Informed Consent Guidelines for Immunization

Population and Public Health Branch

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Applicable to: All Immunization Providers in Manitoba

1. 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 an 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.

2. 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 client 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.

3. Definitions:

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

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

Legal or Appointed Decision-maker: For the purpose of this guideline, a legal or appointed decision-maker is any person or organization that has legal custody of a minor, and pursuant to that legal custody, is authorized by law to provide informed consent for health care for that minor, including immunizations.

Mature Minor: A mature minor is a child under 18 years old, who has the capacity to fully appreciate the nature and consequences of a proposed health treatment and is capable of giving informed consent. It is not based primarily on age but on capacity to understand and make decisions.

Reportable Adverse Event: An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence in a vaccine that follows immunization. It may be any unfavourable and/or unintended sign, abnormal laboratory finding, symptom or disease. The vaccine or its administration may not necessarily have been the cause.

Vaccines, Biologics and Immunizations: 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.

4. Obtaining Informed Consent for Immunization From the Client

A. Criteria for informed consent

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

a) the expected benefits and material risks of the vaccine or biologic;

b) the risks of the disease in the absence of immunization;

c) 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 an informed decision about the immunization; and

d) 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.

In addition to the above minimum requirements, immunizations providers are also encouraged to provide the following information during the informed consent process:

e) the benefits to the community of immunization programs; and

f) the risks to the community of not being immunized.

B. Consent if the client is a mature minor

In Manitoba, a youth aged 16 or 17 is generally considered to be a mature minor unless there is evidence to the contrary, and a youth under 16 years of age can be assessed to be a mature minor.

If the client is a mature minor, the information from section 4A must be given to the mature minor.

Notwithstanding the above, it is recommended that a reasonable attempt be made by the immunizer to encourage the mature minor to involve the parent or legal decision-maker in the immunization discussions and decision process for informed consent. However, it is up to the mature minor to determine if they wish to do so.

C. Consent if the client is not a mature minor

If the client is:

- a child under the age of 16, or
- 16 or 17 years of age and the provider determines that the child is not able to understand the consequences of both obtaining and not obtaining healthcare,

then the child cannot consent to the immunization.

Consent must then be obtained from the child's parent or legal or appointed decision-maker and under *The Public Health Act*, the information from the section 4A must be given to that parent or legal or appointed decision-maker.

D. Duration of Consent

Consent is normally valid no more than one year after it is given.

In Manitoba, providers can set their own durations for consent for treatment by policy, as long as the policy is consistent with any relevant acts or regulations.

E. Who should obtain consent?

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

F. Form of Consent

Informed consent can be given verbally or in writing.

G. 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.

5. Obtaining Informed Consent From Someone Other Than the Client

A. Person authorized to consent for an adult who is not competent to consent: The Immunization Regulation made under *The Public Health Act* provides that 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.

B. Relatives and others who may consent for adult patients if no person is available from those listed in section A: If the immunization provider administering the vaccine or biologic reasonably believes that no person described in section A 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 client 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 client'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.

6. 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 or appointed decision-maker provided the required legal authority for a procedure, but only if the consent form is directly related to said procedure.
- 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

7. Information to be Recorded on Client's Health Record

Immediately after administering a vaccine or biologic, the immunization provider must record the following information on the client'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 (including product and manufacturer), lot number, dosage, route of administration and the location on the body where the agent was administered.

8. Absence of a Parent or the Legal or Appointed 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 or appointed 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 or appointed decision-maker (e.g. fact sheet(s), consent form, and other related documents if needed). When information is forwarded to the legal or appointed 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 the client's legal or appointed 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 or appointed decision-maker for verbal consent (or refusal).

In circumstances where parental consent, or consent from the legal or appointed decision-maker, cannot reasonably be obtained (e.g. on the day of a school immunization clinic), the immunization provider may determine whether a student is a mature minor and is authorized to then consent to their own immunization (based on section 4B).

9. References & Sources

The Public Health Act, SM 2006, c 14

Immunization Regulation, Man Reg 36/2009

Canadian Immunization Guide

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

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Your Child's Best Shot, A Parent's Guide to Immunizations (2002)

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