Module 12
Legal and Ethical Aspects of Immunization

1. Competency ........................................................................................................1
2. Skills Assessment ................................................................................................1
3. Learning Objectives .............................................................................................1
4. Introduction ........................................................................................................1
5. Principles ............................................................................................................1
6. Legislation ...........................................................................................................2
7. Ethical Issues .......................................................................................................3
8. Summary .............................................................................................................3
9. Required Reading ...............................................................................................3
10. References .........................................................................................................3
11. Quiz ...................................................................................................................4
12. Quiz Answers ...................................................................................................6
1. Competency
Acts in accordance with legal and high ethical standards

2. Skills Assessment
- Discuss the implications of the individual’s rights, confidentiality, privacy, informed consent and informed refusal.
- Discuss the issues arising from mandatory versus voluntary immunization.

3. Learning Objectives
By the end of this module you will be able to:
- Discuss the implications of the individual’s rights, confidentiality, privacy, informed consent and informed refusal.
- Describe the legislations that impact immunization practice in N.S.
- Identify your professional scope of practice as it relates to immunization.
- Discuss the issues arising from mandatory versus voluntary immunization.

4. Introduction
Legal and ethical standards guide immunization practice. This module describes the legal requirements, scope of practice and ethical principles and issues pertaining to immunization.

5. Principles

5.1 Individual Rights
Individuals have the right to choose or refuse immunizations that are available to them and retain responsibility for their own or their child’s health.

5.2 Confidentiality
Confidentiality is an integral part of the nurse-client relationship.

Confidentiality is defined as the prevention of disclosure of personal information to other than authorized individuals.

Nurses have an ethical and legal responsibility to maintain the confidentiality of information they obtain in the context of their professional relationships.

5.3 Privacy
The law imposes obligations on both private and public bodies to safeguard the privacy of personal information.

Nurses are required under law to exercise care in the use, storage, collection and disclosure of personal information.
5.4 Informed Consent

Informed consent is the voluntary agreement of a capable client (or his/her representative) to immunization services after having been provided with standard information about the immunization. Information regarding the risk and benefits of both receiving and not receiving the vaccination would be provided, along with the opportunity to ask questions.

- Steps

The following lists the eight step process for obtaining informed consent:

1. Provide resources
2. Determine who has the authority to consent for the series
3. Assess the capability of the client or representative
4. Provide standard information
5. Assess that the client understands the provided information
6. Answer the client's questions
7. Confirm consent or dissent
8. Document the consent

- Informed Refusal

An individual's perception of risk is influenced by experience as well as personal, religious and cultural contexts. Some individuals will express reluctance or refusal to accept immunization for themselves or their children. If after following the eight step process for obtaining informed consent the client refuses recommended immunizations, document as an informed refusal.

6. Legislation

There are various pieces of legislation or Acts which impact immunization programs.

- N.S. Health Protection Act
- Freedom of Information and Protection of Privacy Act

6.2 N.S. Health Protection Act

The NS Health Protection Act provides the authority for public health officials to take action to protect and promote the health of Nova Scotians. Immunization is voluntary and unimmunized children are not excluded from school, unless there is an outbreak. For example, if a child is unimmunized against measles and there is a measles outbreak in the school, the NS Health Protection Act permits the Medical Officer of Health to exclude the child from school until the outbreak is over.

The NS Health Protection Act can be accessed from the following website: http://www.gov.ns.ca/hpp/cdpc/health-protection-act.asp

6.3 Freedom of Information and Protection of Privacy Act

The Freedom of Information and Protection of Privacy Act (FOIPOP), governs the use, collection, storage and disclosure of personal information in the possession of public bodies.
The Freedom of Information and Protection of Privacy Act can be accessed from the following website: [http://foipop.ns.ca/](http://foipop.ns.ca/)

### 7. Ethical Issues

#### 7.1 Voluntary Programs

Immunization is voluntary in Canada. Three provinces (Ontario, New Brunswick, Manitoba) have legislation or regulations under their health-protection acts to require proof of immunization at school entrance. In these provinces, exceptions are permitted for medical or religious grounds and reasons of conscience.

#### 7.2 Mandatory Programs

In the United States, the courts have upheld mandatory vaccination laws, citing the substantial public health benefit afforded to society by vaccinations. However, personal exemptions based on religious and/or philosophic reasons are permitted to varying degrees.

#### 7.3 Voluntary vs. Mandatory Strategies

There are differing opinions on which immunization strategy, mandatory or voluntary, results in the best immunization rates and therefore the least morbidity and mortality from vaccine preventable diseases. Research has not shown one strategy being more effective than the other. With mandatory regulations, parents may choose not to vaccinate because they see this as an infringement on their personal rights. When immunizations are voluntary people become complacent because they no longer see or fear vaccine preventable diseases.

Whether immunization is mandatory or voluntary, research has shown that the risk of vaccine preventable diseases is elevated in those choosing not to immunize.

### 8. Summary

Nurses should have an understanding of the legislation that impacts immunization services.

### 9. Required Reading

Chapter 3 Informed Consent N.S. Immunization Manual

### 10. References

Chapter 3 Informed Consent N.S. Immunization Manual


11. Quiz

Question #1
A parent states that she is in a hurry, has read the information on the immunizations for her 2 month old. She states that she "just wants the shots done". Which one of the following is the process for obtaining informed consent?

A. Proceed with immunizations and document parent's refusal discuss information
B. Confirm understanding of standard information and proceed with immunizations
C. Explain that you must review all the information and if she doesn’t have time then rebook her appointment

Question #2
During a school immunization program, a 14 year old girl states that she would like to receive the HPV vaccine even though her parents have signed a refusal for the vaccine. Obtain informed consent and proceed with immunizations.

A. True
B. False

Question #3
Which of the following N.S. legislations states that immunization is voluntary and unimmunized children are not excluded from school, unless there is an outbreak?

A. Health Protection Act
B. Freedom of Information and Protection of Privacy
Question #4
As soon as a vaccine is licensed for use in Canada, it becomes part of the N.S. routine immunization program.

A. True

B. False
12. Quiz Answers

Question #1
Answer: B
Use clinical judgment to confirm the person providing consent understands the Standard Information. Ways to assess understanding include assessing non-verbal cues, assessing questions and clarifying reasons for silence or refusal to engage in discussion.

Question #2
Answer: True
A mature minor has the authority to give, refuse or revoke consent for their immunizations.

Question #3
Answer: A
The Health Protection Act is the provincial legislation that states that immunization is voluntary and unimmunized children are not excluded from school, unless there is an outbreak.

Question #4
Answer: False
Vaccines may be licensed and for sale in Canada but provincial jurisdictions will decide if vaccines will be part of a routine immunization practice.