Program Name: Immunization Competencies Education Program  
Module 10- Documentation

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CCCEP:
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This online CME event is an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification program of the Royal College of Physicians and Surgeons of Canada. This program is recognized as 1 hour(s) of Continuing Professional Development.

Family physicians may claim one (1) credit per hour of participation under Mainpro-M2.

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**Competency:** Documents information relevant to each immunization encounter in accordance with national guidelines for immunization practices and jurisdictional health information processes.

**Learning Objectives**
Upon successful completion of this section the health professional will be able to perform the following:

1. Describe the role and importance of immunization records.
2. Identify the information to be documented on an immunization record.
3. Record an immunization encounter on the appropriate documentation instruments accurately and completely.
4. Facilitate the transfer of information in the vaccination record to other providers and to appropriate agencies in accordance with requirements.
5. Record the reason and planned follow-up action when a scheduled immunization is not given.

**National Immunization Registry**

In 2003 the National Immunization Strategy (NIS) called for the development of a national registry network that would allow for monitoring of the immunizations given to all Canadians.\(^1\)

This national registry would:

- Enhance surveillance of immunization coverage rates
- Facilitate the transfer of and access to individual immunization records
- Measure progress towards national immunization goals and objectives
- Facilitate linkage of surveillance data of vaccine preventable diseases and adverse events following immunization (AEFI)

Unfortunately this national registry has not been implemented in practice and parents, healthcare professionals and public health officials have to rely on the current system that have different reporting strategies depending on the province of the patient.

Whether a national registry is available or not, it is crucial that all immunizers adequately document the correct amount of immunization information. Maintenance of accurate immunization records assure that our population is adequately protected from vaccine preventable diseases, individuals are not administered excess dosages, adverse events following immunization are tracked and patients who may have been immunized with a recalled vaccination product can be tracked through the use of lot numbers.

**Meeting the Documentation Standards – “Providers should ensure that all vaccinations are accurately and completely recorded”**

The Canadian Immunization Guide has listed documentation as a key component to the immunization process.\(^2\) For each immunization given, the appropriate information should be recorded in three locations: \(^2\)

- The personal immunization record held by the person or his or her parent/guardian
The patient record (chart) maintained by the health care provider who gave the immunization
The local or provincial registry (if one exists)

For each immunization the following should be recorded:
1. trade name of the product
2. disease(s) against which it protects
3. date given (day, month and year)
4. dose
5. site and route of administration
6. manufacturer
7. lot number
8. name and title of person administering the vaccine
9. any post-injection reactions observed, how they were managed (including an anaphylaxis worksheet if appropriate) and planned follow-up should be recorded in the client or patient chart

Practice Note:
A great method to remember when completing immunization documentation:
Ensure that every component to be documented is actually recorded

The Canadian Immunization Guide encourages manufacturers to develop pre-printed bar-coded labels as this would allow for rapid documentation and would facilitate the input of the information in a computerized database. In the absence of pre-printed bar-coded labels and/or computerized databases, complete documentation as outlined by the National Guidelines for Immunization Practices, is required by all immunization providers. Many provinces and territories have reciprocal notification forms that can serve as documentation both for the immunization provider and the provincial public health system. Immunization providers should be familiar with their provincial/territorial requirements and document accordingly.

Documentation is also important when a scheduled immunization is not administered. In these situations the reason for not immunizing should be recorded, as well as planned follow-up. There are many reasons why a scheduled immunization is not given and include the following:
- Refusal by parent/guardian/patient
- Previous disease
- Receipt of immune globulin or blood products
- Protective antibody/antitoxin serology
- Severe illness warranting deferral
- Contraindication to a specific vaccine
Personal Immunization Records

Each person who is immunized should be given a personal immunization record.\(^2\) Individuals should be instructed to keep the record in a safe place and bring it to immunization visits.\(^2\) Parents should maintain these records on behalf of their children and pass them on to their children at the appropriate time, such as when they are leaving home.\(^2\) Some jurisdictions require immunization records in order for children to attend school or child-care centres.\(^2\) Adults may be required to produce these records to work in certain professions, such as health care, teaching or occupations requiring foreign travel. Relevant information, such as rubella and hepatitis B serology or tuberculin skin test results, can also be recorded in the personal immunization record.\(^2\)

Practice Note:

A personal immunization record is a Health Passport

Many times, it is the ONLY complete list of the immunizations received.

For this reason, it is crucial to keep it in a safe place.

Healthcare Provider Records

Health care providers must also maintain a record of all vaccinations provided.\(^3\) In addition to information about vaccinations given, the health care provider’s record should include all relevant serologic data (e.g., rubella serologic results, hepatitis B surface antibody titres) and should document adverse events following immunization as well as contraindications, exemptions or reasons for deferring vaccination as noted above.\(^2\) It is recommended that a summary of immunizations, serologic results and any significant adverse vaccine reactions be stored in an easily retrievable manner that permits regular checking and updating of

The Importance of the Lot Number:

The lot number is crucial component of documentation as it:

- Facilitates recall if a problem with a vaccine batch is identified
- Provides another method to identify the immunization given
- Is a crucial component of any adverse event following immunization (AEFI) report

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the individual's immunization status (e.g. in the office each patient should have immunization record in a table form in front of the chart and on a separate immunization card in a separate file easily accessible when parents call). Electronic medical records used by health care providers should have the capacity to collect and easily retrieve all required vaccination information. Vaccine providers should forward the immunization information to other providers and/or to agencies, such as public health, as appropriate or required by legislation.

**Immunization Registries**

There are several advantages to maintaining immunization records in a registry. On an individual level, immunization registries prevent immunizations already given by another health care provider from being duplicated and allow for catch-up of missed immunizations. A comprehensive immunization registry system will serve the following functions:

- Facilitate the timely, accurate recording of all relevant immunization information regardless of where and by whom the vaccines were administered
- Identify children and adults who are overdue for immunizations and generate reminders and recalls for these individuals
- Allow health care providers to review immunization status at each encounter in a confidential, secure manner and produce immunization records for their patients
- Allow for sharing of immunization data, but still respect the patient's confidentiality and privacy

Provide data for public health professionals to assess immunization rates, and plan and evaluate targeted interventions for populations with less than optimal immunization rates.

Where immunization registries exist, immunization providers should be aware of legislative or other requirements to report immunization information to these registries. Incomplete information can significantly decrease the benefits derived from an immunization registry. Strategies should be employed to maximize participation by health care providers.
Vaccine Errors

No matter how careful immunizers are including having all the safety methods in place, vaccine errors do occur. The Canadian Immunization Guidelines state that “immunization errors should be reported by providers to their local jurisdiction”

Immunization errors and related incidents should be monitored as a patient safety issue. All immunization errors should be reported by the vaccine provider to the agency or local sector that assumes accountability for the quality of immunization programs. Immunization errors commonly include an error in:

- Vaccine type
- Dose
- Site
- Route
- Person
- Time or schedule
- Diluent

Immunization-related incidents include a range of events, such as needle injury caused by failed restraint of children, immunization without consent, or fainting with a fall resulting in injury.

Methods to detect immunization errors or incidents may include provider self-reporting, direct observation or record audits. Decreasing immunization errors requires an accurate system of error reporting in an open environment that focuses on positive reinforcement rather than punitive action. Activities to prevent immunization error in an agency or organization are a better barometer of quality than the error rate alone. Publishing or sharing information about immunization errors is a first step towards an immunization quality-improvement program that strives to reduce the incidence of errors. Immunization errors can be effectively reduced by systematically identifying, eliminating or minimizing both human and system related factors.

Vaccine Errors – A Study from the CDC

Vaccine errors are a concern for all immunizers. Reducing these errors is imperative for the safety of the patient and the protection of the patient and public from vaccine preventable diseases. Between Jan 1, 2006 and Sept 30, 2007 a group of researchers at the CDC in the United States reviewed the adverse event reports submitted to the CDC listing a vaccine error had occurred.

Some of the reasons cited for these vaccine errors are:

- A large number of new vaccines available for licensure
- Increasing complexity in the immunization schedule
- Changes in the combination vaccines

This research provides a look at the type of errors that are most common and methods that immunizers can implement to reduce the risk of problems. Fortunately in their review they found only 3.9% of reported adverse events following a vaccine error as serious. Only 0.3% of the adverse events were serious due to vaccine error.
The most common errors found (their frequency is in brackets) were: Wrong Drug (37.9%)
Wrong Vaccine (24.5%)
Incorrect Dose (6.4%)
Incorrect Route (4.8%)
Inappropriate Site (2.1%)
Expired Drug (1.3%)

They have provided some practical examples that can help reduce an error in your practice.
- Do not cut open boxes of vials until ready to administer. Sometimes vials spill out of open boxes and are put in wrong box
- Separate similar vaccines in different areas of the refrigerator
- Post a chart to show vaccines given by the IM route and those administered by the SC route
- Separate childhood vaccines from adult vaccines

**Key Learning Points**
1. A national immunization registry would allow for the surveillance, tracking and monitoring of all immunizations given to Canadians
2. Unfortunately a national registry is not yet available
3. Documentation of the vaccine given is a crucial component of the immunization process
4. The personal immunization record is a “Health Passport” and many times the only complete immunization record
5. Immunizers have a responsibility to report any vaccine related errors
6. The risk of vaccine related errors would be reduced with some minor steps to improve safety

**Discussion Forum**
1. What do you feel are the key barrier(s) to ensuring adequate documentation of immunization?
2. What do you feel will be the key advantage(s) of a vaccine registry?
3. Are there any tips that you can share with your colleagues that improves or simplifies immunization documentation?
4. In your experience what is/are the most common vaccine related error(s)?

**Quiz**
1. Which of the following is NOT recommended to be documented after immunization
   a. Trade name
   b. Site of injection
   c. Expiration date of the vaccine
   d. Name and title of the person administering the vaccine
2. Which of the following statements regarding the personal immunization record is true?
a. It is many times the only complete immunization record
b. Parents should be told to bring it to each appointment and to keep it in a safe place
c. The information in this record may be required for certain professions
d. All of the above

3. According to the National Immunization Strategy, which of the following is a key advantage of vaccine registries?
   a. Patients would not be responsible for ensuring their child is immunized
   b. Measure progress toward national immunization goals
   c. Target conscientious objectors to minimize their input to other parents
   d. All old personal immunization records with immunization information could be destroyed

4. Why is it important to record the lot number on immunization documentation?
   a. It can facilitate recalls if a problem occurs with a lot
   b. Shortens the documentation process
   c. Is a crucial piece of information for the Adverse Event Following Immunization (AEFI) report
   d. Both (a) and (c)

5. Which of the following is the most common vaccine related error in the United States?
   a. Incorrect route
   b. Expired drug
   c. Inappropriate site
   d. Wrong drug

References