the Medical Health Officer in their region and/or local policies whenever deemed necessary. Provision has been made for the inclusion of regional/jurisdictional policies to be inserted in some SIM chapters. Agency-specific policies are written and authorized by local agencies responsible for regional public health immunization services.

SIM content meets all of the competencies outlined in the *National Immunization Competencies for Health Professionals,* published by the Public Health Agency of Canada (2008), available at: http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf. SIM content is regularly reviewed and updated by the Ministry of Health. Suggested changes or comments from readers are welcome and should be directed to your agency representative responsible for immunization, or to:

Chief Medical Health Officer Population Health Branch Saskatchewan Ministry of Health 3475 Albert Street REGINA SK S4S 6X6	Public Health Nursing Consultant - Immunization Population Health Branch Saskatchewan Ministry of Health 3475 Albert Street REGINA SK S4S 6X6

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1.1 SIM Purposes

1. The SIM:
   - Stipulates publicly funded immunization program directives, including evidence-based practice standards and recommendations, as authorized by the provincial Chief Medical Health Officer or designated Deputy Chief Medical Health Officer.
   - Enhances the efficiency, safety and effectiveness of publicly funded immunization programs and services.
   - Provides immunization competency standards in Saskatchewan, via a collaborative approach between the Ministry of Health, and those agencies and providers responsible for immunizing Saskatchewan residents.
   - Ensures maintenance of vaccine and biological product potency and reducing wastage of publicly funded products.
   - Provides guidelines for the standardized management and reporting of adverse events.
   - Assists in meeting future accreditation standards.

- It is the responsibility of all immunizers to ensure that they are using the most current version of the SIM posted on the Ministry of Health website at: http://www.ehealthsask.ca/services/manuals/Pages/SIM.aspx. **The SIM should be reproduced in whole and not in part, as sections are cross-referenced.**

2. The SIM is intended to be used in conjunction with the following resources:
   - The most current edition of the Canadian Immunization Guide, available at: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php
   - The Canada Communicable Disease Reports, available at: http://origin.phac-aspc.gc.ca/publicat/ccdr-rmtc
   - The Saskatchewan Communicable Disease Control Manual, available at: http://www.ehealthsask.ca/services/manuals/Pages/CDCManual.aspx
   - The National Vaccine Storage and Handling Guidelines for Immunization Providers (PHAC, 2015), available at: http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/index-eng.php
   - The PHAC Adverse Events Following Immunization report form and user guides, available at: http://www.phac-aspc.gc.ca/im/aefi-form-eng.php
   - National Advisory Committee on Immunizations (NACI) statements available at: http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php
   - The PHAC *Immunization Competencies for Health Professionals (*PHAC, 2008*)*, available at: http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

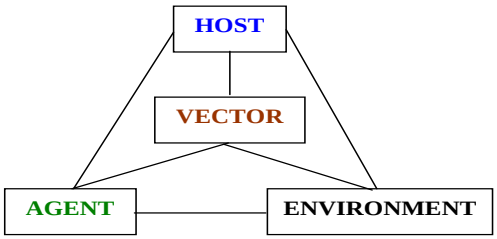
2.0 POPULATION HEALTH AND VACCINE-PREVENTABLE DISEASE PREVENTION

2.1 Disease Transmission Factors

As a primary population-based disease prevention method, publicly funded routine and mass immunization programs have key objectives in protecting the health of individuals and communities by:

1. Effectively protecting the greatest number of people from developing or re-developing vaccine-preventable diseases upon exposure to pathogens via multiple modes of transmission:
   - **Direct** (e.g., [infected] person to [susceptible] person contact)
   - **Indirect**
     - Common vehicle
       - Single exposure (e.g., luncheon resulting in food poisoning)
       - Multiple exposure (e.g., same food served for supper that evening and lunch the next day)
       - Continuous exposure (e.g., contaminated well water used by a community)
     - Vector (e.g., mosquitoes and malaria transmission)
   - The epidemiologic triad of a disease demonstrated four key factors significant to disease transmission is presented in Figure 1 below.

Figure 1: Epidemiological Triad



2. Preventing, controlling and/or eliminating the transmission of vaccine-preventable diseases and causative pathogens. These objectives assist to reduce disease prevalence (generally, the number of individuals that have a disease at a point in time) and incidence (generally, the number of individuals developing the disease in a specific period of time).
3. Minimizing disease-attributed morbidity (complications) and mortality (death) among individuals and communities.

2.2 Community Immunity

As the number of fully immunized individuals increases and is sustained in a community, the general susceptibility of the whole community population to vaccine-preventable diseases decreases. This effect is referred to as *community or herd immunity*, because the entire population (including non-immunized individuals or those who have poor immune responses to vaccines) is protected from the occurrence and transmission of vaccine-preventable diseases, generally as long as immunization rates can be sustained. It is important to note that tetanus is a vaccine-preventable disease, but it is not affected by community (herd) immunity.

An example of community immunity is the presence of a highly immunized healthcare workforce. Healthcare workers (HCWs) are subject to direct exposures to pathogens while caring for clients/patients. Along with diligent use of standard precautions, fully immunized HCWs reduce their own risk of developing vaccine-preventable diseases, and greatly reduce the risk of their families, colleagues, and clients being directly exposed to and developing vaccine-preventable diseases. This is important for the following reasons:

1. Some people who are exposed to, infected with, or are carriers of a pathogen may be asymptomatic or have subclinical disease, but can spread pathogens to other susceptible persons.
2. For several vaccine-preventable diseases, life-long immunity may not be conferred by natural disease (e.g., pertussis), and vaccine-induced immunity may decrease over time.
3. Vaccine-preventable diseases may be endemic, epidemic, or pandemic in occurrence:
   - **Endemic** – Disease is habitually present or usually occurs in a geographic region (e.g., hepatitis A in northern regions).
   - **Epidemic** – Disease occurs in excess of expected occurrence in a community or geographic region from a common source (e.g., pertussis outbreak in a community).
   - **Pandemic** – Disease occurs and is transmitted worldwide (e.g., H1N1 in 2009-2010 influenza season).

In contrast, as the number of incompletely or unimmunized individuals in a community increases, the susceptibility of the whole community to vaccine-preventable diseases greatly increases. This is because many disease pathogens are directly transmitted while the infected person begins to show disease symptoms. A relevant Saskatchewan example of a disease outbreak among incompletely or non-immunized populations is pertussis incidence among children. For perspective, in the early 20th century in Canada:

- An effective vaccine against pertussis was not developed until the 1950's.
- Social living conditions were poor (e.g., larger families, crowded living conditions, payment required for medical care, poor nutrition) and significantly contributed to the spread of Bordetella pertussis bacteria.
- Prior to routine immunization of children against pertussis, 30,000 – 50,000 cases occurred in Canada, with 50 to 100 individuals (children and adults) dying per year.
- 5 out of every 1,000 children born in Canada died of pertussis before five years of age, and the highest mortality rate was among infants less than 12 months of age.

In the 21st century, several unique trends contribute to pertussis outbreaks in Saskatchewan:

- The availability of immunization services and vaccine uptake rates among children and adolescents has been historically consistent, but some regions encounter barriers in achieving higher immunization coverage statistics.
- In 1997, an acellular pertussis antigen replaced the effective whole-cell pertussis antigen in routine childhood vaccines.
- Disparities in social and living conditions continue to exist in many communities.
- More adults were developing pertussis upon exposure because of waning immunity of childhood immunizations or past pertussis disease, compared to children and adolescents.
- Many disease symptoms are common to other minor illness like the common cold, and may be improperly diagnosed in adults and children or treated by a healthcare practioner.

To proactively address an increasing infant mortality rate attributed to pertussis disease, an infant cocooning strategy (indirect protection) was introduced in April 2010. This was the first primary prevention program of its kind in Canada. Parents and adult caregivers were offered tetanus-diphtheria-acellular pertussis (Tdap) vaccine once an infant was born, and vaccine uptake among them was very high. As well, caregivers of children who were delayed in their immunizations were encouraged to get their children immunized to protect the infant.

2.3 Barriers and Strategies that Effect Vaccine Uptake

Immunization coverage rates are important data to assess a population's potential susceptibility to specific vaccine-preventable diseases. In Saskatchewan, a provincial immunization registry provides immunization rate data for childhood and adolescent immunization programs. Segments of the population encounter socioeconomic, geographical or systematic barriers to access immunization services that result in the unintentional delay of immunizations for their children. Examples of these health determining factors as they apply to parents and caregivers of young children are as follows:

1. **Socioeconomic, individual and demographic barriers** – May include low income and education levels, young parental age, few prenatal care visits, smokers, birth order of infants (e.g., third child in family), unreliable transportation or communication methods (e.g., no telephone accessibility), significant stressors that affect sense of control over life situation, previous unpleasant immunization or health clinic experiences.
2. **Geographic barriers** – May include unavailable mobile immunization services, clinics not situated in neighbourhoods with greatest need, distances between residences and clinics, public transportation accessibility, rural vs. urban setting, neighbourhood/community characteristics.
3. **Systematic barriers** – May include long clinic waitlists, clinic hours/days of operations, translated materials and translation services unavailable, inaccessible immunization records related to jurisdictional boundaries.

By actively applying evidence-based health promotion and systematic strategies, these barriers can be reduced and achieve measurable outcomes like high population-wide protection and improved community immunization rates. Strategies are categorized as client-oriented intervention, provider-oriented interventions, and system interventions. Some examples of evidence-based effective interventions are presented in Table 1: *Evidence-Based Strategies to Improve Vaccine Uptake*.

Table 1: Evidence-Based Strategies to Improve Vaccine Uptake

Client Oriented (continue and sustain adherence)	Provider Oriented (reduce missed opportunities)	System Oriented (improve service delivery quality/methods)
Effective reminder interventions: • At post-natal visit, provide a copy of provincial immunization schedule to parent and encourage them to review imms fact sheets online • At post-natal visit, provide date of pre-scheduled 2 mo. immunization appointment to parent • Provide immunization record showing next due date to parent • Remind parent to pre-book next appointment prior to leaving health centre • Remind parent to enter appointments into electronic calendars • Encourage use of immunize.ca app to track child's imms and appointments • Use reminder recalls, auto-calls, post-cards and letters • Provide computerized or personal reminder phone calls 1-3 days before appointment • Send email reminders from non-reply address	• Establish partnerships with community agencies to promote and provide venues for immunizations • Promote immunization at community events • Accommodate clients that were unable to attend booked appointments due to unforeseen circumstances ASAP • Offer an individual private appointment or home visit at provider's discretion to avoid lengthy waitlist • Immunization competency for PHNS to ensure they are prepared to accurately answer client questions and provide resource materials • Identify risk indicators of immunization program dropout (e.g., child falling behind in schedule, intentional delay of immunizations) and provide client oriented interventions as appropriate • Follow up with providers that did not administer vaccines for which client is eligible (if not noted in Panorama) • Review and update client risk factors at each visit • Ensure staff have access to laptops and Wi-Fi • Ensure staff are trained in Panorama and know where to access policies and bulletins	• Have dedicated appointments in CHC schedules for newborns and 1 year olds so that they start on time (preferably pre-scheduled appointments) to avoid waitlists • Use e-scheduling if possible • Ensure agency culture is client centered and immunization and service goals are clearly communicated to all staff • Offer and promote clients to access mobile clinics and alternate sites for childhood immunization • Review records in EHR viewer/Panorama • Clearly indicate conscientious objectors on immunization records • Conduct monthly immunization audits to assess target rates • Offer extended service hours e.g., weekends, evenings, lunch hours, drop in clinics • Add and staff additional clinics if waitlists are beyond 2 weeks, esp. for newborns • Refer client to regional Facebook or webpage. • Link SHA/AHA pages to MoH, Immunize.ca, etc. • Commit to Social Marketing. • Visibly promote immunizations during national *Immunization Week*; request local politicians declare national *Immunization Week* in community; seek stories from those affected by diseases • Have a communication process in place to respond to anti-vaccination propaganda in community/region • Establish referral process for practitioners to refer clients to health centre if delay in schedule or hesitancy to immunize is apparent • Encourage GPs and NPs to ask about child's imms status at each visit, have imms schedule posted and reinforce importance of imms on time • Review neighbourhood imms rates and target specific interventions
Education: • Provide consistent messaging and information to parents re: importance of on time immunizations • Encourage dialogue between parent and immunization provider • Review routine schedule at every visit • Importance of adherence to schedule • Provide language-appropriate immunization information resources to clients • Translation services and translated resources accessible for clients		
Other: • Ask parents if they encountered barriers to making or getting to an appointment • Explain to parent that others can bring in child if consent grant is documented • Ask parent where sources of vaccine info are sought and provide Ministry SIM resource page • Discuss pain reduction strategies with parents • Discuss immunization at prenatal classes • Implement onsite Kindergarten Health Fairs for caregivers and children • Offer services outside of clinic setting (e.g., immunization van, community agency, day care, client home, drop-in, immigrant centres) • Confirm and update client's current address, JOrg, phone number sand email addresses		

3.0 NATIONAL IMMUNIZATION STRATEGY

> "*The Canadian reality is a patchwork of approaches across the country. Access to vaccines that have been recommended by a national panel of experts sometimes depends on what province or territory you live in.*" (Dr. Cordell Neudorf, past chair, Canadian Public Health Association, 2010).

In Canada, immunization is a shared responsibility between federal, provincial and territorial governments. The majority of immunization-related costs are borne by the provinces and territories, as they are responsible to plan, fund, and deliver their respective publicly-funded immunization programs. A national immunization schedule does not exist at this time; therefore provinces and territories adjust their recommended immunization schedules and the vaccines used based on the National Advisory Committee on Immunization (NACI) or other expert advisory committee recommendations, and on local epidemiological, programmatic, and financial considerations.

To address these issues, in 2003 a National Immunization Strategy (NIS) was designed with specific goals intended to harmonize provincial and territorial public health systems regarding immunization services. The nine goals are as follows:

1. Provide high, achievable and measurable coverage of publicly funded immunization programs for all Canadians.
2. Provide complete coverage of all children with routine childhood vaccines recommended by the proposed national immunization committee.
3. Ensure equitable access to these routinely recommended vaccines – among jurisdictions and in special populations while considering jurisdictional program implementation differences.
4. Promote public and professional acceptance of recommended programs.
5. Provide optimal program safety, effectiveness and acceptance.
6. Improve coordination and efficiency.
7. Provide optimal cost-effectiveness and affordability of programs.
8. Ensure security of vaccine supplies.
9. Provide national intervention when required.

The five components of the NIS are as follows:

1. National goals and objectives;
2. Vaccine procurement;
3. Immunization program planning;
4. Immunization registry network; and
5. Vaccine safety.

The supporting activities, which cut across and support the five strategy components, include:

- Immunization research
- Public and professional education
- Approaches to special populations
- Vaccine-preventable disease surveillance

It is anticipated that the NIS will be associated with the following important benefits:

- Improved security of vaccine supply
- Enhanced affordability of vaccines
- Improved access to timely vaccine programs
- Better vaccine safety monitoring and response
- Improved efficiencies
- Reduction in vaccine-preventable diseases
- Public confidence in vaccines/response to growing anti-immunization concerns

Progress has been made in actualizing some of the NIS goals, such as the establishment of the Canadian Immunization Committee in 2004. However, there is still much inter-governmental work to be done in order for the NIS to be fully implemented, including securing sustainable and equitable funding, and interim evaluations. The full NIS final report is available at: http://www.phac-aspc.gc.ca/im/nis-sni/index-eng.php

4.0 VACCINE DEVELOPMENT AND LICENSING

Vaccines are evaluated according to three criteria: efficacy, effectiveness, and efficiency.

1. **Efficacy** refers to ensuring that the vaccine 'works' under ideal, controlled conditions (lab setting).
2. **Effectiveness** refers to how well a vaccine works upon use in the 'real world'. This can include:
   - Whether the vaccine is accepted by people and they choose to receive it;
   - The numbers of healthy and high-risk people immunized with the vaccine;
   - The number of persons immunized that develop an adequate immunogenic response to the vaccine (series); and
   - The number of persons immunized with the vaccine that do or do not develop clinical or sub-clinical disease upon future pathogen exposure.
3. **Efficiency** refers to the cost-benefit ratio of the vaccine and immunization program. Cost can refer to the ability of the vaccine to offer the best protection for the lowest cost (cost of purchase and deliver by health care provider). It can also refer to the cost related to side effects and adverse event (e.g., pain, absenteeism from school/work, short or long-term discomfort), and social stigma (e.g., parents refusing HPV vaccines for grade 6 girls for religious reasons).

To meet the Public Health Agency of Canada (PHAC) immunization competencies for health professionals, the following information is a direct reproduction of the Health Canada (2011) article, *The Regulation of Vaccines for Humans Use in Canada*, available at: http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/fs-fi/vaccin-reg-eng.php (refer to diagram in Appendix 1.1: *Vaccine Development Stages*).

Note: Some homeopathic products called nosodes are marketed and sold by homeopaths and naturopaths as 'vaccine alternatives' that offer the same immune protection as vaccines. Health Canada has not licensed **any** homeopathic medicines for the purpose of providing immunity to communicable or vaccine-preventable diseases. The Canadian Homeopathic Pharmaceutical Association released a statement regarding homeopathic medicines and immunization on March 27, 2013 (http://www.chpa-aphc.ca/home.html): *"Our association and its members cannot recommend the use of any homeopathic medication, in lieu of conventional medical vaccinations. To our knowledge there have been no homeopathic substances thoroughly tested as consistently effective replacement therapeutics for conventional medical vaccinations*." In 2014, Health Canada guidelines for the licensing of nosodes will require that all nosode packages will need to be labelled with the following warning: "*This product is not intended to be an alternative to vaccination*."

4.1 Questions and Answers: The Regulation of Vaccines for Humans Use in Canada

Refer to Appendix 1.2: *Questions and Answers: The Regulation of Vaccines for Humans Use in Canada.*

4.2 Websites Related to Vaccine Safety

Public Health Agency of Canada: http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php
Health Canada: http://www.hc-sc.gc.ca/dhp-mps/brgtherap/index-eng.php
World Health Organization: http://www.who.int/vaccine_safety/en/
Immunization Action Coalition: http://www.immunize.org/safety

5.0 HISTORY OF IMMUNIZATION IN SASKATCHEWAN

5.1 School Immunization Programs

VACCINE	SCHOOL YEAR(S)	GROUP	COHORT DEFINED
HB	1995/96 - 2004/05 - 3 doses	Grade 6	Born since Jan. 1, 1984
	2005/06 - 2009/10 - 2 doses		
	2010/11 - 3 doses		
	2011/12 - present - 2 doses		
HPV	2008/09 (HPV-4)	Grade 7 girls	Born since Jan. 1, 1996
	2008/09 –2016/17 (HPV-4) (2-dose series as of 2015/16)	Grade 6 girls	Born since Jan. 1, 1996
	2017/18 to present (HPV-9)	Grade 6 boys	Born since Jan. 1, 2006
		Grade 6 girls	Born since Jan. 1, 1996
Men-C-C	2004/05 - 2010/11	Grade 6	Born since Jan. 1, 1993
Men-C-ACYW-135	2011/12 - present	Grade 6	Born since Jan. 1, 2000
Men-P-ACYW-135	1993	Children up to and including 18 years	
Td	Early 1980s - 2002/03	Grade 8	
Tdap	2003/04 - present	Grade 8	Born since Jan. 1, 1990
Varicella	1 dose: 2004/05 – 2014/15	Grade 6	Born since Jan. 1, 1993
	2-doses: 2015-16 to present		Born since Jan. 1, 2004
MMR	2011/12 - 2012/13	Grade 6	
	2008/09 - 2012/13	Grade 8	
	2007/08 - 2011/12	Grade 12	
	1991/92	High school and post-secondary males	
Measles-Rubella (MMR as of 2001)	1996/97 - 2003/04	Grade 6	
	1996/97 - 1997/98	Grade 8	
	Spring 1997	Grades 9 – 12	
Rubella	1970/71	Grade 7 girls	
	1970/71 - 1974/75	Grade 1	
Measles	1981 - 1982	Children 1 year up to and including 14 years	
MMRV	2012 - present	Disease susceptible Grade 6 students who are 13 years & older	Eligible for MMRV until they begin their Grade 7 school year

5.2 History of Publicly Funded Immunizations and Programs in Saskatchewan

Vaccine	Year	Indication/Comment
Diphtheria Tetanus Pertussis and Polio containing vaccines	1956-1957	Salk polio campaigns
	1959	DPT-IPV became available
	1963	Sabin (oral) mass polio immunization for all preschool children
	1963	DPT and OPV for routine immunization
	1978	Polio vaccine schedule change
	1980	DPT and Td adsorbed vaccine introduced
	June 1994	OPV replaced by IPV in DPT-Polio and in Td-P
	1996-2001	Monovalent acellular pertussis vaccine adsorbed available (Acel-P™)
	July 1997	Acellular pertussis vaccine combined for routine immunization (DTaP-IPV-Hib; DTaP-IPV)
	Spring 1999	Td-IPV not used for Gr. 8 as long as primary polio series completed already
	Dec. 2000	Single antigen Tetanus Toxoid Adsorbed and Diphtheria Toxoid for reactors discontinued
	Sept. 2003	Tdap replaces Td for grade 8 students
	April 2010-present	Mothers/adult caregivers of infants ≤ 6 months eligible for Tdap as infant cocooning strategy
	April 2011-present	Adults ≥ 18 years eligible for one dose Tdap to replace a Td vaccine dose.
	July 2012-October 2012	DTaP-IPV-Hib approved for short-term use for 4-6 year school entry booster during national DTaP-IPV shortage
	Sept. 2017 to present	Tdap-IPV replaces DTaP-IPV as school entry booster dose.
	Oct. 2017 to present	All pregnant women offered Tdap (usually at 27 weeks gestation)
	May 2018	OPV doses received as of April 1, 2016 replaced with IPV as per age requirements.
Hib	May 1988	Prohibit (Conhib) at age 18 months
	April 1992	MSD-HIB (PedvaxHib) replaced Prohibit
	May 1992	Act-HIB introduced, given with DPT (combined)
	June 1994	DPT-IPV+ Act-HIB for 2-18 months (Pentacel)
HA	August 1994	Havrix-720 available in Canada (3-dose series)
	July 1996	Havrix-1440 available (2 dose series)
	August 1996	Havrix begun for outbreak control in northern Saskatchewan
	1996	VAQTA available for travellers
	1997-present	Routine for children 1-15 years living in northern health regions or reserves in Saskatchewan (excluding Creighton, Air Ronge, La Ronge)
	June 2001	Havrix 1440 discontinued as multidose vial; Havrix Jr used for 1st and 2nd doses
	2002-present	HA vaccine available for all non-immune hepatitis C infected persons
HB	Oct. 1982 - Aug. 1990	Available free for high-risk clients (Heptavax-B - plasma-derived vaccine)
	Sept. 1995 - present	Grade 6 student program implemented
	January 1996	Engerix B for sale to any person regardless of risk
	1997	Recombivax HB available
	2002-present	HB vaccine available for all non-immune hepatitis C infected persons
	2003	Expanded the eligibility for high-risk programs
	2007	Recombivax Pediatric & Recombivax Dialysis formulas available
	March 2013 - present	40 mcg HB for persons ≥18 years and double dose HB for those younger than 18 years approved for HIV or specific high risk conditions

Vaccine	Year	Indication/Comment
HAHB	1998	Twinrix (combined Havrix and Engerix) available
	1999	Twinrix-Jr available
	2000-present	Available for high risk persons ≥ 1 year who are eligible for publicly funded HA and HB vaccines
HPV	Sept. 2008 – Aug. 2017 **HPV-4**	• Grade 6 girls born since Jan. 1, 1996. • Grade 7 girls in 2008-09 • Immune compromised females 9-26 years inclusive with the following risk factors: acquired complement deficiency; congenital immunodeficiency; HIV; related to Disease; and Treatment – Specify • HIV positive boys 9-17 years as of December 2015.
	Sept. 2017 - **HPV-9**	• Grade 6 girls born since Jan. 1, 1996. • Grade 6 boys born since Jan, 1, 2006
	Nov. 2017	• Immune compromised males 9-26 years inclusive with the following risk factors: acquired complement deficiency; congenital immunodeficiency; related to Disease; and Treatment – Specify.
Influenza	1967	Influenza vaccine free to high-risk persons Fluviral
	1991	Persons ≥ 65 years eligible for free vaccine
	October 2005	Influenza vaccine available to children 6-23 months of age
	Oct. 2007	Pregnant women eligible to receive seasonal flu vaccine
	Oct. 2009	• H1N1 Pandemic – all residents eligible to receive H1N1 vaccine • Seasonal vaccine available for high risk persons
	Oct. 2010	All residents eligible to receive publicly-funded seasonal influenza vaccine
	2011/12	FLUAD for those ≥ 65 years who reside in LTC facilities
Measles Mumps Rubella containing vaccines	1966	Measles vaccine introduced for ages 1-3 (Lirugen - live, further attenuated)
	1970	Measles vaccine extended to ages 1-7 (ATTENUVAX - live, further attenuated)
	1970	Rubella vaccine for grade 7 girls. (MERUVAX and MERUVAX-II); Cendevax (rubella vaccine) used ~1970-72
	1970-1975	Rubella vaccine for grade 1 students (MERUVAX)
	1971	Rubella vaccine available to physicians for susceptible women at premarital exams
	1979	MMR vaccine for age 1 year
	1981 - 1982	Review of measles immunization for children ages 1-14, followed by program to raise coverage to > 98%
	Fall 1991 to 1992	Mass MMR immunization for teen-aged boys in high schools and post-secondary institutions
	Fall 1996	• Second dose Measles & Rubella (MR) added to 18 months. • Catch-up program included school entry, Grade 6 and 8.
	Spring 1997	MR immunization of Grades 9-12
	2001	MMR used exclusively for all 1st and 2nd doses; MR discontinued by Berna
	2003 - 2004	2 dose mumps catch-up in Grade 6
	2007 - 2013	2-dose mumps catch-up for eligible Grade 12 students
	2008 - 2013	2-dose mumps catch-up for eligible Grade 8 students
	2011 - 2013	2nd dose provided to eligible Grade 6 students
	May 2013	Adult born since Jan. 1, 1970 eligible for 2 MMR doses

Vaccine	Year	Indication/Comment
MMRV	October 2010	1 dose for varicella-susceptible children born since Oct. 1, 2009 at 12 months to replace 1st MMR and monovalent Var vaccine doses
	April 2011-present	2 doses for varicella-susceptible children ≥ 12 months of age born since Oct. 1, 2009 to replace 2nd MMR and monovalent Var vaccine doses
	Sept. 2011	MMRV available for varicella-susceptible children 12 months up to and including 12 years of age who require MMR and cohort-appropriate varicella vaccines
	Sept. 2012-present	MMRV approved for Grade 6 students 13 years and older until they begin their Grade 7 school year
Meningo-coccal vaccines	1990	Mass immunization for children 2-18 years in Athabasca region.
	1993	Mass immunization across Saskatchewan for ages 2-19 (MENOMUNE/MENOTET)
	2002	High risk persons
	October 2004	Meningococcal conjugate C (Men-C-C) routine for: • All children at 12 months of age born since October 1, 2003 • Preschool catch-up for children born since October 1, 2000 • Grade 6 students born January 1, 1993 to Dec. 31, 1999
	Sept. 2011	• Meningococcal conjugate ACYW-135 for Grade 6 students born since January 1, 2000. • Menveo® approved for children ≥ 2 months of age for outbreaks
	January 2015	Men-C-ACYW-135 for selected high risk persons
	Dec. 2015	MenB for selected high risk persons
	January 2016	Men-P-ACYW-135 no longer available
	Dec. 2017	HIV positive children eligible for Men-C-ACYW-135 vaccine series.
Pneumo-coccal vaccines	Sept. 1998	Pneumococcal polysaccharide 23-valent provided to residents of long term and personal care homes and those at highest risk
	Sept. 1999	Pneu-P-23 available for all high risk clients ≥ 2 years
	Sept. 2002	Pneumococcal conjugate 7-valent (Prevnar™) for high risk children < 2 years
	October 2003	Prevnar™ for high risk children expanded to children age 2-59 months (< 5 years)
	April 2005-March 2012	4-dose Prevnar 7-valent infant series for all children 2 months of age who are born since April 1, 2005
	May 2010	Prevnar 13-valent (Prevnar 13) replaces Prevnar 7-valent
	April 2012	3-dose series for healthy infants introduced (2, 4 and 12 months)
	April 2013	One dose Pneu-C-13 approved for high risk children 60 months - 17 years of age who are Pnue-C-13 naïve.
Rotavirus	Nov. 1/12 - Oct. 1/18	ROTARIX™ (Rot-1) 2-dose series for infants born before April 1, 2018 (pending availability)
	April 2018	RotaTeq (Rot-5) 3-dose series for infants born as of April 1, 2018
Varicella	Jan. 2005 - present	• 1 dose for susceptible children 12 months of age born since January 1, 2004 • 1 dose for susceptible children in Grade 6 (until Aug. 31, 2015)
	April 2011 - present	2-dose series for children born since October 1, 2009
	July 2014	Publicly funded for RHA/SCA/FNJ HCWs and HCW students, and non-immune women of childbearing age.
	Sept. 2015	Second dose for Grade 6 student (born since Jan. 1, 2004)

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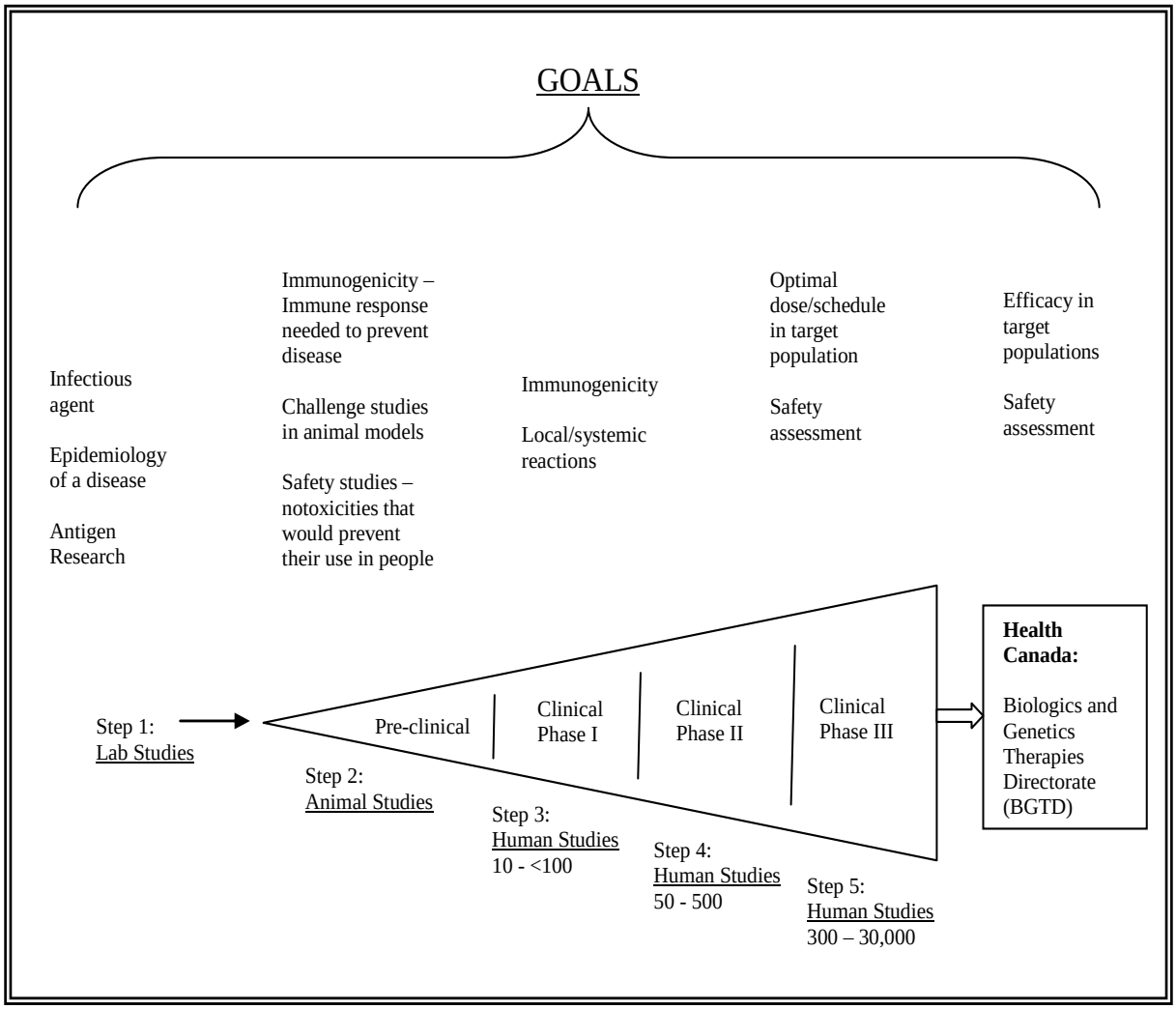
7.0 APPENDICES

Appendix 1.1: Vaccine Development Stages



(Source: BCCDC Immunization Manual, 2009).

Appendix 1.2: Questions and Answers: The Regulation of Vaccines for Humans Use in Canada

(Source: Health Canada (2011). Available at: http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/fs-fi/vaccin-reg-eng.php)

1. Who regulates vaccines in Canada?

Health Canada is the regulatory authority in Canada responsible for working to maximize the quality, safety, and efficacy of all biologic drugs, including vaccines for human use. The Biologics and Genetic Therapies Directorate (BGTD), within the Health Products and Food Branch (HPFB) of Health Canada, is responsible for Canada's vaccines regulatory program in collaboration with the HPFB Inspectorate and the Marketed Health Products Directorate.

2. How are vaccines regulated in Canada?

Canada, like many other countries, exercises tight regulatory oversight over vaccines because they are usually given to very large numbers of healthy individuals. Vaccines in Canada are subject to the *Food and Drugs Act* and the *Food and Drug Regulations.* Vaccines are regulated under a specific set of regulations for a subset of drugs known as biologic drugs.

3. Why are vaccines considered unique?

Vaccines differ from chemical drugs because of the biological nature of the source materials (such as those derived from microorganisms and viruses), the biological methods used to test them and because they are highly complex substances. Some vaccines consist of live microorganisms suitably changed to ensure that they no longer produce disease but can still produce a suitable immune response. Special expertise and procedures are needed for their manufacture, control, and regulation. Vaccines are also unique in that they are often recommended as part of Canadian public health programs, which means they are administered to very large numbers of healthy people, including infants and children; thus safety and quality are paramount.

4. How are vaccines authorized for sale in Canada?

Before a vaccine can be submitted to Health Canada to be considered for approval, sufficient scientific and clinical evidence must be collected to show that it is safe, efficacious and of suitable quality. This scientific evidence includes results from human clinical trials. For clinical trials performed in Canada, a clinical trial application must be filed to BGTD.

When a manufacturer believes that they have sufficient scientific and clinical evidence about the vaccine, a New Drug Submission (NDS) is filed to BGTD. The NDS should demonstrate the safety, quality, and efficacy of the vaccine. In addition, information regarding the manufacturing facility, the method of manufacture and quality control of the vaccine is included in the submission.

Prior to market authorization, BGTD staff may conduct an on-site evaluation to assess the quality of the manufacturing process and to determine that the manufacturer is able to carry out the necessary quality controls for the vaccine. The manufacturer must also provide samples of three to five consecutive batches or "lots" of the vaccine for testing in the laboratories of BGTD. This allows BGTD to ascertain that the manufacturers can consistently produce high quality lots of vaccine. Clinical studies are reviewed to ascertain that no significant safety concerns have been identified and that the vaccine is able to elicit an adequate immune response in vaccinated subjects.

If, after completion of the review, the conclusion is that the benefits of the vaccine outweigh any risks, then the vaccine is issued a Notice of Compliance (NOC) and a Drug Identification Number (DIN) indicating that it is authorized for sale in Canada.

5. How are seasonal influenza vaccines authorized for sale in Canada?

There are unique challenges associated with the development and regulatory evaluation of influenza vaccines. The influenza virus strains circulating the globe change on a regular basis and the composition of the vaccine must be modified each year to include new circulating strain(s). As such, the process for influenza vaccine development starts off on a global scale annually. Each year, the World Health Organization (WHO) selects three influenza virus isolates which form the basis for influenza vaccine production for the following fall and winter flu season.

Given the short timeframe between the identification of the strain composition by a WHO expert committee and the need to use the vaccine to protect Canadians, an abbreviated market authorization process with expedited review timelines is used to regulate these vaccines. It is important to note that the abbreviated market authorization process with expedited review timelines at no time compromises the safety of the vaccine to be used by Canadians.

The seasonal influenza vaccines are authorized each year via the filing of manufacturing and quality data and revised labelling material together with data from a small clinical trial. Close coordination is needed between the manufacturers and Health Canada. The Health Canada publication*, Access to the Seasonal Flu Vaccine in Canada: How the flu shot makes its way from the laboratory to the doctor's office,* describes the pathway for the development, regulation and distribution of seasonal influenza vaccines in Canada.

6. Are all vaccines authorized?

Vaccines are authorized for sale by Health Canada only after undergoing rigorous reviews to maximize their quality, safety, and efficacy. If there is insufficient evidence to support safety, efficacy or quality claims, BGTD will not authorize the vaccine, and the product cannot be sold in Canada. In certain situations, such as public health emergencies (e.g., influenza pandemics), special authorizations may be used to provide emergency access to a vaccine.

7. Once a vaccine is authorized, how is it monitored?

A. Risk-Based Lot Release Program

As in other major jurisdictions such as in the United States and Europe, vaccines are subject to an ongoing lot release evaluation after approval. In the majority of cases, for each lot of vaccine to be sold in Canada, the manufacturer must submit the results of its own testing as well as samples for independent evaluation by BGTD. If a vaccine lot meets specifications, a formal Release Letter is issued which approves the sale of that lot in Canada. Manufacturers of biologic drugs, including vaccines are also required to submit a Yearly Biologic Product Report (YBPR). This annual report is used to assess the ongoing quality of the vaccine, and to highlight any trends. The lot release program and the YBPR are tools which enable Health Canada and the manufacturer to monitor consistency in the vaccine manufacturing process.

B. Post-Market Changes

After a new vaccine has been authorized for sale, it is not uncommon for sponsors to make changes to its manufacturing process or to its indication for use. For example, a sponsor may make improvements to the manufacturing process over time or provide evidence to support the use of the vaccine in a different age group. Any proposed changes that may have an impact on the quality, safety, efficacy or effective use of the vaccine are reviewed by Health Canada before they can be implemented by the manufacturer.

C. Post-Market Surveillance

Maximizing the quality, safety, and efficacy of vaccines is well recognized as an essential component of any successful immunization program. With this level of regulatory oversight, vaccines have an excellent safety record. However, even when the best regulatory controls are in place, adverse events, which are very rarely serious may occur. Surveillance systems are used to monitor any potential adverse events following immunization. A combination of mandatory and voluntary reporting is used in Canada. The Food and Drug Regulations require manufacturers of all drugs, including vaccines, to report serious [unexpected or unusual] adverse events that occur in Canada as well as serious unexpected adverse events that occur internationally within 15 days of receiving the information. Manufacturers also develop safety reports in the form of Periodic Safety Update Reports (PSURs). The HPFB Inspectorate performs post-market reporting compliance inspections to assess compliance with regulatory requirements for post-market reporting.

The Public Health Agency of Canada is responsible for the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), a spontaneous reporting system in which health care providers (mainly public health nurses and physicians) report adverse events following immunization (AEFI) to local and provincial/territorial public health authorities (refer to SIM, Chapter 11, *Adverse Events Following Immunization*). Provinces and territories issue guidance to their health care providers on what to report, with an emphasis on reporting temporally associated events that are serious or unexpected or unusual as well as those that are expected but occurring more frequently than usually observed. In addition to this voluntary reporting system, the Public Health Agency of Canada funds IMPACT, an active, pediatric hospital based surveillance system that closely monitors admissions for selected adverse events of particular importance.

D. Compliance and Enforcement Activities

The HPFB Inspectorate performs compliance verifications as well as investigations of potential health hazards and other violations. In addition, regular inspections of manufacturers, packagers/labellers, testing laboratories, importers, distributors and wholesalers of vaccines are conducted to ensure that they comply with Good Manufacturing Practices (GMP). When deemed necessary, enforcement action may be taken by the Inspectorate in accordance with their Compliance and Enforcement Policy.

Appendix 1.3: Sample Provision of Publicly Funded Biological Products by Public Health Nurses

Date effective: _____
Date to be reviewed: _____
Issuing authority: _____

A Registered Nurse (RN) Clinical Protocol outlines a series of registered nursing actions that are implemented in pre-determined situations to provide specialized client care in Saskatchewan. A RN who implements a RN Clinical Protocol must meet the criteria as outlined in the current Saskatchewan Registered Nurses' Association (SRNA) *Standards for RN Specialty Practices*. This RN Clinical Protocol contains evidenced-informed content that is used in conjunction with a RNs critical thinking and clinical judgment in determining when it is appropriate to implement a RN Clinical Protocol appropriate to the client's presenting health situation.

HIGH ALERT
Refer to:

- The *Saskatchewan Immunization Manual* (SIM) Chapter 6 *Contraindications and Precautions*.
- The SIM Chapter 7, Section 3.0 *Immunocompromised Conditions* and consult a regional MHO for specific directives (e.g., Appendices 7.2, 7.3, and 7.6).

DEFINITION

- RNs provide publicly funded biological products through *RN Specialty Practice* criteria as defined by the Saskatchewan Registered Nurses Association (SRNA, 2015). A RN Clinical Protocol requires specific theory and practice. Public Health Nurses (PHNs) function under a medical directive from a regional Medical Health Officer (MHO) and must achieve and maintain immunization competence in order to immunize (SRNA, 2015). The Public Health Agency of Canada (PHAC) document *Immunization Competencies for Health Professionals* (2008) is used as the immunization education framework.
- PHNs are expected to adhere to policies/procedures relating to the administration, management, and documentation of biological products in accordance with the SIM.
- This protocol is specific for publicly funded biological products. The parameters for the programs that support this are outlined in the SIM and any associated memos and communications from the Ministry of Health.
- It is the responsibility of the employer to circulate programmatic memorandums from the Ministry of Health, RHA or other relevant stakeholder in the program in a timely manner to the public health nursing staff.
- Publicly funded biological products may include:
  - Vaccines;
  - Immune globulins (for specific diseases such as rabies, tetanus, hepatitis A or varicella or others); and
  - Diagnostic agents (e.g., Tubersol®).

BACKGROUND

- Publicly funded biological products are intended to prevent vaccine-preventable diseases and communicable disease outbreaks.
- The health of the individual and the population is at risk if they are exposed to and develop vaccine-preventable diseases.

OBJECTIVES

- Refer to SIM Chapter 1 *Introduction*.
- To provide publicly funded immunization programs to protect the health of individuals and communities that are serviced by Public Health Nurses including (but not exclusive to): pre-school populations; schools; mass influenza clinics; community populations.
  - To improve vaccine coverage rates as a health status indicator for the province.
  - To educate and foster confidence in the public regarding vaccines and immunization programs.
  - To support provincial national monitoring and surveillance of vaccine safety.

ASSESSMENT

The PHN will use standard work for the assessment of clients based on the following:

- Refer to SIM Chapter 3 *Informed Consent to obtain* consent directives from clients before the administration of publicly funded vaccines.
- If English is an alternative language for the client, identify the client's language of comprehension, and use an appropriate translated fact sheet and/or use of a translator.
- Refer to SIM Chapter 5 *Immunization Schedules* to assess client eligibility, exemptions, and scheduling for publicly funded vaccines.
- Refer to SIM Chapter 6 *Contraindications and Precautions* to assess for contraindications and precautions that may affect the client.
- Refer to SIM Chapter 7 *Immunization of Special Populations* to assess eligibility and scheduling of publicly funded vaccines for clients who are identified as having a risk factor.
- Refer to SIM Chapter 8 *Administration of Biological Products* to conduct client health screening and immunization techniques.
- Refer to SIM Chapter 10 *Biological Products* for detailed information regarding client eligibility, scheduling, ingredients, and adverse events of biological products.
- Refer to the Panorama Gateway site for policies and procedures regarding the documentation of risk factors, exemptions and other special considerations.

NURSING DIAGNOSIS AND THERAPEUTIC ACTIONS

- Client readiness for enhanced knowledge related to routine immunization schedules
  1. Determine client's current immunization status by performing a clinical assessment as outlined in the preceding section on ASSESSMENT.
  2. Assist the client to develop or strengthen immunization knowledge through informed consent as outlined in the following section on EDUCATION
- Client readiness for enhanced immunization status related to accepting and receiving eligible vaccines
  1. Determine client's eligibility for publicly funded vaccines as outlined in the preceding section on ASSESSMENT
  2. Obtain client/ guardian/substitute decision maker's informed consent
  3. Administer vaccines for which the client is eligible for and have consented to.

INTENDED AND UNINTENDED OUTCOMES

Intended:

- To maintain or improve provincial and regional immunization coverage rates.
- Prevention of vaccine preventable diseases and outbreaks of communicable diseases.
- Reduce vaccine hesitancy and improve vaccine uptake in specific population groups.

Unintended:

- Refer to SIM Chapter 3 Informed Consent regarding vaccine hesitancy/ refusals.
- Refer to SIM Chapter 6 Contraindications and Precautions regarding vaccine administration to a client that has a contraindication to a vaccine or precaution that has not been assessed.
- Refer to SIM Chapter 11 Adverse Events Following Immunization for any adverse events following an immunization (AEFI).
- Refer to SIM Chapter 12 Anaphylaxis Management regarding anaphylaxis following an immunization.
- The treatment of anaphylaxis in a community health setting is a medical directive approved by a regional MHO.

COMMUNICATION

To the Ministry of Health, according to *The Public Health Act, 1994*:

- Reportable AEFIs, especially those that are severe, unusual and unexpected.

To regional MHOs:

- When anaphylaxis management is initiated as per regional policy.
- All reportable AEFIs for MHO recommendations.

To PHN Managers/Supervisors:

- Reportable AEFIs, especially those that are severe, unusual and unexpected
- All other unusual and critical situations such as parental custody issues, vaccine errors, etc.

PHN to Parent/Guardians:

- Through the Provincial School Immunization Program
- Through Child Health Clinics; Postnatal visits; informed consent process
- If English is an alternative language for the client, identify the client's language of comprehension, and use an appropriate translated fact sheet and/or use of a translator.

EDUCATION

Education for the client for informed consent or refusal of vaccine(s):

- SIM Chapter 3 *Informed Consent* to obtain consent directives from clients before the administration of publicly funded vaccines.
- SIM Chapter 3 *Informed Consent* Appendix 3.1 *Recommended Immunization Websites, Book and Articles for Parents and Caregivers* to support client education.
- SIM Chapter 13 – *Principles of Immunology* for content related to vaccines and immunology.
- SIM Chapter 14 Appendix 14.3 *Immunization Fact Sheets* and provide these to client for review at every immunization appointment.

- If English is an alternative language for the client, identify the client's language of comprehension, and use an appropriate translated fact sheet and/or use of a translator.
  - Provide every client with the following most current Ministry of Health fact sheets:
  - *Protecting the Privacy of Your Immunization Record; and*
  - *Caring for Your Child's Fever;*
  - *Immunization fact sheets.*
  - Risk of adverse events following immunization.
  - Expected reactions post-administration of biological products.
  - Addressing questions related to screening questions and vaccine ingredients.
  - Safety precautions such as 15 minute wait at clinic following immunization.

Public Health Nursing requirements:

- Active licensure with the SRNA.
- Approval to provide immunization services and implement anaphylaxis management as per the RHAs regional policies and procedures.
- Yearly update and review of this protocol

To provide management of anaphylaxis to clients, PHNs further require:

- Current CPR Certification.
- Access to recommended resources as indicated in SIM Chapter XX and RHA policy to manage anaphylaxis.

DOCUMENTATION

Refer to:

- SIM Chapter 4 *Documentation* to accurately record vaccine administrations.
- Panorama Gateway site to access and review policy documents relating to documentation of consent directives and special precautions in the client's Panorama immunization record.

REFERENCES

- Saskatchewan Immunization Manual (SIM) http://www.ehealthsask.ca/services/manuals/Pages/SIM.aspx
- The Public Health Agency of Canada (PHAC) document *Immunization Competencies for Health*
- Immunization Fact Sheets http://www.saskatchewan.ca/residents/health/accessing-health-care-services/immunization-services#immunization-forms-and-fact-sheets
- Panorama Gateway site http://www.ehealthsask.ca/services/panorama/immun/Pages/TrainingTOC.aspx
- Standards for RN Specialty Practices - http://www.srna.org
- SRNA and CPSS Joint Statement document http://www.srna.org/images/stories/Nursing_Practice/Leading_Change/Joint_Statement_on_RN_Clinical_Protocols_between_CPSS_and_SRNA_2015.pdf
- NANDA Nursing Diagnoses 2015-2017
- Critical Incidents: https://www.saskatchewan.ca/government/government-structure/ministries/health/critical-incidents
- Substitute Decision Maker: http://www.qp.gov.sk.ca/documents/English/Statutes/Statutes/H0-001.pdf

MEDICAL DIRECTIVE

- Refer to the Provincial Directive in **SIM- Chapter 1 *Introduction***.

Medical Directive: As Registered Nurses, Public Health Nurses shall practice and deliver publicly funded immunization services as prescribed in the Saskatchewan Immunization Manual and its future revisions; and as prescribed in current and future publicly funded immunization programs notifications and amendments issued by the Ministry of Health.

Approved by: _____ _____ _____

Chief Medical Health Officer Saskatchewan Ministry of Health | Date Approved (yyyy/mmm/dd) | Date for review(yyyy/mmm/dd)

Appendix 1.4: Sample Anaphylaxis Management in a Clinic or Community Setting by Public Health Nurses Post- Administration of Publicly Funded Biological Products

Date effective: _____
Date to be reviewed: _____
Issuing authority: _____

A Registered Nurse (RN) Clinical Protocol outlines a series of registered nursing actions that are implemented in pre-determined situations to provide specialized client care in Saskatchewan. A RN who implements a RN Clinical Protocol must meet the criteria as outlined in the current Saskatchewan Registered Nurses' Association (SRNA) *Standards for RN Specialty Practices.*
This RN detailed clinical protocol contains evidenced-informed content that is used in conjunction with a RNs' critical thinking and clinical judgment in determining when it is appropriate to implement a RN Clinical Protocol appropriate to the client's presenting health situation.

HIGH ALERT

Refer to:

- The *Saskatchewan Immunization Manual* (SIM) Chapter 6 *Contraindications and Precautions*.
- The Saskatchewan Immunization Manual Chapter 12 *Anaphylaxis Management.*
- In the event that anaphylaxis occurs, Emergency Medical Services (EMS) must be contacted by calling 911.
- The Ministry of Health's specific directions regarding epinephrine and diphenhydramine hydrochloride administration are part of this protocol.

DEFINITION

- Registered Nurses can implement anaphylaxis management in accordance with the RN Specialty Practice criteria as defined by the SRNA (SRNA, 2015). A RN Clinical Protocol requires specific theory and practice. Public Health Nurses (PHN)s, employed by a regional health authority, function under a medical directive from the regional Medical Health Officer (MHO) and must achieve and maintain competence in order to immunize and implement management of anaphylaxis. The Public Health Agency of Canada document *Immunization Competencies for Health Professionals* (2008) is used as the immunization education framework.
- PHNs are expected to provide all immunizations as per the Provision of Publicly Funded Biological Products by Public Health Nurses protocol and must also be trained in the management of adverse events and anaphylaxis that occur in a community or clinic setting.
- It is the responsibility of the employer to circulate programmatic memorandums from the Ministry of Health, RHA or other relevant stakeholder in the program in a timely manner to the public health nursing staff.

BACKGROUND

- The risk of anaphylaxis from the administration of one vaccine or multiple vaccines at one time is very low, estimated to be less than 1 incidence in 1 million persons immunized. (CIG, 2006, p. 80).
- PHNs must take all measures to prevent adverse events such as anaphylaxis by asking pre-immunization screening questions as outlined in the Saskatchewan Immunization Manual (SIM) Chapter 8 – *Administration of Biological Products*), and be prepared and competent to manage anaphylaxis, according to SIM Chapter 12 *Anaphylaxis Management.*
- Anaphylaxis Kits must be maintained with epinephrine and other emergency supplies.

OBJECTIVE

- To identify signs of anaphylaxis post immunization in children and adults, and implement recommended anaphylaxis protocols to prevent a severe client outcome.

ASSESSMENT

The PHN will use standard work for the assessment of clients based on the following:

Refer to SIM Chapter 6 *Contraindications and Precautions* to assess for contraindications and precautions that may affect the client.

Refer to SIM Chapter 8 *Administration of Biological Products* to conduct client health screening and immunization techniques.

Refer to SIM Chapter 10 *Biological Products* for detailed information regarding client eligibility, scheduling, ingredients, and adverse events of vaccines and other biological products.

Refer to SIM Chapter 11 *Adverse Events Following Immunization* (AEFI) for detailed information to manage adverse immunization events.

Refer to SIM Chapter 12 *Anaphylaxis Management* for the Ministry of Health's recommended protocol to manage anaphylaxis.

NURSING DIAGNOSIS AND THERAPEUTIC ACTIONS

- Potential for compromised biological systems related to anaphylactic response to an administered publicly funded biological product.

INTENDED AND UNINTENDED OUTCOMES

Intended:

- PHN screens client for possible allergens prior to administering a biological products to ensure patient safety.
- PHN has the competency to implement management of anaphylaxis and incident documentation.
- Anaphylaxis reaction is slowed or averted.
- Client does not sustain permanent injury or death from anaphylaxis.

Unintended

- Any adverse events following immunizations including anaphylaxis.
- Patient injury or death related to anaphylaxis.

COMMUNICATION

To regional MHO:

- According to regional protocols whenever anaphylaxis management is initiated.

To PHN Managers/Supervisors:

- Initiation of anaphylaxis management.
- All required documentation, including critical incident reporting, is completed and situation is debriefed.

To Emergency Medical Services (EMS):

- All relevant information is provided to EMS; appropriate documentation as per regional protocols.

PHN to client:

- The PHN should review of potential adverse reactions, when they may occur and how to manage them before and after immunizing the client.
    - It is important for the client to stay in the clinic for 15 minutes after getting any vaccine because there is an extremely rare possibility of a life-threatening allergic reaction called anaphylaxis. This may include hives, difficulty breathing, or swelling of the throat, tongue or lips.
    - If this happens after the client leaves the clinic, call 9-1-1 or the local emergency number. This reaction can be treated, and occurs in less than one in one million people who get the vaccine.

EDUCATION

Education for the client for informed consent or refusal of vaccine(s):

- Risk of adverse events following immunization.
- Expected reactions post-administration of biological products.
- Most current Ministry of Health immunization fact sheets.
- Addressing questions related to screening questions and vaccine ingredients.
- Safety precautions such as 15 minute wait at clinic following immunization.

Nursing requirements:

- Active licensure with the SRNA.
- Approval to provide immunization services and implement anaphylaxis management as per the RHAs regional policies and procedures.
- Yearly update and review of this protocol

To provide management of anaphylaxis to clients, PHNs further require:

- Current CPR Certification.
- Access to recommended resources as indicated in SIM Chapter 11 and RHA policy to manage anaphylaxis.

DOCUMENTATION

Refer to:

- SIM – Chapter 11 - *Adverse Events Following Immunization*; Chapter 4 *Documentation.*
- Panorama Gateway site (reference for Bulletins, etc.)

http://www.ehealthsask.ca/services/panorama/immun/Pages/TrainingTOC.aspx

- Regional documents
- AEFI report form
- Anaphylaxis Treatment Worksheet

REFERENCES

- Saskatchewan Immunization Manual
  http://www.ehealthsask.ca/services/manuals/Pages/SIM.aspx
- Standards for RN Specialty Practices - Saskatchewan Registered Nurses' Association (SRNA)
  www.srna.org
- Panorama Gateway site
  http://www.ehealthsask.ca/services/panorama/immun/Pages/TrainingTOC.aspx
- Joint statement form College of Physicians and Surgeons of Saskatchewan(CPSS) and SRNA (www.srna.org)
- Regional policy and documents
- Public Health Agency of Canada document *Immunization Competencies for Health Professionals* (2008)
  http://www.phac-aspc.gc.ca/php-psp/ccph-cesp/pdfs/cc-manual-eng090407.pdf
- Canadian Immunization Guide (2006) http://publications.gc.ca/collections/Collection/HP40-3-2006E.pdf
- Critical Incidents: https://www.saskatchewan.ca/government/government-structure/ministries/health/critical-incidents

MEDICAL DIRECTIVE

- **Refer to the Provincial Directive in SIM Chapter 1 *Introduction*.**

Medical Directive: As Registered Nurses, Public Health Nurses shall practice and deliver publicly funded immunization services as prescribed in the Saskatchewan Immunization Manual and its future revisions; and as prescribed in current and future publicly funded immunization programs notifications and amendments issued by the Ministry of Health.

Approved by: : _____ _____ _____

Chief Medical Health Officer Saskatchewan Ministry of Health	Date Approved (yyyy/mmm/dd)	Date for review (yyyy/mmm/dd)

- **Regional Medical Directive (to be inserted next page)**