

Informed Consent Guidelines for Immunization

Public Health Branch

Date Approved: July 2013 ~ Date Amended: April 2015
Applicable to: All Immunization Providers in Manitoba

Purpose:

- To guide immunization providers in developing their own policies and procedures regarding informed consent for immunizations, in accordance with *The Public Health Act*.
- To ensure all Manitobans are informed before receiving immunization. This information should include that all immunizations are voluntary.
- It is the ethical and legal responsibility of the immunization provider to obtain the informed consent.

Background:

The need to obtain informed consent prior to an immunization is based on the principle that a client is autonomous and has the right to determine what happens or does not happen to them. Information, comprehension and willingness to participate (voluntariness) are fundamental elements of the informed consent document. The consent should adequately convey all the information needed for the subject to understand the immunization event, in addition to being in a language understandable to the client. A client's consent to participate must be free from coercion. Above all, the client should be able to understand the information presented in order to make an informed decision.

Immunization in Manitoba is voluntary. *The Public Health Act* does not require proof of immunization for school entry and/or childcare attendance.

Definitions:

Immunization (or vaccination): A method of providing protection against a disease caused by an infection. Immunization can be administered through several routes: oral, intramuscular, intradermal, intranasal or subcutaneous.

Immunization provider: A health care professional who is registered or licensed to provide health care under an Act of the

Legislature and who is authorized under that Act to administer vaccines.

Client: For the purpose of this guideline, a client is a person or individual receiving an immunization. A client is also a resident or a patient.

Vaccines and Biologics: Refers to all biological substances used for active or passive immunization of humans, including live and inactivated viral and bacterial vaccines, toxoids, immune globulins, antitoxins and antivenins.

Guiding Principles:

A. Criteria for valid consent for immunization

Before obtaining consent, the immunization provider administering a vaccine or biologic must ensure that the patient or person authorized to consent on the patient's behalf is informed, orally or in writing, of:

- a) the expected benefits and risks of the vaccine or biologic;
- b) the risks of the disease in the absence of vaccination;
- c) The benefits to the community of immunization programs and, the risks to the community of not being immunized;
- d) any other information (ex: common side effects, contraindications, route of administration) that a reasonable person in the same circumstances would require in order to make a decision about the immunization; and
- e) the importance of immediately consulting with the person administering the vaccine or biologic, or with another health care professional, if a reportable adverse event occurs following immunization.

B. Person authorized to consent for an adult who is not competent to consent:

As stated in *The Public Health Act* (2009) Immunization Regulation, the following persons are authorized to consent to the

administration of a vaccine or biologic on behalf of an adult patient in accordance with the authority granted to them by law:

- a proxy appointed by the patient under *The Health Care Directives Act*;
- a committee appointed for the patient under *The Mental Health Act* if the committee has the power to make health care decisions on the patient's behalf;
- a substitute decision-maker for personal care appointed for the patient under *The Vulnerable Persons Living with a Mental Disability Act* if the granting of consent relates to the powers and duties of the substitute decision-maker.

C. Relatives and others who may consent for adult patients if no person is available from those listed in section B:

If the immunization provider administering the vaccine or biologic reasonably believes that no person described above exists, or that no such person is readily available, the person authorized to consent is the adult person listed first in the following clauses who has had contact with the patient in the preceding 12-month period and is readily available and willing to make the decision as to whether or not to consent on the patient's behalf:

- a) spouse, with whom the individual is cohabiting, or a common-law partner;
- b) a son or daughter;
- c) a parent;
- d) a brother or sister;
- e) a person with whom the individual is known to have a close personal relationship;
- f) a grandparent;
- g) a grandchild;
- h) an aunt or uncle; or,
- i) a nephew or niece.

D. Consent if client is a child

If the patient is a child, the information from section A must be given to the child's parent or guardian if the child:

- is under 16 years of age, unless the immunization provider reasonably believes the child is able to understand the nature and effect of the information and is able to

appreciate the consequences of a decision; or

- is 16 years of age or older, if the immunization provider reasonably believes the child is not able to understand the nature and effect of the information or able to appreciate the consequences of a decision.

E. Consent when a series of vaccines will be given (e.g. hepatitis B vaccine):

- The number of doses should be clearly stated in the consent form or communicated verbally.
- Consent should be "updated" between doses if necessary. This means the provider should communicate any important new information that could alter a decision to be immunized. This could include changes to the vaccine formulation (e.g. now contains an additional antigen) or a change in the risk for adverse reactions based on reactions occurring after a previous dose.

F. Duration of Consent

- Consent should not normally be considered valid more than one year after it is given.

G. When possible, informed consent should be obtained by the person who is administering the vaccine.

H. Informed consent can be given verbally or in writing.

Documentation of Informed Consent:

- The process for obtaining informed consent (including refusal of immunizations) must be documented.
- A consent form may be evidence that a client or their legal decision-maker provided a legally sufficient consent to a procedure, but only if the consent form reflects what actually occurred.
- A client's medical chart or electronic health record may be used to document the process to obtain informed consent to, or the refusal of, a vaccine. At minimum, the following elements must be documented for consent:

- a) client identification (name and date of birth)
- b) statement of consent or refusal
- c) name of vaccine series
- d) date of consent
- e) name of person consenting or refusing
- f) relationship of the person consenting to the client being immunized
- g) name of person obtaining informed consent

Information to be recorded on patient's health record:

Immediately after administering a vaccine or biologic, the immunization provider must record the following information on the patient's health record:

- the date of administration;
- the name of the health care professional who administered the vaccine or biologic;
- the name of the vaccine or biologic, its lot number, dosage, route of administration and the location on the body where the agent was administered.

Absence of a parent or the legal decision-maker at the time of the vaccine administration:

In situations where the client, in the professional opinion of the immunization provider, is not able to give informed consent and their legal decision-maker will be absent at the time of immunization, written or verbal consent may be obtained by forwarding all the necessary documents to the legal decision-maker (e.g. fact sheet(s), consent form, and other related documents if needed). When information is forwarded to the legal decision-maker, the immunization providers are expected to make a reasonable attempt to contact the client's legal decision-maker for verbal consent (or refusal). This includes:

- a) **Residents of personal care homes or other chronic care facilities:** the consent may be obtained on admission. Each year, the facility should communicate with the client or their legal decision-maker (either in writing or verbally, depending on the RHA policy) to

ensure there are no changes and the consent is still valid.

b) School based immunization programs:

Immunization providers should obtain consent from the parent or their legal decision-maker prior to the start of the immunization program. In circumstances when the consent form has not been returned or returned with incomplete information e.g. no parental signature, the immunization providers should make a reasonable attempt ("reasonable attempt" as defined by the respective RHA or other employing agency) to contact the parent or the legal decision-maker for verbal consent (or refusal).

References:

National Advisory Committee on Immunization

The Public Health Act

Canadian Immunization Guide

Canadian Health Facilities Law Guide: 175–175
12–01

College of Registered Nurses of Manitoba

College of Physicians and Surgeons of Manitoba

Canadian Nurse Protective Society

Your Child's Best Shot, A parent's Guide to vaccinations (2002).

Canadian Paediatric Society. Grabenstein, J.D. (2002).

Other sources:

WRHA Immunization Manual

British Columbia Communicable Diseases Immunization Manual

Gouvernement du Québec, Ministère de la Santé et des Services Sociaux, Direction Générale de la Santé Publique (1999). Protocole d'immunization